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Understanding Female Condom Use and Negotiation among Young Women in Cape Town,
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Understanding Female Condom Use and Negotiation among Young Women in Cape Town, South Africa

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B.A., University of Washington, 2012 Emory University 2015

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An abstract of
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Abstract

Understanding Female Condom Use and Negotiation among Young Women in Cape Town,
South Africa
By Julia Martin

Background In many countries, female condoms are not well known. Uptake has been slow outside of communities targeted for promotion. Brazil and South Africa are exceptions; knowledge and prevalence of female condoms are relatively high. South Africa has the fourth highest HIV prevalence in the world and was chosen as the site for this study focusing on how women and men successfully introduce female condoms and negotiate their use.

Methods The study took a qualitative approach and conducted 27 in-depth interviews with men and women who had used female condoms in two Cape Town sites. Two primary research questions were asked: how do women negotiate female condom use, and how do male partners negotiate or respond to negotiations of female condom use? Thematic analysis was used to identify key patterns in the data.

Results Participants discussed barriers to female condom use, differences between male and female condoms, education issues, and partners' reactions to female condom negotiations. Participants evidenced that female condom use was easier for women to negotiate than male condoms, largely because this method was understood to be under a woman's control. The main discomfort participants described with female condoms was related to unfamiliarity and lack of education. Personal comfort issues and tensions with partners usually resolved following the first use of the female condom.

Discussion These findings shed positive light on the potential for increased female condom education and distribution. Unfamiliarity hindered use, however this study found little evidence that negative partner reactions hindered use. There is little doubt that female condom availability empowers women to initiate barrier method use in various circumstances, and especially where male condom use might be refused. Results suggest a few key improvements in program efforts; female condom programming should be directed toward men as well as women, and toward couples who go for couples testing. Education should include a discussion on gender dynamics and responsibility. Finally, comprehensive female condom education is as important as increased availability, and improved training for providers and educators is likely a critical first step in the process.

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I. INTRODUCTION

1.1 Introduction

The female condom, a female-initiated barrier method, provides great potential for reduction in HIV incidence, other STIs and unintended pregnancy. The female condom is available in a few different brands, generally as a lubricated sheath with two rings, one of which is inserted into the vagina and anchors against the cervix. Different brands of female condoms are made of different materials. The FC2, the most commonly used and available female condom in South Africa, is made of synthetic nitrile and coated with a silicone lubricant. Although overall perfect-use failure rates for female condoms are higher than for male condoms (5-11% vs. 2%) (CDC, 1993; Hatcher, Trussell, & Nelson, 2007), breakage as a reason for method failure is extremely rare (0.3% in a randomized clinical trial) (Macaluso et al., 2007). Additionally, it is likely that there is greater variation in failure rates due to population and conditions, such as proper use education. This indicates that many types of method failure could be easily reduced.

In many countries, female condoms are not well known. Low use poses a considerable challenge for qualitative study. Even in the United States, where numerous brands are available, both knowledge and use of female condoms have remained largely low. In the US and globally, uptake has been slow outside of communities that specific programs have targeted for promotion, and sometimes despite this. However, Brazil and South Africa stand out as ideal potential research sites. Women in both countries have higher knowledge of the female condom and higher use, largely due to government and NGO-based promotion and distribution campaigns (Cairns, Gus). South Africa was chosen for this study due to existing institutional relationships.

Understanding barriers to female condom use as a pregnancy or STI prevention method in long-term relationships, where condom use is lowest in South Africa (Ackermann & de Clerk, 2002), is essential to improving reproductive health outcomes. The barriers presented in South Africa, taboos surrounding the female body and reproductive anatomy, gender-based violence, and gender power disparities, have not been adequately explored (Ackermann & de Clerk, 2002; Guerra & Simbayi, 2013; Joanne E Mantell et al., 2011; van Loggerenberg et al., 2012). In particular, it is essential to determine the feasibility for women in the general population to use the female

condom to gain control of sexual encounters. As noted by Beksinska et al. in a 2012 study on barriers to condom use in South Africa, concerns have been noted that abuse and violence could increase if women attempt to introduce the female condom with a partner, but there is not yet evidence supporting or refuting this claim (Beksinska, Smit, & Mantell, 2012).

This study was designed for the context of South Africa, where HIV prevalence is fourth highest in the world, and women are disproportionately affected. Knowledge and prevalence of female condoms are relatively high. In this context, it is essential to understand how women successfully navigate and overcome barriers to female condom use, and how men respond to these negotiations. In order to explore this question, 27 semi-structured, in-depth interviews were conducted with both men and women who had used female condoms in Cape Town, South Africa, during July of 2014. In order to get at the main objective of the study, understanding barriers to female condom use among young women in Cape Town, two separate research questions were asked: how do women negotiate female condom use, and how do male partners negotiate or respond to negotiations of female condom use?

II. BACKGROUND

2.1 HIV in South Africa

South Africa has the fourth-highest HIV prevalence globally, with a prevalence of 17.9% among the general adult population (CIA, 2012), constituting a hyper-epidemic state (Beksinska et al., 2012). Around 6.1 million South Africans are living with HIV, the largest number for any country in the world, and 240,000 people die yearly due to AIDS-related illnesses. Like other countries, there are large disparities by province, and additionally by a variety of demographic factors (AVERT, 2014). For instance, HIV prevalence is around 40% in Kwa-Zulu Natal compared to 18% in both the Northern and Western Cape provinces.

Following province, HIV prevalence in South Africa shows next-greatest disparity by gender. Women are both disproportionally affected and are affected earlier in life than men. Female HIV prevalence peaks between 25 and 29 years of age at 32.7%, whereas in men the peak occurs between 30 and 34 years of age with a prevalence of 25.8% (Beksinska et al., 2012; J. E. Mantell et al., 2014). The HIV gender disparity is further highlighted by the fact that incidence is four times higher among 15-24 year old women than their male counterparts (2.5% versus 0.6%) (J. E. Mantell et al., 2014).

The country has a well-developed HIV/AIDS program, with over a billion dollars invested annually. Over a decade of programs specifically targeting youth have slowed the epidemic in this population, with the prevalence among youth decreasing from 10.3% to 8.6% between 2005 and 2008, based on Demographic and Health Survey data (Beksinska et al., 2012). Along with decreasing prevalence in youth overall, the South African HIV epidemic has also taken a lesser toll on those in higher education; however, nationally, 3.7% of these sexually active students are currently living with HIV. This prevalence is higher in Kwa-Zulu Natal at 6.1%, and even higher among tertiary students of Black African ethnicity in the province, at 8.7%. (Joanne E Mantell et al., 2011).

Outside of youth populations, however, HIV prevalence has continued to rise, despite simultaneously increasing levels of HIV/AIDS-related knowledge. Part of the explanation for this is that increased awareness of HIV risk has not translated into behavioral change, at least among high-risk women (van Loggerenberg et al., 2012). Like many other sub-Saharan African countries, the bulk of HIV transmission occurs in

heterosexual relationships. The lack of behavioral change with HIV education points directly to gendered barriers regarding condom negotiation for South African women. This link to socio-cultural determinants of sexual risk among South African women was more thoroughly explored in a 1995 study among sex workers, but otherwise studies have only discussed the probable causality theoretically (Karim, Karim, Soldan, & Zondi, 1995; Joanne E Mantell et al., 2011).

Overall, the major cited causes of the continuing severity of the HIV epidemic in South Africa are patterns of sexual partnership (e.g. concurrency), heavy alcohol abuse, significant gender power inequities, violence, and poverty (Beksinska et al., 2012; Jewkes, Dunkle, Nduna, & Shai, 2010). These are all driving forces for lack of barrier method use or inconsistent use. Compounding issues arise from frequent barrier method failure due to both incorrect use and breakages. This is generally acknowledged as a problem in South Africa—studies document a history of condom failure reported by between one third and two fifths of respondents (Kalichman, Simbayi, Cain, & Jooste, 2009; Simbayi & Kalichman, 2007).

