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Comes in all sizes: custom-fitted condoms as a potential sexual health intervention among heterosexual men in Cape Town

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An abstract of

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Abstract

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Background: South Africa has one of the highest levels of HIV prevalence in the world, with incidence among key demographics rising. Despite free condom distribution programs, condom utilization may be declining. Issues of condom fit are correlated with breakage, slippage and non-use. Custom-fitted condoms have been shown to reduce condom failure, but no research has been conducted to determine whether heterosexual men in South Africa would be more likely to use condoms if they were custom-fitted.

Objective: To explore issues of condom non-use, and assess overall interest in custom-fitted condoms as a sexual health intervention, among heterosexual men in Cape Town, South Africa

Methods: A survey focusing on condom experiences and opinions was conducted in Cape Town, South Africa (n = 124). Demographics and sexual experiences were analyzed for associations with: condom use at last sex (CUALS), recent condom failures, history of condom failure, perfect use of condoms, preference for brand-name over free condoms, and a higher likelihood of using condoms, were custom-fitted options were available. Further multivariate analyses were conducted to examine the relationships between multiple exposures and selected outcomes.

Results: A high percentage of participants reported CUALS (68%), which was inversely related to relationship level ($p < 0.004$). Condom errors/failures were also common (58%). Almost a third (31%) reported condom failure within the previous 30 days. Condom dissatisfaction was high, and 24% reported they would be too embarrassed to use free condoms. The majority, 73%, supported more condom sizes.

Uncircumcised men were more likely to report recent condom failures compared to circumcised men ($p < 0.004$). Men reporting a history of condom failure were more likely to report a higher likelihood of using condoms, if custom-fitted options available ($p < 0.007$).

Conclusions: Participants reported a high prevalence of condom failure, especially among uncircumcised men, and high dissatisfaction with current condom options. Most participants expressed a desire for additional sizing options, and would be more willing to use condoms, were custom-fitted condoms available. Our data suggests that the introduction of additional condom sizing options could positively affect condom utilization among heterosexual males in South Africa.

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Chapter I: Introduction

The HIV/AIDS pandemic has been especially devastating in South Africa, which has one of the world's highest rates of HIV prevalence (Shisana, Rehle, Simbayi, Zuma, & Jooste, 2009; L. Simbayi et al., 2014). Additionally, the country's rate of unintended pregnancy is high (Mchunu, Peltzer, Tutshana, & Seutlwadi, 2013). Responding to these trends, the South African government introduced *Choice* condoms and made them freely available. Studies indicate that the correct and consistent use of male condoms is highly effective in the prevention of HIV transmission and the prevention of unintended pregnancy. However, issues with condom fit have resulted in usage errors as well as reduced acceptability (Reece, Herbenick, & Dodge, 2009). Though the South African government supplies and distributes free condoms throughout the country, incidence of HIV infection among key demographics is rising (L. Simbayi et al., 2014).

Objectives and Aims

The objective of this study is to explore issues of condom non-use, and assess overall interest in custom-fitted condoms among heterosexual men in Cape Town, South Africa. Additionally, we will be providing preliminary research for future studies regarding these, and similar, issues. Our aims are broken down as follows:

1. To describe men's personal experiences with standard condoms, including their previous history of condom acquisition and use, and any issues experienced therein

2. To describe men's beliefs and attitudes about standard condoms and their use, including rationale for condom use and non-use, factual knowledge base, and perceptions of men's roles in regards to sexual health
3. To gauge interest in custom-fitted condoms as an alternative to standard condoms
4. To determine whether or not men believe that custom-fitted condoms would increase overall condom use

Background

Of the 35 million people living with HIV/AIDS worldwide, 71% live within the region of sub-Saharan Africa ("UNAIDS Gap Report," 2014). South Africa, in particular, represents a disproportionately high percentage of the overall disease burden, with an estimated 6.8 million individuals living with HIV (UNAIDS, 2014). The most recent study by the Human Subjects Research Committee (HSRC), the governing body for research in South Africa and one of its primary research entities, described a national prevalence rate of 12.6%. This statistic rose to 18.9% amongst people aged 15-49 – those considered the most sexually active. This is an increase from the previous study's findings, and noted to be a statistically significant increase in *overall* incidence. That being said, one of the most troubling findings was a rise in *specific* incidence – that among heterosexual couples living together (L. Simbayi et al., 2014). As studies continue to identify heterosexual sex as the leading mode of transmission of HIV in the region (De Cock, Jaffe, & Curran, 2012), youth aged 15-24 are the most sexually active age group in South Africa, putting them at an increased risk for HIV transmission (Shisana et al., 2009).

While the issue of HIV/AIDS is at the forefront of the reproductive health discussion in southern Africa, unintended pregnancies have also presented pressing social, economic, and health concerns. The Guttmacher Institute reports that 60% of pregnancies in southern Africa are unplanned (Singh, Sedgh, & Hussain, 2010). A 2012 study conducted under the auspices of the HSRC found that 16.2% of female adolescents participants had an unwanted pregnancy (Mchunu et al., 2013). In 2006, the Kaiser Family Foundation found that, among young South African females reporting at least one pregnancy, 66% cited failure to use contraception as the primary reason for pregnancy (Panday, Makiwane, Ranchod, & Letsoalo, 2009). Amongst teenage girls in South Africa, there is a strong correlation between HIV infection and pregnancy, with 12.9% of pregnant teens aged 15-19 HIV positive (Panday et al., 2009). A nation-wide study indicated that from 2008-2010, 40.5% of maternal deaths in South Africa were related to HIV/AIDS infection (National Committee on Confidential Enquiries into Maternal Deaths, 2011).

Female sex workers bear a high burden of HIV in South Africa and are a high-risk population of interest for the HSRC and this study. In three separate studies conducted in Kwa-Zulu Natal, Johannesburg, and Cape Town, researchers reported HIV prevalence rates of 46.4%, 59.6%, and 34% respectively (Fraser-Hurt et al., 2011). The high prevalence among female sex workers has proven to result in an increased risk of HIV amongst male clients. A 2008 HSRC study found that men who reported visiting sex workers were 2.9 times more likely to be HIV-positive, based on multivariate analysis (Fraser-Hurt et al., 2011). This coincides with a study conducted in Cape Town that found that nearly a third of men surveyed reported engaging in transactional sex (Jewkes et al., 2008).

The correct and consistent use of male condoms has proven to be highly effective in the prevention of HIV transmission and the prevention of unintended pregnancy. Studies have indicated that condom errors, including inconsistent condom use, occur frequently and reduce their effectiveness (Sanders et al., 2012). The fit and feel of male condoms has presented as one of the leading barriers to consistent use (Reece et al., 2009). Multiple studies conducted across countries have indicated that men often report condom fit as being either too long, too short, too loose, or too tight (Potter & de Villemeur, 2003; Reece et al., 2008). Other studies have also suggested that men who report poor condom fit are more likely to report condom errors, including breakage and slippage, as well as sexual difficulties, and reduced sexual pleasure for both partners (R. A. Crosby, Yarber, Graham, & Sanders, 2010).

In the United States, most condoms are produced in a remarkably limited range of sizes, with available widths between standard condoms and large condoms varying by less than 10%: substantially less than the known variability of penis sizes. (Richters, Gerofi, & Donovan, 1995; Smith, Jolley, Hocking, Benton, & Gerofi, 1998). For example, the width of a 'standard' Trojan condom is 53 mm, while the 'large' Trojan condom is 54 mm. Only recently approved for use in the United States, custom-fitted condoms have been implemented throughout Europe (M. Cecil, 2012). A presentation at the 2012 International AIDS Meeting found that European men who purchased condoms from an expanded array of sizes only chose a size currently available in the United States 12% of the time (M. Cecil, 2012). South Africa relies on the same condom sizing standards that limit the range of sizes as in the U.S., making condom sizes similar between the two countries. For example, the condoms used for free distribution by the South African government are 52 mm wide. South Africa does not have a regulatory body that governs condom quality, so

most manufacturers seek the CE certification mark (approval by the European Union) and/or FDA approval (Choice Condoms, N.D.).

In a 2008 study conducted in the United States, researchers found that condom breakage and slippage were lower for men that used fitted condoms specific to their individual penile dimensions than for those who used standard condoms during intercourse (Reece et al., 2008). In light of these findings, some researchers and clinicians have called for the availability of a broader range of condom sizes (Michael Cecil, Nelson, Trussell, & Hatcher, 2010).

To date, few studies have compared the success of fitted versus standard condoms in terms of increasing condom acceptability and decreasing condom errors. Particularly within the context of South Africa, research has not been conducted to evaluate men's desire for fitted condoms, as well as the feasibility of utilizing fitted condoms in clinics and in the context of commercial sex work. We hope to explore whether the introduction of fitted condoms in South Africa would encourage individuals to revisit the idea of using condoms to prevent HIV/AIDS and unintended pregnancy.

Significance and Implications for Global Health

Despite the continued burdens created by HIV/AIDS and unintended pregnancy throughout the world, obstacles to condom use threaten to prolong these public health issues. This study aims to identify current barriers to condom use, and explore whether the lack of variation in condom sizes prevents heterosexual men from using condoms consistently and correctly. The successful integration of fitted condoms into the South African market could lead to increased rates of condom use, while decreasing transmission of HIV/AIDS and unintended

pregnancies. Knowledge gleaned in this setting could inform programs in other countries facing similar public health challenges.

Chapter II: Literature Review

HIV/AIDS in South Africa

The HIV/AIDS epidemic affecting South Africa has long been recognized and investigated by both domestic and international entities. Domestically, four population-based household surveys have been carried out by the South African government under the auspices of the HSRC, allowing for an unprecedented understanding of the complicated dynamics involved in the propagation of HIV. This unrelenting investigation has made it clear that HIV is heterogeneous in regards to age, sex, race, socio-economic status and location (Shisana et al., 2009), affecting the people of South Africa from all walks of life, though, perhaps not equally (**Figure 1**). More specifically, in its last national survey, the HSRC estimated a prevalence rate of 12.6% (95% CI: 11.7 – 13.5) for 2012, significantly higher ($p < .001$) than its 2008 estimate of 10.9% (95% CI: 10.0 – 11.9) (L. Simbayi et al., 2014).

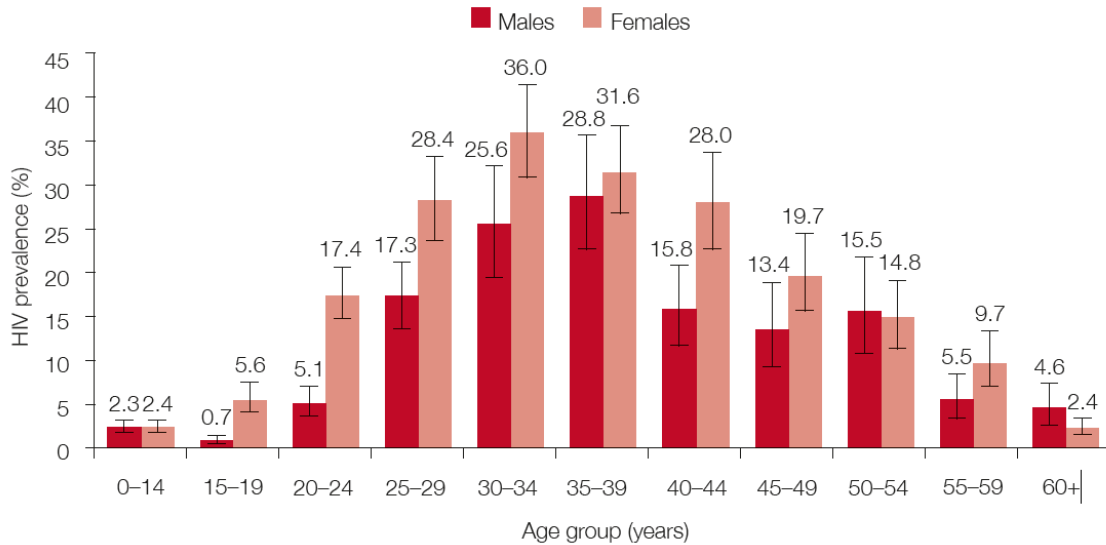


Figure 1. Prevalence of HIV by sex and age, South Africa 2012, taken from (L. Simbayi et al., 2014)

Though prevalence continues to climb as both a function of the chronic nature of HIV, and increasing life expectancy among those who live with it, the growth has stabilized to more predictable patterns (Rehle et al., 2010; Shisana et al., 2009; L. Simbayi et al., 2014). That being said, certain key demographic have been identified as disproportionately affected by the epidemic, including Black African females aged 20 – 34; Black African males aged 25 – 49; those living in urban, informal settlements (Connolly, Colvin, Shishana, & Stoker, 2004; Rehle et al., 2010; Shisana et al., 2009); recreational drug users (L. Simbayi et al., 2014; Wechsberg, 2015) sex workers; and truck drivers (Ramjee, Gouws, & Eleanor, 2002; Ramjee, Karim, & Sturm, 1998; Richter & Chakvinga, 2012; Wechsberg, 2015).

