



Exploring Intravaginal Ring Acceptability for Disease Prevention Among At-Risk Community Members in Cape Town

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Abstract

South Africa has the highest prevalence of HIV in the world, with young black women at greatest risk of infection. New protective biotechnologies continue to be developed, including an intravaginal ring (IVR) that releases antiretroviral medications over a four-week period. An IVR is currently under development that could protect against HIV, STIs, and pregnancy concurrently. However, uptake and adherence to this product is unknown. This project explored access and acceptability by interviewing 28 at-risk women and men in Cape Town and consulting with five stakeholders. Data revealed that familiarity with similar intravaginal products (tampons, female condoms), relationship dynamics, and product distribution channels must be considered as IVR products undergo further development.

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Executive Summary

Black women in South Africa are at the epicenter of South Africa's human immunodeficiency virus (HIV) epidemic, and are also at high risk for sexually transmitted infections (STIs) and unplanned pregnancy (Morrow Guthrie et al., 2015). Currently, the only methods of dual protection against these health issues are the male and female condom; however, these products have not been widely accepted by South African populations (Statistics South Africa, 2017). Women continue to struggle to protect themselves as they find it difficult to negotiate the use of disease preventative and contraceptive methods in male-dominated relationships (Pettifor, Measham, Rees, & Padian, 2004). The introduction of a female-initiated intravaginal product could be a potential solution to this issue as the discreet nature of the product would allow women to protect themselves without needing to negotiate use with their partners. A multipurpose IVR currently being developed at the University of Massachusetts Medical School is intended to protect against HIV, gonorrhea, and pregnancy simultaneously. However, as the product is still in development and IVRs are not yet available in the South African public health sector, it is unclear how it will be received by the public. Clinical trials assessing the efficacy of similar IVRs aiming to limit HIV infections have not demonstrated accurate levels of efficacy due to varying levels of adherence. Therefore, an exploration of the various factors that affect adherence to the product is needed to advise its development and introduction in South Africa.

The goal of this project was to explore IVR acceptability and accessibility preferences within at-risk populations outside of the context of a clinical trial in order to assess promoters and barriers to product adherence that may ultimately affect product efficacy. To accomplish this, we conducted semi-structured interviews with 28 individuals (22 women and 6 men) living in Philippi, a low-income 'township' community on the outskirts of Cape Town, South Africa, in order to explore individual and community perceptions of the product. The project was conducted in collaboration with Sizakuyenza, a non-profit organization based in the Philippi township. Five interviews with relevant stakeholders likely to be involved in the introduction of the IVR were also conducted to explore the costs, distribution methods, and marketing strategies associated with the IVR and related products.

Our data, consistent with previous work, suggests that the multipurpose IVR could address ongoing concerns around inconsistent condom use (Statistics South Africa, 2017), and the influence of relationship dynamics on negotiating the use of various forms of



contraception and disease prevention products as well as product acquisition (Pettifor et al., 2004). Also, consistent with prior observations (Beksinska et al., 2015), our data show limited use of intravaginal products including female condoms and tampons in the study populations. Limited use of intravaginal products may present an obstacle to the insertion of the IVR, as women only have a theoretical understanding of vaginal insertion. Consultations with expert stakeholders indicated that this product, much like similar HIV prevention products in South Africa such as pre-exposure prophylaxis (PrEP), will likely involve a highly regulated release of the product including by prescription only. Such restrictions on distribution are likely to influence the use of and adherence to the product, and consequently product efficacy.

One potential advantage of the IVR is that it can address ongoing concerns surrounding inconsistent condom use within relationships, as it would allow partners to no longer use condoms, which our data suggest is highly desirable. Another promising feature of the product is that it allows women the opportunity (and burden) of managing their disease and contraception risk in a more discrete manner. However, our data suggest that many participants would still disclose product use to their partners. Some participants raised concerns that the discrete nature of the product may lead to concerns of infidelity if a relationship partner discovered the female was using the product but had not disclosed it. However, the consensus was that the additional protection would be appreciated by both the men and women in relationships.

The effect of various policies, programs, and resources must be considered as possible factors affecting IVR use. As a novel product, the IVR may be largely unfamiliar to the at-risk population, which may lead to misuse or stigmatization of the product. Previous clinical trials have recorded women inserting the product periodically to extend product efficacy duration or sharing the ring with friends to offer protection to those they perceived to be more at-risk at a given moment. Such misuses of the product driven by misconceptions of product mechanism of action and efficacy as well as economic limitations will compromise the efficacy of the product in its current design. The product requires a constant, low-dose exposure to medications to prevent disease and pregnancy. In addition, the association of the product with illness and promiscuous behavior, may decrease the willingness of women to use the product. To prevent similar instances of misuse and stigmatization, resources will need to be allocated towards efforts to inform community members of the product and market the product appropriately. From a biotechnology design perspective, product developers may need to reconsider the design of the device such that it is more intuitive for users.



This project highlights the importance of the interdisciplinary collaboration between social science and technology in the development of a novel medical technology. No matter the efficacy of the product, without sufficient uptake and proper adherence among the target population, the product will not achieve its intended effectiveness. Therefore, an investigation of the social, environmental, economic, and interpersonal factors influencing product introduction and uptake is of paramount importance.

Authorship

This report represents the collaborative work of Josephine Bowen, David Lech, Shion Matsumoto, and Abigail Roane. Each team member was critical to the completion of the project and all members contributed equally.



(left to right): Shion Matsumoto, Abigail Roane, Josephine Bowen, David Lech

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List of Acronyms

API	Active pharmaceutical ingredient
ARV	Antiretroviral
DTHF	Desmond Tutu HIV Foundation
HIV	Human Immunodeficiency Virus
NNRTI	Non-nucleoside reverse transcriptase inhibitors
NRTI	Nucleoside reverse transcriptase inhibitors
IVR	Intravaginal ring
MSM	Men-who-have-sex-with-men
MPT	Multipurpose technology
NGO	Non-governmental organization
PrEP	Pre-exposure prophylaxis
STI	Sexually Transmitted Infection
WHO	World Health Organization

Introduction

HIV, gonorrhoea, and unplanned pregnancy are three major health concerns in South Africa. South Africa is at the center of the global HIV epidemic, with young women disproportionately affected by the disease (Morrow Guthrie et al., 2015). In addition to HIV, a global study conducted by the World Health Organization (WHO) found that the prevalence of gonorrhoea in southern Africa is higher compared to other countries studied, with a rate as high as 11.6% among women aged 18 to 49 in the Mopani district of the Limpopo province of South Africa (Newman et al., 2015). This is particularly concerning as untreated gonorrhoea increases the risk of HIV infection (Ramjee & Daniels, 2013). Finally, southern Africa has the highest rate of unintended pregnancy in Africa and the fourth highest among any region in the world, with 55% of all pregnancies in southern Africa occurring unintentionally (Sedgh, Singh, & Hussain, 2014).

The most effective current preventative method for most sexually transmitted infections (STIs), HIV, and pregnancy is the male condom. However, the male condom is male-initiated, with males, ultimately, having the power to choose to use protection or not. Many women are unable to negotiate and initiate condom use, which leads to an increased susceptibility to HIV and other STIs (Pettifor et al., 2004). Other preventative methods such as birth control pills, female condoms, and microbicides, are also available and used, but none have proven highly successful among the South African population. Birth control pills, although an effective contraceptive method in some contexts, are not ideal because they are unable to protect against HIV and gonorrhoea (Planned Parenthood, 2017). In addition, the birth control pill requires strict adherence to a set daily regimen in order to be effective. Female condoms were introduced as a potential disease preventative method in South Africa, but they were unsuccessful as most “[male] partners were not willing to try the method” (Beksinska, Rees, McIntyre, & Wilkinson, 2001, p. 676). Microbicides, on the other hand, provide a promising solution to preventing HIV. However, the current delivery method for the product, a vaginal gel, is not ideal as it needs to be applied once or twice a day and requires users to maintain a consistent application regime (Ravel et al., 2012). Currently, a female-initiated method combining contraceptive and disease prevention technologies to prevent pregnancy, gonorrhoea, and HIV does not exist, and could prove highly effective in the South African context.



The IVR has been developed as a female-initiated contraceptive device. The IVR is inserted monthly, with low-dose hormones released gradually into the vagina. This product, marketed as the NuvaRing, is not currently available in South African public health sector. Clinical trials are currently testing IVR technology for HIV prevention, with the IVR releasing antiretroviral (ARV) medications. New developments have considered the capabilities of IVR technologies in concurrently releasing hormonal contraception, ARVs for HIV prevention, and antibiotics for gonorrhoea prevention. Such a device would allow women to take the initiative in protecting themselves against unwanted pregnancy, HIV, and gonorrhoea regardless of the desires or disease states of their partners.

As the development of the IVR progresses, clinical trials have been conducted in the United States and several sub-Saharan African countries to assess the efficacy of the product. Topics such as physical characteristics of the ring, insertion methods, drug concentration, and impact on the user's sex life were among the common themes discussed by trial participants (Fan et al., 2016). Various trials conducted to assess the efficacy of the product showed high acceptability of the product; however, users had concerns such as the ring getting lost in their body, inserting it incorrectly, and having to remove the ring for cleaning (Baeten et al., 2016; Fan et al., 2016; Montgomery et al., 2012; Nel, Bekker, et al., 2016; van der Straten et al., 2014). Despite high acceptability, product efficacy has not been accurately measured due to adherence-related issues, which these clinical trials failed to explore. Therefore, in order to advise the development of the product and its introduction in South Africa, the various factors that may affect IVR adherence must be understood.

Our goal was to explore IVR acceptability and accessibility preferences among at-risk populations residing in the Philippi township of Cape Town, South Africa including an investigation of the costs, marketing strategies, and distribution methods associated with the implementation of the product outside the scope of a clinical trial. In order to accomplish this, we explored at-risk women's perceptions, acceptability, and accessibility preferences of the IVR, explored men's perceptions of the IVR and the influence that these perceptions may have on women's acceptability of the product, and investigated the accessibility of the IVR with regards to cost, distribution methods, and marketing strategies.

Background

The Intravaginal Ring: A Promising New Technology

The IVR is a promising new medical technology capable of delivering agents to protect women against the transmission of HIV and other STIs and prevent pregnancy (Morrow Guthrie et al., 2015). The IVR is described as a “flexible, torus-shaped drug delivery system that can easily be inserted and removed by the woman and that provides both sustained and controlled drug release, lasting for several weeks to several months” (Thurman, Clark, Hurlburt, & Doncel, 2013, p. 696) (see Figures 1 and 2). The most commonly known and utilized IVR, the NuvaRing, is a contraceptive vaginal ring that administers a continuous, low dose of female hormones to prevent pregnancy, instead of bursts of doses as in injections or oral administration, thus minimizing hormonal side effects (Thurman et al., 2013). The IVR technology is now expanding to include drugs that can protect users from HIV and other STIs.



Figure 1. NuvaRing from http://whisperedinspirations.com/wp-content/uploads/2011/09/nuvaring_0.jpg

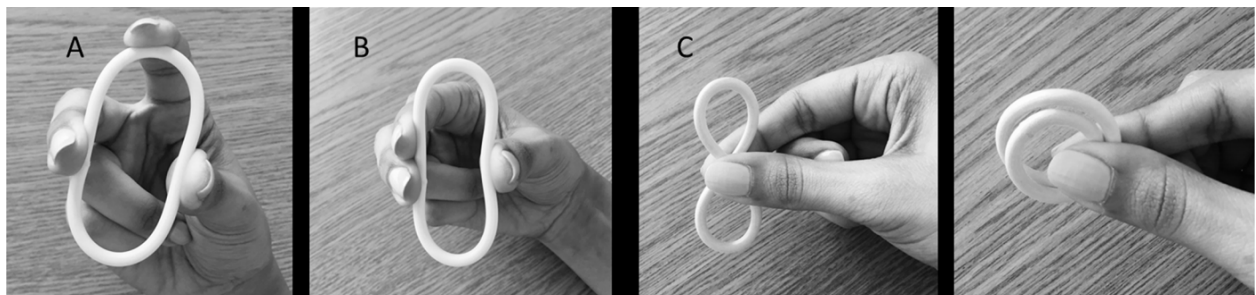


Figure 2. Variations in participant folding/squeezing techniques for IVR insertion

Utilizing the IVR to prevent HIV and other STIs involves the delivery of sustained doses of microbicides, specifically ARVs, in the vagina over an extended duration (Lopez, Grimes, Gallo, Stockton, & Schulz, 2013; Nel, van Niekerk, et al., 2016; Thurman et al.,



2013). This is in contrast to vaginal microbicidal gels, a localized topical technology currently in use for HIV prevention, which offer higher rates of delivery in greater quantity but require pre-coital application (Thurman et al., 2013). Pre-exposure prophylactic oral therapy for HIV prevention is another method that requires systemic exposure to low and continuous doses of ARVs, but requires regular administration (a once daily tablet) that risks poor adherence and an increased likelihood of drug resistance (Lopez et al., 2013; Thurman et al., 2013). The reduced dosage and localized delivery capable with the IVR limits systemic exposure to pharmaceuticals including contraceptive hormonal steroids to prevent pregnancy, ARVs for HIV prevention, and other disease preventing pharmaceuticals. As a result, the IVR reduces the risk of developing ARV resistance, a common concern with oral dosing and microbicidal gels, and has been shown to have fewer hormonal side effects as the first pass metabolism in the gut is bypassed (Thurman et al., 2013). Tables 1 and 2 compare the features of IVRs and traditional contraceptive and HIV and STI prevention methods.