2.2 Unintended Pregnancy & STIs

Female condoms are the only alternative barrier method to male condoms for HIV prevention; they are also extremely effective for preventing other STIs. Further, in contexts where it is challenging or undesirable to access other forms of birth control, they offer protection against pregnancy. Thus, desire for fertility control options may drive female condom uptake and use. In these contexts, female condom uptake is likely to reduce negative health outcomes like STIs and unintended pregnancy, along with reducing resulting economic impacts from unplanned children and morbidity and mortality due to unsafe abortion.

Despite South Africa's relatively high contraceptive prevalence rate of 65%, a 2004 population-level survey estimated that over one third of South African women 15-24 had had an unintended pregnancy (Pettifor, Rees, Steffenson, Hlongwa-Madikizela, & MacPhail, 2004). Secondary analysis of 1998 South African DHS data showed an unintended pregnancy rate of 71% among a sub-sample of 1,395 women aged 15-24 who were either currently pregnant or had experienced a pregnancy in the last 3 years (Ibisomi

& Odimegwu, 2007). However, as both population-level analyses were restricted to those aged 15-24, this level of unintended pregnancy is only documented among young adults. Among participants in the female condom comparison study of 170 women in Durban with a broader age distribution (Joanis et al., 2011), 21% reported having had an unintended pregnancy, but this data is not generalizable or comparable.

Population-level STI data is better, but still sparse. Nationally-representative microbiological data is only available for syphilis, with seroprevalence around 10% (LF Johnson, Coetzee, & Dorrington, 2005). Otherwise, sentinel surveillance data is the norm. A surveillance review of 47 studies on STI prevalence from 1985 to 2003 in South Africa described overall high levels of STI prevalence, represented in the table below. Estimates vary depending on the types of studies available on the disease. As some studies used STI clinic data, some data are understandably high estimates. However, the majority of studies used were based among either general populations or family planning clinics. The majority of studies other than those on syphilis and HSV-2 were among women, not men.

South Africa STI Prevalence Estimates			
Disease	Overall Prevalence	Men	Women
Syphilis	10%		
HSV-2	17-80%	17%	53%
Gonorrhea			5-31%*
Chlamydia			5-41%
Trichomoniasis			20%
Bacterial Vaginosis			15-59%
Candidiasis			20-40%

Data from (LF Johnson et al., 2005). Blank cells had little or very poor data.

Overall, these data represent an STI burden in the country, indicating the need for continued and increasingly effective condom promotion campaigns. Johnson et al. estimated the overall STI burden based on years of life lost and years lived with disability, and concluded that it is one of the largest in the world (Leigh Johnson, Bradshaw, Dorrington, & Collaboration, 2007). This overall conclusion, however, took HIV burden into account. In the stratified analysis, much like with HIV, women bore the greater burden of sexually transmitted infections (with 299,000 deaths and 31,000 DALYs lost to non-HIV STIs, and 3,498,000 deaths and 54,000 DALYs lost to cervical cancer).

^{*}Indicates an estimate among high-risk women—5% among low risk.

Among smaller studies with non-generalizable data, the Mantell et al. behavioral intervention study collected data on 296 participants, and revealed that 19% of participants at a higher education institution in Kwa-Zulu Natal had "ever [been] diagnosed with an STI."

2.3 Male Condoms in South Africa

Multiple types of condoms are marketed and distributed by the South African government, in addition to a wide variety of private brands. Promotion campaigns have had significant impact on awareness of condoms as an effective method for HIV prevention, and three comprehensive HIV surveys (2002, 2005, and 2008) have documented overall increases in condom use at last sex (Beksinska et al., 2012). Condom use among youth, in particular, has risen between 2002 and 2008, with increases from 57.1% to 87.4% among males and 46.1% to 73.1% among females (Joanne E Mantell et al., 2011). These positive results, however, stand in contrast to South Africa's high prevalence and incidence of HIV, other STIs, and teen pregnancy, revealing significant problems with correct and consistent use. The lack of consistent use has been documented in multiple studies. A study in Durban documented condom use as normalized and accepted among students at higher education facilities. However, only a quarter of these students reported actually using condoms for every act of intercourse (Maharaj & Cleland, 2006).

2.4 Female Condoms in South Africa

The female condom has been demonstrated to be effective, frequently preferred by women once familiarity is gained, empowering for women in regards to their sexual health, and even capable of reducing STI incidence in other countries (Hoke et al., 2007; Mathenjwa & Maharaj, 2012; Vijayakumar, Mabude, Smit, Beksinska, & Lurie, 2006). South Africa introduced the female condom in 1998 primarily through public-sector clinics and community-based programs (Holt et al., 2013). Now, with over 300 designated public-sector distribution sites, South Africa has one of the largest female condom promotion and distribution programs globally (Beksinska et al., 2012). Overall, distribution has been increasing annually, with 4.2 million female condoms distributed in

2008, 5.1 million in 2010, and was projected to be 11 million for 2012 (J. E. Mantell et al., 2014; Smit et al., 2012).

A 2013 population-level survey showed that there is also a high prevalence of knowledge of the female condom as a barrier method option, 78% (Guerra & Simbayi, 2013). Use rates were 7% overall, yet varied significantly by province and age group, with highest use among those 25 and older. The authors also reported a usage prevalence of over 10% in three provinces: Northern Cape, Free state, and Limpopo, compared to only 3% in Kwa-Zulu Natal, where HIV prevalence is also highest. Despite South Africa's high prevalence of female condom knowledge and relatively high distribution, the national 7% use prevalence stands out as low. This gap between relatively high knowledge and distribution coupled with low use has not been adequately explored.

Studies suggest that barriers to female condom use include a number of factors, many of which overlap with those that fuel the HIV epidemic, including a steep learning curve with initial use of the female condom, limited familiarity with the device, taboo of condom use in long-term relationships, gender power disparities, cost, and stock-outs of the female condom (Joanis et al., 2011; Joanne E Mantell et al., 2011; J. E. Mantell et al., 2014; Mathenjwa & Maharaj, 2012; van Loggerenberg et al., 2012). Qualitative methods are particularly suited to exploring these gaps in knowledge, yet the Mantell et al. 2011 study was the only qualitative study that elicited in-depth data regarding some of these barriers. Their male focus group participants, who were all students at higher-education institutions, explained that lack of familiarity with and exposure to female condoms were the greatest inhibitors to use. Men said that they would not want to try to use something that they did not know how to use. Many of them falsely believed female condoms to be expensive. Another misconception that inhibited use was the belief that one must wait between 2 and 8 hours after condom insertion before initiating sex. Many of the participants also found the large appearance of the female condom to be a deterrent, and a few voiced concerns about possible lessening of sexual pleasure.

The Mantell et al. 2012 study was a randomized intervention trial conducted at a tertiary institution, and found that implementation of female condom interventions resulted in increased use (2014). However, the study did not explore specific barriers to use. The Jewkes et al. study conducted a longitudinal analysis of data from a randomized

controlled trial in the Eastern Cape province, and found that gender power inequities and intimate partner violence both significantly increased HIV incidence (2010). This study did not address female condoms, but the findings highlight the importance of gender power disparity and gender-based violence in HIV outcomes in South Africa. Those realities highlight the importance of female condom promotion and availability in the country.

Lastly, a study on female condom use among sex workers in Swaziland concluded that due to the abundance of both quantitative and qualitative data on female condom use among sex working populations and the relative paucity of data otherwise, research on female condoms among general populations is necessary to increasing uptake (Mathenjwa & Maharaj, 2012). Among sex-working populations, the female condom is an empowering device. However, the degree to which this empowerment might translate to the general population, and particularly to those in long-term relationships, has not yet been explored. This is the point of departure for the current study.