The trajectories of HIV incidence rates within South Africa are much less amenable to extrapolation (**Table 1**). Extensive and continuous research has shown that the circuit of incidence is much more fickle, increasing or decreasing from group to group through a variety of both known and as yet unclear means.

Table 1. Incidence of HIV by behavioral and socio-demographic factors for those aged 15-49, South Africa 2012, taken from (L. Simbayi et al., 2014)

Variables	n	HIV incidence % (95% CI)
Marital status		
Married	3,660	0.55 (0.45–0.65)
Living together	1,499	3.08 (2.48–3.68)
Going steady	4,276	1.99 (1.61–2.37)
Single	4,432	2.28 (1.82–2.74)
Number of sexual partners		
One partner in the past 12 months	8,639	1.67 (1.33–2.01)
More than one partner in the past 12 months	1,058	2.43 (1.95–2.91)
Selected at-risk populations		
Black African females 20–34 years	2,532	4.54 (3.64–5.44)
Black African males 25–49 years	2,120	1.84 (1.48–2.20)

For example, though there has been a clear and dramatic drop in vertical transmission (NDOH, 2010), incidence has recently risen for heterosexual, non-married couples aged 15-24, and dropped for children aged 2-14; risen for Black Africans, and dropped for all other races; spiked among citizens of informal urban settlements, and declined for the rural demographic (L. Simbayi et al., 2014). A recent article by Gray et al., focused on sub-Saharan Africa, calculated “1-2 cases of HIV transmission per 1000 coital acts” (R. H. Gray & Wawer, 2012). Though the authors’ full findings are similar to those of other recent publications, Gray admits that the figures are not sufficient to explain the observed rate of infection in the region, falling far short of actual cases seen. In short, the myriad factors affecting HIV transmission within South Africa have yet to be fully understood, and will continue to benefit from further exploration.

Thankfully, analyses of possible variables contributing to HIV infection both writ large, and particular to South Africa, are multitudinous and ongoing. Key determinants of transmission in the region have been identified, and are the focus of continued scrutiny:

- In regards to non-modifiable variables, research has found that females are more susceptible to HIV infection than males as a function of their physiology (Quinn & Overbaugh, 2005), particularly in developing nations, such as South Africa (Pettifor et al., 2005). However, a more recent meta-analysis argues that infection rates are equal between men and women (Boily et al., 2009).
- One semi modifiable factor is that of male circumcision, which has been shown in to be protective against HIV infection (Auvert et al., 2005; Bailey et al., 2007; Byakika-Tusiime, 2008; R. H. Gray et al., 2007; R. H. Gray & Wawer, 2012). So strong is the evidence that the South African government has made the practice a priority, introducing the Voluntary Medical Male Circumcision (VMMC) program in 2010, with hopes of reaching 80% of HIV negative men aged 15-49 by the end of 2015 (SANAC, 2011).
- Cultural and/or religious beliefs may also alter one's risk of HIV infection (Kalichman & Simbayi, 2004) as a function of partaking or not of particular high risk behaviors, or by influencing interpretation and future use of information regarding HIV/AIDS. For example, strict belief in a supernatural propagation of HIV was correlated with a higher likelihood of eschewing condoms (Kalichman & Simbayi, 2004). Relatedly, religious practices have been shown to indicate difference in HIV prevalence in Sub-Saharan Africa (Garner, 2000; P. B. Gray, 2004; Velayati et al., 2007). However, this information should be taken with a grain of salt, as other studies have found that religious beliefs may result in a propensity to obfuscate irreligious and/or risky behaviors. This leads to unsafe practices, such as non-reporting of extramarital liaisons, followed by intercourse without protection (Takyi, 2003).

- Knowledge of HIV/AIDS remains an incontrovertible defense against transmission when paired with an appropriate change to model behaviors (MDG Report 2014). Unfortunately, such knowledge has been shown to be low in sub-Saharan Africa in general (Bankole, Biddlecom, Guiella, Singh, & Zulu, 2007; J. U. N. P. o. H. A. UNAIDS, 2012), and in South Africa, in particular (Table 2) (Shisana et al., 2009; L. Simbayi et al., 2014). More troubling is the finding that correct knowledge pertaining to HIV/AIDS fell from the 2008 survey to the 2012 survey, especially among those groups most at risk.

Table 2. Correct knowledge regarding the transmission of HIV, and rejection of major misconceptions about the transmission of HIV for those aged 15+, South Africa 2012, taken from (L. Simbayi et al., 2014)

Variable	n	%	95% CI
Sex			
Male	11,464	26.2	24.6–27.8
Female	15,080	27.3	25.8–28.9
Age group (years)			
15–24	7,154	28.6	26.8–30.4
25–49	11,634	27.7	26.0–29.4
50 +	7,756	22.4	20.5–24.4
Race			
Black African	15,231	23.6	22.1–25.2
White	2,868	43.3	39.1–47.6
Coloured	4,942	30.3	27.4–33.5
Indian/Asian	3,438	41.4	37.4–45.5
Locality type			
Urban formal	15,686	31.7	29.6–33.8
Urban informal	2,701	21.9	19.1–25.0
Rural informal	5,597	20.8	19.0–22.7
Rural formal	2,560	24.8	21.2–28.8
Province			
Western Cape	3,263	29.5	26.5–32.5
Eastern Cape	3,332	25.6	22.4–29.0
Northern Cape	2,049	28.0	22.7–33.9
Free State	1,980	34.7	30.3–39.5
KwaZulu-Natal	6,216	24.4	22.1–26.9
North West	1,826	20.8	18.1–23.9
Gauteng	3,659	31.7	28.4–35.3
Mpumalanga	1,905	21.9	18.1–26.4
Limpopo	2,314	19.3	16.0–23.2
Total	26,544	26.8	25.5–28.1

- Of note, while participants’ understanding of HIV/AIDS risks was low, so too was their perception of personal risk (L. Simbayi et al., 2014). Similarly, even in cases where knowledge was found to be high, there was a discrepancy between their awareness of

said knowledge, reported behaviors (James, Reddy, Taylor, & Jinabhai, 2004) and even their HIV status upon testing (Peltzer, Matseke, Mzolo, & Majaja, 2009). In fact, in some instances, those reporting the *lowest* level of potential risk were found to be HIV positive upon testing (Stringer et al., 2004). This divergence seems ripe for potential intervention, as an individual who has little to no understanding of their susceptibility to infection has little rationale to take prudent measures to protect themselves.

- Regular testing is an integral component in the fight against HIV, as knowing one's status is crucial to combating its spread. Thankfully, South Africa shines in this particular regard, with one of the highest proportions of citizens knowing their HIV status (Shisana et al., 2009). Overall, more than 90% of participants in the latest house-to-house survey were able to name a nearby location to receive an HIV test, with nearly two-thirds (65.5%) reporting they had been tested for HIV. Furthermore, there was a significant increase in recent testing since the previous study, with 66.2% testing within the last year for the 2012 survey, compared to 49.1% in the 2008 survey (Shisana et al., 2009; L. Simbayi et al., 2014).

Condom Use in South Africa

To describe the role condoms play in South Africa as “complicated” is an understatement of national proportions. Though the use of condoms has time and again been proven to be a safe, reliable and inexpensive method to reduce STIs and pregnancy, their consistent and correct use in South Africa has been difficult to achieve (Beksinska, Smit, & Mantell, 2012).

However, it has not been for lack of trying. The “Choice” condom, provided for free by the South African government and distributed far and wide, from McDonald’s restrooms, to township clinics, to hotel lobbies, has long been a symbol of the country’s commitment to slowing and ultimately reversing the HIV epidemic. Unfortunately, multiple studies and a slew of anecdotal evidence suggest that citizens find Choice condoms to be insufficient to meet the needs of the people they are supposed to serve. A recent study carried out by Médecins Sans Frontières (MSF) found high levels of disinterest in the government brand among township citizens, a key demographic. Qualitative examples from the participants paint a picture thick with dissatisfaction, as Choice are described as “too thick and too oily,” “[painful] due to the poor fit,” and that they “smelled awful and didn’t fit well” (Ashmore & Henwood, 2015).

Relatedly, a six month survey carried out by the AIDS Foundation of South Africa in 2012 found that 95% of respondents felt that the Choice condom was in need of reformulation and rebranding (AIDS Foundation of South A. F. o. S. Africa, 2013). “It’s better to buy condoms from a shop because they have better quality than those provided by the government,” said one participant. Another provided the following statement regarding his view of Choice condoms: “I would not want to be seen using a free government condom when I’m on a date. This will reduce my status, and even if the government were to re-brand, I would rather buy one.”

In fact, criticisms of the Choice brand are easy to find, and come in a variety of forms. The most common complaints revolve around three core issues, echoed above: failings of the “one-size fits all” mentality (Child, 2012; Skoch, 2010); repeated Choice condom recalls with controversial etiologies, leading to suspicions of inferior quality (IRIN, 2007; Press, 2012); and embarrassment in using government condoms (Skoch, 2010).

Regrettably, the population level behavioral data support the anecdotes: the HSRC's national surveys measured condom use at last sex (CUALS; a standard set by the Millennium Development Goals) in each of its four surveys from 2002 to 2012 (Figure 2). Though the initial three showed a dramatic increase in CUALS, the most recent figures depict a sharp decline; this was true for both males and females, and for both youth and adult populations (L. Simbayi et al., 2014).

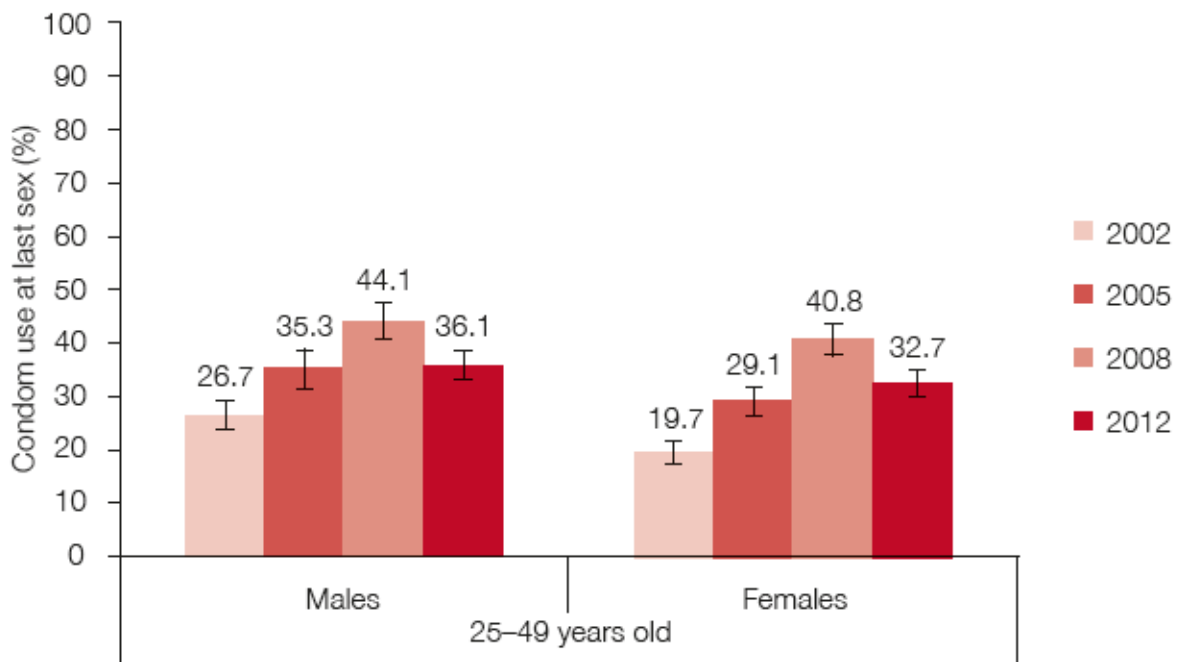
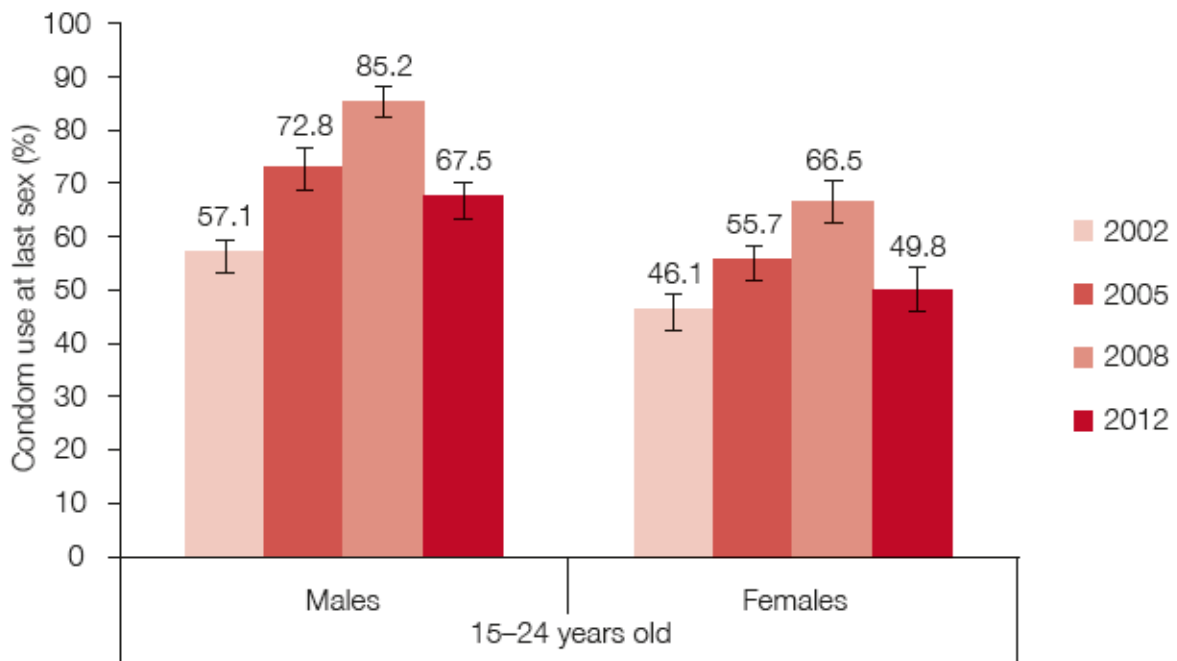


Figure 2. Condom use at last sex by age group and year of survey, South Africa 2012, taken from (L. Simbayi et al., 2014)

This decline is in sharp contrast to the total number of condoms distributed over the same interim, which nearly doubled from 283,000,000 in 2008 (NDOH, 2009), to 501,000,000 in 2012 (NDOH, 2013).

