Microbicides, sexuality and sexual health in KwaZulu-Natal, South Africa

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Declaration

I, Mitzy Gafos, confirm that the work presented in this thesis is my own.

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Abstract

There is an urgent need for additional HIV prevention options for women. Evidence supporting the benefit of microbicides in reducing the risk of vaginally acquired HIV acquisition has provided a major breakthrough. Despite the wealth of evidence supporting microbicide acceptability in Africa, there are still gaps in our understanding about how women will incorporate microbicides into their everyday lives.

In this thesis I examine whether vaginal microbicides are compatible with socio-cultural norms regarding sexuality and sexual health in a predominantly rural area of KwaZulu-Natal, South Africa. Using qualitative and quantitative data collected as part of the MDP 301 clinical trial at the Africa Centre, I adopt a mixed methods approach to evaluate microbicide acceptability from a cultural perspective. I explore the compatibility of microbicides with socio-cultural norms that relate to intravaginal cleansing, intravaginal insertion, love medicines and sexual communication.

I found that the desired effects of using intravaginal insertions to enhance sexual pleasure are compatible with the experiences of using microbicides; that contemporary socio-cultural norms relating to sexual communication in the context of the HIV epidemic are compatible with the introduction of microbicides; that women distanced microbicides from 'love medicines' in terms of separating microbicides from the supernatural; and, finally, that post-coital intravaginal cleansing practices could undermine a microbicides roll out programme if we fail to address these practices.

Overall I found that microbicides are compatible with socio-cultural norms relating to intravaginal insertion and sexual communication, but they may be less compatible with norms relating to intravaginal cleansing and love medicines. While incompatibility with socio-cultural norms raises challenges for intravaginal cleansing, the fact that love medicines are incompatible with microbicides could be advantageous for their introduction. Ultimately these findings have implications for future research and service delivery, as well as offering insights into microbicides, sexuality and gender equality.

Abbreviations

ABC	Abstain, be faithful, condomize
ACASI	Audio computer-assisted self-interview
Africa Centre	Africa Centre for Health and Population Studies
AIDS	Acquired immune deficiency syndrome
ANC	African National Congress
ARV	Antiretroviral
AVAC	AIDS vaccine advocacy coalition
BAT24	Before-after-two-24
BV	Bacterial vaginosis
CAB	Community advisory board
CAPRISA	Centre for the AIDS Programme of Research in South Africa
CAR	Central African Republic
CASI	Computer-assisted self-interview
CD	Coital diary
CD4	Cluster of differentiation 4
CDC	Centers for Disease Control
CI	Confidence interval
CONRAD	Contraceptive Research And Development Program
CRF	Case report form
CS	Cellulose sulfate
CT	Chlamydia trachomatis
DFID	Department for International Development
DRC	Democratic Republic of Congo
DSMB	Data and safety monitoring board
FACTS	Follow-on African Consortium for Tenofovir Studies
FAQ	Frequently asked questions
FDA	Food and Drug Administration
FGD	Focus group discussion
FHI	Family Health International
FSW	Female sex worker
FTC	Emtricitabine
GCLP	Good clinical laboratory practice
GCP	Good clinical practice
GPP	Good pharmacy practice
GSVP	Gender, sexuality and vaginal practices
HEC	Hydroxyethylcellulose (placebo)
HIV	Human immunodeficiency virus
HPTN	HIV Prevention Trials Network (subsequently MTN)
HSV2	Herpes simplex virus 2
IVC	Intravaginal cleansing
IDI	In-depth interview
IPM	International Partnership for Microbicides
iPrEX	Pre-Exposure Prophylaxis Initiative
KZN	KwaZulu-Natal
LRT	Likelihood ratio tests