III. METHODS

3.1 Overview

In order to explore how women in Cape Town, South Africa experienced female condom use and navigated decision-making, the researcher conducted 27 in-depth, semi-structured interviews in two Cape Town locations: Khayelitsha and Kraaifontein.

Recruitment was conducted in collaboration with a partner non-profit organization,

Partners in Sexual Health. Thirty participants were recruited; however, three interviews were discarded because the participants discontinued the interviews before much relevant data was collected. The remaining 27 interviews ranged between seven and 49 minutes, averaging 25 minutes.

3.2 Partners in Sexual Health

Partners in Sexual Health (PSH) is a non-governmental organization founded in 2008 that operates throughout South Africa; however most projects had not expanded past the Western Cape until 2014. Their work is focused on sexual and reproductive health with a particular focus on HIV/AIDS among vulnerable and high-risk populations. Their head office is located in Parow, a suburb of Cape Town, and field offices are in Khayelitsha, Kraaifontein, Beaufort West, and Clanwilliam. The organization runs varying programs at other sites across the country, including a Truckers Health Project that operates out of truck stops, and an HIV Voluntary Counseling and Testing project, which operates via outreach at various central sites in each community. The HIV VCT program offers a variety of on-site medical services beyond HIV testing, including condom distribution and education. Community members in field sites may access male and female condoms at the field offices themselves, but do so more frequently at outreach locations.

3.3 Khayelitsha & Kraaifontein

Khayelitsha and Kraaifontein may both be considered 'suburbs' of Cape Town. However, the two places are quite distinct. Khayelitsha, located in the Cape Flats, a Southern Suburbs, is largely African demographically, and over 90% Xhosa. It is also a township, characterized by poverty. It is well known as a site of forceful relocation

during Apartheid, and as one of the largest townships in South Africa. It is thus a popular place for NGOs and foreigners to target development projects or recruit research participants. Kraaifontein, on the other hand, is a rather diverse suburb: around a third Xhosa, slightly over a third Coloured, and just under fifteen percent White. Kraaifontein is technically a part of the Northern Suburbs, distinguished from the Southern Suburbs by being middle class, suburban, and not predominantly African.

3.4 Participant Demographics

All 27 participants were between 19 and 41 years of age, and the majority of interviews were conducted in Khayelitsha (19, with 8 interviews conducted in Kraaifontein). An even distribution was sought and obtained for gender: 14 participants were female and 13 were male.

Participant Distribution: Gender & Location		
	Khayelitsha	Kraaifontein
Female	10	4
Male	9	4

All participants spoke Xhosa as their first language and were at least conversational in English, though not all had completed secondary schooling. A large number of participants (around half) were currently unemployed, and the majority had at least one child (4 participants had no children they were aware of, and 4 did not discuss whether they had children). Only two participants were HIV-positive and disclosed their status; they did so immediately at the beginning of the interview, as a defining factor in their identity.

3.5 Recruitment

Participants were recruited in person by PSH field workers who were familiar with PSH clientele and the community, in which they also lived. The field workers recruited them by visiting them at their houses or occasionally elsewhere in the neighborhood, and asking if they would be interested in participating. As the field workers were local, they knew who was likely to have used female condoms.

Inclusion and exclusion criteria for participation are presented below:

Inclusion Criteria (must meet all):	Reasons for Exclusion (any excludes):
 Strong English speaking ability 	 English skills not adequate for
(conversational, minimally)	interview
 At least 18 years of age 	 Appears not sober or not cognitively
 Has used a female condom, 	capable of consenting to interview
preferably with a long-term partner	 Has not used a female condom

3.6 Data Collection

An in-depth interview guide was developed to explore female condom use with various partners. It began with an open-ended question on thoughts about condoms in general which led to prompts to describe specific instances of female condom use with each partner where one had been used. The bulk of each interview focused on how participants introduced condom use and how their partners responded to initial and continued use. The guide focused on all aspects of female condom use in each relationship: how participants and their partners came to know about, try, discuss, and obtain female condoms as well as the experience of actually using them for the participant and their partner. This was based on the participant's perception and what they reported that their partner said to them, as couples were not interviewed.

Interviews began with the statement, "Tell me about yourself." Often, in the first few minutes, participants would then provide their age; if not, this demographic question was later inserted before proceeding. After gathering background information on the participant, the researcher inquired as to how many partners the participant had ever used a female condom with, and usually went on to discuss these relationships chronologically if there were more than one. In a few cases, participants had a strong desire to discuss one relationship and condom use in that relationship. If they continued to return to that despite probing into other female condom use, the researcher followed their lead. Interviews closed with a few questions about what the participants thought might convince more people, and women in particular, to try female condoms.

Interviews were conducted in private rooms in the PSH field offices in both Khayelitsha and Kraaifontein. At the Khayelitsha location, a separate, empty building with comfortable chairs was available, assuring auditory privacy. At the Kraaifontein location, a private room was provided, however, participants were aware that at times

others in the building might be able to hear parts of the conversation depending on noise levels.

Before each interview, written consent for participation and recording was obtained, and compensation explained. Following the close of the interview, each participant was reimbursed 50 rand (just under 5 USD) for their time, based on standard reimbursement rates of researchers at the Human Sciences Research Council in Cape Town. All interviews were digitally recorded with participants' consent.

Due to a compressed timeline after issues with edits submitted to the South African Research Ethics Committee (REC), all interviews were conducted during the last 3 weeks of July 2014.

Due to the short data collection period, transcription took place after collection, in August and September. All interviews were transcribed verbatim and then de-identified by the researcher. Prior to travel to South Africa, Emory IRB consent and exemption from further review was obtained. South African REC submissions were also made, and following edits, final approval was obtained prior to beginning data collection in July of 2014.

3.7 Data Analysis

Following transcription, all interviews were imported into MAXQDA 11, and all analyses were conducted using this software. A thematic approach was used to analyze the 27 interviews. An initial code list was developed deductively based on the research question and large themes related to the topic that participants discussed frequently. Because the list was developed after numerous readings of the data, there may have been an inductive element to some of the code choices, but largely they were deductive.

Six transcripts were selected for initial coding: three men and three women, four from Khayelitsha and two from Kraaifontein. These transcripts were coded three times separately in order to refine and define the code list, which ultimately included 13 codes. After each coding, the code list was refined and the coding deleted from the documents. After the third coding, the researcher felt that all relevant data was being indexed by the codes. Subsequently, all 27 documents were coded in order to prepare for code-by-code data retrieval and analysis.

Analysis proceeded with the retrieval of text coded with large and complex codes such as "negotiation & discussion," when they co-occurred with smaller, concrete codes such as "access & variety." The researcher brought coded segments of text into MAXMAPS, a virtual whiteboard in MAXQDA, and then arranged segments in groups to determine properties and dimensions of themes discussed by all participants. Code summaries were then written for each code, beginning with the more complex codes and proceeding to the remaining codes by developing tables for retrieved coded segments and writing summaries for these themes.

Finally, all code summaries were re-read by the researcher in order to understand the interrelationships between themes and how they were related to the research question. Once these relationships were conceptualized, an outline of the larger picture was drafted, and the individual code summaries were interwoven in order to summarize across participants and inter-related themes.

IV. RESULTS

1.1 Condoms: Personal Use Patterns and Choices

Participants described a variety of condom use patterns. Around a quarter of participants reported consistent condom use with any and all partners for every act of intercourse. Slightly less than a quarter of participants reported consistent condom use with a partner for a period of time prior to pregnancy, STI and HIV testing, or coming to trust the relationship's monogamy. The majority – just over half – described regular but inconsistent condom use. These participants either consistently used condoms with secondary partners, or used condoms with their main and only partner, but not for every act of intercourse. Several reasons were cited for inconsistent use. First was a preference for unprotected sex contributing to occasional acts of unprotected sex, despite its known risks. Suspicions that a partner had recently cheated also triggered occasional condom use in otherwise monogamous relationships. Inconsistency of condom use was never explained as solely caused by lack of an available condom in the moment.