More generally, an extensive paper providing in depth analysis of the problems and challenges to condom use in South Africa cited possible confounding factors. Major findings include the following:

- condom use falls significantly between couples after the six month mark, regardless of known testing (Chimbindi, McGrath, Herbst, San Tint, & Newell, 2010; Harrison, Cleland, & Frohlich, 2008; Taylor et al., 2007)
- a panoply of condom use errors and condom failures (41% of males, and 37% of females) reduce condom effectiveness (Jama Shai, Jewkes, Levin, Dunkle, & Nduna, 2010; Khumalo, 2007; L. C. Simbayi & Kalichman, 2007)
- acceptability of the Choice brand has consistently found to be low (Beksinska et al., 2012; Mulwo, Tomaselli, & Dalrymple, 2009).

Recent quotes by Aaron Motsoaledi, South Africa's Health Minister, acknowledge that the current formulation of the Choice condom may be inadequate. When asked to explain the recent dip in condom use he responded, "the standard-issued Choice condoms just aren't cool enough" (BBC, 2014). Motsoaledi promised that the South Africa Department of Health would combat the "condom fatigue" by providing condoms that would be "flavoured, coloured and are smelling very nice" at colleges and universities (Cullinan, 2012). As was quickly pointed out, however, by age 21, 50% of the population is no longer enrolled in any manner of education, thus limiting the use

of such a change (S. S. Africa, 2012; Ashmore & Henwood, 2015). Moreover, this policy change does not address the lack of a variety of condom sizes, a chief complaint.

Other researchers have sought *predictors* of condom use in South Africa. A survey of sexually experienced young adults (15 – 24 years old) found that condom use at sexual debut and optimism about the future to be significant predictors of CUALS (Hendriksen, Pettifor, Lee, Coates, & Rees, 2007).

Condom Fit as a Function of their Use

As detailed above, though the correct and consistent use of condoms has proven to be an effective and inexpensive tool in the prevention of HIV transmission, people must first be willing and able to use them. Barriers to effective condom use are many, from religious objections, to scarcity, to issues of condom failure.

Studies both internationally and within the South African milieu have indicated that condom errors, including inconsistent condom use, occur frequently and reduce their effectiveness (Jama Shai et al., 2010; Khumalo, 2007; Sanders et al., 2012; L. C. Simbayi & Kalichman, 2007). More specifically, the fit and feel of condoms has presented as one of the leading barriers to consistent use (Reece et al., 2009), with the one size fits all policy of Choice being cited as a particular concern (Child, 2012; Skoch, 2010). Multiple studies conducted across a broad spectrum of countries have indicated that men often report condom fit as being either too long, too short, too loose, or too tight (Potter & de Villemeur, 2003; Reece et al., 2008). Other studies have suggested that men who report poor condom fit report a higher incidence of condom errors, including

breakage, slippage, sexual performance difficulties, and reduced sexual pleasure for both partners (R. Crosby, Sanders, Yarber, & Graham, 2003; R. Crosby, Yarber, Sanders, Graham, & Arno, 2008; R. A. Crosby, Graham, Yarber, & Sanders, 2004; R. A. Crosby et al., 2010; R. A. Crosby et al., 2007).

In the United States, condoms are generally produced within a remarkably limited range of sizes, with the width between “standard” condoms and “large” condoms often varying by less than 10%- substantially less than the known variability of penis sizes. (Jamison & Gebhard, 1988; Richters et al., 1995; Smith et al., 1998). South Africa relies on the same condom sizing standards that limit the range of sizes as in the U.S., making condom sizes similar between the two countries. For example, the condoms used for free distribution by the South African government are 52 mm wide, quite similar to the “standard” size sold by most American brands. A presentation at the 2012 International AIDS Meeting found that European men who purchased condoms from an expanded array of sizes only chose a size currently available in the United States 12% of the time (M. Cecil, 2012).

Though they have not been approved by the FDA for use in the United States, custom-fitted condoms have been implemented throughout Europe (M. Cecil, 2012). Custom-fitted condoms, a product of TheyFit, are available in 14 different lengths, and 12 widths, with a total product line of 95 differently sized condoms.

In a 2008 study conducted by Reece, et al., researchers found that condom failures, in this case defined as breakage and slippage, were lower for men that used fitted condoms specific to their individual penile dimensions than for those who used standard condoms (Reece et al., 2008). In

light of these findings, researchers and clinicians have called for the availability of a broader range of condom sizes (Michael Cecil et al., 2010).

Gaps in literature

The breadth and quality of research carried out to better understand the HIV epidemic in South Africa is staggering in its proportions. Longitudinal research performed under the auspices of the Human Subjects Research Committee (HSRC) creates a backbone for other studies to attach to, allowing for an unprecedented familiarization with how the spread of HIV is manifest. That being said, small but significant gaps remain: questions created by the results of previous explorations. Patterns in the national data must be chased down to the local level; findings writ large must be examined to divine the “whos, whys, wheres and hows” from the recently elucidated “whats.”

For example, while many studies have been carried in regards to barriers to condom use, not nearly enough have asked questions particular to Choice condoms. As one of South Africa’s most enduring and symbolic mechanisms to combat the spread of HIV, any information gleaned as to why citizens won’t use the free and effective prophylactic would benefit the realization of the end goal. Additionally, while we now have a better grasp of what may prevent an individual from *initially* using condoms, we know little about what causes interruptions once their use begins, or difficulties experienced during use.

Still new on the international scene, even fewer studies have compared custom-fitted versus standard condoms in terms of increasing condom acceptability and decreasing condom errors.

Moreover, though the Ministry of Health has promised to rebrand the Choice condom, offering new colors and flavor options, the issue of ill fit has yet to be addressed.

In this study, we hope to explore heterosexual men's' experiences and attitudes with standard condoms, and to determine whether the introduction of fitted condoms in South Africa would encourage individuals to revisit the idea of using condoms.

Chapter III: Manuscript

Comes in all sizes: custom-fitted condoms as a potential sexual health intervention among heterosexual men in Cape Town

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Abstract

Title: Comes in all sizes: custom-fitted condoms as a potential sexual health intervention among heterosexual men in Cape Town

Background: South Africa has one of the highest levels of HIV prevalence in the world, with incidence among key demographics rising. Though condoms are freely provided by the government, and have proven to be a safe and effective method of preventing the transmission of HIV, a recent study indicates that condom utilization may be dropping. Issues of condom fit have repeatedly been shown to be correlated with lower condom acceptance and use, with those reporting sizing problems more likely to experience breakage or slippage. Custom-fitted condoms have been shown to reduce condom failure for anal sex application. No research has been carried out to determine whether heterosexual men in South Africa would be more likely to use condoms were they custom-fitted.

Objective: To explore issues of condom non-use, and assess overall interest in custom-fitted condoms as a sexual health intervention, among heterosexual men in Cape Town, South Africa

Methods: A survey focusing on condom experiences, beliefs and opinions was conducted in clinics and truck stops in and around Cape Town, South Africa (n = 124). Participant selection was convenience based, and surveys were self-administered to protect privacy. Descriptive data was collected, and analyses were performed comparing demographics, circumcision status, and sexual experiences against six selected outcomes: condom use at last sex; recent condom failures; ever condom failure; perfect use of condoms; reporting a preference for brand name condoms over free condoms; and reporting a higher likelihood of using condoms in the future, were custom-fitted condoms available. Further multivariate analyses were conducted to examine the relationships between multiple exposures and the selected outcomes. .

Results: Participants were heterogeneous in regards to age, race, religion, education, sexual experience, and income level. The median age was 30. Most (68%) of participants classified themselves as Black African, followed by 20% as Colored, 7% White, and 3% as Other. Most men reported being circumcised (59%).

The percentage who reported using a condom at last sex was relatively high, at 68%. However, condom errors/failures were also common, as 58% of participants reported ever having at least one problem with condom fit or function. Almost a third (31%) reported a condom failure within the previous 30 days. Dissatisfaction with condoms was high: 33% reported disliking the feel of condoms and 24% reported that they would be too embarrassed to use Choice condoms. The vast majority, 73%, supported the idea that condoms come in more sizes. This support was sustained regardless of education level, race, religious affiliation, or income. Moreover, 67% reported that they would be more likely to use condoms in the future, were custom-fitted options available. Men who reported recent condom failure(s) did, on average, report a greater likelihood of using condoms in the future, were custom-fitted options available compared to men who did not report recent condom failure(s) (mean score 3.7 versus 4.0, $p < 0.02$). This finding was also true among those who had ever experienced condom breakage ($p < 0.007$) or slippage ($p < 0.01$).

Condom use at last sex (CUALS), was inversely related to level of relationship commitment, with those who reported themselves as married (54%), in a relationship (66%), and single (93%) ($p < 0.004$). Uncircumcised men were more likely to report recent condom failures compared to circumcised men ($p < 0.004$).

Conclusions: Though rates of HIV infection in South Africa are climbing among key demographics, condom use at last sex has fallen. There is a high prevalence of condom failure, especially among uncircumcised men, and dissatisfaction with current condom options is high. More than three-quarters of participants desire additional sizing options; this desire was seen across all demographic breakdowns. The majority of men surveyed would be more willing to use condoms, were custom-fitted condoms available. Our data suggests that the introduction of additional condom sizing options could positively affect condom utilization among heterosexual males in South Africa, a question that merits further research.

Introduction

The HIV/AIDS pandemic has been especially devastating in South Africa, which has one of the world's highest rates of HIV prevalence (Shisana et al., 2009). Though the South African government supplies and distributes free condoms throughout the country, incidence of HIV infection among key demographics is rising, while, concurrently, self-reported measures of condom utilization are falling (L. Simbayi et al., 2014). Reports specific to the environment of South Africa suggest dissatisfaction with the Ministry of Health's free Choice condom, citing complaints of ill-fit, as well as embarrassment in using a government condom.

Studies indicate that the correct and consistent use of male condoms is highly effective in the prevention of HIV transmission and the prevention of unintended pregnancy. However, issues with condom fit have resulted in usage errors as well as reduced acceptability (Reece et al., 2009). In a 2008 study conducted in the United States, researchers found that condom breakage and slippage were lower for men that used fitted condoms specific to their individual penile dimensions than for those who used standard condoms during intercourse (Reece et al., 2008).

To date, few studies have compared the success of fitted versus standard condoms in terms of increasing condom acceptability and decreasing condom errors. Particularly within the context of South Africa, there is a research gap in evaluating men's desire for fitted condoms. We hope to explore whether the introduction of fitted condoms in South Africa would encourage individuals to revisit the idea of using condoms to prevent HIV/AIDS.

Background

Of the 35 million people living with HIV/AIDS worldwide, 71% live within the region of sub-Saharan Africa. ("UNAIDS Gap Report," 2014). South Africa, in particular, represents a disproportionately high percentage of the overall disease burden, with an estimated 6.8 million individuals living with HIV (UNAIDS, 2014). The most recent study by the Human Subjects Research Committee (HSRC), the governing body for research in South Africa and one of its primary research entities, described a national prevalence rate of 12.6%. This statistic rose to 18.9% amongst people aged 15-49 – those considered the most sexually active. This is an increase from the previous study's findings, and noted to be a statistically significant increase in *overall* incidence. One of the most troubling findings was a rise in *specific* incidence – that among heterosexual couples living together (L. Simbayi et al., 2014). As studies continue to identify heterosexual sex as the leading mode of transmission of HIV in the region (De Cock et al., 2012), we believe this is a critical area for continuing research.