MCC	Medicines Control Council
MDP	Microbicides Development Programme
MRC	Medical Research Council
MSM	Men who have sex with men
MTCT	Mother-to-child-transmission
MTN	Microbicide Trials Network
OR	Odds ratio
N-9	Nonoxynol-9
NG	Neisseria gonorrhoea
NIH	National Institutes of Health
NRTI	Nucleotide reverse transcriptase inhibitor
NSP	National strategic plan
PEP	Post exposure prophylaxis
PIS	Participant information sheet
PO	Participant observation
PrEP	Pre-exposure prophylaxis
S1	Stage 1 literature review
S2	Stage 2 literature review
SA	South Africa
SOP	Standard operating procedure
STI	Sexually transmitted infections
TDF	Tenofovir disoproxil fumarate
TV	Trichomonas vaginalis
UK	United Kingdom
UNAIDS	Joint United Nations Programme on HIV/AIDS
USA	United States of America
VOICE	Vaginal and oral interventions to control the epidemic
WHO	World Health Organization

1 Introduction

Summary

In this thesis I investigate the interface between microbicides, sexuality and sexual health in KwaZulu-Natal, South Africa. This chapter will serve as an introduction to these topics. I start by mapping the epidemiology of the Human Immunodeficiency Virus (HIV) in South Africa from the start of the epidemic to the present day. I continue by outlining the role that gender inequality plays as a social driver of the epidemic in KwaZulu-Natal. I also discuss female sexuality in South Africa and the extent to which positive images of sexuality have been marginalised in HIV discourse. I proceed by describing the existing HIV prevention options available in South Africa and discuss the limitations, for women, of prevention messages that focus on abstinence, being faithful, condoms and circumcision. Next, I explain the potential new HIV prevention technologies, including vaccines, pre-exposure prophylaxis and microbicides. I argue that in preparation for the implementation of microbicides, we need to understand more about the ways in which socio-cultural norms might facilitate or impede the use of new prevention technologies. Finally I summarise the main objectives of this thesis.

1.1 HIV in South Africa

1.1.1 Political context

South Africa was slow to respond to HIV when it first emerged in the early 1980's. During the political instability of the late 1980's and early 1990's, both the ruling apartheid National Party and the exiled African National Congress (ANC) promoted mis-information and conspiracy theories about HIV and the acquired immunodeficiency syndrome (AIDS) (Susser, 2009). In 1990 when ANC leaders and other anti-apartheid activists released their first collective statement on HIV and AIDS in Southern Africa, less than 1% of women attending antenatal clinics were HIV positive (DoH, 2010). When the ANC were elected as the first democratic government of South Africa in 1994, HIV prevalence among antenatal clinic attendees had increased eight fold. Despite this, implementation of the first National AIDS Strategy was overshadowed by the demands of political transition to a non-racial democracy. When the second democratically elected president of South Africa took post in 1999, HIV prevalence among women attending antenatal clinics had risen to over 22%. The optimism generated by the release of the first National Strategic Plan (2000 to 2005) soon dissipated as South Africa's response to HIV was paralysed by AIDS denialism. In 2002, when the South African government lost a yearlong fight in the High Court and Constitutional Court trying to defend their decision not to provide antiretroviral (ARV) drugs to pregnant women, 27% of pregnant women in