All but one participant had used female condoms more than once, and usually this meant a minimum of three to four uses. Around a third of participants reported having used the female condom with only one partner. For all but one of these participants, this was their primary partner. The other two-thirds had used a female condom with at least two partners.

Around one fifth of participants described alternating between female and male condoms; it should be noted that other participants may have also alternated their use of female and male condoms, but focused their discussion on their preferred method. In this group, that tended to be the female condom, with most preferring female condoms. Reasons described for alternating use were the desire to share responsibility for condom use with partners, a preference for variety of condom type, and the immediate availability of one condom type but not the other.

Three male participants talked about regularly doubling up—using both a male condom and a female condom at the same time. All three men discussed doing this as a risk reduction method, but two said that they enjoyed sex this way. It was unclear whether the enjoyment was due to a greater feeling of safety, increased physical pleasure, or a combination of both. Sometimes doubling up seemed related to a belief that the male

condom protects only men and the female condom protects only women. An example of this was Patrick, who said, "I like to use mine. For me, to combine it. To protect her, and then to protect myself" (line 79). Madala said, "She had it. I also had mine, the male condom...because you know sometimes when you have sex, some of the condoms they just tear, so that's the only thing that I can say" (line 43).

1.2 Condoms: Access and Variety

Over half of participants (16) talked about issues of access and variety surrounding female condom use. In terms of access, participants talked about using any condom available in the moment, or about regularly using the method easiest to access. This access challenge was due to distance to acquire the condoms or cost. In terms of variety, participants either talked about preferring to have both male condoms and female condoms as options, or about the variety of male condoms available and the lack of variety of female condoms. For half of these participants (8), desire for variety was a motivating factor for initial female condom use.

For two female participants, difficulty in accessing the female condom prevented them from using it as a regular method. Though they preferred the female condom, they said that they usually did not use it due to having to travel further to obtain it from a clinic. For two participants, the female condom functioned as a back-up method to the male condom. Seth described this saying, "I…convinced her that let's try this one, not this one…because one of these days we are not having my condoms, and the only condom we have, it's yours" (line 45). Nobantu said, "When he doesn't have his condom, we use a female condom" (line 41). For one participant, the female condom was his preferred barrier method specifically because it eliminated cost for both partners, with the female condom only available from clinics at no cost, and male condoms sometimes requiring purchase.

Among those who talked about condom variety, three participants, both men and women, wondered why there was only one type of female condom available to them.

Three male participants also noted the greater variety of male condoms. Two thought this was a good thing and preferred the colorful and scented brands for purchase, finding the

free government brand desensitizing. One said the opposite: he had experienced failures with some of the alternative brands and preferred the government brand male condoms.

1.3 Reasons for Female Condom Use and Non-Use

Driving reasons for female condom use were varied, and there were numerous factors that were consistent across male and female participants. There were also a number of reasons specific to either female or male participants. Individual preferences and awareness of the female condom's existence, efficacy, and use played a role for all participants in motivating use. As discussed above, around two-thirds of both men and women preferred female condoms to male condoms. The most common single reason cited to prefer the female condom was male condom breakage. At least eight participants had personally experienced this, and a few more mentioned it as a problem with male condoms, whether or not they had personally experienced a breakage.

Around half of participants talked about the possibility or even assumption that their partner was cheating, regardless of the seriousness of the relationship. This was a motivation for condom use in general, but often for female condom use specifically, due to preference for the female condom. Participants in a range of relationship types said things like, "He has more than three girlfriends" (Lovisa, line 21), "He goes outside and he's cheating, even me maybe I'm cheating, that's why I use condoms" (Kenna, line 27), and "[I use condoms] when I fight with my boyfriend or when I think my boyfriend has gone with another girlfriend" (Maudisa, line 101). All of these participants at some point stated something like, "You can't trust anyone" or, "You can't trust 100%."

There were some gender differences in reasons for preferring female condoms. Women appreciated a method they trusted more due to their control over the method. Women also cited lack of trust in the supposed monogamy of their relationships as a reason for use. When men preferred female condoms, they always cited increased pleasure as a reason. However, over a third of men also mentioned that a driving factor for use was the perceived reduction of their own responsibility to provide a condom.

Reasons for non-use mentioned by both men and women included lack of familiarity and education, relative difficulty of accessing female condoms, and discomfort with a new type of barrier method. Additionally, three male and two female

participants had concerns about female condom failure. One man was concerned that his penis could enter the vagina to the side of the female condom instead of within it. His concern was due to the "openness" of the female condom outside the vagina, saying, "You don't trust them the female condom. Cause like, two sides are open" (Samuel, line 61). This participant and two more also voiced concerns about invagination, when the entire female condom, including the outer ring, is pushed inside the vagina during intercourse.

Three men, but no women, described women as shy about their bodies. They talked about how this inhibited female condom use, saying that they would not try to introduce a female condom with a casual partner due to this perception. Richard said, "Females, they tend to be shy with their bodies, and so I expect that. So I don't want to ask a person can you use this?" (Richard, line 104).

Some of the reasons for non-use described by women were related to different aspects of partner negotiation. One participant said that she herself did not like using the female condom and chose not to use it, because her husband was willing to use a male condom. If her husband had not been willing to use male condoms, however, she would have used a female condom. For a number of women, a partner's negative reaction discouraged female condom use; for one participant, it resulted in discontinuation. For a few women (3), serious issues did not persist, but periodically their partners still resisted female condom use (in addition to male condoms), resulting in sex not occurring on those occasions, or in unprotected sex.

Around half of female participants (6) also talked about initially feeling fear with the female condom. Similarly, one male participant described having partners who were afraid to use the female condom. Samuel said, "They [women] don't bother with them always. They're scared. And men are also scared of that thing. But, if it can go inside of her vagina, she's also scared, that's why I don't think they trust those condoms" (Samuel, line 70). Lovisa explained how this fear played out the first time she used a female condom, saying, "It was difficult, because...it was difficult for me even to insert it. I just saw this big thing. How am I going to use it? And I was scared! I was crying because I want to try this but it's too big, how am I going to put it?" (Lovisa, line 13).

Yet, for around three quarters of women, these issues resolved with first use and the female condom was subsequently an accepted regular method in the relationship. Ultimately, almost all participants described a change in comfort level or acceptance of the female condom over time and with increased use. There were only two exceptions to this increase in acceptability: one participant never used it again, and another felt completely comfortable with it the first time she used it.

2.1 Introduction of the Female Condom

Participants usually discussed the value of communication in a relationship. Most discussions and negotiations with partners did end in successful female condom use. However, this was not universally true, and certainly not true with all partners that participants had. There were usually situation-specific reasons surrounding what type of partner one might introduce a female condom with and why.

Almost all female participants had introduced the female condom with all partners with whom they had used it. Two had discussed and decided upon use mutually with their partners, but none of them had partners who introduced the female condom to them. The introduction dynamics were different for men: about half of the men had introduced it to their partners, while just over a third of men had had the condom introduced to them by a partner, and for two it was a mutual decision. Two of the men who introduced the female condom to their partners had worked for sexual health NGOs and became curious to try female condoms while learning about them at work.

A third of male participants (4) stated that they would not introduce it to a woman either because it was "hers to use" or because it might make her uncomfortable. Either way, these participants suggested that she must be the one to introduce, and provide, the female condom. Of those who introduced the condom, discussions went more smoothly and reactions were much more positive with secondary or casual partners, and were especially uneventful with sex workers who provided them when asked if they had a condom available.