Knowledge of HIV/AIDS remains an incontrovertible defense against transmission when paired with an appropriate change to model behaviors (MDG Report 2014). Unfortunately, such knowledge has been shown to be low in sub-Saharan Africa in general (Bankole et al., 2007; J. U. N. P. o. H. A. UNAIDS, 2012), and in South Africa, in particular (Shisana et al., 2009; L. Simbayi et al., 2014). More troubling is the finding that correct knowledge pertaining to HIV/AIDS fell from the 2008 survey to the 2012 survey, especially among those groups most at risk.

Of note, while participants' understanding of HIV/AIDS risks was low, so too was their perception of personal risk (L. Simbayi et al., 2014). Similarly, even in cases where knowledge was found to be high, there was a discrepancy between their awareness of said knowledge, reported

behaviors (James et al., 2004) and even HIV status upon testing (Peltzer et al., 2009). As pointed out by the latest survey, those *most* at risk, heterosexual non-married couples aged 15-19, believe themselves to be among those with the least risk.

Studies both internationally and within the South African milieu have indicated that condom errors, including inconsistent condom use, occur frequently and reduce their effectiveness (Jama Shai et al., 2010; Khumalo, 2007; Sanders et al., 2012; L. C. Simbayi & Kalichman, 2007). More specifically, the fit and feel of condoms has presented as one of the leading barriers to consistent use (Reece et al., 2009), with the one size fits all policy of Choice being cited as a particular concern (Child, 2012; Skoch, 2010). Multiple studies conducted across a broad spectrum of countries have indicated that men often report condom fit as being either too long, too short, too loose, or too tight (Potter & de Villemeur, 2003; Reece et al., 2008). Other studies have suggested that men who report poor condom fit report a higher incidence of condom errors, including breakage, slippage, sexual performance difficulties, and reduced sexual pleasure for both partners (R. Crosby et al., 2003; R. Crosby et al., 2008; R. A. Crosby et al., 2004; R. A. Crosby et al., 2010; R. A. Crosby et al., 2007). In regards to the Choice brand, its acceptability among the South African population has consistently found to be low (Beksinska et al., 2012; Mulwo et al., 2009). In fact, criticisms of the Choice brand are easy to find, and come in a variety of forms. The most common complaints revolve around three core issues: failings of the “one-size fits all” mentality (Child, 2012; Skoch, 2010); repeated Choice condom recalls with controversial etiologies, leading to suspicions of inferior quality (IRIN, 2007; Press, 2012); and embarrassment in using government condoms (Skoch, 2010).

Recent quotes by Aaron Motsoaledi, South Africa's Health Minister, acknowledge that the current formulation of the Choice condom may be inadequate. When asked to explain the recent dip in condom use he responded, "the standard-issued Choice condoms just aren't cool enough" (BBC, 2014). Motsoaledi promised that the South Africa Department of Health would combat the "condom fatigue" by providing condoms that would be "flavoured, coloured and are smelling very nice" at colleges and universities (Cullinan, 2012). As was quickly pointed out, however, by age 21, 50% of the population is no longer enrolled in any manner of education, thus limiting the use of such a change (S. S. Africa, 2012; Ashmore & Henwood, 2015). Moreover, this policy change does not address the lack of a variety of condom sizes, a chief complaint.

In the United States, condoms are generally produced within a remarkably limited range of sizes, with the width between "standard" condoms and "large" condoms often varying by less than 10%- substantially less than the known variability of penis sizes. (Jamison & Gebhard, 1988; Richters et al., 1995; Smith et al., 1998). South Africa relies on the same condom sizing standards that limit the range of sizes as in the U.S., making condom sizes similar between the two countries. For example, the condoms used for free distribution by the South African government are 52 mm wide, quite similar to the "standard" size sold by most American brands. A presentation at the 2012 International AIDS Meeting found that European men who purchased condoms from an expanded array of sizes only chose a size currently available in the United States 12% of the time (M. Cecil, 2012).

Though they have not been approved by the FDA for use in the United States, custom-fitted condoms have been implemented throughout Europe (M. Cecil, 2012). Custom-fitted condoms, a

product of TheyFit, are available in 14 different lengths, and 12 widths, with a total product line of 95 differently sized condoms.

In a 2008 study conducted by Reece, et al., researchers found that condom failures, in this case defined as breakage and slippage, were lower for men that used fitted condoms specific to their individual penile dimensions than for those who used standard condoms (Reece et al., 2008). In light of these findings, researchers and clinicians have called for the availability of a broader range of condom sizes (Michael Cecil et al., 2010).

Despite the continued burdens created by HIV/AIDS throughout the world, obstacles to condom use threaten to prolong this significant public health issue. This study aims to identify current barriers to condom use, and explore whether the lack of variation in condom sizes prevents heterosexual men from using condoms consistently and correctly. The successful integration of fitted condoms into the South African market could lead to increased rates of condom use, while decreasing transmission of HIV/AIDS and unintended pregnancies. Knowledge gleaned in this setting could inform programs in other countries facing similar public health challenges.

Methods

Overview: A quantitative assessment was conducted among males at seven clinics and one truck stop in and around Cape Town, South Africa. Participants were asked to complete a survey to examine experiences with standard male condoms and determine interest in fitted-condoms.

Target Population: The target population for the quantitative assessments were men aged 18 years or older who self-reported sexual intercourse with a women in the previous 6 months, and who were proficient in English.

Inclusion Criteria:

- Male
- Aged 18 years or older
- Having had vaginal or anal sex with a woman in the last 6 months
- Have proficiency in reading and speaking English

Exclusion: Criteria:

- Female, ? transgender?
- Under 18 years
- Not having had vaginal or anal sex with a woman in the last 6 months
- Not proficient in reading and speaking English

Sample Size, Recruitment and Selection of Participants: Recruitment for the quantitative assessment was conducted among seven clinics and one major truck-stop in and around Cape Town, South Africa. Clinical sites were pre-selected by our research partners at the Human Subject Research Council (HSRC) for their high traffic, diversity of location, and mélange of clientele base. The truck stop was an education and outreach location designated and maintained by Partners in Sexual Health (PSH), another key collaborator during our study. Our study sites included Cape

Town proper, multiple Cape Town suburbs, nearby townships and a more eclectic smattering of individuals via a high volume short and long distance truck stop.

A key variable in our survey is the proportion of men who feel condoms do not fit them properly. We conducted power analyses, seeking to determine a minimal sample size required to gain a precision of plus or minus 20% of the proportion, and a targeted size seeking to determine plus or minus 15% of the proportion. For this analysis, we used a $\alpha=.05$ and an estimated proportion of .48, with the conservative Exact Binomial, Clopper-Pearson estimation method (Brown, Cai, & DasGupta, 2001). The estimated proportion for this analysis comes from preliminary data from men in the United States for the same question, which found that 48% of men reported poor condom fit. These analyses revealed a targeted sample size of 200, and a minimum sample size of 120. In order to properly power the analyses for this component of the study, we hoped to survey 120-200 individuals.

Convenience sampling was utilized to identify potential participants, who were then approached for study inclusion and screened for eligibility. They were read the following summation:

“Hello, my name is [.....]. We are conducting a survey with the HSRC exploring men’s experiences and attitudes about condom use, here in Cape Town. It will take about 30 minutes, and will ask about your opinions on condoms, and your sexual experiences. Your answers will remain completely anonymous, which means your answers will not be associated with your name, at all. Since you fill out the survey yourself, not even we will know your answers, though we can help with any questions you may have. If you are able to take the survey, you will receive 40 rand and some condoms. Would you like to be in the survey?”

Those who were not interested or were not proficient in English were thanked for their time.

Individuals who showed interest or wanted to hear more were read the following:

“In order to be in the study, you will first be given a five question screener: if you are found to be eligible, you will be asked to participate in the full study. If not, you cannot participate in the study.”

Screening Procedures: Each participant approached for study inclusion was given a five question screening, which selected for participation based on the inclusion/exclusion criteria as seen above. Excluded individuals were thanked for their time and participation. Successfully screened individuals were then asked if they would like to continue with the study. Those who indicated their interest continued on to the Informed Consent portion of the study.

Informed Consent: Following screening, potential participants were presented with the “Information Sheet,” which detailed the study aims, processes, the participant’s rights, and contact information for concerns/questions. At this point, the potential participant decided if he had interest in participating in the study. If interest was expressed, potential participants were asked to follow study personnel to a previously designated private study area. There, the informed consent process began, and study personnel gave the potential participant the “Informed Consent Sheet.”

The potential participant was given 10 minutes to read and review the “Informed Consent Sheet,” which contained the same details as the “Information Sheet” as described above, with additional details describing the consent process. Study personnel asked the individual if he had any questions, specifically addressing each topic heading: the subject of the study, privacy considerations, question response or refusal without repercussion, use of generated data, and compensation. After all questions had been answered to the individual’s satisfaction, study personnel asked if he felt comfortable, and willing to continue with the study. If not, the individual was thanked for his time. If he decided to proceed, he indicated this decision by signing the

“Informed Consent Sheet”, which study personnel countersigned as witness. A copy of this “Informed Consent Sheet” was provided to the participant per request.

Data Collection: The survey took place on an electronic tablet through SurveyGizmo, a secure online site, and lasted approximately 30 minutes. Each survey was self-administered to ensure the participant felt he was able to answer each question confidentially.

The following information was obtained:

- Demographic information
- Sexual partner specific information
- Information on up to three sexual partners within the last six months
- Relationship type per the above partners
- Frequency of sexual intercourse
- Condom use and breakage/slippage experience
- Self-identified barriers to consistent condom use, attitudes towards condom use, and availability of condoms
- Whether participants have ever measured their erect penises and if so, self-reported erect penis size

Compensation: Participants who took part received 40ZAR and a bag of two custom-fitted male condoms and two standard male condoms as compensation.

Ethical Considerations: Ethical review was conducted and overseen by Emory University’s Institutional Review Board, as well as the Human Sciences Research Council’s Research Ethics Committee. Given that our proposed study processes were limited to collecting anonymized data in a non-invasive, benign fashion, our project was determined to be “limited research available for expedited approval.” Informed Consent was obtained from every individual, with appropriate measures taken to ensure understanding, as detailed above.

Data Analyses: Before performing any analysis, all variables included in the analysis were checked for out-of-range and missing values. Data entry errors were corrected, and any out of

range or missing values that could be logically imputed from a different question were replaced. No concerning amount of missing data was observed (defined as >5%) for the majority of our variables of interest, except for questions concerning recent sexual episodes and condom use. Missing data mechanisms were explored, but missingness was not found to be related to any of our primary variables of interest. Missing data is reported and all bivariate and multivariate analyses were conducted on complete case sets.

Descriptive statistics were obtained for all variables. Our continuous variables were all non-normally distributed and were summarized using medians and ranges. All categorical variables were summarized using absolute number and percentages. Univariate descriptions included all available levels of our categorical variables (**Table 1**), but most were further collapsed for analysis (**Tables 6-9**). The following variables were generated from existing variables:

Preference to pay for brand condoms: A participant was considered to have a preference to pay for brand condoms if they agreed or strongly agreed with the statement, “I would prefer to pay for brand male condoms than get free male condoms.” They were considered to not have such a preference if they strongly disagreed, disagreed or were neutral about this statement.

More likely to use condoms if they were custom fit: A participant was considered to report being more likely to use condoms if they were custom fit if they agreed or strongly agreed with the statement, “I would be more likely to use male condoms if they were custom fitted.” They were considered to not have such a preference if they strongly disagreed, disagreed or were neutral about this statement.

History of condom failure: A participant was considered to have a positive history of condom failure if they reported ever experiencing breakage, slippage or both. They were considered to have a negative history of condom failure if they reported no history of breakage or slippage.

Bivariate relationships between all categorical candidate variables and our primary outcomes were examined using chi-square tests or Fishers Exact tests (if >20% of our expected cell counts were less than 5). Bivariate relationships between the non-normally distributed continuous outcomes and our primary outcomes were examined using Wilcoxon Rank Sum Tests. Bivariate relationships were confirmed using logistic regression and both Wald's p-values and p-values for trend were reported (Tables 6-9). Multivariate analyses were conducted using logistic regression and mutually adjusting for all candidate variables. Due to a substantial amount of missing data for two of our planned outcomes, Recent condom error and Perfect condom use, multivariate analyses were not conducted.

All analyses were conducted with Stata software (v 13; StataCorp, College Station TX). All statistical tests were two-sided and a p-value of <0.05 was considered statistically significant. A p-value of 0.05-0.099 is considered a trend.

Results

Demographics

Our participants represented a multitude of demographic backgrounds, heterogeneous in regards to age, race, religion, SES, educational achievement and sexual experience (**Table 1**). Median age was 30 years old, with a range of 18-69 years old. More than two-thirds (68%) identified as black African, followed by coloured (20%), then white (7%). Religious ideologies were primarily Catholic (34%), Protestant (17%) and Traditional African Beliefs (22%). The majority (91%) had attended a minimum of eight years of schooling, with 15% having attended college/university or higher. Incomes ranged from “no income” (20%) to R192,001- R384,000 (3%), spread evenly in-between the two extremes. More than three-fourths of participants (76%) were currently in some sort of romantic relationship.