Table 1. Features of various commonly used contraceptives

Method	Initiator	Contraceptive	Frequency of Use	STI Prevention Capability
Injectable	Female	Yes	4x per year	No
Pill	Female	Yes	Daily	No
Male Condom	Male	Yes	During Intercourse	Yes
Vaginal Barrier Methods	Female	Yes	During Intercourse	Yes
IVR - NuvaRing	Female	Yes	Monthly	No



Table 2. Advantages and disadvantages of common STI prevention methods

Method	Advantages	Disadvantages
Male Condom	<ul style="list-style-type: none"> • Effective if used correctly 	<ul style="list-style-type: none"> • Male initiated • Frequently used incorrectly • Use stigmatized in “faithful” relationships⁶
Female Condom ³	<ul style="list-style-type: none"> • Effective if used correctly • Female-initiated⁴ 	<ul style="list-style-type: none"> • Not widely accepted in South Africa⁵ • Male partners unwilling to use²
Microbicidal Gels ^{1,7}	<ul style="list-style-type: none"> • Female-initiated 	<ul style="list-style-type: none"> • Requires frequent application
IVR ⁷	<ul style="list-style-type: none"> • Female-initiated • Contraceptive or non-contraceptive option 	<ul style="list-style-type: none"> • Not available in South Africa • Not effective STI prevention method for anal or oral sex

¹(Auslander, Perfect, Breikopf, Succop, & Rosenthal, 2007) ²(Bekinska et al., 2001) ³(Last, 2007) ⁴(Martin, Lora, Rochat, & Andes, 2016) ⁵(Reproductive Health Matters, 2009) ⁶(Robinson, 2016) ⁷(Thurman et al., 2013)

A 2015 study of contraceptive use worldwide found that married or in-union couples had a condom usage rate of 4.9% in South Africa, a significantly lower rate than other countries in southern Africa such as Botswana (35.8%), Lesotho (16.7%), Namibia (12.3%), and Swaziland (21.9%) (United Nations, 2015). Additionally, a 2012 study utilizing information from countrywide surveys on unintended pregnancies adapted to be used on a worldwide scale found that southern Africa had the highest rate of unintended pregnancy in Africa and the fourth highest among any region in the world, with 55% of the total number of pregnancies being unintentional (Sedgh et al., 2014). An estimated 7% of South African women become unintentionally pregnant even with the use of contraceptives, where 31.9% of the unintentional pregnancies occurred while using condoms, 24.9% while using Depo-Provera shots, and 24.0% while using oral contraceptives (Le, Connolly, Yu, Pinchevsky, & Steyn, 2015).

Compared to traditional contraceptive and STI prevention methods that are currently available in South Africa, the IVR presents numerous advantages. Unlike condoms, which are male-initiated, the IVR is female-initiated. Combined with the possibility for discreet use, the IVR provides women with greater control over their risk of acquiring HIV and STIs or becoming pregnant regardless of their partner’s desires or disease statuses (Thurman et al., 2013). Furthermore, the IVR does not require daily or coital-associated application, as with ARVs and microbicidal gels, and provides protection over extended periods of time. Studies have shown the IVR to maintain its efficacy for four weeks at a time (Lopez et al., 2013; Nel, Bekker, et al., 2016; Nel, van Niekerk, et al., 2016). This allows women to insert the IVR



once every four weeks to protect themselves from disease and unplanned pregnancies resulting from rape or unplanned sex (Becker et al., 2004; Montgomery et al., 2012). The most promising aspect of the IVR, however, is its ability “to deliver more than one prevention active pharmaceutical ingredient (API), a concept known as multipurpose technologies (MPT)” (Morrow Guthrie et al., 2015, p. 2). By including APIs to prevent pregnancies and the transmission of HIV and other STIs, IVRs are able to achieve greater efficiency with regards to cost, access, and delivery (Holt & Lusti-Narasimhan, 2013). This efficiency stems largely from the capitalization on the demands of the population by “using one product type to achieve uptake and use of a second product” (Holt & Lusti-Narasimhan, 2013, p. 2).

This versatility offered by IVRs has presented researchers with the opportunity to revolutionize contraceptive and STI prevention technologies through the delivery of other localized preventive pharmacology. Researchers at the University of Massachusetts Medical School are currently in the process of developing an IVR containing an anti-gonorrhea agent in addition to, and independently from, anti-HIV and contraceptive agents. Unlike previous IVRs that have only prevented HIV and pregnancy, this particular IVR is able to prevent gonorrhea as well. By utilizing a novel approach that targets a specific epitope common among various strains of *Neisseria gonorrhoeae*, this IVR can prevent the transmission of a broad range of strains of gonorrhea and reduce the likelihood of the bacteria developing drug resistance (Gulati et al., 2013), a crucial addition, as drug resistant strains of gonorrhea have emerged (World Health Organization, 2017). This is significant, as gonorrhea and other STIs have been shown to increase risk for acquiring HIV due to the resulting inflammatory response that compromises the body’s natural defenses. Conversely, people infected with HIV are also more likely to acquire STIs (Ramjee & Daniels, 2013; Workowski & Levine, 2002; World Health Organization, 2017).

ARV-based microbicides, the preventive agents employed to prevent HIV, work by either blocking the virus from entering the cell (entry or fusion inhibitors), or by preventing the replication of the virus (reverse transcriptase inhibitors) (International Partnership for Microbicides, 2017b). Current IVRs utilize reverse transcriptase inhibitors such as dapivirine, a “highly potent ARV drug” that prevents “HIV from replicating its genetic material after the virus enters a healthy cell” (International Partnership for Microbicides, 2017a) and tenofovir to interfere with the replication of the virus (International Partnership for Microbicides, 2017b). Reverse transcriptase inhibitors can be classified into two classes: non-nucleoside reverse transcriptase inhibitors (NNRTIs) and nucleoside reverse transcriptase inhibitors



(NRTIs) (International Partnership for Microbicides, 2017b). NNRTIs such as dapivirine, as explained by the International Partnership for Microbicides (2017a), bind to HIV enzymes, thereby blocking initiation sites for the viral replication process and prevent HIV from proliferating. NRTIs such as tenofovir, on the other hand, mimic nucleotides, the basic building blocks of viral DNA, and incorporate themselves into viral DNA. By doing so, they prevent subsequent nucleotides from linking thereby blocking the reverse transcription process and, ultimately, inhibiting viral replication (International Partnership for Microbicides, 2017b). Figure 3 is an illustration of the phase of the HIV replication process that dapivirine and tenofovir inhibit.

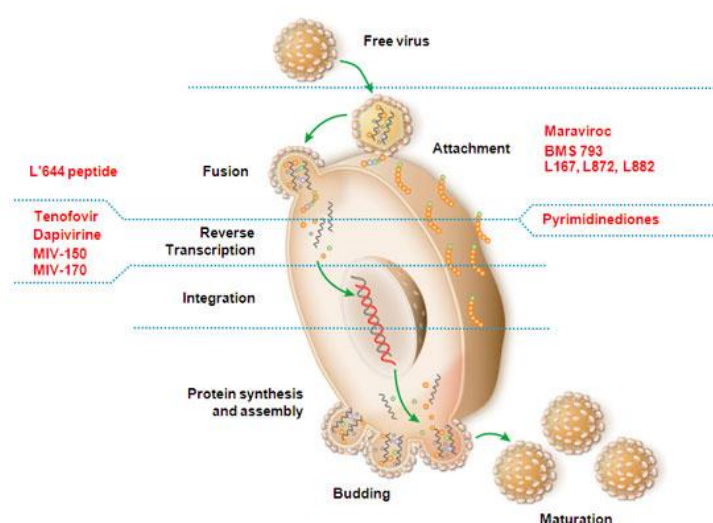


Figure 3. ARV-based microbicides work by directly targeting HIV and interfering with one of the phases in the HIV life cycle — cell attachment, cell fusion or reverse transcription (International Partnership for Microbicides, 2017b).

Tenofovir was the first microbicide shown to be effective at preventing HIV acquisition in women in the Center for the AIDS Program of Research in South Africa (CAPRISA) 004 trial (Thurman et al., 2013). This double-blind, randomized, controlled trial comparing the efficacy of tenofovir gel with a placebo gel in sexually active, HIV-uninfected women aged 18 to 40 in KwaZulu-Natal, South Africa, found that women with high gel adherence had a 54% reduction in HIV acquisition compared to women in the placebo group (Abdool Karim et al., 2010). However, despite the efforts of investigators to emphasize gel adherence, issues of nonadherence among the study participants affected the trial's ability to accurately predict the efficacy of the tenofovir gel (Abdool Karim et al., 2010). Another promising microbicide, dapivirine is in development and is currently in phase IIIb of trials (U. S. Department of Health Human Services, 2017). This trial is currently being conducted



to “support publication claims and to prepare [for the] launch [of the product]” (Bahadur, 2008, p. 3). In order to assess the effectiveness of the IVR that releases dapivirine, the clinical trial, A Study to Prevent Infection with a Ring for Extended Use (ASPIRE), was launched in Uganda, Malawi, Zimbabwe, and South Africa (Baeten et al., 2016). The trial recruited 2,629 healthy, non-pregnant, HIV-uninfected, sexually active women between the ages of 18 and 45 and randomly assigned them to either the dapivirine ring or placebo group in a double-blind test to assess the effectiveness of the IVR in a clinical trial (Baeten et al., 2016). Baeten and colleagues (2016) found that there was a 27% reduction in the incidence rate of new HIV infections with the use of the IVR, although the relative reduction in HIV incidence was 61% for women 25 and older but only 10% among women under the age of 25 (see Figure 4). The authors concluded that this stark discrepancy may be the result of both behavioral and physiologic factors (Baeten et al., 2016).

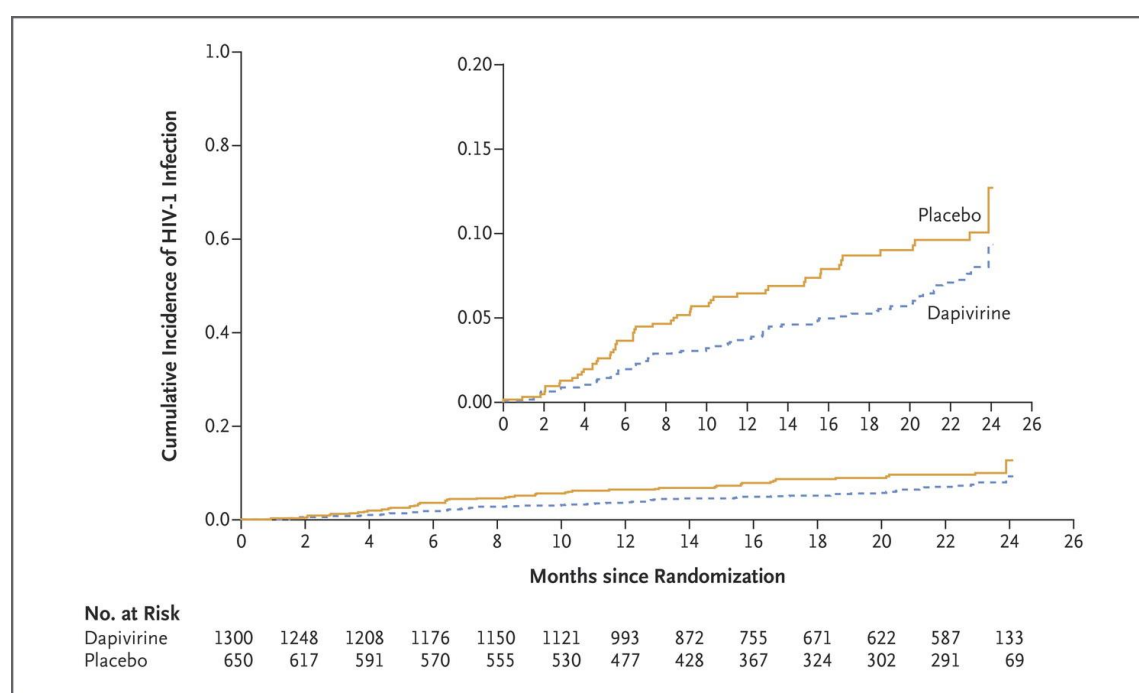


Figure 4. Cumulative incidence of HIV infection among women using a placebo ring and a dapivirine ring (Baeten et al., 2016)

In the ASPIRE study and other similar trials assessing adherence to HIV treatment methods and contraceptives conducted in South Africa, persons under 21 years of age have shown lower levels of protection compared to persons over 21 years of age (Baeten et al., 2016; Blanc, Tsui, Croft, & Trevitt, 2009; Evans et al., 2013; Kharsany & Karim, 2015). It was speculated that this lower success rate may be due to “physiologic differences in the



genital tract of younger women, lower adherence to ring use, more frequent vaginal or anal sex, or a combination of these factors” (Nel, van Niekerk, et al., 2016, p. 2140). In order to address this dilemma, research must be extended beyond understanding physiological differences among different age groups and determining levels of efficacy – an exploration of how the product is accepted and may be received by different groups within the target population is necessary. Since such a study requires sensitivity to the sociocultural norms of the population being studied, a clinical trial environment is not conducive to such an exploration.