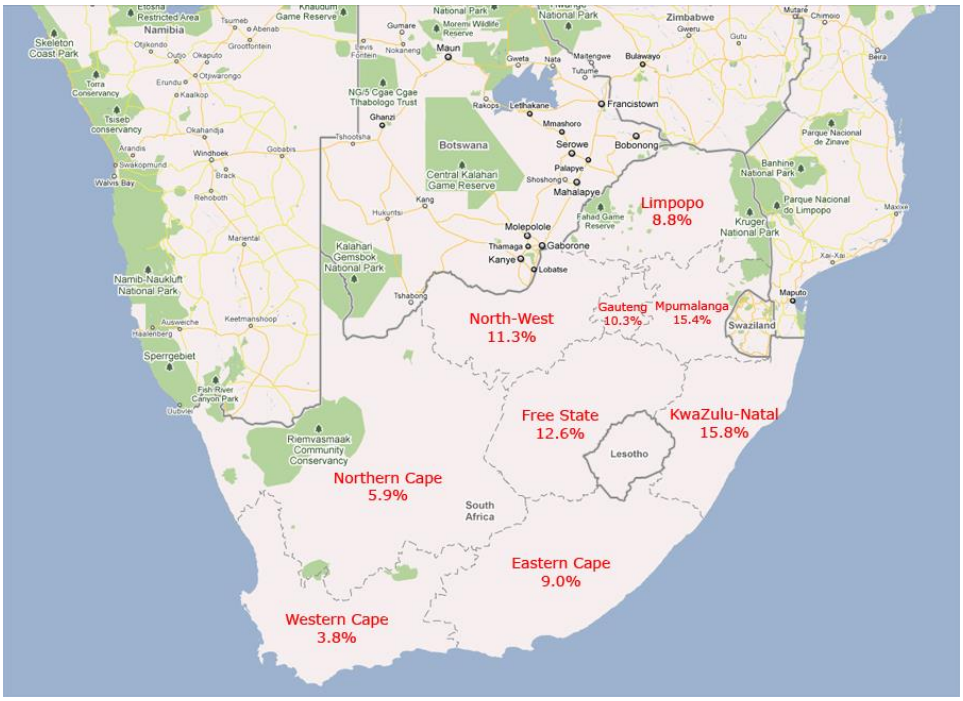
antenatal clinics were HIV positive (Coovadia, 2009). By the time the South African government finally started rolling out antiretroviral drugs in 2004, HIV prevalence in antenatal clinics had reached 30%.

The period of AIDS denialism left many South Africans confused about the cause of HIV, the association between HIV and AIDS, and the safety of antiretroviral drugs (Robins, 2005). Accurate information about HIV prevention and treatment was undermined by government leaders who legitimized myths such as the preventive benefit of showering after sex and the treatment benefits of garlic, olive oil, lemon and beetroot (McGregor, 2009). Given this history, it is perhaps no surprise that in 2009 South Africa had more people living with HIV than any other country in the world. An estimated 5.6 million South Africans were HIV positive, which was equivalent to 11% of the total population (UNAIDS, 2010).

1.1.2 HIV prevalence

The distribution of HIV in South Africa is by no means uniform. Racial classification in South Africa is divided into 4 groups representing 11 official language groups; Black African, Coloured, Indian or Asian, and White (Erasmus, 2008). HIV affects Black Africans more than any other racial group in South Africa. The 2008 national survey of everyone aged 2 years old or above reported 14% prevalence among Black Africans, compared to 1.7% among Coloured women and men, and 0.3% each for White and Indian populations (Shisana, 2009).

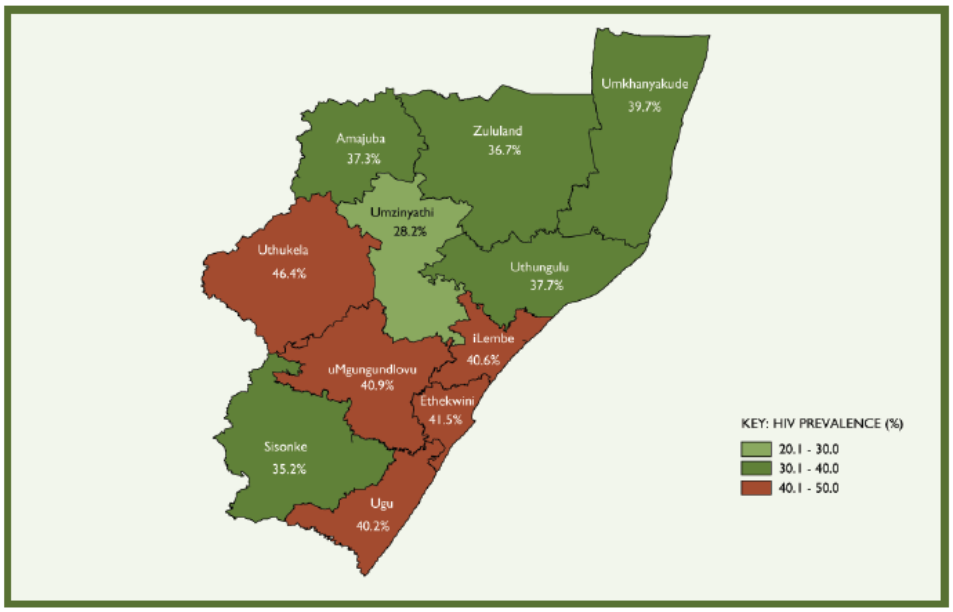
Figure 1-1: Map of South Africa showing HIV prevalence in the 9 provinces in 2008