Table 1. Demographic Characteristics of Sample, N=137			
Age, yrs.			
Mean (SD)	30.76	8.86	
Median (Range)	30	18-69	
Categorical Age, N(%)			
18-19	7	5.11%	
20-24	32	23.36%	
25-29	28	20.44%	
30-34	27	19.71%	
35-40	22	16.06%	
40+	21	15.33%	
MISSING	0	0%	
Education, N(%)			
No Schooling	0	0%	
Grades 1-5	2	1.46%	
Grades 6-7	7	5.11%	
Grades 8-11	45	32.85%	
Grade 12	60	43.80%	
Higher	21	15.33%	
MISSING	2	1.46%	
Religion, N(%)			
Catholic	47	34.31%	
Protestant	23	16.79%	
Jewish	1	0.73%	
Hindu	2	1.46%	
Islamic	5	3.65%	
Traditional African Beliefs	30	21.90%	
Other	19	13.87%	
No Religious Affiliation	6	4.38%	
MISSING	4	2.92%	
Race, N(%)			
Black	93	67.88%	
Coloured	27	19.71%	
White	9	6.57%	
Asian/Indian	4	2.92%	
Other	2	1.46%	
MISSING	2	1.46%	
Relationship Status, N(%)			
Married	42	30.66%	
Living Together	16	11.68%	
In a relationship	45	32.85%	
Separated/Divorced	5	3.65%	
Widowed	0	0.00%	
Single	26	18.98%	
MISSING	3	2.19%	
Income per year, N(%)			
No income	27	19.71%	
< R6 000	17	12.41%	
R6 001 - R12 000	14	10.22%	
R12 001 - R24 000	11	8.03%	
R24 001 - R48 000	25	18.25%	
R48 001 - R96 000	22	16.06%	
R96 001 - R192 000	14	10.22%	
R192 001 - R384 000	4	2.92%	
> R384 0001	0	0.00%	
MISSING	3	2.19%	

The majority of men in our sample (59%) were circumcised, slightly higher than the national average of 46.4% reported in the most recent national survey (L. Simbayi et al., 2014).

Sexual & condom experiences¹The vast majority of men in our sample (85%) had used a condom in the previous six months. The median number of reported sexual partners within the last six months was one, with a mean of 2.06, and a range from 1-16. The median number of reported sexual episodes within the previous thirty days was five, with a mean of 7.86, and a range of 0-34.

Among those reporting any sexual episodes within the last 30 days (n=133), the median number of condom uses was 3, with a mean of 5.48, and a range from 0-31. However, a substantial minority of our study population (14%) chose not to answer this question. Perfect condom use, defined here as a 1:1 ratio of sexual episodes and condom use episodes, was low at 35%, though, once again, approximately one in five respondents (20%) chose to forgo answering this question.

Recent condom failure was high; among those reporting any sexual episodes within the last 30 days, nearly one-third of men (31%) reported at least one episode of condom breakage or slippage in the same time period. In regard to overall condom failure, more than half (51%) of participants reported ever experiencing condom breakage, and 39% reported any instance of condom slippage. The majority of men (58%) had experienced either, or both types of condom failure.

¹ Please note that for the purposes of this study, the definition of a “sexual episode” was limited to heterosexual vaginal or anal penetration. This limitation was clearly explained to participants before every survey section. Additionally, persons who had zero sexual partners within the previous six months were screened out, and thus did not contribute to these analyses.

Reported condom use at last sex (CUALS) was high (68%), nearly double the national average (L. Simbayi et al., 2014). Among those who had used condoms in the last 30 days, rationale for use was strongly protective: 95% either agreed or strongly agreed with the statement “I use male condoms to prevent becoming infected with HIV or other STIs;” 93% that “I use male condoms to prevent infecting *others* with a disease that I may have or not know I have,” and a slightly smaller percentage (85%) either agreeing or strongly agreeing with the statement “I use male condoms to prevent causing pregnancy.”

Condom Beliefs and Attitudes

In terms of factual statements, understanding of the protective properties offered by standard condoms was good: with 85% agreeing or strongly agreeing with the statement “Male condoms can prevent STIs;” 91% with the statement “Male condoms can prevent pregnancy;” and 85% agreeing or strongly agreeing that “Male condoms can prevent STIs and HIV.”

However, there was a mixed perspective on the role, feel, and importance of condoms (**Table 2**). While many professed agreement or strong agreement with statements such as “Male condoms create a sense of safety,” (88%), a significant percentage agreed with negative statements, such as “If I suggest male condoms, my partner would think I have an STI or HIV” (25%). In addition, men reported negative attitudes towards condoms, including “condoms ruin the mood (24%) and believing that “contraception is a women’s business and men should not have to worry about it” (31%).

When participants were specifically asked about the more tactile-based aspects of condoms, there was a high degree of negative attention: 33% agreed that “Male condoms are

uncomfortable; 42% agreed that “Using a male condom makes sex not enjoyable;” and 39% agreed that “Male condoms produce a loss of pleasure and sensation during sex.”

Similar negativity surrounded free condoms: almost half of our respondents (47%) agreed or strongly agreed with the statement “I would prefer to pay for brand male condoms than get free male condoms;” 43% felt “I think that sex feels better with brand male condoms than free male condoms;” and nearly a quarter (24%) agreed or strongly agreed with the statement “I feel embarrassed to use free male condoms because they are not brand name.”

Specific to ideas surrounding fit, 35% of our sample agreed with the statement “Poor fit of condoms makes me not want to use them;” and 73% agreed with the statement “I would prefer if there was a greater variety of male condom sizes available.”

There was a strong interest in the possibility of custom-fitted condoms entering the sexual health landscape, as well as a belief that such options would improve the user’s sexual experience: nearly two-thirds of participants (64%) agreed or strongly agreed with the statement “I think custom-fitted male condoms would make sex more pleasurable than standard male condoms.” There was also a significant percentage who agreed that custom-fitted condoms would decrease instances of breakage (54%) and decrease instances of slippage (57%), which increased to 68% and 71%, respectively, if limited to those individuals who had ever experienced condom breakage and/or slippage. Perhaps most telling, two-thirds of participants (67%) agreed or strongly agreed with the statement “I would be more likely to use male condoms if they were custom-fitted.” All that being said, there was a discrepancy noted, as 64% of our sample agreed that “I am satisfied with the male condom size options currently available.”

Table 2. Beliefs and attitudes about condoms among respondents: Participants were asked to choose their level of agreement or disagreement to each of the following questions						
	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree	Missing
I use condoms to prevent becoming infected with HIV or other STIs	0.00%	3.65%	1.46%	39.42%	52.55%	2.92%
I use condoms to prevent infecting others with a disease that I may have or not know I have	1.46%	1.46%	2.19%	37.23%	53.28%	4.38%
I use male condoms to prevent causing pregnancy	2.19%	6.57%	5.84%	41.61%	40.88%	2.92%
Male condoms can prevent STIs	2.92%	2.92%	5.11%	43.80%	41.61%	3.65%
Male condoms can prevent pregnancy	1.46%	2.19%	1.46%	49.64%	40.88%	4.38%
Male condoms can prevent HIV/AIDS	1.46%	5.84%	3.65%	42.34%	43.07%	3.65%
Contraception is women's business and men should not have to worry about it	21.90%	29.93%	10.95%	22.63%	8.03%	6.57%
Male condoms ruin the mood	23.36%	25.55%	10.95%	29.93%	4.38%	5.84%
Sex does not feel as good with a male condom	18.98%	29.20%	6.57%	32.12%	9.49%	3.65%
Male condoms create a sense of safety	1.46%	2.19%	5.11%	52.55%	35.04%	3.65%
Male condoms are not necessary when you and your partner agree not to have sex with anyone else	11.68%	34.31%	10.22%	27.01%	13.14%	3.65%
If I suggest male condoms, my partner would think I have an STI or HIV	22.63%	40.15%	8.03%	20.44%	3.65%	5.11%
Male condoms are uncomfortable	18.98%	35.04%	8.76%	24.82%	8.03%	4.38%
Using a male condom makes sex not enjoyable	20.44%	24.82%	9.49%	34.31%	7.30%	3.65%
I would avoid using male condoms if at all possible	22.63%	35.77%	5.84%	24.82%	7.30%	3.65%
Poor fit of condoms makes me not want to use them	17.52%	35.77%	8.03%	27.74%	6.57%	4.38%
Male condoms produce a loss of pleasure and sensation during sex	13.14%	37.23%	6.57%	32.12%	6.57%	4.38%
I dislike the feel of male condoms	13.14%	35.04%	13.14%	29.93%	4.38%	4.38%
I think free male condoms are just as reliable/effective as brand male condoms	8.76%	19.71%	6.57%	43.80%	16.06%	5.11%
I would prefer to pay for brand male condoms than get free male condoms	11.68%	27.74%	8.76%	33.58%	13.87%	4.38%
I feel embarrassed to use free male condoms because they are not brand name	18.98%	41.61%	10.22%	16.06%	8.03%	5.11%
I think that sex feels better with brand male condoms than free male condoms	13.87%	27.74%	10.22%	29.20%	14.60%	4.38%
I would prefer if there was a greater variety of male condom sizes available (custom-fitted male condoms)	2.92%	6.57%	12.41%	52.55%	20.44%	5.11%

Of note, 40% of our respondents agreed or strongly agreed with the statement “Male condoms are not necessary when you and your partner agree not to have sex with anyone else.”

Lastly, we asked participants to pick from a list the chief reason people may elect not to use condoms (**Table 3**). Getting back to previous findings, nearly a quarter (23.4%) reported the main reason for non-use as “being in a safe relationship where condoms are unnecessary,” second only to condoms reducing sexual pleasure (25.6%). Additionally, 18.9% of men reported being too embarrassed to buy condoms as the principle reason for condom non-use. There were no respondents who reported condoms not fitting as the chief reason for non-use.

Can't find them easily	6.57%
Can't afford them	1.46%
Too embarrassed to buy them	18.98%
They are in a safe relationship where condoms are unnecessary	23.36%
They don't work	2.92%
They don't fit	0.00%
Reduces sexual pleasure	25.55%
Other	13.87%
Missing/non-response	7.30%

Condom Acquisition

Men reported a variety of locations as being the “most comfortable” for obtaining condoms (**Table 4**). More than four-fifths (82%) of our sample thought it was either easy or very easy to obtain condoms. When asked to report where they felt most comfortable obtaining condoms, nearly two-fifths (39%) reported a government clinic or hospital as their preferred location. No respondent chose online as their condom acquisition location of choice.

Government clinic or hospital	39.42%
Private clinic or hospital	4.38%
Pharmacy/Chemist	10.95%
Shop/Supermarket/Café	10.22%
Garage/Filing Station	11.68%
Club or Bar	4.38%
Shebeen/Tavern	7.30%
Community Organisation	2.19%
From a sex worker	0.00%
Online	0.00%
Other	2.19%
Missing/non-response	7.30%

Bivariate analyses between selected outcomes and exposures

We identified 6 outcomes as especially pertinent to our research purpose: preference of branded condoms over Choice condoms; increased likelihood of using condoms in the future, were custom-fitted condoms available; recent condom error; ever having experienced a condom failure; perfect condom use; and condom use at last sex (CUALS). These were analyzed against demographic exposures, sexual experience, and ever having experienced a condom failure (**Table 5**).

Compared to circumcised men, uncircumcised men were more likely to report a preference for paying for brand condoms over using Choice condoms ($p < 0.02$). This was similarly found for men reporting a larger penile girth (Fisher’s $p < 0.02$), and men who reported ever experiencing condom breakage ($p < 0.03$). Additionally, the mean and median number of partners within the last six months were significantly higher among those endorsing paying for brand condoms over using Choice condoms ($p < 0.02$). A negative correlation was found between endorsing the reliability

and effectiveness of Choice condoms and increasing endorsement of preferring to pay for brand condoms over using Choice condoms, on a Likert scale ($p < 0.04$). Positive correlations for preferring to pay for branded condoms over using Choice condoms were found for those who endorsed embarrassment in using Choice condoms ($p < 0.0001$); those who endorsed having better sex with branded condoms ($p < 0.0001$); and endorsing higher likelihood of using condoms in the future, were, custom-fitted options available ($p < 0.02$).

Compared to men who have never experienced condom breakage, those who have ever experienced condom breakage were more likely to report an increased willingness to use condoms, were custom-fitted option available ($p < 0.007$). This significant finding was similarly seen among men who reported ever experiencing condom slippage ($p < 0.01$). Positive correlations were found amongst those more willing to pay for brand condoms over using Choice condoms ($p < 0.02$); endorsing a preference for a larger range of condom sizing option ($p < 0.0001$); endorsing the belief that custom fitted condoms would allow for more pleasure during sex ($p < 0.0001$); and a belief that use of custom-fitted condoms would decrease breakage ($p < 0.0001$), and slippage ($p < 0.0001$). No difference in this regard was found between those who reported perfect use of condoms within the last 30 days, and those who did not; nor between those who endorsed the belief that condoms are uncomfortable.