Young and At-Risk: Characteristics of Women Most Vulnerable to HIV, STIs, and Unplanned Pregnancies

A survey involving 38,431 South African participants, conducted by the Human Sciences Research Council (2014) determined that black females aged 20 to 34 years have a significantly higher HIV prevalence (31.6%) than other race, age, and gender groups. The survey determined that 15% of the black population in South Africa had HIV, compared to 0.3% in the white population, 3.1% in the colored population, and 0.8% in the Asian and Indian populations (Shisana et al., 2014). The main factors responsible for the discrepancy in HIV prevalence by race were determined to be lower marital status and a lower likelihood to take preventive methods or treatment than other races (Shisana et al., 2014). To further support this, several HIV prevention trials conducted in South Africa also indicated that women “under the age of 25 years, having had one STI in the past and being unmarried were significantly associated with high risk of HIV seroconversion” (Wand, Whitaker, & Ramjee, 2011, p. 1). In addition, young women aged 15 to 24 years in South Africa have higher HIV incidence rates than their male counterparts, acquiring HIV five to seven years earlier than their male peers (Kharsany & Karim, 2015), and young women account for 25% of new infections (Shisana et al., 2014). The prevalence of HIV by gender is also markedly different; 13.3% of females are HIV-positive compared to 4.0% of males, a 3.3-fold difference (Statistics South Africa, 2016). Physiologically, women are also at higher risk of contracting HIV than men due to the “greater mucosal surface area exposed to pathogens and infectious fluid for longer periods during sexual intercourse and are likely to face increased tissue injury” (Ramjee & Daniels, 2013, p. 2).

Relationship dynamics are a known factor in affecting women’s risk for HIV and STI infections and pregnancy in South Africa. Dunkle and colleagues (2004) conducted a study of



relationship dynamics and risk of HIV infection by interviewing women seeking antenatal care at four clinics located in Soweto, South Africa. The study found a significant association between controlling behavior and violence from male partners and an increased risk of HIV infection (Dunkle et al., 2004). This finding was also supported by a study that surveyed 415 men and 127 women receiving services from an STI clinic in Cape Town. This study revealed that male-dominated relationships were associated with an increased risk of acquiring HIV and other STIs (Kalichman et al., 2005). In a national survey on sexual power and HIV risk, 11,904 interviews were completed and determined women with low relationship control were 2.10 times more likely to use condoms inconsistently, and those experiencing forced sex were 5.77 times more likely to use condoms inconsistently compared to women with high relationship control (Pettifor et al., 2004). Pettifor and colleagues (2004) demonstrated the correlation between women's lack of sexual power in their relationships and their inability to negotiate condom use and other protective measures, was significantly associated with higher rates of HIV and STI prevalence. Marital status was an additional factor that affected condom use, where the majority of married men and women disapproved of condom use in marriage as it encouraged promiscuity and was therefore "unsuitable for committed sexual relationships" (Maharaj & Cleland, 2004, p. 120).

Violence against women is a global problem and another well-recognized risk factor for HIV and other STIs (Ackermann & De Klerk, 2002; Higgins, Hoffman, & Dworkin, 2010). An examination of sexual violence used country-specific studies to determine the worldwide prevalence of non-partner violence. The study's estimates concluded that countries in southern sub-Saharan Africa (Namibia, Zimbabwe, and South Africa) had the second highest prevalence of non-partner sexual violence in the world (Abrahams et al., 2014). In 2005, 40% of women in Cape Town reported experiencing sexual assault and one in five men openly admitted to perpetrating sexual assault (Kalichman et al., 2005). A study of gender-based violence among South African women attending health care clinics found that the experience of being sexually assaulted by a male partner was significantly associated with increased risk of HIV infection (Dunkle et al., 2004). High-risk behavior was demonstrated in an anonymous street intercept survey in South Africa that found that women who experienced sexual assault were more likely to have unprotected sex and feared asking partners to use condoms (Kalichman et al., 2005). Furthermore, sexual assault of women in Cape Town was associated with an increase in high risk behavior such as using shared injection drug equipment and pursuing sex work after the sexual assault (Kalichman et al., 2005). The latter is particularly concerning as female sex workers that provide sexual services



in exchange for money, goods, and other benefits, are common in South Africa (Vandepitte et al., 2006), and HIV prevalence among sex workers in Cape Town was estimated to be as high as 40%, with young female sex workers under 25 years carrying most of the HIV burden (Shisana et al., 2014).

The socioeconomic status of women in South Africa also affects their overall risk of contracting HIV and STIs. A national survey of 1.3 million households found that men are predominantly the head of the household in every province of South Africa (Statistics South Africa, 2016). To support this, interviews with women in Cape Town suggested that men are predominantly the primary financial earners and decision makers of the household (Strebel et al., 2006). It was found that South African women who depend on the male partners for economic stability, lack the socioeconomic power to control sexual negotiations for safer sex (Gilbert & Walker, 2002). On the contrary, women who are in a position of generating more revenue than the male partner can also stimulate violent conflict as a result of the perceived disruption in socially accepted gender roles (Boonzaier, 2005; Strebel et al., 2006). Money and material acquisition are also the main factors for women to enter age-disparate relationships (adolescent women dating significantly older men) (Leclerc-Madlala, 2008), causing women to be put at a substantially higher risk of HIV incidence (Maughan-Brown, Kenyon, & Lurie, 2014) and adolescent pregnancy (Toska, Cluver, Boyes, Pantelic, & Kuo, 2015).

Stigma is an additional factor in HIV risk that causes women to be reluctant to enact HIV prevention (Poundstone, Strathdee, & Celentano, 2004). Also, stigma and fear of status disclosure are well-known factors inhibiting individuals seeking treatment (Poundstone et al., 2004; Pulerwitz, Michaelis, Weiss, Brown, & Mahendra, 2010; UNAIDS, 2012). A survey of 486 women that measured the result of HIV stigma in South Africa found that HIV positive women are subject to gossip (52.3%), verbal harassment (28.3%), exclusion from social activities (18.8%), physical assault (15.5%), exclusion from family gatherings (15.5%), and exclusion from religious activities (10.3%) (dos Santos, Kruger, Mellors, Wolvaardt, & van, 2014). Women in South Africa have the heaviest burden of HIV stigma, as being infected with HIV is considered failing to uphold moral traditions of their society (Poundstone et al., 2004).



Acceptability of the Intravaginal Ring: The Importance of Factors Beyond Product Efficacy

Given the various socio-ecological factors that increase the risk of women to HIV, STIs, and unplanned pregnancies, it is imperative to consider the established sociocultural, political, economic, and historical context in order to achieve a seamless integration (including correct usage and product adherence) of the IVR.

The importance of male influence on product use and adherence has been documented as an essential component to the success of female-initiated STI prevention methods (Montgomery et al., 2011; Montgomery et al., 2015) and has been a topic of discussion in many stakeholder conversations (Geary & Bukusi, 2014). In a clinical trial assessing the safety and acceptability of a placebo IVR in 170 HIV-negative, African women aged 18 to 35, 86% of women found their partner's approval of the IVR to be important; yet, only 78% of them disclosed their participation in the study to their partners producing a discrepancy between the women's theoretical desire for their partner's approval and their actual disclosure of information (Montgomery et al., 2012). A similar study of 1,916 participants in Zimbabwe and South Africa indicated that women with male partners who "strongly liked" the product were two to three times more inclined to like the product themselves and continue using the product (Montgomery et al., 2011).

The influence of various external stakeholders on the introduction of the IVR must also be considered. External stakeholders can be divided into two main categories according to their role in the implementation of the IVR: policy makers and influentials, and health care service providers. Federal, municipal, and local government officials, nongovernmental organization (NGO) representatives, research institutions, and professional medical bodies comprise the policy makers and influentials category. They are the bodies responsible for determining various policies and implementing programs in order to facilitate the successful distribution of the product. The health care service providers include public health nurses and doctors as well as employees of various reproductive and sexual health facilities. Their importance lies in their experience interacting with the at-risk populations that the IVR is targeted towards.

Becker and colleagues (2004) conducted a study in the Western Cape province of South Africa to determine the factors that both facilitate and undermine access to and use of microbicides. The study involved interviews and focus groups with community members, health care providers, government officials, representatives from NGOs, and health



professionals (Becker et al., 2004). With regards to distribution, policy makers, providers, and community participants all believed that the product should be readily available in various locations (Becker et al., 2004). Not only should the product be available in health clinics, family planning, well-baby, maternal health, and voluntary counseling and testing (VCT) centers, it should also be available in common places where women congregate (Becker et al., 2004). A study conducted among 504 women in Ghana assessing the acceptability of vaginal microbicides determined that women were most comfortable purchasing these products from health-related facilities, and also considered cosmetic shops and supermarkets as viable options (Abdulai et al., 2012). In addition, the results indicated that women preferred the vendors to be the same age or older and someone they were not socially familiar with, suggesting a preference for privacy (Abdulai et al., 2012). Although distributing the product in non-health related facilities may increase accessibility, a venue where personal counseling on product use is unavailable could pose a potential problem as improper or incomplete instructions on the use of the product will encourage improper usage and nonadherence, which will compromise the effectiveness of the product.

Cost is another important factor, as even if the product is easily accessible to clients, it also needs to be affordable. According to Becker and colleagues, “national and provincial policy makers, key policy informants, and providers all stressed that microbicides should be accessible to clients and provided at low cost or free” (2004, p. 4). However, a few factors must be taken into consideration when introducing a free product to the health care market. Users may feel that the product is inferior if it is being offered for free, and if the health care system is going to fund this product there needs to be a strong justification for why this product is superior to any other product currently offered on the market (Becker et al., 2004). In the study of vaginal microbicide awareness and acceptability in Ghana, an affordable price was considered to be between R10 and R20 (0.75-1.50 USD) for each instance of sexual interaction (Abdulai et al., 2012). Although substantial government funding will be required, the South African government is currently working to increase their contribution to the HIV response and are looking into methods to decrease the number of new HIV infections (Health Policy Project, 2016). They have created a plan for 2012 to 2016 to reduce new infections by at least 50%. In the FY 2016/2017, the government continued to fund the HIV response with 82.9% of funding coming from the government, 3.8% from the Global Fund, and 13.3% from PEPFAR (Health Policy Project, 2016).

The marketing strategy employed to introduce the product to the market contributes to how successfully the product will be adopted as well. In the aforementioned study conducted



by Becker and colleagues, community members “cautioned against ‘medicalization’ of the product and stressed the need to present products as appealing, fun and ‘normal’” (2004, p. 53). They believed that users would be more likely to use a product perceived as ‘normal’ and associated with a healthy and modern lifestyle rather than one perceived as a medical device associated with sickness (Becker et al., 2004).

Based on previous clinical trials and interviews, a method most likely to successfully distribute, fund, and market the IVR can be developed. However, since the multipurpose IVR has not been released in South Africa, there are no results on previous attempts at implementation specific to the IVR that can be used to develop a plan to introduce the product. With the recent approval of PrEP in South Africa, the implementation methods used for PrEP might be used as a model to advise the introduction of the IVR. Various clinical guidelines have been established to streamline and regulate PrEP distribution. Due to the similarity in the purpose of the product as well as the medications being used, these guidelines, which detail contraindications, eligibility criteria, and prescription intervals for PrEP, might guide distribution of the IVR (National Department of Health, 2016). The cost and population-level impact of introducing PrEP to key populations such as female sex workers, men-who-have-sex-with-men (MSM), and adolescent girls and young women have been determined through mathematical modeling (Gomez et al., 2013). A similar model can be developed to predict the costs and population-level impact of the IVR, as well to advise the distribution of the IVR to its respective key populations.

In addition to the various external factors that may affect the reception of the IVR, the potential users’ impressions of the physical characteristics of the IVR must be taken into consideration. Multiple studies have been conducted to assess potential users’ preferred characteristics of an IVR (Becker et al., 2004; Fan et al., 2016; Morrow Guthrie et al., 2015; van der Straten et al., 2014). In each of the studies, the women were provided with physical samples of IVRs and were asked for their opinions on the characteristics of an ideal IVR and what user requirements led them to their decision. The location, study participant characteristics, and methods employed to assess the study participants’ thoughts on the IVR for each study are shown in Table 3.