Similarly, HIV prevalence varies dramatically across the 9 provinces in South Africa (Figure 1-1). This thesis is based on research conducted in the province of KwaZulu-Natal, which has reported the highest rates of HIV since sentinel surveillance commenced in 1990. While national prevalence among everyone over the age of 2 years olds was almost 11% in 2008, prevalence in KwaZulu-Natal was at almost 16% (Shisana, 2009).

HIV prevalence by district is only available for antenatal clinic attendees. KwaZulu-Natal includes 11 districts (Figure 1-2). This thesis is based on research conducted in the Umkhanyakude district of KwaZulu-Natal. In 2009 it reported the 6th highest prevalence from antenatal data in the KwaZulu-Natal province (39.7%).

Figure 1-2: HIV prevalence distribution among antenatal women by district in KwaZulu-Natal, 2009



The higher prevalence in antenatal clinics reflects the fact that the epidemic is at its peak in women of reproductive age. Among all 15 to 49 year old South Africans, the female to male infection ratio was approximately 1.5 to 1 for women compared to men in 2008 (Shisana, 2009). In the Umkhanyakude District just over half of all 25 to 29 year old women were living with HIV in 2004 (Welz, 2007). HIV prevalence appears to have stabilised since then (Shisana, 2009, Rice, 2007). However, the combination of race, geographic location, sex and age, continues to place Black African women of reproductive age living in KwaZulu-Natal at the highest risk of HIV in South Africa.

1.1.3 HIV incidence

By 2005, the South African Department of Health had implemented a comprehensive HIV prevention and treatment programme. Despite this, HIV incidence has only declined among women aged 15 to 24 years old which appears to correspond with a significant increase in condom use among this age group (Shisana, 2009). In all other age groups HIV incidence has remained stable (Rehle, 2010).

In the Umkhanyakude district of KwaZulu-Natal, between 2003 and 2007 HIV incidence among 15 to 49 year old women has been stable at around 3.8 per 100 person years (Bärnighausen, 2008a, Bärnighausen, 2009, Bärnighausen, 2008b). South Africa failed to achieve its goal of reducing the national HIV incidence rate by 50% from 2007 to 2011 (NSP, 2007) and on the basis of the available evidence, it is unlikely that it will meet this same target by 2016 (NSP, 2012). Bärnighausen concluded his evaluation of HIV incidence in Umkhanyakude by stating that: "without a renewed emphasis on HIV prevention, it seems unlikely that the HIV epidemic in rural South Africa will be conquered" (Bärnighausen, 2008a).

1.2 Social drivers of HIV infection in KwaZulu-Natal

There are a range of biological drivers that increase women's risk of HIV acquisition in KwaZulu-Natal, such as the high prevalence of other sexually transmitted infections (STIs). Equally there are a range of social drivers that increase women's susceptibility to HIV infection. Social drivers refer to individual, social, cultural, and structural level factors that impede an individuals' ability to mitigate the risks of HIV acquisition (UNAIDS, 2007). Auerbach (aids2013 social drivers working group (2009;2)) explains that social drivers are "complex, fluid, non-linear, and contextual, and they interact dynamically with biological, psychological, behavioral, and other social factors".