In regards to ever experiencing a condom failure, the mean and median age was significantly lower (27 vs 33.5) among those who reported ever experiencing a condom failure ($p < 0.001$). The mean and median number of reported sexual partners in the previous six months was higher among those ever reporting a condom failure ($p < 0.0001$). Those ever experiencing a condom failure report more agreement “male condoms are uncomfortable” ($p < 0.049$). Similar

results were found among those who agreed that use of “custom-fitted condoms would decrease condom breakage ($p < 0.002$), slippage ($p < 0.002$) and those who report that they would be more likely to use condoms, were custom-fitted condoms available ($p < 0.01$).

When limiting the analyses to those who had experienced condom failures within the last 30 days, uncircumcised men were more likely to report recent condom failures compared to circumcised men ($p < 0.004$). Those who experienced recent condom failure also reported that they would be more likely to use condoms, were custom-fitted condoms available ($p < 0.0002$), and similarly feel that custom-fitted options would decrease issues of breakage ($p < 0.02$) and slippage ($p < 0.001$).

Perfect condom use, defined as a 1:1 ratio between number of sexual episodes within the previous 30 days, and instances of condom use within the previous 30 days, was also analyzed. An inverse relationship was found between level of relationship commitment and perfect condom use, with those men who reported a married status also reporting the lowest perfect condom use, and those who reported themselves as single reporting higher levels of perfect condom use ($p < 0.02$). Those practicing perfect use in the last 30 days report less agreement with the statement “Male condoms are not necessary when you and your partner agree not to have sex with anyone else.” (2 vs 3, $p < 0.03$).

Condom use at last sex (CUALS), was similarly inversely related to level of relationship commitment, with those who reported themselves as married=54%, in a relationship=66%, and single=93%. This was a significantly different percentage ($p < 0.004$).

Table 5: Bivariate analyses between selected outcomes and exposures – significant comparisons shown in bold

	"I would prefer to pay for brand male condoms than get free male condoms."		"I would be more likely to use male condoms if they were custom fitted"		History of Condom Failure,		Condom Failure Recent		Perfect Condom Use		CUALS	
Age	z-score	0.72	z-score	1.92	z-score	3.22	z-score	1.39	z-score	0.02	z-score	1.29
	p-value	0.47	p-value	0.06	p-value	0.001	p-value	0.16	p-value	0.98	p-value	0.20
Education	chi-square	0.87	chi-square	2.34	chi-square	0.72	chi-square	1.87	chi-square	3.86	chi-square	3.19
	p-value	0.65	p-value	0.31	p-value	0.70	p-value	0.39	p-value	0.15	p-value	0.20
Religion	chi-square	7.48	chi-square	2.20	chi-square	4.72	chi-square	0.84	chi-square	6.18	chi-square	1.83
	p-value	0.06	p-value	0.53	p-value	0.19	p-value	0.84	p-value	0.10	p-value	0.61
Race	chi-square	2.52	chi-square	3.96	chi-square	0.46	chi-square	3.37	chi-square	2.61	chi-square	2.07
	p-value	0.28	Fisher's p-value	0.17	p-value	0.80	Fisher's p-value	0.19	p-value	0.27	Fisher's p-value	0.38
Relationship Status	chi-square	2.33	chi-square	3.44	chi-square	2.31	chi-square	2.39	chi-square	7.83	chi-square	11.23
	p-value	0.31	p-value	0.18	p-value	0.32	p-value	0.30	p-value	0.02	p-value	0.004
Income per year	chi-square	2.71	chi-square	4.97	chi-square	8.37	chi-square	10.62	chi-square	2.58	chi-square	3.98
	p-value	0.62	p-value	0.29	p-value	0.08	p-value	0.03	p-value	0.63	p-value	0.41
Use of condoms, 6 mo.	chi-square	0.07	chi-square	2.68	chi-square	0.87	--	--	--	--	chi-square	1.34
	Fisher's p-value	0.8	p-value	0.10	p-value	0.35	--	--	--	--	p-value	0.25
Number of Partners, 6 mo.	z-score	-2.31	z-score	-1.21	z-score	-4.11	z-score	-1.79	z-score	1.17	z-score	-1.55
	p-value	0.02	p-value	0.23	p-value	<0.0001	p-value	0.07	p-value	0.24	p-value	0.12
Uncircumcised	chi-square	5.89	chi-square	2.78	chi-square	0.68	chi-square	2.91	chi-square	0.004	chi-square	1.22
	p-value	0.02	p-value	0.095	p-value	0.41	p-value	0.09	p-value	0.95	p-value	0.27
Penis Length	chi-square	9.28	chi-square	1.97	chi-square	3.10	chi-square	8.45	chi-square	10.34	chi-square	10.76
	Fisher's p-value	0.07	Fisher's p-value	0.91	Fisher's p-value	0.69	Fisher's p-value	0.09	Fisher's p-value	0.07	Fisher's p-value	0.05
Penis Girth	chi-square	11.6	chi-square	1.16	chi-square	5.16	chi-square	1.44	chi-square	3.46	chi-square	2.60
	Fisher's p-value	0.02	p-value	0.89	Fisher's p-value	0.28	Fisher's p-value	0.89	Fisher's p-value	0.47	Fisher's p-value	0.66
Experienced breakage, Ever	chi-square	4.52	chi-square	7.29	--	--	--	--	chi-square	0.96	chi-square	0.43
	p-value	0.03	p-value	0.007	--	--	--	--	p-value	0.33	p-value	0.51
Experienced slippage, Ever	chi-square	0.68	chi-square	6.72	--	--	--	--	chi-square	0.32	chi-square	4.00
	p-value	0.41	p-value	0.01	--	--	--	--	p-value	0.57	p-value	0.046

Multivariate Analyses

Preference to pay for brand condoms

Multiple logistic regression was used to estimate the mutually adjusted association between preference to pay for brand condoms, modeled as a binary variable, and: age, education, religion, race, religion, relationship status, income, number of recent sexual partners, circumcision, penis size, and history of condom failure (**Table 6**). Age and number of sexual partners were both modeled continuously. Though the full model was significant overall ($p < 0.001$), only circumcision and penis size were independently associated with preferring to pay for brand condoms over receiving free condoms. The odds of this preference among uncircumcised men is 4.41 times the odds among circumcised men (OR=4.41, 95%CI=1.33-14.60; $p \leq 0.02$). The odds of this preference among men with a self-reported erect penis length of 10-20 cm is nearly 5 times the odds among those with a self-reported erect penis length of less than 10 cm (OR=4.98, 95%CI=1.61-15.40; $p=0.01$). No difference was observed between men with a self-reported erect penis length of greater than 20 cm and those with estimated self-reported erect penis length of less than 10 cm (OR=0.95, 95%CI=0.14-6.66; $p=0.96$).

More likely to use male condoms if they were custom fit

Multiple logistic regression was used to estimate the mutually adjusted association between endorsing that condom use would be more likely with a custom fit condom, modeled as a binary variable, and: age, education, religion, race, religion, relationship status, income, number of recent sexual partners, circumcision, penis size, and history of condom failure (**Table 7**). Age and number of sexual partners were both modeled

continuously. Though the full model approached significance ($p=0.06$), only race was independently associated with this outcome. The odds of endorsement among men who fell into the Other race category (including White, Asian, Indian, or some other race) is over 15 times the odds among Black men ($OR=15.39$, $95\%CI=1.06-223.27$; $p=0.045$). No difference was observed between men identifying as Coloured and Black men ($OR=2.67$, $95\%CI=0.59-12.03$; $p=0.68$).

History of Condom Failure

Multiple logistic regression was used to estimate the mutually adjusted association between any history of condom failure, modeled as a binary variable, and: age, education, religion, race, religion, relationship status, income, number of recent sexual partners, circumcision, and penis size (**Table 8**). Age and number of sexual partners were both modeled continuously. The full model was significant ($p=0.003$) and age, religion and number of sexual partners were independently associated with this outcome after adjustment. The odds of having a history of condom failure decreased by 7% for each advancing year of age ($OR=0.93$, $95\%CI=0.86-0.998$; $p=0.045$), but nearly doubled for every additional sexual partner ($OR=1.99$, $95\%CI=1.27-3.13$; $p=0.003$). The odds of a history of condom failure were 78% less among those who fell into the Other religion category (including Jewish, Islamic, Hindu, or some other religion) when compared to Catholics ($OR=0.22$, $95\%CI=0.05-0.96$). No other religious differences were observed.

Condom Use at Last Sex (CUALS)

Multiple logistic regression was used to estimate the mutually adjusted association between CUALS, modeled as a binary variable, and: age, education, religion, race, religion, relationship status, income, number of recent sexual partners, circumcision, penis size, and history of condom failure (**Table 9**). Age and number of

sexual partners were both modeled continuously. The full model was not significant ($p=0.27$) and only relationship status was independently associated with this outcome after adjustment. The odds of CUALS among single participants was over 14 times the odds of married participants (OR=14.42, 95%CI=1.78-116.55; $p=0.01$). The odds of participants reporting being in a relationship did not differ from married participants (OR=1.16, 95%CI=0.22-6.11; $p=0.87$).

Table 6: Descriptive table and analyses for primary outcome: "I would prefer to pay for brand male condoms than get free male condoms."										
R ² = 0.27	YES (n=65)		NO (n=66)		BIVARIATE MODELS			MULTIVARIATE MODEL (n=115)		
	Median or N	Range or %*	Median or N	Range or %*	Unadjusted OR (95%CI)	p-value	p-value for trend	Adjusted** OR (95%CI)	p-value	p-value for model
Age, yrs	29	(18-43)	31	(19-69)	0.97 (0.93-1.01)	0.18	0.17	0.95 (0.88-1.03)	0.24	0.001
Education										
<12 years	27	42%	23	35%	1.00	ref	0.65	1.00	ref	
12 years	27	42%	32	48%	0.72 (0.33-1.53)	0.39		0.71 (0.25-2.06)	0.53	
>12 years	9	14%	11	17%	0.69 (0.25-1.97)	0.50		0.39 (0.09-1.82)	0.23	
MISSING	0	0%	3	5%						
Religion										
Catholic	24	37%	20	30%	1.00	ref	0.05	1.00	ref	
Protestant	16	25%	7	11%	1.90 (0.65-5.54)	0.24		1.22 (0.26-5.83)	0.80	
Traditional African Beliefs	10	15%	19	29%	0.43 (0.16-1.16)	0.10		0.43 (0.11-1.66)	0.22	
Other	13	20%	18	27%	0.60 (0.24-1.52)	0.28		0.27 (0.07-1.08)	0.07	
MISSING	2	3%	2	3%						
Race										
Black	43	66%	49	74%	1.00	ref	0.28	1.00	ref	
Coloured	15	23%	9	14%	1.90 (0.76-4.78)	0.17		1.36 (0.32-5.81)	0.68	
Other	5	8%	8	12%	0.71 (0.22-2.34)	0.58		0.79 (0.10-6.44)	0.83	
MISSING	2	3%	0	0%						
Relationship Status										
Married/Living Together	27	42%	28	43%	1.00	ref	0.31	1.00	ref	
In a relationship	18	28%	25	38%	0.74 (0.33-1.67)	0.48		0.77 (0.18-3.34)	0.72	
Unmarried/Not in a Relationship	18	28%	12	18%	1.56 (0.63-3.83)	0.33		1.67 (0.39-7.13)	0.49	
MISSING	2	3%	1	2%						

Income per year									
<i>No income</i>	12	18%	15	23%	1.00	ref	0.65	1.00	ref
< R12 001	16	25%	13	20%	1.54 (0.54-4.42)	0.42		2.04 (0.51-8.13)	0.31
R12 001 - R48 000	14	22%	21	32%	0.83 (0.30-2.30)	0.73		1.14 (0.29-4.47)	0.85
R48 001 - R96 000	11	17%	8	12%	1.72 (0.53-5.62)	0.37		3.18 (0.51-19.74)	0.22
R96 001 +	10	15%	8	12%	1.56 (0.47-5.19)	0.47		3.81 (0.61-23.83)	0.15
MISSING	2	3%	1	2%					
Number of Partners, 6 mo.	2	1-16	1	1-6	1.33 (1.03-0.72)	0.03	0.01	1.36 (0.97-1.89)	0.07
Circumcision Status									
<i>Circumcised</i>	33	51%	47	72%	1.00	ref	0.01	1.00	ref
<i>Uncircumcised</i>	31	48%	18	28%	2.45	0.02		4.41 (1.33-14.60)	0.02
MISSING	1	2%	1	2%					
Estimated Penis Length									
<10 cm	15	23%	29	45%	1.00	ref	0.01	1.00	ref
10-20 cm	40	62%	26	40%	2.97 (1.34-6.59)	0.01		4.98 (1.61-15.40)	0.01
20+ cm	4	6%	8	12%	0.97 (0.25-3.74)	0.96		0.95 (0.14-6.66)	0.96
MISSING	6	9%	3	5%					
History of condom error									
<i>Yes</i>	41	63%	36	55%	1.39 (0.68-2.82)	0.37	0.37	0.67 (0.24-1.88)	0.45
<i>No</i>	23	35%	28	43%	1.00	ref		1.00	ref
MISSING	1	2%	2	3%					

* Due to rounding, totals may not sum to 100%. ** Mutually adjusted for all other variables reported on table.