Table 3. Summary of studies conducted to assess preferred IVR characteristics

Study	Location	Study Participants	Methods
Becker et al., 2004	Langa, Cape Town	23 focus groups (218 total participants), 38 in-depth interviews	Interview and focus groups conducted with community members, health care providers, government officials, representatives from nongovernmental organizations, and health professionals
Fan et al., 2016	Pittsburgh, Pennsylvania, USA	12 focus groups (84 total women) 18-30 years old	Group discussion on preferred characteristics of an IVR with placebo and actual IVR available for examination
Morrow Guthrie et al., 2015	Southeast New England, USA	4 focus groups (21 women total) 18-45 years old. Used IVR in past 12 months	Semi-structured focus groups to assess participants' perceptions of their experience with the IVR
Van et al., 2012	South Africa (Durban, Johannesburg, Cape Town) Tanzania (Moshi)	157 HIV negative women used a placebo ring 6 focus groups (48 total women, 18-35 years old). 19 interviews with male partners	Women received a placebo ring to wear for 12 weeks. A questionnaire was administered every 4 weeks to assess acceptability. Exit interview with focus groups were conducted to promote discussion. Male partners were contacted for participation with female permission.

When considering the ease and accuracy of use, many women preferred an IVR that would be easily handled and inserted so as not to be “lost” during insertion; for this a certain level of opacity, size, and texture were desired for visual discernibility (Fan et al., 2016). Texture was a topic of debate among women as some argued a smooth, thin film would be easier to insert while others argued that some texture was necessary to prevent slippage through the fingers, detect adequate insertion, and prevent rapid dissolving of the medication (Morrow Guthrie et al., 2015). The effect of physical characteristics on the efficacy of the product was also commonly mentioned; participants associated porousness, opacity, and a square profile with increased drug delivery (Fan et al., 2016) and textured surfaces with a decreased likelihood of the involuntary expulsion of the IVR upon insertion (Morrow Guthrie et al., 2015). Of particular importance to the participants in the trial by Fan and colleagues (2016) was the maintenance of drug efficacy while inebriated as many of their higher-risk sexual encounters involved alcohol. This directly correlated with the participants desires for a drug with extended efficacy due to the possibility of sudden, unplanned sex (Fan et al., 2016). Considerations for user and, in particular, partner discretion, however, led participants to desire previously undesired traits: smoothness, thinness, and small size (Fan et al., 2016; Morrow Guthrie et al., 2015). Additional characteristics included being tasteless and odorless



to avoid detection by their partners (Fan et al., 2016). One particularly interesting point was the participants' desires for a high concentration of drugs with regards to efficacy, but a low concentration with regards to minimizing the impact on the vagina due to their perception that an opaquer and thus more “concentrated” IVR would have a greater likelihood of discoloring vaginal fluid (Fan et al., 2016). The last theme identified by product assessment studies, impact on sex, highlights concerns about the product hampering sexual interest and its versatility in various types of sexual activity (Fan et al., 2016; Morrow Guthrie et al., 2015). A summary of the main themes for an ideal IVR or microbicidal film and the respective characteristics for each theme obtained from the studies is listed in Table 4.

Table 4. Compilation of preferred characteristics of an IVR or microbicidal film from various studies

Major Themes	Preferred Characteristics
Accuracy and ease of use	<ul style="list-style-type: none">• Disparity between smooth and textured with regards to ease of insertion and detection of insertion¹• Matte finish for ease of handling^{1,2}• Translucent or opaque film for visibility¹
Desire for efficacy	<ul style="list-style-type: none">• Textured to prevent involuntary expulsion during use¹• Effective when inebriated¹• Porousness to facilitate drug delivery²• Square shape for greater coverage inside vagina¹• Higher opacity for increased concentration¹• Extended duration of use^{1,4}
Discretion	<ul style="list-style-type: none">• Tasteless/odorless/translucent or clear to avoid detection¹• “Listerene pack size”¹• Partner does not notice^{1,2,3}• Smooth and thin to avoid detection by partner during sex¹
Minimal impact and comfort	<ul style="list-style-type: none">• Does not change natural color of vaginal fluid¹• Smooth, thin, soft, flexible for comfort in vagina^{1,2}
Impact on sex	<ul style="list-style-type: none">• Conducive to all sexual activity types: oral, vaginal, anal¹• Cannot be felt during sex^{1,2,3}• Smooth, thin, and small for ease of insertion^{1,2}• Avoid medicinal packaging^{1,4}• Inoffensive taste for oral sex¹• Portability to allow rapid, unplanned use^{1,3}

¹(Fan et al., 2016) ²(Morrow Guthrie et al., 2015) ³(van der Straten et al., 2012) ⁴(Becker et al., 2004)

In addition to documenting favorable characteristics through visual and manual inspections of sample IVRs, various clinical trials have been conducted to assess factors that



affect adherence to IVRs (Baeten et al., 2016; Nel, Bekker, et al., 2016; Nel, van Niekerk, et al., 2016). Throughout the 12-weeks, all three trials saw positive outcomes with over 95% of women describing the ring as comfortable and not being bothered by it during daily activities. Each trial, however, had women worried that the IVR could get “lost” in their body and experiencing difficulty removing the ring. An additional concern that was frequently documented in the clinical trials was the voluntary removal of the IVR. Although the research staff had advised the participants against the removal of the IVR, a small number of participants removed the ring, generally to clean it (Nel, Bekker, et al., 2016). A similar study exploring the acceptability and safety of a placebo IVR in 170 HIV-negative South African women aged 18 to 35 experienced similar issues with voluntary ring removal due to the misconception that the ring was to be cleaned during or after menses (Montgomery et al., 2012). Both studies concluded that a more thorough explanation on this culturally sensitive topic would need to be provided. Another similar study of IVR adherence in women in Durban, Johannesburg, and Cape Town in South Africa and Moshi, Tanzania, participants indicated similar concerns; but minimized these concerns with study procedures that included explanations and demonstrations using a translucent pelvic model along with instructions on what to do if the ring were to come out (van der Straten et al., 2012). While proper insertion of the IVR was raised as a concern by study participants, insertion was not identified as a significant challenge, with 81% of the study participants able to successfully insert the IVR on their first attempt (van der Straten et al., 2012).

Due to the unfamiliarity of the majority of the people residing in Cape Town with the IVR, an adequate prediction of women’s comfort with inserting the IVR cannot be obtained. However, the population’s familiarity, or lack thereof, with tampon use may correlate with the level of comfort women have inserting the IVR due to the similarity in insertion method. A study conducted at an urban reproductive health clinic in Durban, South Africa of 124 women between the ages of 18 and 45 (most had completed secondary school, spoke isiZulu, been pregnant at least once, and half were not working or studying) found that 10.9% of participants reported using tampons as their main hygiene product, followed by 20.0% using tampons “usually,” and 43.6% never having used tampons before (Beksinska et al., 2015). The large disparity in the usage of sanitary protection is evident as “one in 10 African adolescent girls misses school during her period” (Euromonitor International, 2015, p. 1), likely because she cannot access products such as tampons and sanitary pads. Assuming that these data suggest a possible lack of experience with the insertion of tampons, the lack of



comfort with the administration of IVRs may pose an issue for the proper insertion of and adherence to the product.

A multitude of clinical trials have been performed to measure adherence to the IVR through the lens of efficacy. However, due to the varying levels of adherence among study participants, the efficacy of the product has not been accurately measured. The inability of the clinical setting to accurately predict product efficacy was documented in the Vaginal and Oral Interventions to Curb the Epidemic (VOICE) study, which tested the effectiveness of ARVs in tablet and vaginal gel form (Stadler, Scorgie, van der Straten, & Saethre, 2016). Although the study participants reported good levels of adherence, the trial concluded that none of the products in the trial were effective in preventing HIV acquisition (Marrazzo et al., 2015). Without proper adherence, the efficacy of the product will be substantially compromised, regardless of the theoretical efficacy of the product. In addition, the effect of clinical settings on the behavior of participants is well documented; the added health benefits, financial reimbursements, and sense of camaraderie are exclusive to clinical trials and do not accurately reflect a real-life setting. Furthermore, the inherent self-selection bias in clinical trials has been speculated to affect the results, as those who voluntarily participate in clinical trials are likely to possess a higher sense of resolve compared to those who do not participate (Stadler, Delany, & Mntambo, 2008). Therefore, an exploration of the various promoters and barriers to IVR adherence outside the context of a clinical setting is necessary to understand individual, interpersonal, environmental, community, societal, and economic factors that dictate IVR acceptability.

Methods

This project was designed to explore IVR acceptability and accessibility preferences among at-risk populations residing in the Philippi township of Cape Town, South Africa in collaboration with the community organization, Sizakuyenza. In addition, we investigated the costs, distribution methods, and marketing strategies by interviewing stakeholders that would be involved in the implementation of a multipurpose IVR. By exploring the various factors that either promote or impede adherence to IVRs outside of a clinical setting, we investigated policies, programs, and considerations necessary to promote IVR adherence if the product were to be made available in South Africa. This project aimed to address the following objectives:

1. Explore at-risk women's perceptions, acceptability, and accessibility preferences of the IVR
2. Explore men's perceptions and acceptability of the IVR and the influence these perceptions may have on women's acceptability of the product
3. Investigate the costs, distribution methods, and marketing strategies associated with the IVR

A mixed methods approach was used to address the stated objectives using various nonprobability sampling strategies to recruit participants. Our main method of inquiry was face-to-face, semi-structured interviews. Face-to-face interviews were the most favorable method as the circumstances dictate a more spontaneous response from the interviewee (Opdenakker, 2006). In addition, the interviewer can gather information from various social cues such as voice, intonation, and body language – information that could not be obtained through a phone or email interview (Opdenakker, 2006). However, the synchronous nature of face-to-face interviews that provide them with their advantages also require the interviewer to be much more engaged and concentrated on the questions to be asked and the answers given (Opdenakker, 2006). Wengraf (2001, p. 194) termed this added concentration as “double attention”: he explains that “[the interviewer] must both be listening to the informant's responses to understand what he or she is trying to get at, and, at the same time, you must be bearing in mind your needs to ensure that all your questions are liable to get answered within the fixed time at the level of depth and detail that you need.”



Semi-structured interviews are the most frequently used method of qualitative research. The nature of a semi-structured interview allowed our questions to be developed as we discovered more thematic areas. Similarly, questions that were not effective in previous interviews were removed from subsequent interviews. Both individual and group semi-structured interviews were utilized. In individual interviews, the participant is able to communicate deeply about social and personal matters, compared to the group interview where it is unnatural to do so (DiCicco-Bloom & Crabtree, 2006). However, a group interview can be advantageous as it collects a wider range of experience from the participants (DiCicco-Bloom & Crabtree, 2006).

Interviews with At-Risk Women and Men

We accomplished the first objective by conducting interviews with at-risk women who discussed their perceptions of the IVR as well as their thoughts regarding accessibility and convenience using the product through open-ended questions. We addressed the second objective by interviewing men in order to explore the male perspective of the IVR and how their perspectives affect female acceptability and accessibility. Interview questions were focused on individual experiences as well as understanding group opinions and community dynamics. Since every question may not have applied directly to the interviewee, the interviewee had the option to answer from a community perspective. All participants received 20 ZAR (approximately 1.47 USD) for transportation and were served light refreshments as compensation for their participation in the study. An English-isiXhosa translator was arranged when the participant was unable to or uncomfortable with conducting the interview in English.

Sampling Method

The primary sampling method was a convenience sample of participants met through our sponsoring organization, Sizakuyenza, that functioned as a pipeline to the surrounding community. Sizakuyenza is a non-profit organization located in the Philippi township that provides free health and wellness services to surrounding communities. Since its founding in 2007 by the Western Cape Government, the organization has grown and expanded to create a large network of community members and staff (Western Cape Government, 2015).

One of Sizakuyenza's primary functions is to serve as a "House of Smiles," a safe house for women experiencing domestic violence (Sizakuyenza, 2017). Some women seeking



refuge in the “House of Smiles” served as participants who provided us with insight on the acceptability of the IVR. Another one of Sizakuyenza’s major points of focus is its dedication to the HIV Prevention for Young Adolescents program (Sizakuyenza, 2017). Through various community outreach efforts, the prevention program connects the organization with members of at-risk populations. Additionally, Sizakuyenza commits itself to creating a strong network of South African women. Sizakuyenza’s health improvement efforts combined with its wide network gives the organization an established community presence. This provided connections with interview participants – mainly women, but also some men – within the community who participated in the interviews. Interviews took place during Sizakuyenza’s operational hours, 8h30 to 16h30.