Social and cultural factors that influence HIV transmission are rooted in the historical, political and economic context of South Africa. This context has resulted in the construction of socio-cultural norms that place women in unequal relations to men. The unequal position of women in relationships, families, societies and public domains creates and reinforces fundamental vulnerabilities for women in terms of HIV. The ways in which gender inequalities impact on the risk of HIV acquisition for women in Zulu society are multiple and complex. Socio-cultural norms not only define gender relations, but also expectations regarding relationship dynamics, marriage, fertility, monogamy, couples residency patterns and gender based violence (Stockard, 2002). At an individual level gender inequality diminishes women's ability to refuse sex, to insist on mutual monogamy or to negotiate condom use. At a societal level gender inequality reinforces or even promotes higher risk behaviours such as multiple and concurrent

sexual partners for men, sex without a condom, alcohol abuse by men and tolerance toward violence against women.

In this gender inequitable context, poverty, migration, relationship structures and gender based violence present independent and overlapping challenges for women that increase their vulnerability to HIV. Gender inequalities prevent many women from being able to implement the behavioural changes necessary to reduce their risk of HIV acquisition. Whilst it is important to minimise the impact of these socio-cultural drivers on women's lives, future HIV prevention options must offer women the potential to protect themselves from HIV even in the presence of these socio-cultural realities.

1.2.1 Poverty

Approximately half of rural households in the Umkhanyakude district of KwaZulu-Natal are defined as living below the poverty line (below $2 per person per day) (StatsSA, 2010). The correlation between poverty and HIV is not clear cut in the Umkhanyakude district. In this impoverished environment (Case, 2004), risk factors for HIV prevalence and incidence have been both negatively (Bärnighausen, 2007, Tanser, 2009) and positively (Welz, 2007) associated with indicators of relative poverty. However, poverty has the potential to increase women's vulnerability to HIV in a number of ways. Poverty increases the chances of women entering into transactional sexual relationships (Lees, 2009). Poverty further exacerbates power inequalities in relationships and increases women's dependency on men for economic security (Weiser, 2007, Varga, 1997, Pivnick, 1993). This in turn decreases the chance of mitigating HIV related risk factors by diminishing some women's ability to implement safer sex practices or dissolve relationships. Poverty indicators have been linked to lower condom use (Tladi, 2006), lower rates of contraceptive use (Subramanian, 2008), and higher rates of concurrent partnerships (Mishra, 2009). Reducing poverty through microfinance initiatives has been shown to reduce HIV related risk behaviours among women (Kim, 2009). For women, living in poverty exacerbates their unequal relationship with men further hindering their ability to mitigate the risk of HIV.

1.2.2 Migration

Almost a third of all household members spend the majority of their time away from the rural household in the Umkhanyakude district (Muhwava, 2007). Migration is a well-established risk factor for HIV for both women and men (Lurie, 2006). Men who migrate for work are over twice as likely to have HIV (34%) than men who do not migrate (14%) (Welz, 2007). Women who migrate are also more likely to be HIV positive (41%) than women who don't (27%) (Welz, 2007). Women's economic dependence on their male partners is often increased in

relationships with labour migrants, reducing their bargaining power for safer sex options (Hankins, 2006). Women with partners who migrate are also more likely to have additional sexual partners (Lurie, 2003a). Women who migrate are more likely to enter into casual or transactional relationships (Gay, 2010). Being in a relationship with a migrant labourer or being a migrant labourer presents particular challenges to structures and patterns of sexual relationships which increase the risk of exposure to HIV for women.

1.2.3 Relationship structures

Whilst non-marital sex is frowned upon in Zulu culture, Zulu traditional authorities lend legitimacy to non-marital relationships, for example by defining familial responsibilities relating to non-marital childbirth (Berglund, 1976). KwaZulu-Natal has unusually low rates of marriage, high rates of non-marital child-birth, low rates of cohabitation among couples and high rates of multiple partnerships compared to the rest of Africa (Bongaart, 2006, McGrath, 2009a, Camlin, 2004, Hosegood, 2009).