2.2 Responsibility for Condom Provision and Use

Slightly less than half of participants (5 women, 7 men) talked about

responsibility when talking about both female and male condoms. What specifically, and how much participants had to say on the topic, differed between men and women. The general sense was that female condoms are a woman's responsibility. This responsibility was both to acquire them as well as to suggest them in a particular context or relationship. However, there were nuances to how participants interpreted or felt about this supposed norm. Even participants like James, who later described feeling uncomfortable with the assumption of female responsibility for the female condom, still described women as typically initiating use:

Because matter of fact, she will be the one that will initiate the usage of the female condom...for us now it's more like, most of the time it's actually guys that initiate sex than females themselves (line 42).

Thus, it was clear that women were viewed as responsible for female condom use. Male participants, when talking about responsibility and the female condom, said with some consistency (5 of 7 men) that they appreciated that the woman could be responsible for condom acquisition, provision, and use. However, three, like James, also felt that this should not necessarily be the case. James said, "Maybe it's a part of the foreplay that I insert. Because I think I'd be more comfortable with it if we're *both* into it, you know, more than actually you giving the responsibility to somebody else" (line 92). Joe described not choosing to continue using female condoms frequently, saying, "The responsibility to have the condom is with the man you know? So you go back again to get your own condoms" (line 65).

A few men (3) mentioned increased pleasure with the female condom, and described it as resulting in part from their partner being the one to wear it, indicating a possible connection between a shift to female responsibility and male pleasure. Caca described this, saying he liked the female condom:

Because it's not being worn by me. It's being worn by her, and I don't feel as if I'm inserting on the condom. You feel like you're the one making sex with her...yeah, I can feel her, that's what I like about it, unlike if it was me that was wearing the condom (line 74).

Most women (4) spoke of responsibility in terms of assuming responsibility when male partners did not want to use male condoms, when male condoms were not available, or when they did not trust men to use them. Some preferred the female condom, but here preference was linked to female control. One female participant, however, talked about

responsibility in terms of sharing the burden of protection between partners. She and her partner regularly alternated condom type depending on preference, mood, and availability. She said, "I think it's like he'll say, oh we're both using the condoms, so that I'm not the one who has the condom, only. Also you have a condom. Like I was joking, he was saying, we'll use the *big* ones [this time]" (Bukiwe, line 91).

Overall, a preference for female responsibility for condoms was a driver of both preference and use for men and women who enjoyed the female condom. However, for men this was more frequently about lifting the responsibility from them and assigning it to their female partners. For women, it was more frequently about having an option to gain control in contexts where men were hesitant to assume responsibility for barrier method use by wearing male condoms. James, one of the only men who did not appreciate the shift in responsibility, said, "For me, one of the words I hear is the *female* condom. It, it takes away the responsibility from you. It's not my, it's not my thing. It's *her* thing. It's a female condom" (James, line 90).

2.3 Partner Responses

The full range of reactions exhibited across participants and their partners spanned from immediate acceptance (just looking for a condom, and it didn't matter the type) to curiosity or shock. With certain partners, negative reactions were occasionally followed by utter refusal to try it.

Of the six male participants who had had a female condom introduced to them, most described their own reactions as immediately accepting. For instance, Madala responded to a non-exclusive partner saying, "No, it's fine. As long as I know that at the end of the day both of us we're not going to infect each other. With the STIs or getting pregnant" (line 18). There were two exceptions: Thomas, who described being shocked and put off by the large appearance of the condom before accepting its use, and Mpepho, who had himself introduced it with a previous partner because he wanted to try something new, and thus was already familiar with it.

Female participants on the other hand, who had all introduced the female condom with the exception of two, recounted initially negative or at least hesitant reactions from partners. The exceptions to this were when a female participant introduced the condom

due to her own or her partner's known positive HIV status, which was true in three cases. Among the instances not related to HIV status, the partner's initially negative reaction was followed by one of a few scenarios. For around three quarters of female participants, any issues experienced resolved following first use, and the female condom then became a regular and accepted method in the relationship. In one case, a partner's negative reaction resulted in the condom being used once and then never again. For a few women, it then became an ongoing issue and a source of tension or fighting with their partners. Sarah was an example of this, saying of negotiating FC use with her partner of two years, "Sometimes it's okay, sometimes it's not okay. He was getting angry, you know?" (line 55). Yet,

2.4 Female Agency?

The use of female condoms was described as easier for women to negotiate than male condoms. Women spoke of these negotiations from a personal perspective, yet male participants' comments echoed what female participants said. The essential narrative here was that while female condom use may still be difficult for women to negotiate due to their unfamiliarity, ultimately they were easier to negotiate than male condoms for two reasons: the female condom was for a woman to use (and implied no need for a man to "use" a condom), and a woman could refuse sex if her partner would not accept it.

Lovisa noted the increased ease in her personal negotiations with her partner saying, "He don't want *his*, but he doesn't have a problem with *mine*." (line 19). Another participant spoke at length about how she perceived interactions surrounding condom use for other women in the community:

It's hard to talk about condoms, for females to talk with men...[he'll say], 'Why do we need a condom, I don't have HIV, I don't have [an] STD, I love you, what?' Those things...and then they sleep without condom. They do that.

I: And so if a man says that, then is there anything a woman can say?

Yeah. 'If you don't want to, if you don't want to use a condom, then we are not going to make sex!' (Joy, line 138).

James echoed the responses of other men, described a nearly identical narrative from his own perspective:

If the woman, if she's the one who decides to use this condom, I will not actually insist that, "No way, I'm not using that." Because the woman will also have the right to say, 'Okay, if that's what you say, okay I guess no sex tonight." So it's going to be very difficult for a guy. So he will actually bow down and say, "Okay, I hear what you mean, it's okay, let's try it" (line 79).

When asked what they thought might make men more willing to accept the female condom, men and women said very similar things. They discussed female access to information and female empowerment in communicating with male partners. They said that women needed to first have information about female condoms in order to feel comfortable approaching the topic with their partners, and that they then needed to be empowered to discuss these topics with their partners.

In essence, because the female condom is "hers to use," the male partner is unlikely to say no in the end, although she may still encounter some resistance. Of course, this is only true in the context of a relationship where a woman feels comfortable refusing sex to her partner. Around half of the women in this study either did exactly that (said "no sex if you don't accept the female condom"), or said they would do so if a problem ever arose. Male participants paralleled this dynamic, although some were initially hesitant; they said that they decided to accept the device because of the possibility of sex being refused.

3.1 A Condom's a Condom

For at least a quarter of participants, a condom was a condom, and they would use whatever condom was available to them. These participants said that they saw no difference between male and female condoms, even if at some point during the interview they went on to describe some type of distinction.

All other participants who mentioned that they would use any condom available also mentioned directly or implied that if there were no condom available, then they would not have sex. Joe felt this way, saying, "If there's no condom there, there's no sex, uh? Cause I don't trust *anyone*. I am scared of HIV. I don't wanna get sick. I don't trust; I don't wanna risk it" (line 39). Samuel, when asked how the female condom compared to the male condom, said, "It's still the same, it's the same feeling when I use the male condom. Still the same feeling, yeah. I didn't see any difference" (line 33), and went on to

say, "Whatever is there, just have to put it on. Even if there was no condom, we wouldn't have sex" (line 43).

Functional differences described between male and female condoms included concerns about failure, familiarity with use, responsibility for acquisition and donning or insertion, as well as preference and comfort distinctions. Yet, these more detailed differences did not change the end result: condoms protected against STIs, HIV, and unintended pregnancy. In this sense, both condoms were ultimately the same, and fulfilled the same need for barrier protection. Bukiwe described this lack of difference saying, "They're doing the same job. There is nothing wrong, I see no difference, because it's like there is nothing inside of me, but I know there is a condom" (line 42). And Faith said, "They're different just because the male condom is common" (line 37).