Our female interview sample represented a population that is most at risk of contracting HIV, which in the case of South Africa are young, black females (Shisana et al., 2014). We focused on interviewing people aged 16 to 34. The lower age limit for our sample was chosen based on a study that gathered information from 1,149 women and 1,067 men about their sexual debuts (Richter, Mabaso, Ramjith, & Norris, 2015). The study found that over 25% of women in South Africa had their sexual debut prior to age 16, and over 40% of women in South Africa had their sexual debut prior to age of 18 (Richter et al., 2015). Since such a high percentage of women in South Africa have their sexual debut before the age of 18, it was necessary to include women as young as 16 in our research in order to have a fully representative sample of the at-risk population. The upper age limit of our sample (34 years) was determined because black South African women aged 20 to 34 have a very high HIV prevalence (31.6%) (Shisana et al., 2014). We conducted interviews with women and men in order reach a point of thematic saturation (Guest, Bunce, & Johnson, 2006).

Semi-Structured Interviews

Prior to the start of the interview, the participant was asked to sign an informed consent form. The participant was made aware of his or her right to refuse to answer a question or halt the interview at any time. At the end of the consent form, the interviewee was asked whether or not he or she would allow the interview to be recorded. Throughout the interview, one group member served as the primary interviewer and the other as the primary note taker while they monitored the interview to ensure all the questions were addressed and interjected as necessary. The interviewers were divided according to gender, and the



interviewee was asked if he or she was comfortable interviewing with the pair of male or female interviewers.

The semi-structured interview began with a discussion of the interviewee's initial impressions of the IVR. Since the topics discussed in the interview portion of this method were delicate and personal, it was difficult to get interviewees to open up about their lives immediately. Instead of starting with personal questions, we asked questions about the IVR to open up a product-oriented line of questioning. The interviewers introduced the IVR, presented a placebo model of the device outside of the package for the interviewee to hold, and explained its functionality. After introducing the IVR, the interviewees were asked about their initial opinions on the product with, "What do you think of the IVR?" followed by, "What concerns do you have about the IVR?" The interviewers were able to probe the responses and get a deeper understanding of the meaning of the response. This insight was useful in understanding perceptions of the IVR in this project. Additionally, in the context of this project, this question was used as an ice-breaker and an opportunity to determine major concerns and misconceptions about the product.

The remainder of the interview involved a series of thematic questions related to the acceptability of the IVR, including IVR characteristics, relationship dynamics, gender-based violence, stigma, socioeconomics, and distribution and cost preferences. Males had an adjusted interview to exclude female-oriented questions, but used the same thematic areas to understand the impact of male thoughts and opinions on female acceptability of the IVR. Relationship dynamics, gender-based violence, stigma, and socioeconomics were thematic areas identified to have a possible relationship with IVR acceptability as they are based on factors that increase the risk of health issues the IVR can prevent. Each interview lasted between 30 and 90 minutes and followed a list of open-ended questions.

Demographic and Situational Questions

At the end of each interview, participants were asked to answer a short questionnaire on demographics and situational circumstances. The demographic portion explored possible correlations between acceptability of the IVR and age (Kharsany & Karim, 2015; Shisana et al., 2014), relationship status (Shisana et al., 2014; Wand et al., 2011), occupation (Boonzaier, 2005; Gilbert & Walker, 2002; Strebel et al., 2006), and frequency of sexual activity. The situational questions explored factors that may affect the acceptability of the IVR, such as sexual activity, number of children, desire to get pregnant, and type of



contraception used, if any. Female participants were asked additional situational questions that may affect IVR acceptability, such as products used during menstruation as a measure of comfort and familiarity inserting the IVR. The demographic and situational questions were asked at the end of the interview to prevent modified responses or bias from early exposure to factors relevant to the analysis of the data (Sinclair, Hardin, & Lowery, 2006).

Interviews with External Stakeholders Involved in Implementation of the IVR

To address the third objective, face-to-face and phone interviews with various stakeholders that will likely have an influence on the successful implementation of the IVR in Cape Town were conducted. Stakeholders included government officials, NGO representatives, local health care providers, and professors. A list of the individuals that were interviewed are categorized according to their influence on the implementation of the IVR and compiled in Table 5. The organization was categorized into either *policy makers and policy influentials*, or *health care providers*, based on their field of work. Due to transportation and time constraints, scheduling face-to-face interviews was not always feasible; therefore, phone interviews were conducted as a secondary option. The phone interview required a similar level of engagement and concentration as the face-to-face interview (Wengraf, 2001). Although the exact response of the interviewee differed according to the method of inquiry, the same analytical methods were utilized to analyze data from the two forms of interviews.

Table 5. Organizations of interviewees interviewed categorized according to their field of work. Names of individual representatives are excluded for purposes of confidentiality.

Organization	Category	Influence
City of Cape Town Health Department	Policy maker/influential	Provide range of primary health care: municipal health (environmental health) services and personal primary health service options, to all residents through network of clinics and other health care facilities.
Desmond Tutu HIV Foundation	Policy maker/influential	Involved in research, treatment, training and prevention of HIV and related infections in southern Africa.
University of Cape Town	Policy maker/influential	Involved in public health research and related technology research
TB/HIV Care Association	Health services provider	Prevent, find, and treat HIV and TB in the general population as well as in key groups such as inmates, sex workers and people who inject drugs.



We used a purposive sampling strategy to identify appropriate individuals to interview. This strategy was also used by Becker and colleagues (Becker et al., 2004) in their study on the introduction of microbicides in South Africa. Purposive sampling allowed for the “identification and selection of information-rich cases for the most effective use of limited resources” (Palinkas et al., 2015, p. 2). By focusing on a specific population, we identified interviewees that were most likely to enable us to answer our research questions (Lærd Dissertation, 2012). This, however, was difficult due to the constraints set by the seven-week time frame. To address this possible lack of data, a snowball sampling method was simultaneously employed to establish relationships with influential individuals and organizations suggested by previous interviewees that we may not have met otherwise. Although this strategy was useful to obtain a greater quantity of data, the tendency for interviewees to suggest other possible interviewees with similar characteristics presented bias that required consideration in our analysis (Palinkas et al., 2015). As a result, the effects of selection biases were considered and individuals and organizations with contrasting viewpoints and missions were represented in the data. In order to establish contact with various individuals and organizations, we emailed either the individual or the organization initially and organized a location and time for the interview. We also attended the 2017 AIDSImpact conference from the 13th to 15th of November to integrate ourselves into the current conversations and network with scholars and implementers with similar lines of inquiry. Through this conference, we were able to expand our network and organize additional interviews.

Semi-Structured Interviews

Prior to the start of the interview, the informed, verbal consent of the interviewee was obtained and the interviewee was made aware of his or her right to refuse to answer a question or halt the interview at any time. Then, the verbal consent to audio-record the interviews was requested. As all the interviewees provided their consent to be recorded, an audiotape recorder was used to record the dialogue while notes were taken simultaneously.

The semi-structured interviews revolved around three thematic areas and its impact on the introduction of the IVR to Cape Town: cost, distribution methods, and marketing strategies. These thematic areas were heavily discussed by Becker and colleagues (2004) and are the main sources of influence that affect the perception, acceptability, and accessibility of the product to potential female users and their male partners in the target population. Unlike



the interviews with the at-risk populations, each stakeholder interview required a different set of open-ended questions and topics of discussion tailored according to the area of expertise of the interviewee, which then led to the emergence of other questions that continued to carry the dialogue between the interviewer and interviewee (DiCicco-Bloom & Crabtree, 2006). Due to the semi-structured nature of the interviews, the interviews varied in length from 40 minutes to 80 minutes. The thematic areas, sub-topics, and questions are illustrated in Figure 6: the green represents major themes, blue represents sub-topics within the themes, and purple represents the various questions and considerations associated with the sub-topics.

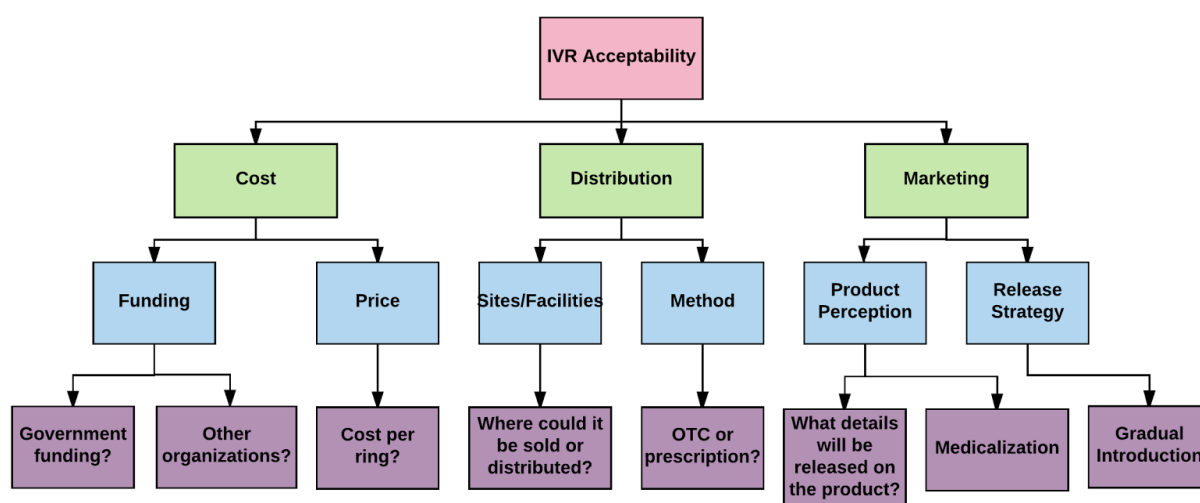


Figure 5. Breakdown of IVR acceptability in themes, sub-topics, and questions

The time and location of the interviews was based on the convenience and availability of the team members and the interviewee. Since the data was not time-sensitive, the interviews were conducted during the operational hours of the interviewee's organization. If the interviewee was unable to schedule a face-to-face interview and the interviewee was still willing to participate, the possibility of a phone interview was suggested. At least two members of the team were present during each interview and the same data collection strategy was used.

Due to the short time frame, interviews were rapidly conducted with a variety of contacts. Since this method was focused on gathering specific information regarding cost, accessibility, and marketing strategies from various stakeholders, data saturation was not considered when determining an adequate sample size; rather, the importance of this method was selecting key individuals and organizations that will influence IVR implementation. Prior to scheduling a large number of interviews, the time required to transcribe each interview was considered.



Data Analysis

A modified grounded theory approach was used to analyze interview notes and transcripts, identifying themes and adapting them to account for new and different data. The modified grounded theory technique allows researchers to find themes and patterns within the data (Corbin & Strauss, 2014). This analysis technique helped to avoid preconceptions (Martinez Perez, Mubanga, Tomas Aznar, & Bagnol, 2015) and instead rely mostly on the information presented in the interviews. However, we began our analysis with expected themes such as cost, stigma, and relationship dynamics, among others, that were identified through our research, allowing for additional themes to emerge.

Transcriptions were analyzed by formulating a codebook and tagging elements of text by code (Coffey & Atkinson, 1996). The codes were used to sort content and generate thematic areas. Transcriptions were periodically revisited to update codes as more thematic areas were discovered and understood. Once themes and interests were identified, they were sorted together and compared against each other. The similarities and differences among responses in specific categories were noted and analyzed to understand what made them similar or different.

Ethical Considerations

In all our interviews, we remained conscious of four ethical concerns that can be applied to the project: reducing the risk of unanticipated harm, protecting the interviewee's information, effectively informing interviewees about the study, and reducing the risk of exploitation (DiCicco-Bloom & Crabtree, 2006). The risk of unanticipated harm was a primary issue due to the nature of the participants and the questions that were asked. Factors relevant to research such as HIV and STI history and unplanned pregnancies may have been uncomfortable for participants to discuss; however, the interviewers were prepared to sense distress and move the interview forward to minimize distress for the interviewees. Prior to the start of every interview, the interviewees were informed about the study and were required to provide their informed consent. Interviewees were also made aware at the start of the interview that they had the right to refuse to answer any question or disengage from the interview at any time. Information that was communicated through interviews was protected due to the sensitive data that was collected. All data were stored in password-protected folders and was only accessible to members of the team, but is available to the sponsors, project advisors, or the Worcester Polytechnic Institute Institutional Review Board if the



circumstances require it. The confidentiality of the participants is also maintained in the report. The names and any other details that may identify an interviewee are not mentioned in the report or in any presentations without the prior consent of the individual. Reducing exploitation was a minor consideration in the context of this project considering that all participation was voluntary and consensual.

Results

Study Participants

In total, 28 black individuals (22 females and 6 males) were interviewed at Sizakuyenza. Twenty of the 22 female interviews were conducted individually, with one group interview of two women. Three of the six males were interviewed individually, with one group interview of three men. One female participant exceeded our maximum age limit of 35 and was excluded from our analysis. In addition, one female participant chose not to answer the demographics survey; however, her responses were used in our analysis. One male participant did not complete the demographics questionnaire in its entirety as he omitted occupation and number of sexual partners in the last three months. Although not represented in our demographics or included in our analysis, we also conducted a group interview of 15 women and 2 men, which served to confirm our findings from our individual interviews. Participant demographics and behavioral characteristics are shown in Table 6.