Marriage can have a protective effect for some women, by reducing the number of sexual partners involved in the sexual network (Bongaart, 2006, Tanser, 2009, Welz, 2007, Bärnighausen, 2008a). Conversely marriage can increase the risk of infection for other women, by preventing women from being able to abstain from sex, reducing women's ability to refuse sex, increasing sexual frequency, and decreasing condom use (Clark, 2004, Hearst, 2004, Green, 2003, Ahmed, 2001, Bessinger, 2003, Maharaj, 2005a, Lurie, 2003b, Ndinda, 2007, Maharaj, 2005b, Camlin, 2003). In the province, unprotected sex among young unmarried couples is common with the vast majority of first births being out of marriage to young women at an average age of 19 years old (McGrath, 2009a, Camlin, 2004).

In Umkhanyakude, cohabitation is low among married and unmarried couples with a third of men not permanently residing with their long-term female partner (Hosegood, 2009). This sits alongside the fact that approximately a quarter of men report multiple or concurrent partnerships (McGrath, 2009b). Multiple and concurrent partnerships increase the risk of HIV infection for women and men (Lurie, 2003b). Concurrent relationships offer specific risks by facilitating the swift spread of HIV across the sexual network in the period following seroconversion, when infectivity is at its peak (Halperin, 2004, Mah, 2010, Halperin, 2007). These socio-cultural patterns of relationship structures and fertility place many women in KwaZulu-Natal at specific risk of HIV acquisition and undermine their ability to protect themselves from infection.

1.2.4 Gender based violence

Gender based violence is an important aspect of gender inequality in South Africa (WHO, 2010). Socio-cultural norms define the extent to which women are blamed for violence by men. Violence is viewed as a normal marker of masculinity and intimate partner violence is tolerated and established as a taboo subject, limiting female victims' ability to challenge it (Ilika, 2005, Petersen, 2005, Fox, 2007). A recent review of the literature in South Africa demonstrated that women's relative disempowerment in relationships with men reduced their ability to refuse sexual advances and negotiate safer sexual practices (Ncube, 2010). Attempts to refuse sex or insist on safer sex can result in verbal, economic, psychological, physical or sexual abuse (Ncube, 2010). For women who are economically dependent on their partners for household security and stability, even the threat of abandonment can be sufficient to discourage negotiations for safer sex. There is a strong correlation between both power inequality in relationships and intimate partner violence, and HIV infection for women (Jewkes, 2010b).

A series of interventions have demonstrated the positive impact that reducing gender inequality, economic dependency, and intimate partner violence can have on improving HIV prevention and promoting safer sex practices (Jewkes, 2008, Hargreaves, 2010, Michau, 2008, Barker, 2007). HIV prevention has to address gender inequality at multiple levels if it is to change the social, cultural, economic and political drivers of the epidemic for women.

1.3 HIV and sexuality

I have outlined above that gender inequality is a major factor in the spread of HIV and in preventing women from being able to mitigate the risks of HIV infection. However, gender inequality is not a universal, immutable aspect of African women's lives. HIV discourse has tended to exclusively depict African women as passive victims of HIV made vulnerable due to being 'subjects' of male domination through their socio-cultural and economic disempowerment (Berger, 2004). This view ignores women's enactment of agency, self-determination and resistance to both male hegemony and HIV. Boyce argues that by presenting a monolithic image of passive vulnerable African women, HIV discourse limits women's resistance and reifies the disempowerment of women in society (Boyce, 2007).

This view of African women as passive victims has hindered broader discussions about women as sexual beings. By exclusively talking about sex in terms of 'risk' and 'danger', HIV discourse has lost sight of the fact that African women enjoy sex for the sake of sex as much as other women and men around the world (Berger, 2004). HIV discourse has taken a reductive view of sexuality defining it as either a practice in terms of the act of sex or as an identity in terms of

who sex is occurring with. Equally this discourse has reduced the sexual experiences of African women to economic functionality, social responsibility, or passive acquiescence. Sex is about more than just with whom, when and how an act of sex occurs. Sex is part of a much broader meaning of sexuality which incorporates love, intimacy, passion and pleasure. The failure to include women's desire for sexual pleasure within the parameters of safer sex decision making has meant that women are far more likely to be described as "not able" to use condoms than "not willing" to. We need to consider female sexual pleasure and physical fulfilment within our paradigm of HIV prevention if we are to develop options that meet women's sexual needs as well as their health needs.