Table 7: Descriptive table and analyses for primary outcome "I would be more likely to use male condoms if they were custom fitted"											
R ² = 0.21	YES (n=92)		NO (n=36)		BIVARIATE MODELS			MULTIVARIATE MODEL (n=115)			
	Median or N	Range or %*	Median or N	Range or %*	Unadjusted OR (95%CI)	p-value	p-value for trend	Adjusted** OR (95%CI)	p-value	p-value for model	
Age, yrs	29	(18-54)	33	(18-69)	0.96 (0.92-1.00)	0.05	0.049	0.95 (0.87-1.03)	0.20	0.06	
Education											
<12 years	37	40%	14	39%	1.00	ref	0.29	1.00	ref		
12 years	37	40%	19	53%	0.74 (0.32-1.69)	0.47		0.59 (0.20-1.80)	0.53		
>12 years	16	17%	3	8%	2.02 (0.51-8.01)	0.32		2.53 (0.44-14.61)	0.30		
MISSING	2	2%	0	0%							
Religion											
Catholic	29	32%	12	33%	1.00	ref	0.51	1.00	ref		
Protestant	19	21%	4	11%	1.97 (0.55-7.01)	0.30		1.31 (0.25-6.87)	0.75		
Traditional African Beliefs	18	20%	10	28%	0.74 (0.27-2.08)	0.57		1.40 (0.32-6.00)	0.65		
Other	22	24%	10	28%	0.91 (0.33-2.49)	0.86		0.67 (0.16-2.82)	0.58		
MISSING	4	4%	0	0%							
Race											
Black	59	64%	30	83%	1.00	ref	0.12	1.00	ref		
Coloured	19	21%	4	11%	2.42 (0.75-7.74)	0.14		2.67 (0.59-12.03)	0.68		
Other	12	13%	2	6%	3.05 (0.64-14.52)	0.16		15.39 (1.06-223.27)	0.045		
MISSING	2	2%	0	0%							
Relationship Status											
Married/Living Together	34	37%	19	53%	1.00	ref	0.16	1.00	ref		
In a relationship	30	33%	12	33%	1.39 (0.58-3.35)	0.45		1.38 (0.31-6.10)	0.67		
Unmarried/Not in a Relationship	25	27%	5	14%	2.79 (0.92-8.50)	0.07		5.18 (0.89-30.11)	0.07		
MISSING	3	3%	0	0%							

Income per year									
<i>No income</i>	19	21%	7	19%	1.00	ref	0.29	1.00	ref
< R12 001	18	20%	12	33%	0.55 (0.18-1.72)	0.31		0.70 (0.18-2.80)	0.62
R12 001 - R48 000	27	29%	6	17%	1.66 (0.48-5.72)	0.42		2.17 (0.45-10.50)	0.34
R48 001 - R96 000	14	15%	4	11%	1.29 (0.32-5.28)	0.72		1.54 (0.22-11.01)	0.67
R96 001 +	11	12%	7	19%	0.58 (0.16-2.09)	0.40		1.83 (0.29-11.54)	0.52
MISSING	3	3%	0	0%					
Number of Partners, 6 mo.	1	1-16	1	1-10	1.15 (0.90-1.48)	0.21	0.21	1.00 (0.75-1.35)	0.98
Circumcision Status									
<i>Circumcised</i>	53	58%	26	72%	1.00	ref	0.09	1.00	ref
<i>Uncircumcised</i>	38	41%	9	25%	2.07 (0.87-4.92)	0.10		3.21 (0.88-11.73)	0.08
MISSING	1	1%	1	3%					
Estimated Penis Length									
<10 cm	15	16%	29	81%	1.00	ref	0.86	1.00	ref
10-20 cm	40	43%	26	72%	0.87 (0.36-2.07)	0.75		0.56 (0.19-1.69)	0.31
20+ cm	4	4%	8	22%	0.69 (0.17-2.74)	0.17		0.22 (0.03-1.44)	0.11
MISSING	6	7%	3	8%					
History of condom error									
<i>Yes</i>	60	65%	15	42%	2.67 (1.20-5.94)	0.02	0.02	1.90 (0.65-5.56)	0.24
<i>No</i>	30	33%	20	56%	1.00	ref		1.00	ref
MISSING	2	2%	1	3%					
* Due to rounding, totals may not sum to 100%. ** Mutually adjusted for all other variables reported on table.									

Table 8: Descriptive table and analyses for primary outcome – History of Condom Failure (either breakage and/or slippage)										
R ² = 0.26	YES (n=79)		NO (n=52)		BIVARIATE MODELS			MULTIVARIATE MODEL (n=115)		
	Median or N	Range or %*	Median or N	Range or %*	Unadjusted OR (95%CI)	p-value	p-value for trend	Adjusted** OR (95%CI)	p-value	p-value for model
Age, yrs	27	(18-54)	34	(20-69)	0.93 (0.89-0.97)	0.002	0.001	0.93 (0.86-0.998)	0.045	
Education										
<12 years	30	38%	21	40%	1.00	ref	0.69	1.00	ref	
12 years	34	43%	25	48%	0.95 (0.45-2.04)	0.90		1.08 (0.38-3.09)	0.89	
>12 years	13	16%	6	12%	1.52 (0.50-4.63)	0.47		1.37 (0.29-6.36)	0.69	
MISSING	2	3%	0	0%						
Religion										
Catholic	29	37%	15	29%	1.00	ref	0.51	1.00	ref	
Protestant	15	19%	7	13%	1.11 (0.37-3.30)	0.85		0.49 (0.11-2.16)	0.75	
Traditional African Beliefs	17	22%	12	23%	0.73 (0.28-1.93)	0.53		0.45 (0.11-1.83)	0.65	
Other	14	18%	18	35%	0.40 (0.16-1.03)	0.06		0.22 (0.05-0.96)	0.045	
MISSING	4	5%	0	0%						
Race										
Black	59	75%	30	58%	1.00	ref	0.80	1.00	ref	
Coloured	19	24%	4	8%	0.80 (0.32-1.95)	0.62		0.30 (0.08-1.17)	0.08	
Other	12	15%	2	4%	0.73 (0.23-2.35)	0.6		0.40 (0.05-3.25)	0.40	
MISSING	2	3%	0	0%						
Relationship Status										
Married/Living Together	29	37%	26	50%	1.00	ref	0.31	1.00	ref	
In a relationship	27	34%	15	29%	1.61 (0.71-3.68)	0.26		0.41 (0.10-1.71)	0.22	
Unmarried/Not in a Relationship	21	27%	10	19%	1.88 (0.75-4.73)	0.18		0.56 (0.14-2.33)	0.43	
MISSING	2	3%	0	0%						

Income per year									
<i>No income</i>	19	24%	8	15%	1.00	ref	0.08	1.00	ref
< R12 001	12	15%	16	31%	0.32 (0.10-0.96)	0.04		0.25 (0.06-1.05)	0.06
R12 001 - R48 000	24	30%	11	21%	0.92 (0.31-2.74)	0.88		1.43 (0.36-5.66)	0.61
R48 001 - R96 000	14	18%	6	12%	0.98 (0.28-3.48)	0.98		2.86 (0.50-16.42)	0.24
R96 001 +	8	10%	10	19%	0.34 (0.10-1.17)	0.09		0.54 (0.09-3.11)	0.50
MISSING	2	3%	1	2%					
Number of Partners, 6 mo.	1	1-16	1	1-10	1.69 (1.17-2.44)	0.01	0.0004	1.99 (1.27-3.13)	0.003
Circumcision Status									
<i>Circumcised</i>	46	58%	34	65%	1.00	ref	0.41	1.00	ref
<i>uncircumcised</i>	33	42%	18	35%	1.36 (0.66-2.80)	0.41		1.78 (0.57-5.54)	0.32
MISSING	0	0%	0	0%					
Estimated Penis Length									
<10 cm	24	30%	20	38%	1.00	ref	0.82	1.00	ref
10-20 cm	40	51%	26	50%	1.28 (0.59-2.77)	0.53		1.68 (0.57-5.01)	0.35
20+ cm	7	9%	5	10%	1.17 (0.32-4.24)	0.17		1.09 (0.14-8.78)	0.08
MISSING	8	10%	1	2%					
Estimated Penis Girth									
<4 cm	28	35%	25	48%	1.00	ref	0.86	1.00	ref
4 cm	23	29%	13	25%	1.58 (0.66-3.76)	0.30		1.97 (0.64-6.11)	0.24
5+ cm	20	25%	13	25%	1.37 (0.57-3.32)	0.48		2.48 (0.55-11.17)	0.24
MISSING	8	10%	1	2%					
* Due to rounding, totals may not sum to 100%. ** Mutually adjusted for all other variables reported on table.									

Table 9: Descriptive table and analyses for primary outcome – Condom Use At Last Sex (CUALS)											
R ² = 0.26	YES (n=72)		NO (n=33)		BIVARIATE MODELS			MULTIVARIATE MODEL (n=94)			
	Median or N	Range or %*	Median or N	Range or %*	Unadjusted OR (95%CI)	p-value	p-value for trend	Adjusted** OR (95%CI)	p-value	p-value for model	
Age, yrs	28	(18-48)	30	(20-51)	0.95 (0.90-1.01)	0.11	0.10	0.98 (0.87-1.11)	0.80	0.27	
Education											
<12 years	27	38%	7	21%	1.00	ref	0.19	1.00	ref		
12 years	33	46%	18	55%	0.48 (0.17-1.31)	0.15		0.62 (0.17-2.20)	0.46		
>12 years	11	15%	8	24%	0.36 (0.10-1.22)	0.10		1.10 (0.21-5.87)	0.91		
MISSING	1	1%	0	0%							
Religion											
Catholic	21	29%	14	42%	1.00	ref	0.61	1.00	ref		
Protestant	12	17%	5	15%	1.60 (0.46-5.55)	0.46		1.84 (0.32-10.42)	0.49		
Traditional African Beliefs	19	26%	6	18%	2.11 (0.68-6.60)	0.20		4.47 (0.81-24.72)	0.09		
Other	18	25%	8	24%	1.50 (0.51-4.39)	0.46		2.86 (0.47-17.54)	0.26		
MISSING	2	3%	0	0%							
Race											
Black	53	74%	23	70%	1.00	ref	0.80	1.00	ref		
Coloured	8	11%	7	21%	0.50 (0.16-1.53)	0.62		1.03 (0.19-5.67)	0.96		
Other	10	14%	3	9%	1.45 (0.36-5.75)	0.60		1.42 (0.13-15.77)	0.77		
MISSING	1	1%	0	0%							
Relationship Status											
Married/Living Together	21	29%	18	55%	1.00	ref	0.002	1.00	ref		
In a relationship	25	35%	13	39%	1.65 (0.66-4.13)	0.29		1.16 (0.22-6.11)	0.87		
Unmarried/Not in a Relationship	25	35%	2	6%	10.71 (2.22-51.60)	0.003		14.42 (1.78-116.55)	0.01		
MISSING	1	1%	0	0%							

Income per year									
<i>No income</i>	19	26%	4	12%	1.00	ref	0.39	1.00	ref
< R12 001	14	19%	6	18%	0.49 (0.12-2.08)	0.33		0.83 (0.14-4.86)	0.84
R12 001 - R48 000	19	26%	9	27%	0.44 (0.12-1.69)	0.24		0.77 (0.15-4.00)	0.76
R48 001 - R96 000	10	14%	7	21%	0.30 (0.07-1.28)	0.10		0.63 (0.06-6.21)	0.70
R96 001 +	9	13%	7	21%	0.27 (0.06-1.17)	0.08		0.87 (0.10-7.51)	0.90
MISSING	1	1%	0	0%					
Number of Partners, 6 mo.	2	1-16	1	1-5	1.26 (0.92-1.71)	0.15	0.08	1.19 (0.70-2.02)	0.53
Circumcision Status									
<i>Circumcised</i>	50	69%	19	58%	1.00	ref	0.27	1.00	ref
<i>Uncircumcised</i>	21	29%	13	39%	0.61 (0.26-1.47)	0.27		1.54 (0.40-5.89)	0.53
MISSING	1	1%	1	3%					
Estimated Penis Length									
<10 cm	24	33%	20	61%	1.00	ref	0.03	1.00	ref
10-20 cm	40	56%	26	79%	1.81 (0.35-9.41)	0.48		0.45 (0.12-1.64)	0.23
20+ cm	7	10%	5	15%	8.89 (1.29-61.06)	0.03		0.12 (0.01-1.68)	0.12
MISSING	8	11%	1	3%					
Estimated Penis Girth									
<4 cm	31	43%	9	27%	1.00	ref	0.31	1.00	ref
4 cm	19	26%	12	36%	0.46 (0.16-1.30)	0.15		0.40 (0.10-1.52)	0.18
5+ cm	20	28%	7	21%	0.83 (0.27-2.58)	0.75		0.72 (0.11-4.78)	0.73
MISSING	2	3%	5	15%					
History of Condom Error									
<i>Yes</i>	24	33%	14	42%	1.00	ref	0.36	1.00	ref
<i>No</i>	46	64%	18	55%	1.49 (0.63-3.51)	0.36		1.29 (0.37-4.49)	0.69
MISSING	2	3%	1	3%					
* Due to rounding, totals may not sum to 100%. ** Mutually adjusted for all other variables reported on table.									