Table 6. Participant demographics for semi-structured interviews with at-risk community members

Variable	Female (n=20)	Male (n=6)
	Number of Responses (%)	
Employment status		
Employed	9 (45)	2 (40)
Unemployed	10 (50)	-
Student	1 (5)	3 (60)
Relationship status		
Married	4 (20)	2 (33)
Single	9 (45)	2 (33)
In a relationship	7 (35)	2 (33)
Preferred contraceptive		
Condom	11 (55)	-
Female condom	1 (5)	-
Birth control pills	2 (10)	-
Depot-Provera shot	2 (10)	-
Implant	1 (5)	-
None	3 (15)	-
Sex without condom in last 3 months	9 (45)	2 (33)
Trying to get pregnant	3 (15)	1 (17)
Preferred menstruation product		
Sanitary pads	17 (85)	-
Tampons	1 (5)	-
None	2 (10)	-
Variables	Mean (SD)	
Age	28.7 (4.3)	24.2 (9.0)
Number of children	1.8 (1.0)	0.5 (0.6)
No. sexual partners in the last 3 months	0.9 (0.5)	2.0 (3.4)



Key Findings

Consistent with prior findings, our data suggest that the multi-purpose IVR could address ongoing concerns around inconsistent condom use (Statistics South Africa, 2017) and the influence of relationship dynamics and roles on negotiating and acquiring various forms of contraception and disease prevention products (Maharaj & Cleland, 2004; Pettifor et al., 2004; United Nations, 2015). In addition, our data show the limited use of intravaginal products in the study population, including female condoms and tampons, also consistent with prior observations (Beksinska et al., 2001; Beksinska et al., 2015). This could negatively influence product use as a lack of female familiarity with vaginal insertion may correlate with a lack of female comfort with IVR insertion. Our data indicate that the novelty of the product and the confines of its distribution may affect its utilization, and consequently its efficacy at reducing HIV and STI incidence, and preventing unplanned pregnancy at a population level.

Inconsistent and Undesirable Condom Use

Theoretically, the advantage of the IVR is that it places the control (and burden) of disease prevention and pregnancy planning on the female (Thurman et al., 2013). While contraceptive products that provide women with management over pregnancy are available, currently, STI and HIV prevention is limited to negotiated female or male condom use (Pettifor et al., 2004). Our data indicate that, in the study population, condom use is highly undesirable, with one male participant explaining, “*Some say the condom breaks, some say they don’t feel flesh-to-flesh, having sex how they want to. They want to feel that friction*” (M1). Furthermore, female interviewees shared stories of men deliberately breaking condoms during sex just so they could get women pregnant further supporting the ineffectiveness of the male condom at protecting women from various STIs as well as pregnancy.

Influence of Relationship Dynamics on Product Negotiation and Acquisition

The multipurpose IVR offers women the ability to manage their disease risk, discreetly, if they choose. In several interviews, female participants confirmed that the discrete nature of the product is ideal, explaining how “*it’s perfect*” that she would be the only one to “*know what is happening in [her] body.*” Despite study participants’ positive impressions of the capability for discretion, most participants indicated that they would likely communicate with their partners about product use. Married men and women, in particular, felt strongly about communication being an important factor in ensuring IVR acceptability. In contrast, unmarried men and women agreed that the women had less of an obligation to



discuss disease prevention and contraception with their sexual partners due to the volatility of their relationships, although some said they would disclose product use anyway. As noted by one male interviewee, these considerations of product negotiation are in line with accepted relationship roles, noting *“those who are single, they have the advantage of making their own decisions. Those who are married, they have to first sit down and explain whatever decision they are going to take”* (M6). Some study participants noted concerns over assumptions of infidelity, if such a product was used without first discussing its use, as one female participant pointed out, *“He is going to be like ‘You didn’t tell me’, he is going to think you are sleeping with other men and then if you tell him late he going to be angry, ‘You didn’t tell me you were using this without my confirmation’”* (W16). In spite of this concern, several male and female interviewees pointed out that men usually do not care what disease prevention or contraception women use because they themselves will appreciate additional protection, especially in the absence of condom use.

The effect of relationship roles extends beyond negotiations of product use to concerns around product acquisition. As explained by a senior pharmacist at the City of Cape Town Department of Health, given the nature of the product and the likelihood that in order to enter the public marketplace, it will require significant state and private subsidies and is unlikely to be available without a prescription, the product will only be available at regulated dispensary locations (i.e., pharmacies and hospitals). This may pose a barrier to accessibility as our data reveal significant dislike for doctors and hospitals given prior negative experiences with health care providers. As explained by participants, with regards to the dissemination of contraception and disease prevention products, health care providers lack discretion and sensitivity, with nurses calling on patients by name and reason for their clinic visit in the waiting area. Such publicizing of private information is particularly problematic in a context where expectations of marriage are linked to child production and the undisclosed use of disease prevention and contraceptive methods is highly stigmatized. As expressed by one female participant, *“If you go to the public hospital, they will just say, ‘Family planning, this side.’ Then, if you are married and you will be seen in the family planning side, it’s going to be bad”* (W18). In addition to addressing discretion, clinics will also have to consider potential increases in service utilization, and as such need to address existing barriers to access including long wait times, associated travel costs and work time lost, and limited patient-provider engagement, as described *“[you need to] go with your own information, [because] they don’t have time to explain to you the options for prevention contraceptives”* (W18).



Effects of Exposure to Intravaginal Products on Comfort with IVR Insertion

Limited engagements with health care providers offers one explanation for limited exposure to and experience with products we deemed related to the IVR (those that require vaginal insertion – tampons and female condoms). Confirming the limited use of tampons that was found at an urban reproductive health clinic in Durban (Beksinska et al., 2015), our study population had limited experience with tampons, explaining that they “*fear that the tampon will get stuck inside*” and that it would be “*very uncomfortable*.” Other women explained that they had never considered using tampons because they had been “*raised using pads*.” While cost may be a barrier to tampon use, it was not mentioned by study participants, and price estimates indicate no significant differences in product costs (per product estimate from Clicks: pads 2.10 ZAR; tampons 2.70 ZAR, approximately 0.15 USD and 0.20 USD, respectively). Study participants were familiar with the female condom, but again, few had experience using the product. Some demonstrated a theoretical understanding of the insertion strategy of the female condom and its similarity to the IVR insertion approach – squeezing the inner ring which will expand within the vagina. A medical officer involved in an IVR clinical trial at the Desmond Tutu HIV Foundation (DTHF) suggested that greater exposure to medical providers that corresponds with age and life experiences influences willingness to insert products like the IVR. She further noted that in an ongoing IVR clinical trial, older female study participants “*have had babies, they’ve had pap smears, things in and out of their vaginas*,” making them more comfortable with vaginal insertion compared to their younger study counterparts. However, women’s familiarity or experience with tampons and female condoms have not been associated with their level of comfort with the IVR, due to the limited number of women using these products.

Novelty of the Product and the Confines of its Distribution May Affect its Utilization

Given the current conceptualization of the product, correct usage and adherence will significantly influence efficacy. The importance of correct usage and adherence has been demonstrated through the lowered levels of efficacy seen in clinical trials due to adherence-related issues; however, the clinical trials have not been able to identify the drivers affecting adherence. In addition, the product is still novel in this study population, and as such, various design considerations should be taken into account to ensure appropriate usage. The ongoing clinical trial assessing dapivirine IVRs in multiple study sites (Nel, van Niekerk, et al., 2016) found that participants were initially uncomfortable using the ring, limiting adherence and lowering product effectiveness. Consequently, exposure strategies have been implemented to



improve comfort levels including access to professionals who can insert the product for the study participant as well as hosting participant support groups to discuss product concerns. Beyond the confines of a clinical trial, several study participants reflected a similar idea, advocating for a prescription requirement which would accompany a visit to a professional to obtain specific usage directions and assistance. Having no familiarity with such a product, our study population expressed concerns about product removal, consistent with findings from other studies (Montgomery et al., 2012; Nel, van Niekerk, et al., 2016; van der Straten et al., 2012).

In addition, concerns were raised about product use during menstruation, as documented in clinical trials during which participants voluntarily removed the IVR during menses, generally to clean it (Montgomery et al., 2012; Nel, Bekker, et al., 2016). Furthermore, the DTHF medical officer involved in an IVR safety and efficacy trial discussed how female participants in the study would share their IVR with their peers in greater need of protection. For example, if a friend of the study participant was more likely to have sexual intercourse that night, then the IVR would be lent out. There has also been some anecdotal evidence that in an effort to extend the life of the product, the IVR was removed and inserted only when it is deemed necessary for protection, following the more familiar use dynamics of condoms. Finally, as noted by a postdoctoral scholar at the DTHF, should the product alter menstruation patterns (a common occurrence with hormonal contraception), users must be well informed as they may discontinue use assuming accidental pregnancy.

These alternative use dynamics reflect not only the novelty of having a product inserted into the body for prolonged periods of time but also ongoing economic influencers. Different potential usage patterns reflect a desire to save money by sharing the product with friends, or extending the duration of the product past the efficacy period of three to four weeks. Given that a constant exposure to ARVs as well as hormonal medication is necessary for the IVR to be effective (Thurman et al., 2013), removing the product would compromise product efficacy. However, an investigation of the levels of protection offered at various time intervals post-removal is necessary to further confirm such pharmacokinetics. Alternatively, product developers may need to consider products that have more familiar usage characteristics, such as single-use (possibly 24-hour) products that are equally discrete and female-initiated.

Discussion

Overall acceptability for the multi-purpose IVR was very high among our interviewees despite the sub-optimal levels of comfort and experience with vaginal product insertion. Based on the information provided in interviews with the at-risk population and stakeholders, insertion appears to be a significant obstacle that may hinder acceptance of the IVR, particularly for younger women. Familiarity, and more importantly, experience with related intravaginal products such as tampons and female condoms may decrease insertion-related fears. However, a more thorough investigation into women's use of and familiarity with various vaginal products in South Africa must be conducted to support such a causal relationship. The positive responses to the product despite the lack of intravaginal product insertion familiarity and experience may be attributable to the protection that the IVR offers against STIs and pregnancy. The possible benefits of the product may have negated any insertion-related uncertainties among the participants.

Although pharmacies, clinics, and hospitals can adequately offer the necessary resources for the distribution of the IVR, its fixed location provides a barrier to those without the necessary transportation accommodations or availability. A program manager from TB/HIV Care Association mentioned the inability of youth attending schools to access health care due to the alignment of times attending school with the open hours of the clinics. To address this, she suggested the possibility of a mobile site – a mobile clinic overseen by a registered nurse with a dispensing license on board that runs specific routes and fills scripts. She mentioned that such a distribution scheme would increase the accessibility to the product for those unable to travel to a fixed site because of financial or time-related constraints. With the mobile site, users would still face the barrier of having to visit a doctor to receive a prescription. However, they could receive IVRs from the mobile site for the duration of their prescription, or receive a refillable prescription that would just require collecting the product from the pharmacy periodically for a pre-determined duration.

Throughout our interviews with men and women at Sizakuyenza, as well as consultations with external stakeholders, the recurring theme of information dissemination was emphasized as the key to promoting the correct usage of, adherence to, and acceptability of the IVR. At first glance, information dissemination presents itself as a powerful tool capable of addressing the issues of STIs, HIV, and unintended pregnancy with results that support its positive impact (Kirby, Laris, & Rolleri, 2007). However, as explained earlier, a



variety of individual, interpersonal, socioeconomic, and environmental factors must also be accounted for in the decision-making process of those in at-risk communities. Rational choice theory assumes that, given a set of constraints, the individual chooses the optimal option (Green, 2002); however, potential users of the IVR face constraints that may make the rational choice one that does not involve obtaining and using the IVR. To promote adherence among such a population, information dissemination alone is not sufficient. An investment has to be made into improving existing and developing new social infrastructure that serves to promote the use of and adherence to new medical technologies such as the IVR.

Our data support existing evidence that young females are an ideal target population to market the IVR to in South Africa, as they make up the highest HIV prevalence in the country (Shisana et al., 2014). However, product marketing should not be limited to females, as our data indicate that males, especially in married partnerships, should be engaged in conversations around product options and use. Furthermore, to limit product stigmatization, perceptions that only ill people (product medicalization as identified by Becker et al., 2004) and people engaging in risky behaviors should use the product, the product needs to be marketed in a way that conveys notions of health and responsibility as opposed to illness, carelessness, and promiscuous behavior.

Social media was repeatedly identified as a promising medium through which information regarding new products such as the multipurpose IVR could be disseminated. Of the mentioned social media platforms, Facebook was most popular while Instagram, WhatsApp, and YouTube were mentioned as well. Social media is a promising avenue to market the product given the high percentage of the South African population on social media. Applications such as Facebook, YouTube, and WhatsApp are the three most popular social media platforms in South Africa and may serve as an invaluable medium to disseminate information on the IVR (Qwerty, 2017). In addition, the target population for the IVR (young women) is also the second largest age group of Facebook consumers in South Africa (second only to their male counterparts), with a total of 5 million Facebook users being between ages 18 and 34 (Qwerty, 2017). Given the large presence of youth on social media platforms, this online medium is the most advantageous avenue to inform younger populations on technologies such as the IVR.