New HIV prevention technologies need to be considered and positioned within a broader interpretation of the multiple sexualities of African women and men, in order to meet their diverse needs. HIV prevention has to find ways to mitigate the negative aspects of the social drivers of the epidemic but within a discourse that also incorporates constructive views of sexuality (Philpott, 2006b).

1.4 HIV prevention in South Africa

The reduction in HIV incidence among young women aged 15 to 24 years old (described above in section 1.1.3) is an important achievement for HIV prevention in South Africa. However, three decades into the epidemic, the information, education and communication behavioural change strategies have failed to stem the epidemic among most of the adult population.

1.4.1 HIV knowledge and testing

Despite over 80% of the adult population being exposed to national HIV communication programmes, in 2008 only about a third of women of reproductive age demonstrated correct knowledge about HIV prevention and transmission (Shisana, 2009). Similarly, despite mass promotion of HIV counselling and testing, only about half of women over 15 years of age had ever had a HIV test. Less than a third of 15 to 49 year old women had tested and received their results in the year before the survey. These national levels of knowledge and rates of testing are disappointingly low, and were similar in KwaZulu-Natal.

1.4.2 Abstinence

Abstinence has been widely promoted in South Africa, as has delaying the age of sexual initiation which has been shown to reduce the risk of HIV infection for young women (Pettifor, 2004b, Drain, 2004). In KwaZulu-Natal, the traditional practice of virginity testing has been reintroduced (Leclerc-Madlala, 2001, Scorgie, 2002, Wickström, 2010). However, from 2002 to 2008 there were no changes in the proportion of 15 to 24 year old young men (11%) or women

(6%) who reported having their first sexual encounter before the age of 15 (Shisana, 2009). Among 12 to 14 year olds, 11% of young men and 15% of young women had been sexually active in the previous 12 months (Shisana, 2010). There is no evidence of a decline in the median age of first sex among women in KwaZulu-Natal which remains around 18 years old (McGrath, 2009a, Camlin, 2004).

1.4.3 Being faithful

Being faithful has been extensively promoted as an important HIV prevention strategy. However, the over simplification of this message often misses the point that monogamy only offers protection against HIV when it is exclusive and between partners confirmed to be HIV negative. Nonetheless, there has been no decline in multiple partners among women or men above 15 years old from 2002 to 2008 (Shisana, 2009). Young women are significantly less likely than men to report multiple relationships (6% of women compared to 31% of men) (Shisana, 2009) or concurrent relationships (1% of women compared to 28% of men) (McGrath, 2009b). However, women are more likely to report intergenerational relationships which have been associated with increased risk of HIV infection (Leclerc-Madlala, 2008, Pettifor, 2005). The proportion of 15 to 19 year old women in a relationship with a partner 5 or more years older, increased from 19% in 2005 to 28% in 2008 (Shisana, 2009).

1.4.4 Condoms

The correct and consistent use of male or female condoms remains the only available way to prevent HIV infection during sex for both women and men at the same time. Reported condom use at last sex increased significantly from 2002 to 2008 among women and men in all age groups (Shisana, 2009). The national increases in condom use are mirrored in KwaZulu-Natal, although condom use at last sex remains lower among 15 to 24 year old women than among men in the same age group (Chimbindi, 2010). Despite impressive increases in reported condom use at last sex, the lack of a decline in overall HIV incidence is generally attributed to the challenges of using condoms consistently, especially in long-term relationships (Hearst, 2004, Maharaj, 2005a). In 2004 Hearst claimed that “no clear examples have emerged yet of a country that has turned back a generalized epidemic primarily by means of condom promotion” (2004;41).