4.1 Personal Perceptions and Community-Level Perceptions

Not all participants talked about what others in the community thought about female condoms, or about how they thought it might go for other women who introduced female condoms to their partners. Those who did, however, told the same narratives regarding perception of female condoms: people don't trust female condoms, don't know about female condoms, and are afraid of female condoms. Participants largely said that men would not be likely to accept it as an option. "Other people, they don't used to talk about the condom. Others...others they become like, bad face. They be like, 'Why you talk of a condom with me?' And fighting" (Nobantu, line 93). But others felt that there should be no problem. Bukiwe said:

I don't think it will be hard, because if ever you know, if you are sure about your story, then you can tell your boyfriend, "This is this and this and this. This one is this. Then we have to use this one. Can we try it? For my sake?" And then, if ever your boyfriend loves you, he is going to try. And then who knows, he might like the condom (line 87).

For the most part, what participants had to say about female condom use among others in the community differed from their own experiences.

V. DISCUSSION

It is important to bear in mind that these results are based on a study of people who have chosen to use female condoms. Participants were recruited through a sexual health organization, an organization whose services are usually sought due to a sexual health concern or scare, indicating that the study was likely conducted among a particularly high-risk population for whom accessing health services may be a challenge. The specificity of the study population has two implications, which are not mutually exclusive. The first implication is that extremely negative perceptions and reactions regarding female condom use are less likely to be represented in this population. The second implication is that in this particularly high-risk population, barrier method education, access, and use is of heightened importance. Understanding the research question in this context may in fact be the most important context in which to understand it.

Key Findings

The key findings of the research fell into two major categories. The first finding was that of major driving and inhibiting factors for female condom use. This included the influence of cultural norms of non-monogamy and cheating on condom use. Secondly, the more opaque concepts of perceived responsibility for condom acquisition and provision and female agency over condom use emerged. All of these findings may be used to guide future programming surrounding female condom education and distribution in South Africa, particularly among Xhosa populations.

Driving and Inhibiting Factors for Use

Many of the findings surrounding female condom use and non-use echoed and confirmed previous research. Female condom familiarity and education are key facilitating factors for use; the increased challenge in acquiring and learning to use female condoms is a barrier to use. Essentially, familiarity with the device means comfort with the device, with using it, and trusting its efficacy. Education on the female condom and first-time use itself provide this familiarity, which in turn further promotes use.

Most participants, and particularly females, did not assume exclusivity in their

relationships, whether or not the relationship was defined as monogamous. Even those who came to trust their partners enough to not use condoms regularly returned to condom use when fighting with their partners, or when they were away from each other for a period of time. That one could trust a partner almost fully, but not fully, drove condom use in general, whether that use was periodic or consistent, with side or primary partners. This lack of complete trust in one's partner coupled with other specific issues drove female condom use. These specific issues included a preference for female condoms, greater trust in them due to concerns about male condom failure, a lack of trust in men to use male condoms, and contexts wherein male partners refused to use male condoms.

Condom Responsibility and Female Agency Over Use

Some of the findings regarding condom responsibility and female agency over barrier method use fill gaps in existing research. For instance, where Beksinska, Smit, & Mantell questioned whether violence might increase when women attempt to introduce female condoms (2012), this study paints a more favorable, although complex picture. Only one female participant recounted a negative partner reaction. This resulted in non-use of female condoms and a return to male condoms. The more common narrative was one of ongoing negotiation and sexual health decision-making. This paints an alternative picture of partner dynamics than the commonly cited disempowerment experienced by Xhosa women in South Africa (Guerra & Simbayi, 2013; Joanne E Mantell et al., 2011).

Female participants who introduced the female condom with their partners had to discuss the device and familiarize their partners with it, as they themselves also had to become familiar with it. Sometimes this occurred prior to partner involvement and sometimes it was simultaneous. Regardless, while some partners had reactions that could be described as negative, female participants, with only one exception, did not describe their partner's reactions as inhibiting use. Their own senses of fear regarding a new and unfamiliar type of condom and their comfort level following initial use seemed to determine future use, rather than the challenges experienced by some in the decision-making process with their partners.

A related, and particularly important, finding was the concept of condom responsibility. Participants understood female condoms as belonging to women and male

condoms as belonging to men. When elaborated upon, this included responsibility for condom acquisition as well as use. On a few occasions, the extent to which some participants viewed condoms as gendered included the belief that a female condom would protect only women and a male condom, only men. Though these are also examples of inadequate condom education, they further exhibit the gendered perception of condoms among these participants. These perceptions are important to acknowledge as they may have a range of effects on acceptability and use patterns.

Other Findings

It is of interest that less than half of participants talked about issues accessing female condoms, and that no participants described lack of an available condom as a primary reason why unprotected sex sometimes occurred. However, participants did describe access issues as affecting female versus male condom use. That female condoms are not as readily available negatively impacted their use. For these participants, this seemed to mean that a male condom would instead be used, or that they would not have sex in this context. Yet, participants clearly described female condoms as a method that women may more easily negotiate with partners who are resistant to male condom use. Thus, lack of female condom availability is clearly an issue worth addressing. It should be noted that there may be an element of social acceptability bias in participants' reports that unprotected sex would not occur if a condom wasn't available. If this were the case, then it would be reasonable to assume that a lack of female condom availability may sometimes result in unprotected sex, and one participant did report this.

Conclusion: Programmatic Implications

In terms of programming, these findings shine positive light on increased female condom education and distribution. Unfamiliarity hinders use, however this study found very limited evidence that negative partner reactions to the introduction of female condoms also hinders use. Participants universally cited that when women wish to use female condoms, it is easier for women to negotiate with their partners than male condoms. Additionally, further exposure and first-time female condom use ameliorated the discomfort that was initially experienced by most participants. An increase in comfort

and enjoyment followed rapidly, usually during first or second use.

As discussed, the specific nature of the study population leads to questions about whether use might be as easily negotiated among other women in this community, or in other Xhosa communities in South Africa. The nature of qualitative research means that the findings cannot be generalized. However, when asked what they thought about the capacity of other women in the community to negotiate female condom use, participant responses were either positive or neutral, but certainly not negative. Although some participants thought other women might face greater challenges with female condom negotiation than they did, they still felt that it was possible, and certainly more likely to succeed than male condom negotiation. Further research among a more varied population would provide important insight into whether this might truly be the case.

The findings surrounding perceptions over gendered condom responsibility are the most complex. Based on this study, there is no doubt that female condom availability empowers women to initiate barrier method use with various partner types. Yet male preference for female condoms due to the shift of barrier method responsibility away from them and onto women is of some concern. Most often female condoms are more pleasurable for both men and women—for men because the penis is not constricted, and for women because the outer ring may stimulate the clitoris during sex (Joanne E Mantell et al., 2011). However, when men prefer female condoms because they view them as a women's responsibility, this could reinforced gender inequalities. Yet, the benefits seem to outweigh the risks, given South Africa's HIV and STI burden.

Programming efforts may address this concern by making a number of changes to the way female condom education is conducted. There are a few ways to achieve this, including directing programming toward men as well as women, targeting couples who go for couples testing, and including a discussion on gender dynamics and responsibility as part of women's female condom education. Clearly, more comprehensive female condom education is as important as increased availability. Experience with the female condom was more important than knowledge, and educational experiences in clinics were described as too public. Comprehensive training for providers and educators seems a critical first step in the process.

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APPENDICES

Appendix I: Emory IRB Approval



Institutional Review Board

April 10, 2014

Julia Martin MPH Candidate Principal Investigator Public Health

RE: Exemption of Human Subjects Research

IRB00073301

Understanding Personal Decision-Making on the Use of Female Condoms among Young Adult Women in Cape Town, South Africa

Dear Principal Investigator:

Thank you for submitting an application to the Emory IRB for the above-referenced project. Based on the information you have provided, we have determined on 04/10/2014 that although it is human subjects research, it is exempt from further IRB review and approval.