Another viable option suggested by stakeholders from the Department of Health is marketing in a topic-related setting referred to as “outreach” stations or “gazebos,” where communities are offered various disease prevention and contraception products, education on proper usage of these products, and HIV counseling and testing. Participants in our study also



stressed the importance of community dialogue and community leader acceptance of the product, due to the strong influence of community leaders' decisions on community members. The final method suggested by participants and multiple stakeholders is to educate students about the product directly in school. Education about the IVR would be relevant in a class participants and stakeholders referred to as "Life Orientation," which covers topics such as family planning, pregnancy, STIs, and related topics. This approach would solely target the youth, but also presents several other advantages. Presenting the IVR in schools would allow both males and females to learn about the product together, which would both be acceptable and effective according to participants from our study. One participant pointed out that this will be especially effective if there are sexually active students in the classroom who can promote discussions with their peers.

One potential limitation of this study pertains to the characteristics of the sample population as several participants were employees of Sizakuyenza, or members of the community with strong ties to the organization. The study participants' involvement with the organization that promotes sexual and reproductive health, may have influenced their responses. In addition, their employment with Sizakuyenza may suggest an altered risk profile, mainly due to their higher economic status compared to unemployed community members. This is further supported by one participant whose responses suggested a greater risk for acquiring STIs and becoming pregnant compared to the majority of our interviewees due to her lack of power in negotiating contraceptive and disease prevention use with her partner. Although her circumstances categorize her as an outlier in our data, she mentioned that her situation is common among women in her community claiming that "*9 out of 10 women in Xhosa tribes*" (W18) were experiencing similar circumstances – this led us to believe that we may not have been able to interview a particularly high-risk population in the community. In addition, due to logistical constraints, we were unable to obtain a consistent translator to assist us during our interviews. As some of the translators were previous interviewees, their pre-exposure to the questions may have presented an unexpected source of bias. The seven-week time frame imposed another limitation as we were unable to conduct a large number of interviews to uncover any significant correlations with our demographics. Lastly, our personal limitations due to a lack of experience discussing and probing participants on sensitive topics such as these may have hindered our ability to inquire about the deep-seated drivers of IVR adherence.

Based on the limitations identified in our study, future directions should focus on conducting studies with an extended time frame and an expanded study population. In



addition, separate studies that more specifically investigate the relationship between female intravaginal product familiarity and experience with IVR insertion comfortability may need to be conducted to properly understand this relationship.

Conclusion

The IVR is a novel technology with the potential to address major public health issues in South Africa. However, an understanding of the various promoters and impeters to IVR adherence, which will ultimately influence its effectiveness, has not been explored thoroughly and is necessary to advise the development and introduction of the product. Our project identified various individual, social, economic, and political factors through interviews with members of an at-risk population and external stakeholders that will likely influence acceptability and accessibility of the IVR. In the context of the biotechnology industry, this project highlights the importance of interdisciplinary work. When developing medical technologies, the design of the product must be advised by the investigation and exploration of the context under which it will be utilized. With the advent of user-centered design, product developers must remain conscious of the constraints placed by various social, environmental, economic, and interpersonal factors in order for products to have their desired effect.

References

- Abdool Karim, Q., Abdool Karim, S. S., Frohlich, J. A., Grobler, A. C., Baxter, C., Mansoor, L. E., . . . Taylor, D. (2010). Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science*, 329(5996), 1168-1174. doi:10.1126/science.1193748
- Abdulai, M. A., Baiden, F., Adjei, G., Afari-Asiedu, S., Adjei, K., Tawiah, C., & Newton, S. (2012). An assessment of the likely acceptability of vaginal microbicides for HIV prevention among women in rural Ghana. *BMC Women's Health*, 12(1), 40.
- Abrahams, N., Devries, K., Watts, C., Pallitto, C., Petzold, M., Shamu, S., & García-Moreno, C. (2014). Worldwide prevalence of non-partner sexual violence: A systematic review. *The Lancet*, 383(9929), 1648-1654. doi:10.1016/S0140-6736(13)62243-6
- Ackermann, L., & De Klerk, G. W. (2002). Social factors that make South African women vulnerable to HIV infection. *Health Care for Women International*, 23(2), 163-172. doi:10.1080/073993302753429031
- Auslander, B., Perfect, M. M., Breitkopf, D. M., Succop, P. A., & Rosenthal, S. (2007). Microbicides: Women's "anticipated" sources of information, beliefs, and preferences for insertion. *Journal of Pediatric and Adolescent Gynecology*, 20(2), S146. doi:10.1016/j.jpog.2007.03.084
- Baeten, J. M., Palanee-Phillips, T., Brown, E. R., Schwartz, K., Soto-Torres, L., Govender, V., . . . Hillier, S. (2016). Use of a vaginal ring containing dapivirine for HIV-1 prevention in women. *New England Journal of Medicine*, 375(22), 2121-2132. doi:10.1056/NEJMoa1506110; 28
- Bahadur, N. (2008). *Overview of drug development*. Paper presented at the Review of Drug Development in Clinical Trials, Bangkok, Thailand.
- Becker, J., Dabash, R., McGrory, E., Cooper, D., Harries, J., Bracken, H., . . . Orner, P. (2004). *Paving the path: Preparing for microbicide introduction report of a qualitative study in South Africa*. Retrieved from <http://www.engenderhealth.org>
- Beksinska, M. E., Rees, V. H., McIntyre, J. A., & Wilkinson, D. (2001). Acceptability of the female condom in different groups of women in South Africa—A multicentred study to inform the national female condom introductory strategy. *South African Medical Journal*, 91(8), 672.
- Beksinska, M. E., Smit, J., Greener, R., Todd, C. S., Lee, M.-I. T., Maphumulo, V., & Hoffmann, V. (2015). Acceptability and performance of the menstrual cup in South Africa: A randomized crossover trial comparing the menstrual up to tampons or sanitary pads. *Journal of Women's Health*, 24(2), 151-158. doi:10.1089/jwh.2014.5021
- Blanc, A. K., Tsui, A. O., Croft, T. N., & Trevitt, J. L. (2009). Patterns and trends in adolescents' contraceptive use and discontinuation in developing countries and comparisons with adult women. *International Perspectives on Sexual and Reproductive Health*, 35(2), 63-71.
- Boonzaier, F. (2005). Woman abuse in South Africa: A brief contextual analysis. *Feminism & Psychology*, 15(1), 99-103.
- Coffey, A., & Atkinson, P. (1996). *Making sense of qualitative data: Complementary research strategies*: SAGE Publications.
- Corbin, J., & Strauss, A. (2014). *Basics of qualitative research: Techniques and procedures for developing grounded theory*: SAGE Publications.



- DiCicco-Bloom, B., & Crabtree, B. F. (2006). The qualitative research interview. *Medical Education*, 40(4), 314-321. doi:10.1111/j.1365-2929.2006.02418.x
- dos Santos, M. M. L., Kruger, P., Mellors, S. E., Wolvaardt, G., & van, d. R. (2014). An exploratory survey measuring stigma and discrimination experienced by people living with HIV/AIDS in South Africa: The People Living with HIV Stigma Index. *BMC Public Health*, 14(1), 80. doi:10.1186/1471-2458-14-80
- Dunkle, K. L., Jewkes, R. K., Brown, H. C., Gray, G. E., McIntyre, J. A., & Harlow, S. D. (2004). Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. *The Lancet*, 363(9419), 1415-1421. doi:10.1016/S0140-6736(04)16098-4
- Euromonitor International. (2015). South Africa sanitary protection market: New insights. Retrieved from <https://search.proquest.com/docview/1687206913>
- Evans, D., Menezes, C., Mahomed, K., Macdonald, P., Untiedt, S., Levin, L., . . . Maskew, M. (2013). Treatment outcomes of HIV-infected adolescents attending public-sector HIV clinics across Gauteng and Mpumalanga, South Africa. *AIDS Research and Human Retroviruses*, 29(6), 892-900. doi:10.1089/aid.2012.0215
- Fan, M. D., Kramzer, L. F., Hillier, S. L., Chang, J. C., Meyn, L. A., & Rohan, L. C. (2016). Preferred physical characteristics of vaginal film microbicides for HIV prevention in Pittsburgh women. *Archives of Sexual Behavior*, 46(4), 1111-1119. doi:10.1007/s10508-016-0816-1
- Geary, C. W., & Bukusi, E. A. (2014). Women and ARV-based HIV prevention—Challenges and opportunities. *Journal of the International AIDS Society*, 17(3 Suppl 2), 19356. doi:10.7448/IAS.17.3.19356
- Gilbert, L., & Walker, L. (2002). Treading the path of least resistance: HIV/AIDS and social inequalities—A South African case study. *Social Science & Medicine*, 54(7), 1093-1110. doi:10.1016/S0277-9536(01)00083-1
- Gomez, G. B., Borquez, A., Case, K. K., Wheelock, A., Vassall, A., & Hankins, C. (2013). The cost and impact of scaling up pre-exposure prophylaxis for HIV prevention: A systematic review of cost-effectiveness modelling studies. *PLoS Medicine*, 10(3), e1001401. doi:10.1371/journal.pmed.1001401
- Green, S. L. (2002). *Rational choice theory: An overview*. Retrieved from <https://business.baylor.edu>
- Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. *Field Methods*, 18(1), 59-82. doi:10.1177/1525822X05279903
- Gulati, S., Zheng, B., Reed, G. W., Su, X., Cox, A. D., St. Michael, F., . . . Rice, P. A. (2013). Immunization against a saccharide epitope accelerates clearance of experimental gonococcal infection. *PLoS Pathogens*, 9(8), e1003559. doi:10.1371/journal.ppat.1003559
- Health Policy Project. (2016). *Health financing profile: South Africa*. Retrieved from Washington, D.C.: <https://www.healthpolicyproject.com>
- Higgins, J. A., Hoffman, S., & Dworkin, S. L. (2010). Rethinking gender, heterosexual men, and women's vulnerability to HIV/AIDS. *American Journal of Public Health*, 100(3), 435-445.
- Holt, B. Y., & Lusti-Narasimhan, M. (2013). *Multipurpose prevention technologies (MPTs) for sexual and reproductive health: Meeting a critical need for women and their families*.
- International Partnership for Microbicides. (2017a). Dapivirine (TMC120). Retrieved from <https://www.ipmglobal.org/our-work/arvs-in-the-pipeline/dapivirine-tmc120>



- International Partnership for Microbicides. (2017b). How ARV-based microbicides work. Retrieved from <https://www.ipmglobal.org/why-microbicides/how-arv-based-microbicides-work>
- Kalichman, S. C., Simbayi, L. C., Kaufman, M., Cain, D., Cherry, C., Jooste, S., & Mathiti, V. (2005). Gender attitudes, sexual violence, and HIV/AIDS risks among men and women in Cape Town, South Africa. *Journal of Sex Research, 42*(4), 299-305. doi:10.1080/00224490509552285
- Kharsany, A. B. M., & Karim, Q. A. (2015). HIV Infection and AIDS in sub-Saharan Africa: Current status, challenges and opportunities. *The Open AIDS Journal, 10*, 34-48. doi:10.2174/1874613601610010034
- Kirby, D. B., Laris, B. A., & Roller, L. A. (2007). Sex and HIV education programs: Their impact on sexual behaviors of young people throughout the world. *Journal of Adolescent Health, 40*(3), 206-217. doi:10.1016/j.jadohealth.2006.11.143
- Lærd Dissertation. (2012). Purposive Sampling. Retrieved from <http://dissertation.laerd.com/purposive-sampling.php#explained>
- Last, J. M. (Ed.) (2007) A Dictionary of Public Health (4 ed.). Cape Town, South Africa: Oxford University Press.
- Le, H. H., Connolly, M. P., Yu, J., Pinchevsky, Y., & Steyn, P. S. (2015). The public health and economic consequences of unintended pregnancies in South Africa. *Healthcare in Low-resource Settings, 3*(1).
- Leclerc-Madlala, S. (2008). Age-disparate and intergenerational sex in southern Africa: The dynamics of hypervulnerability. *AIDS, 22*(4), 2533-2542.
- Lopez, L. M., Grimes, D. A., Gallo, M. F., Stockton, L. L., & Schulz, K. F. (2013). Skin patch and vaginal ring versus combined oral contraceptives for contraception. *Cochrane Database of Systematic Reviews*(4). doi:10.1002/14651858.CD003552.pub4
- Maharaj, P., & Cleland, J. (2004). Condom use within marital and cohabiting partnerships in KwaZulu-Natal, South Africa. *Studies in Family Planning, 35*(2), 116-124.
- Marrazzo, J., Ramjee, G., Richardson, B. A., Gomez, K., Mgodini, N. M., Nair, G., . . . VOICE Study Team. (2015). Tenofovir-based preexposure prophylaxis for HIV infection among African women. *New England Journal of Medicine, 372*(6), 509-518. doi:10.1056/NEJMoa1402269
- Martin, J., Lora, P. d., Roach, R., & Andes, K. L. (2016). Understanding female condom use and negotiation among young women in Cape Town, South Africa. *International Perspectives on Sexual and Reproductive Health, 42*(1), 13.
- Martinez Perez, G., Mubanga, M., Tomas Aznar, C., & Bagnol, B. (2015). Zambian women in South Africa: Insights into health experiences of labia elongation. *Journal of Sex Research, 52*(8), 857-867. doi:10.1080/00224499.2014.1003027
- Maughan-Brown, B., Kenyon, C., & Lurie, M. N. (2014). Partner age differences and concurrency in South Africa: Implications for HIV-infection risk among young women. *AIDS and Behavior, 18*(12), 2469-2476. doi:10.1007/s10461-014-0828-6
- Montgomery, E. T., van der Straten, A., Cheng, H., Wegner, L., Masenga, G., von Mollendorf, C., . . . Woodsong, C. (2012). Vaginal ring adherence in sub-Saharan Africa: Expulsion, removal, and perfect use. *AIDS and Behavior, 16*(7), 1787-1798. doi:10.1007/s10461-012-0248-4
- Montgomery, E. T., van der Straten, A., Chidanyika, A., Chipato, T., Jaffar, S., & Padian, N. (2011). The importance of male partner involvement for women's acceptability and adherence to female-initiated HIV prevention methods in Zimbabwe. *AIDS and Behavior, 15*(5), 959-969.