Discussion

Condom Experiences

Condom use for the men in our sample was quite high, as more than two-thirds of respondents (68%) reported CUALS, compared to the 36.4% reported in the most recent national survey (L. Simbayi et al., 2014). Similarly, 85% reported condom use within the past six months. Moreover, the majority of participants (82%) thought it easy or very easy to obtain condoms. This *may* highlight the commendable job the South African government and its partners have done distributing Choice and other branded prophylactics. However, given that all of our participants were recruited from either health clinics or sexual health education locations, it is possible that sampling bias has inflated these figures.

Perfect condom use was not uncommon – nearly one-third of participants (31%) reported the behavior, with escalating percentages as degree of relationship commitment decreased (thus, single men had the highest percentage of perfect use, and married men, the least). This finding was reinforced twice more in the survey: a significant proportion of men (40%) agreed with the statement that “Male condoms are not necessary when you and your partner agree not to have sex with anyone else,” and 23% of men cited being “in a safe relationship where condoms are unnecessary” as the chief indication for an individual not to use a condom. If appropriately timed and effective testing is apparent, and the couple practices strict monogamy, then these are reasonable beliefs. However, if either of the above is erroneous, or unknown, then the false sense of protection elicited by these notions will lead to a scenario burdened with heightened risk.

Our analyses also indicate a relatively high degree of condom failure: nearly one-third of men (31%) reported at least one episode of condom breakage or slippage within the previous 30 days, and the majority of men (58%) had experienced either or both types of condom failure at least once in their lifetime. Possible interventions to deal with this unfortunate reality are divided according to the proposed mechanism of failure, and are discussed at length, below.

Condom Beliefs and Attitudes

While knowledge of the protection offered by condoms was high, there was a notable negativity towards them, with certain expressed sentiments at odds with others. For example, nearly one-fourth of respondents (23%) cited “Too embarrassed to buy them” as the number one reason an individual might eschew condoms. This is a strange finding, as “acquiring and/or using free condoms” (Choice condoms), was also described to inspire embarrassment. Or, it may not be a contradiction at all, and instead suggest that the use of condoms in *any* form, be they brands bought at the store, or free Choice condoms, engender embarrassment in our population. Perhaps most intriguing, however, was the finding that no participant (0%) chose “They don’t fit” as the chief reason not to use condoms. Either they felt other rationale trumped sizing issues, there is a notable disconnect between measurements of ill-fit between sections of the survey, or some manner of user or programmer error was at play.

Overall, our results depict an environment very much in line with previous findings: a general dissatisfaction and disinterest in the condom options currently available, even with an impressive degree of correct condom knowledge among users, and a laudable system of condom distribution and availability. This condom-negative mentality may be due to the significant condom failures generally experienced by our sample, or simple distaste for Choice condoms,

specifically. However, while the “condom fatigue” reported by the South African Minister of Health does seem to be apparent, there *is* profound interest in a more varied condom market, and for more nuanced condom sizing options, in particular. So strong is this desire that most of our participants report they would be *more* willing to use condoms, were custom-fitted options available for their use. Lending credence to the notion that this is a real finding is the fact that those with the most condom difficulties (the uncircumcised; those reporting condom failures) differ significantly from their opposing members.

Though the South African government has recently promised to expand their line of Choice condoms by featuring more colors, textures and even flavors, this evolution sadly does not mitigate the continued problems engendered by the lack of sizing options. Thus, we propose the following interventions, some educational, other physical improvements, to augment and sustain condom use among men in South Africa.

Educational interventions should focus on three distinct groups: non married couples, the uncircumcised, and young men who believe that contraception and sexual health is “a woman’s business.”

The former group represents one of highest HIV incidence demographics, yet research shows that such dyads do not believe themselves to be at high risk for HIV infection, with a correspondingly lower rate of condom use. There is therefore an obvious disconnect in the South African population as to who and what is “risky,” with the unfortunate irony that this very divergence may be the crux of the problem: the discrepancy creates a vicious circuit, wherein a lack of risk appreciation leads to risky sexual behavior, which in turn allows for HIV transmission. This pattern was seen both in our small sample, and in the much more expansive surveys carried

out by the HSRC. This divergence is ripe for potential intervention, as an individual who has little to no understanding of their susceptibility to infection has little rationale to take prudent measures to protect themselves. Targeted messages that inform of this disparity should be disseminated among the South African population, so that the false sense of security experienced and practiced by non-married couples can be replaced with a more realistic view of the sexual health landscape. In short, public perception of what is “safer sex” must be realigned in order to help curb transmission. Simple posters highlighting this information could be posted in health clinics, and medical providers trained to educate their patients with short, simple to understand messages.

Another troubling finding was that uncircumcised men reported a much higher incidence of condom failure, compared to circumcised men, and relatedly purport a greater desire for greater condom options. The difficulties may be due to a multiplicity of factors, from simple physiologic difficulties (the additional foreskin adding girth, thus leading to issues of breakage) to a lack of proper technique in applying condoms to an uncircumcised penis (if not properly “tucked” under the retracted foreskin, issues of slippage commonly occur). Whatever the case, we recommend that extant educational information include examples of uncircumcised men applying condoms, and/or the proper technique for a second party putting a condom on an uncircumcised penis. In regards to girth concerns, improvements in condom sizing options, discussed below, might decrease this type of condom failure.

The last contingent who would benefit from an educational intervention is much more difficult to target- men who profess the belief that sexual health matters are solely a “woman’s business,” as almost 30% of our sample did. We argue that if all parties to any sexual congress feel that it is their responsibility to provide and use prophylactics, then the rate of condom acceptance

and use would increase. Such messages would need to be tailored to the belief structure of those professing the sentiment, so we recommend additional research be carried out to determine the most effective strategy to shift their ideology and enact behavior change.

While Choice condoms were seen to be of inferior quality, engendering embarrassment and distaste, brand condoms were often lauded. With the free Choice condom available at night every bathroom, truck stop and clinic in Cape Town, many still preferred to pay for their brand prophylactics out of pocket. Was this because brand condoms offer a greater variety of color, texture and size? Are they definitely of better quality? Our research did not assess these questions, but what is clear is the notion that the Choice brand could be elevated several levels by simply reformulating, and rebranding the condom, and offering it in a greater variety of sizes. With the They-Fit product already approved for use in the EU and the United States, it is not beyond reason to think that the SA Ministry of Health could team up with the company to solve two problems at once: releasing a branded condom with a greater variety of possible sizes.

Limitations:

Though demographically diverse, this was a limited study, pulling data from a small (n=137) group of men in and around Cape Town, and not a greater breadth of the “Rainbow Nation.” Perhaps representing even more of a subpopulation, many of these men predominantly (some, exclusively) utilize local health clinics for their care, though there was also a sampling of short and long distance truck drivers. That being said, the population who would benefit most from targeted interventions based on this data are they very same we surveyed, so we view this as more of a bonus.

One possible confounder was selection bias. Each participant self-selected into the study, creating a bias for individuals who were comfortable talking about their sexual experiences, sexuality and opinions regarding condoms. Similarly, the survey allowed individuals to skip questions, which could shift the recorded responses and resulting analyses to over-represent those who had no difficulty answering questions, and under-represent those who were stymied by a less advanced grasp of English, embarrassment, or other, unknown concerns or limitations. Such groups might have significantly altered our data pool, thus confounding our results.

Given the delicate nature of the survey material, and the general culture surrounding the importance of safer sex, reporting bias is also a chief concern. We hoped to have minimized that by providing a confidential environment when taking the survey, and explaining to participants that their answers were anonymous to all study personnel.

Lastly, it is important to note that since we screened for individuals proficient in English, this act in and of itself may drastically alter our findings- it is possible that by selecting a subsection of the South African population, our findings represent not the whole of the population, but simply those with the resources, advantages and cultural backgrounds that promote proficiency in English.

That being said, many of our results mirror those of the HSRC, suggesting an overall good mapping of the South African population, and thus generalizability, at least in regards to the matters at hand.

One notable divergence from the national survey is that of CUALS. Condom use at last sex in our sample (68%) was significantly higher than the national average (36.2). This is perhaps due

to the fact that we recruited largely from health clinics and sexual health education locations, though it may be a true finding depicting the higher incidence of condom use specific to the Cape Town area, in general.

In closing, while it is true that condoms are freely obtainable throughout South Africa, these findings suggest those currently available are not fully meeting the needs of the heterosexual male population surveyed. A third of men did not use condoms during their last sexual encounter; two-thirds of men have experienced at least one type of condom problem; and nearly three-fourths of men stated they would be more likely to use condoms if better-fitting options were available. It is not surprising, then, that the desire for more condom sizes is so prevalent across the myriad peoples of South Africa, cutting across divisions of race, religion, educational attainment and even income level. New condom options, be they a greater variety of styles, a rebranding to combat condom fatigue, or condoms made to better fit the South Africa population, are needed. The strong interest in better fitting condoms may indicate that addressing issues of fit could lead to greater condom utilization.

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Chapter IV: Recommendations

The results of our study are clear in a number of respects, and suggest straightforward interventions to augment and sustain condom use in South Africa. While some of these options may be effective in their own right, a combined approach will work to best, synergizing educational interventions with a shakeup of the condom market.

I. Rebrand Choice condoms

This is certainly easier said than done, especially given the current ill regard that Choice condoms evince among the people of South Africa. Be it suspicions of quality, matters of pride or logistics of sizing, Choice condoms are consistently criticized, and it seems, forsworn. Given the significant investment that Choice condoms represent to the Ministry of Health, with its impressively expansive distribution, and ad campaigns, it is only logical that any additional effort made to increase utilization of their product be considered a clear alternative to surrendering their production. Our results indicate that Choice condom use would be amplified by:

- a) Reformulating and rebranding Choice condoms to include a greater variety of colors, textures, flavors and sizes – in effect, making them a suitable a suitable “competitor” to marketplace condoms. This would hopefully deal with myriad of reported issues, from embarrassment using Choice condoms, to issues of ill-fit leading to condom failures.
- b) Collaborating with companies like TheyFit to research a feasible menu of condom sizing options that are appropriate to existing condom distribution systems. Though TheyFit currently produces a whopping 95 types of condoms, such a multiplicity of options is far too much for existing condom distribution and dissemination systems, Instead, researchers

could determine a tenable and sustainable selection, with marketing teams taking the public's pulse as to proper naming conventions. After all, not many would like to openly acquire "small" sized condoms, when "Snug Slim," or the like, is available, instead.

- c) Publically acknowledging previous and current complaints specific to the original formulation of Choice condoms, and creating a marketing campaign that addresses those very concerns/criticisms. Funny and self-deprecating ads are a good combo, acknowledging the viewer's concerns, and immediately offering up a salient alternative.

2. Targeted education for high risk groups

In our sample, two groups stand out as particularly in need of help: uncircumcised men, who, while in the minority, report significantly more condom failures compared to their circumcised brethren; and non-married couples, who believe themselves to be a low-risk group for HIV transmission, when the opposite is actually true.

- a) Educational materials and teachings should specifically teach the proper application technique for uncircumcised penises, and include common pitfalls particular to improper technique (increased risk of slippage, etc..).
- b) The South African government has made the practice of medical male circumcision a priority, introducing the Voluntary Medical Male Circumcision (VMMC) program in 2010, with hopes of reaching 80% of HIV negative men aged 15-49 by the end of 2015. This program may increase its coverage by adding to their current educational pamphlets the finding that circumcised men report more condom failures than their circumcised peers, adding one more bit of info to any parent struggling to make this important decision.

c) Public health campaigns should focus on communicating the finding that non-married couples, who believe themselves to be a low risk group in regards to HIV transmission, are actually among the highest incidence groups. As noted previously, those individuals who do not appreciate their true situation do not have the impetus to alter their behavior to be in line with current guidelines. Targeted marketing for new couples to get tested before moving onto condomless sex should be increased, with the rationale behind the proposed behavior changed clearly and prominently indicated. Public health campaigns focusing on this demographic should be enacted, with suitably enticing offers made to bring in the crowds...perhaps a free sampling of the newly rebranded, custom-fitted condoms?

3. Realigning sexual health as non-stigmatized, and gender neutral

Though we found that factual statements describing the protective characteristics of condoms to be largely agreed with (“Condoms can prevent STIs,” etc), a significant percentage of respondents reported views on condom use that may add to non-utilization, namely agreement with the statement “contraception is a woman’s business, and men shouldn’t have to worry about it,” (31%) and “if I suggest condoms, my partner would think I have an STI or HIV” (24%). Public health services, from local clinics to school based initiatives, should work to counteract these, and similar, ideologies. If sexual health can be changed in the public eye to be *everyone’s* responsibility, and taking measures to protect oneself and others can be seen as the status quo, we believe condom utilization, writ large, can be increased.

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