This determination is good indefinitely unless substantive revisions to the study design (e.g., population or type of data to be obtained) occur which alter our analysis. Please consult the Emory IRB for clarification in case of such a change. Exempt projects do not require continuing renewal applications.

This project meets the criteria for exemption under 45 CFR 46.101(b)(2). Specifically, you will conduct anonymous surveys with adult women and men to understand the barriers to female condom uptake among young women in Cape Town, South Africa, with a focus on how women overcome or negotiate these barriers. While this study's results may not be statistically generalizable to this population, you will still contribute to the scientific literature about decision-making on the use of female condoms.

Documents reviewed with this application:

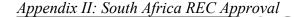
- Martin Female Condoms Protocol Version Date: 04/02/2014
- Martin_Female_Condoms_IDI Guide
- Martin_Female_Condoms_Verbal Consent_Clean_Version Date: 04/08/2014

Please note that the Belmont Report principles apply to this research: respect for persons, beneficence, and justice. You should use the informed consent materials reviewed by the IRB unless a waiver of consent was granted. Similarly, if HIPAA applies to this project, you should use the HIPAA patient authorization and revocation materials reviewed by the IRB unless a waiver was granted. CITI certification is required of all personnel conducting this research.

Unanticipated problems involving risk to subjects or others or violations of the HIPAA Privacy Rule must be reported promptly to the Emory IRB and the sponsoring agency (if any). In future correspondence about this matter, please refer to the study ID shown above. Thank you.

Sincerely,

Carol Corkran, MPH, CIP Team Lead This letter has been digitally signed





RESEARCH ETHICS COMMITTEE ADMINISTRATION

Room 1345 - HSRC Building 134 Pretorius Street, Pretoria Gauteng, South Africa Tel: 27 12 3022012 - Fax: 27 12 3022005 Email: research.ethics@hsrc.ac.za
Website: http://www.hsrc.ac.za/en/about/research-ethics
REC toll free no 0800 212 123

12 June 2014 Ms. Julian Martin 621 McDonald Street SE GA 30312 USA

Dear Ms. Martin

Ethics Clearance of HSRC Research Ethics Committee Protocol No REC 3/19/03/14: Understanding Personal Decision-Making on the Use of Female Condoms among Young Adult Women in Cape Town, South Africa.

The HSRC REC has considered and noted your application dated 19 March 2014.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 27 May 2014 to the queries raised on 19 March 2014 have been noted by a sub-committee of the Research Ethics Committee.

The conditions have now been met and the study is given full ethics Approval and may begin as from 12 June 2014.

This approval is valid for one year from 12 June 2014. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to the HSRC REC on the appropriate HSRC form 2-3 months before the expiry date. Failure to do so will lead to an automatic lapse of ethics approval which will need to be reported to study sponsors and relevant stakeholders.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by HSRC REC prior to implementation.

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www.hsrc.ac.za



Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with HSRC REC ethics requirements as contained in the HSRC REC Terms of Reference and Standard Operating Procedures, all available at http://www.hsrc.ac.za/index.php?module=pagesetter&func=viewpub&tid=132&pid=167

The HSRC REC is registered with the South African National Health Research Ethics Council (REC-290808-015). The HSRC REC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA Organisation No. 0000 6347).

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor D.R Wassenaar

Chair: HSRC Research Ethics Committee

The National Health Act's section 71 governs 'research on or experimentation with human subjects'. This section was made effective from 1 March 2012 by proclamation in the Government Gazette.

The content of this provision has an extremely restrictive impact on research, particularly if the research involves minor participants. No regulations came into effect simultaneously. This presents a problem for compliance because there is no current guidance on how to comply, and the newly proclaimed section 71 is inconsistent with the current SA Department of Health (2004) ethical guidelines and policies.

Until clarity is obtained, the HSRC REC has decided to proceed, in the interim, on the same basis as before the proclamation, i.e. the ethics review process will, in certain circumstances, deviate from the newly proclaimed provisions of s 71, but will follow the same rigorous and comprehensive ethics review process as it has always done. The REC will thus continue to approve methodology, recruitment strategies and informed consent requirements and processes in accordance with current ethics guidelines and policies.

The implications of this decision by the REC for researchers are that changes to methodology and informed consent processes may have to be made if and when the provisions of section 71 are made properly implementable. The full text of the National Health Act may be viewed at

http://www.info.gov.za/view/DownloadFileAction?id=68039

Should you require more information on this matter, please feel free to send your queries to research.ethics@hsrc.ac.za

Appendix III: In-Depth Interview Guide

Thank you very much for your time. This interview is a part of my Master's research in Public Health for Emory University in the United States. The project, which is overseen by the Human Sciences Research Council (HSRC), seeks to understand how women here in Cape Town make decisions about using female condoms. This information can then be used to assist in designing better programs for education on and promotion of female condoms, and will be submitted to Partners in Sexual Health (PSH). PSH is an organization providing sexual and reproductive health services to women and other vulnerable groups in Cape Town.

I am asking you to provide information based on your personal experiences with the use of female condoms. Your opinions are invaluable to this research, and your participation is greatly appreciated. There are absolutely no right or wrong answers for the questions I will be asking; your individual experiences, thoughts, and opinions are the most useful information you can provide. All of the information that you provide to me will be treated as private and confidential.

The interview will not take more than an hour and a half (90 minutes). It will be recorded and then transcribed, so that I can go back to what you have said with accuracy. Additionally, I will be taking notes throughout the interview. Feel free to ask questions at any time. Your participation is completely voluntary and you may change your mind at any time. If you wish to discontinue the interview, please let me know. If there is a question you would prefer to not answer, also let me know. Your identity will be protected throughout the research process. Your real name and all other identifying information will be excluded from notes, transcriptions, and reports. Please let me know if you have any concerns. Thank you so much, again, for your time.

Introductory Questions

1. Tell me a little bit about yourself.

How old are you?

Where are you from?

How long have you lived in Cape Town?

When did you first hear about the female condom?

How did you learn how to use the FC?

Approximately how many times have you used the FC?

Have you used the FC with your current/most recent partner?

2. What do you think about condoms in general?

Probes: casual vs. long-term partners, birth control, STI prevention

3. Tell me about the first time you used a female condom.

Probes: when, with whom, what was the relationship like, why did you and partner choose to use FC, how did you feel about using, how did you introduce/respond to the idea of the FC?

Transition Questions:

Can you tell me about the relationships you have been in? [Use timeline]. With who did you use male condoms? FCs? Why/why not? Are you currently in a relationship? Tell me about your relationship.

Key Questions:

- 4. *Tell me about the most recent time you used a female condom.*Probes: when, with whom, what was the relationship like, why did you and partner choose to use FC, how did you feel about using the FC for the first time, how did you introduce/respond to the idea of the FC?
- 5. How have your opinions of the FC changed over time? Probes: with different partners, ease of use, changes in comfort with use (insertion, removal, confidence in the device)?
- 6. Has there even been a time that you and a partner decided to stop using female condoms?Probes: why, how was the decision made, one specific moment vs. stopping use in general?

Closing Questions

- 7. Describe what are for you the most positive aspects of female condoms.
- 8. What do you think makes women most interested in trying the female condom?
- 9. How do you think women can best introduce the FC with a partner? What do you think is most important for women to know about introducing a female condom with a partner?
- 10. Do you have any questions for me?



Appendix IV: Information & Informed Consent Form

INFORMATION SHEET AND CONSENT FORM

Understanding Personal Decision-Making on the Use of Female Condoms Study

Who we are

Hello, I am Julia Martin. I am working for the Human Sciences Research Council.

What we are doing

We are conducting research on female condom use. We wish to find out about how barriers to use of the female condom can be successfully negotiated by women.