- Montgomery, E. T., van der Straten, A., Stadler, J., Hartmann, M., Magazi, B., Mathebula, F., . . . Soto-Torres, L. (2015). Male partner influence on women's HIV prevention trial participation and use of pre-exposure prophylaxis: The importance of “understanding”. *AIDS and Behavior*, *19*(5), 784-793. doi:10.1007/s10461-014-0950-5
- Morrow Guthrie, K., Vargas, S., Shaw, J. G., Rosen, R. K., van den Berg, J. J., Kiser, P. F., . . . Buckheit, R. W. (2015). The promise of intravaginal rings for prevention: User perceptions of biomechanical properties and implications for prevention product development. *PLoS One*, *10*(12), e0145642. doi:10.1371/journal.pone.0145642
- National Department of Health. (2016). *Guidelines for expanding combination prevention and treatment options for sex workers: Oral pre-exposure prophylaxis (PrEP) and test and treat (T&T)*. Retrieved from South Africa: <http://www.sahivsoc.org/Files/PrEP%20and%20TT%20Guidelines%20-%20Final%20Draft%20-%202011%20May%202016.pdf>
- Nel, A., Bekker, L.-G., Bukusi, E., Hellström, E., Kotze, P., Louw, C., . . . Woodson, C. (2016). Safety, acceptability and adherence of dapivirine vaginal ring in a microbicide clinical trial conducted in multiple countries in sub-Saharan Africa. *PLoS One*, *11*(3), 1-19. doi:10.1371/journal.pone.0147743
- Nel, A., van Niekerk, N., Kapiga, S., Bekker, L.-G., Gama, C., Gill, K., . . . Rosenberg, Z. (2016). Safety and efficacy of a dapivirine vaginal ring for HIV prevention in women. *New England Journal of Medicine*, *375*(22), 2133-2143. doi:10.1056/NEJMoa1602046
- Newman, L., Rowley, J., Vander Hoorn, S., Wijesooriya, N. S., Unemo, M., Low, N., . . . Temmerman, M. (2015). Global estimates of the prevalence and incidence of four curable sexually transmitted infections in 2012 based on systematic review and global reporting. *PLoS One*, *10*(12), 1-17.
- Opendakker, R. (2006). Advantages and disadvantages of four interview techniques in qualitative research. *Forum: Qualitative Social Research*, *7*(4).
- Palinkas, L., Horwitz, S., Green, C., Wisdom, J., Duan, N., & Hoagwood, K. (2015). Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Administration and Policy in Mental Health and Mental Health Services Research*, *42*(5), 533-544. doi:10.1007/s10488-013-0528-y
- Pettifor, A. E., Measham, D. M., Rees, H. V., & Padian, N. S. (2004). Sexual power and HIV risk, South Africa. *Emerging Infectious Diseases*, *10*(11), 1996-2004. doi:10.3201/eid1011.040252
- Planned Parenthood. (2017). All about birth control methods. Retrieved from <https://www.plannedparenthood.org/learn/birth-control>
- Poundstone, K. E., Strathdee, S. A., & Celentano, D. D. (2004). The social epidemiology of human immunodeficiency virus/acquired immunodeficiency syndrome. *Epidemiologic Reviews*, *26*(1), 22-35.
- Pulerwitz, J., Michaelis, A., Weiss, E., Brown, L., & Mahendra, V. (2010). Reducing HIV-related stigma: Lessons learned from Horizons research and programs. *Public Health Reports*, *125*(2), 272-281.
- Qwerty. (2017). *The digital landscape in South Africa 2017: A data driven look at South Africa's relationship with digital*. Retrieved from <http://qwertydigital.co.za/wp-content/uploads/2017/08/Digital-Statistics-in-South-Africa-2017-Report.pdf>
- Ramjee, G., & Daniels, B. (2013). Women and HIV in sub-Saharan Africa. *AIDS Research and Therapy*, *10*(1), 30. doi:10.1186/1742-6405-10-30



- Ravel, J., Gajer, P., Fu, L., Mauck, C. K., Koenig, S. S. K., Sakamoto, J., . . . Zeichner, S. L. (2012). Twice-daily application of HIV microbicides alter the vaginal microbiota. *mBio*, 3(6), 1-8.
- Reproductive Health Matters. (2009). Female condom marginalised in Southern Africa. *Reproductive Health Matters*, 17(33), 219.
- Richter, L., Mabaso, M., Ramjith, J., & Norris, S. A. (2015). Early sexual debut: Voluntary or coerced? Evidence from longitudinal data in South Africa–The birth to twenty plus study. *South African Medical Journal*, 105(4), 304-307.
- Robinson, P. (2016). Condom use: Men still a stumbling block. *Cape Times*. Retrieved from <https://www.pressreader.com/south-africa/cape-times/20160812/281736973847214>
- Sedgh, G., Singh, S., & Hussain, R. (2014). Intended and unintended pregnancies worldwide in 2012 and recent trends. *Studies in Family Planning*, 45(3), 301-314.
- Shisana, O., Rehle, T., Simbayi, L. C., Zuma, K., Jooste, S., Zungu, N., . . . Onoya, D. (2014). *South African national HIV prevalence, incidence and behaviour survey, 2012* (978-0-7969-2483-4). Retrieved from Cape Town, South Africa: <http://www.hsrc.ac.za/en/research-data/view/6871>
- Sinclair, S., Hardin, C. D., & Lowery, B. S. (2006). Self-stereotyping in the context of multiple social identities. *Journal of Personality and Social Psychology*, 90(4), 529-542. doi:10.1037/0022-3514.90.4.529
- Sizakuyenza. (2017). Sizakuyenza. Retrieved from www.sizakuyenza.co.za
- Stadler, J. J., Delany, S., & Mntambo, M. (2008). Women's perceptions and experiences of HIV prevention trials in Soweto, South Africa. *Social Science & Medicine*, 66(1), 189-200. doi:10.1016/j.socscimed.2007.08.021
- Stadler, J. J., Scorgie, F., van der Straten, A., & Saethre, E. (2016). Adherence and the lie in a HIV prevention clinical trial. *Medical Anthropology*, 35(6), 503-516. doi:10.1080/01459740.2015.1116528
- Statistics South Africa. (2016). *Community survey, 2016*. Retrieved from Pretoria, South Africa: <https://www.statssa.gov.za/>
- Statistics South Africa. (2017). *South Africa demographic and health survey 2016*. Retrieved from Pretoria, South Africa: <https://www.statssa.gov.za/>
- Strebel, A., Crawford, M., Shefer, T., Cloete, A., Henda, N., Kaufman, M., . . . Kalichman, S. (2006). Social constructions of gender roles, gender-based violence and HIV/AIDS in two communities of the Western Cape, South Africa. *SAHARA-J: Journal of Social Aspects of HIV/AIDS*, 3(3), 516-528.
- Thurman, A. R., Clark, M. R., Hurlburt, J. A., & Doncel, G. F. (2013). Intravaginal rings as delivery systems for microbicides and multipurpose prevention technologies. *International Journal of Women's Health*, 5, 695-708. doi:10.2147/IJWH.S34030
- Toska, E., Cluver, L. D., Boyes, M., Pantelic, M., & Kuo, C. (2015). From 'sugar daddies' to 'sugar babies': Exploring a pathway among age-disparate sexual relationships, condom use and adolescent pregnancy in South Africa. *Sexual Health*, 12(1), 59-66.
- U. S. Department of Health Human Services. (2017). Dapivirine. Retrieved from <https://aidsinfo.nih.gov/drugs/523/dapivirine/0/professional>
- UNAIDS. (2012). *Women out loud: How women living with HIV will help the world end AIDS*. Retrieved from Geneva, Switzerland: http://files.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/20121211_Women_Out_Loud_en.pdf
- United Nations. (2015). *Trends in contraceptive use worldwide*. Retrieved from New York, NY: <http://www.un.org/en/development/desa/population/publications/pdf/family/trendsContraceptiveUse2015Report.pdf>



- van der Straten, A., Montgomery, E. T., Cheng, H., Wegner, L., Masenga, G., von Mollendorf, C., . . . Woodsong, C. (2012). High acceptability of a vaginal ring intended as a microbicide delivery method for HIV prevention in African women. *AIDS and Behavior*, *16*(7), 1775-1786. doi:10.1007/s10461-012-0215-0
- van der Straten, A., Stadler, J., Montgomery, E., Hartmann, M., Magazi, B., Mathebula, F., . . . Soto-Torres, L. (2014). Women's experiences with oral and vaginal pre-exposure prophylaxis: The VOICE-C qualitative study in Johannesburg, South Africa. *PLoS One*, *9*(2), e89118. doi:10.1371/journal.pone.0089118
- Vandepitte, J., Lyster, R., Dallabetta, G., Crabb, F., Alary, M., & Buu, A. (2006). Estimates of the number of female sex workers in different regions of the world. *Sexually Transmitted Infections*, *82*(suppl 3), iii25.
- Wand, H., Whitaker, C., & Ramjee, G. (2011). Geospatial models to assess spatial variation of HIV infections among women in local communities of Durban, South Africa. *International Journal of Health Geographics*, *10*(1), 28.
- Wengraf, T. (2001). *Qualitative research interviewing: Biographic narrative and semi-structured*. London, United Kingdom: SAGE Publications.
- Western Cape Government (2015). [Sizakuyenza].
- Workowski, K. A., & Levine, W. C. (2002). Sexually transmitted diseases treatment guidelines 2002. *Morbidity and Mortality Weekly Report: Recommendations and Reports*, *51*(RR-6), 1-78.
- World Health Organization. (2017). Antibiotic-resistant gonorrhoea on the rise, new drugs needed [Press release]. Retrieved from <http://www.who.int/mediacentre/news/releases/2017/Antibiotic-resistant-gonorrhoea/en/>

Appendix

Poster Presented at Sizakuyenza's World AIDS Day Event



Exploring Intravaginal Ring Acceptability in Cape Town

Josephine Bowen David Lech Shion Matsumoto Abigail Roane
Bolekwa Gcwabe Jeanine Skorinko Nicola Bulled



South Africa has the **highest** HIV prevalence in the world
(World Health Organization, 2016)

31.6% of HIV prevalence in black South African females aged 20-34
(Human Sciences Research Council, 2014)

4th highest in the world for rates of unintended pregnancy

55% of all pregnancies in southern Africa were unintentional
(Sedgh, Singh, & Hussain, 2014)

Consider a **potential** new solution ... The Intravaginal Ring (IVR) could protect against **HIV**, **gonorrhoea**, and **pregnancy** by slowly releasing medication in the vagina for **up to 4 weeks**

• **Not currently available**

• A **female-initiated** prevention and contraception option

• IVR effectiveness is currently uncertain, as **adherence** to the product in clinical trials has been **inconsistent**



Community Influences

Potential for Misuse:

- Sharing product
- Extending product life through periodic use
- Alternative uses of product

Relationship Dynamics



"Those who are single, they are more able to make their own decisions... Those who are married, it is less easy to be an individual, to make their own decisions. They have to first sit down and explain whatever decision they are going to take."



Policy

"If [the IVR] will be introduced, because of the medicine component ... it will have to be by prescription only."

Individual Preference for Prescriptions

44.4% **55.6%**

Where would the product be available?

What marketing strategies would most effectively promote adherence?

How will this product be funded?