Your participation

We are asking you whether you will allow us to conduct one interview with you about your experiences with female condoms. If you agree, we will ask you to participate in one interview for about 1.5 hours.

Please understand that **your participation is voluntary** and you are not being forced to take part in this study. The choice of whether to participate or not is yours alone. If you choose not to take part, you will not be affected in any way. If you agree to participate, you may stop participating at any time and tell me that you don't want to continue. If you do this, there will be no penalties in any way.

Confidentiality

All identifying information will be kept in a locked file cabinet and will not be available to others. It will be kept confidential to the extent possible by law. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the ethics committee at the Human Sciences Research Council. (All of these people are required to keep your identity confidential.) Otherwise, records that identify you will be destroyed.

We are asking you to give us permission to tape-record the interview so that we can accurately record what is said

Your answers will be stored electronically in a secure place and used for research or academic purposes now or at a later date. We will never use information that might reveal who you are. All future use of the stored data will be subject to further Research Ethics Committee review and approval.

We will not record your name anywhere and no one will be able to connect you to the answers you give. Your answers will be linked to a number or a pseudonym (another name) and we will refer to you in this way in the data, and any other report or other research output.

Risks/discomforts

At the present time, we do not see any major risk of harm from your participation. The possible risks from participation in this study are only a small amount greater than those encountered in daily life. Possible risks include:

• Possible distress if emotional or traumatic events come up in the process of an interview, and the emotional effects of re-visiting these types of events



- Discomfort with talking about sex in detail, or with talking to a stranger about these details.
- Some type of negative social response from others in the community finding out you have participated in the study

We have taken measures to minimize all of these risks, particularly the last by protecting your identity. In terms of emotional distress and/or discomfort, please remember that your participation is voluntary and you are free to discontinue the interview or skip questions at any time (your reimbursement will not be affected).

Benefits

There are no immediate benefits to you from participating in this study. However, this study will be extremely helpful to us to promote understanding of how women can better use female condoms with their partners.

If you would like to receive feedback on our study, we will record your email address on a separate sheet of paper and can send you the results of the study when it is completed sometime after September 2014. If you do not have an email account, we will discuss another way to send you the results.

Who to contact if you have been harmed or have any concerns

I hereby agree to the tape-recording of my participation in the study.

This research has been approved by the HSRC Research Ethics Committee (REC). If you have any complaints about ethical aspects of the research or feel that you have been harmed in any way by participating in this study, please call the HSRC's toll-free ethics hotline 0800 212 123 (when phoned from a landline from within South Africa) or contact the Human Sciences Research Council REC Administrator, on Tel 012 302 2012 or e-mail at research.ethics@hsrc.ac.za.

If you have concerns or questions about the research you may call the project leader, Julia Martin, at +1 206 922 9477, or email her at jemart7@emorv.edu.

CONSENT
I hereby agree to participate in research on female condom use. I understand that I am participating freely and without being forced in any way to do so. I also understand that I can stop participating at any point should I not want to continue and that this decision will not in any way affect me negatively. I understand that this is a research project whose purpose is not necessarily to benefit me personally in the immediate or short term. I understand that my participation will remain confidential.
Signature of participant Date:
CONSENT FOR TAPE RECORDING



Signature of participant	Date:
I understand that the information that I provide will be research purposes now or at a later stage.	pe stored electronically and will be used for
Signature of participant	Date:

Appendix V: Code Definitions

Code	Definition
1. Access & Variety	Any discussion regarding either male or female condoms that has to do with access, availability, cost, or variety (or lack thereof) of condom choices. Includes participant mentioning condom type use or non-use due to either immediate availability issues (didn't have a condom right then, or didn't have a male condom right then), or more general availability issues (using MCs more because of having to travel further to access FCs).
2. Comfort & Familiarity	Applies to comfort with self, body, partner, or a partner's comfort with self or other. Must be specific to barrier method use—but can include discussion of feeling uncomfortable about insertion or actual physical discomfort during or after use of either or both types of condom. Comments about "being scared", "not used to" included.
	Also includes discussion of familiarity with either type of condom—including where participants talk about changes in how they felt about a method over time.
3. Control	Control or lack of control over condom choice/use. Applies to issues of controlling or challenges in controlling either male or female condom use. Does <i>not</i> apply to broader issues of control in relationships when unrelated to condom use.
4. Gender & Condoms	Discussion of one condom type (or both) belonging to one partner based on their gender. Also for discussion of how the female condom differs (or doesn't differ) from the male condom—if this difference is empirical (e.g. different to insert, price, etc.), but also when it is connected to <i>preference</i> . Includes implied differences (e.g. "it was nice to use it because I didn't have to put mine").
5. Knowledge & Use	Broad code covering knowledge of birth control methods, even if the knowledge is incorrect, partially incorrect, or of unknown accuracy. Includes how method knowledge was acquired. Also includes use details (how to use), and personal use patterns (such as doubling up, frequency, etc.). Choosing to use/not use. Use knowledge restricted to female condoms, but other types of method considerations obviously not restricted.
6. Method Failure	Any experiences of condom failure, whether the participant's own or having heard of someone else's. Also concerns about possible condom failure not grounded in concrete experience. Applies to both male and female

	condoms. Does not apply to other types of birth control.
7. Negotiation & Discussion	Any time it is clear there is a condom-related discussion or disagreement with a partner, whether or not it is resolved. Partner and participant's own responses to
	introduction and discontinuation of barrier methods.
	Can include such things as, "He says he doesn't like condoms," even if that is the entire relevant statement, as
	it indicates some inter-partner discussion of barrier
	method use or non-use. Does not include partner negotiations and discussions that are not in some way
	related to barrier method use or non-use. Does apply to
	discussions of just male condoms, even if female condoms are not mentioned in that segment.
8. Pregnancy	Any mention of pregnancy, including desires to avoid or
	achieve, and mention of children in connection to birth
	control choices. Also includes statements clearly connected to pregnancy, such as decisions made
	surrounding birth control (e.g. starting condom use after
_	deciding to discontinue a hormonal method).
9. Preferences	Discussion of likes/dislikes and plusses/minuses. Though
	most commonly about birth control methods, and specifically condoms, may also be applied to preferences
	in a relationship, for a partner, and other types of
	relationship-oriented topics. Does not apply to non-
	relationship-oriented topics. Different from "Gender &
	Condoms" in that it must be about what a participant or
	their partner likes or doesn't like. If it is that they like or do not like a specific condom or condoms in general, this
	code applies and functions as a subcode in those
	instances. Includes experience of using FC (like "it felt
	fine, it felt like nothing, or it felt like that male
	condom"?).
10. Responsibility	Includes responsibility as discussed in terms of SRH health choices (barrier methods, fertility control). Does
	not include discussions of responsibility in other realms,
	e.g. for children, for financial support. Includes broader
	discussion of equality regarding BC/STI control/condom
	use, even if not specific to the participant or their partners.
11. Risk	Restricted to topics surrounding risk in the context of barrier method use/non-use/choices. Includes concrete
	risks such as STIs, HIV, pregnancy, as well as things that
	lead to these risks, such as method failure and non-
	monogamy. Encompasses testing choices as well as
	perceived risks (even if not clearly present). Code any
	time phrases like "safe from" or protects from/against"

	appear.
12. STIs & HIV	All sexually transmitted diseases and testing. Includes
	references to "diseases" and "infections."
13. Trust & Exclusivity	Any time the word "trust" is used. Discussions of cheating
	as well as faithfulness, commitment, monogamy.
	Discussions of not knowing what your partner might be
	doing. Does not apply to issues of trust outside of
	romantic or sexual contexts. Does not apply to trust in the
	sense of condom use—e.g. trusting a man to use a
	condom correctly and to keep it on—these issues are
	coded under control and/or method failure, depending on
	the context.