1.4.5 Circumcision

The most recent addition to the HIV prevention toolkit is male circumcision which reduces the risk of infection for men by approximately 50% (Auvert, 2005, Bailey, 2007, Gray, 2007). Modelling suggests that circumcision could prevent as many as 2 million HIV infections in southern Africa over ten years (Williams, 2006). It is expected that by circumcising men, the

pool of infections will reduce therefore reducing risks for women. However, there is no evidence to suggest that circumcision reduces the individual risk of infection for women and it could in fact increase the risk for women if sexual activity is resumed prior to full healing (Weiss, 2009). While there appears little evidence of sexual disinhibition by men in circumcision trials so far, the impact of circumcision on women's ability to negotiate condom use is still unknown (Pinkerton, 2001). Some authors caution that if condom use decreases as a result of circumcision, HIV incidence could increase among women while declining among men (Kalichman, 2007).

The behaviour change campaigns of abstain, be faithful and condomize (ABC), have been unsuccessful in enabling the majority of women to defer sexual activity, ensure mutual monogamy or consistently use condoms. Circumcision will hopefully reduce population level HIV incidence, but does not equip women with HIV prevention options. The existing HIV prevention options are not sufficient to allow women to overcome the multifaceted social and cultural factors that make them vulnerable to HIV (Varga, 2003).

1.5 New HIV prevention technologies

As I have described above (section 1.4), the existing HIV prevention technologies are insufficient to allow most women to protect themselves from acquiring HIV. Increasing the range of prevention options available could increase overall uptake and positively support behaviour change. This has certainly been demonstrated in family planning programmes (Sundari Ravindran, 1997). In order to address the HIV pandemic, it is vital that we expand the range of HIV prevention options available to women to meet their diverse needs within their social realities.

1.5.1 Vaccines

The ideal preventive option would be a HIV vaccine that prevents infection via any route and protects against all clades and subtypes of the virus. A vaccine would offer the most efficacious prevention option by removing the element of user-dependency. Unfortunately, despite significant financial investment in vaccine research, progress has been slow and been littered with disappointments (AVAC, 2005). While one trial provided proof of concept for vaccines, the effect size (31% effect; 95% confidence interval [CI]: 1, 52) did not justify further development of the product (Rerks-Ngarm, 2009). Although there are over 30 clinical trials of experimental vaccines underway, most are early safety studies or efficacy trials evaluating the effect on reducing the viral load set-point at time of infection (AVAC, 2010). There is little hope of a vaccine for women in Africa in the next decade.

1.5.2 Antiretroviral therapy as pre-exposure prophylaxis

An important breakthrough in HIV prevention in the last few years has been the expanded use of ARV therapy for HIV prevention. ARVs have been used as an effective treatment for HIV since the late 1980's. Different types of ARVs interrupt the viral replication process at different stages. As treatment, the use of ARVs inhibits HIV from replicating thereby reducing the viral load and enabling the body to produce sufficient CD4 cells to protect the body from infection. As prevention, ARVs prevent HIV from being able to replicate, thereby preventing the virus from spreading in the body and reducing the risk of infection. The use of ARVs for post exposure prophylaxis (PEP) and in the prevention of mother-to-child transmission (MTCT) highlights the preventive benefits of ARVs (Chigwedere, 2008, Cardo, 1997).

Among gay men and other men who have sex with men (MSM), the iPrEx (pre-exposure prophylaxis initiative) trial demonstrated that daily oral dosing with the ARV combination drug, Truvada (containing tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC)), as Pre-Exposure Prophylaxis (PrEP) reduces the risk of HIV infection by 44% (95% CI: 15, 63) (Grant, 2010). Among heterosexual women and men in HIV serodiscordant relationships, the Partners PrEP trial demonstrated that daily oral dosing with tenofovir alone or in combination as Truvada, reduces the risk of HIV infection by 62% (95% CI: 34, 78) and 73% (95% CI: 49, 85) respectively (Baeten, 2012). This result was supported by the Centers for Disease Control (CDC) TDF2 trial which demonstrated 63% (95% CI: 22, 83) protection with daily oral dosing of Truvada also among heterosexual women and men (Thigpen, 2012). However, these results were at variance with the FemPrEP trial of Truvada and VOICE (Vaginal and Oral Interventions to Control the Epidemic) trial of tenofovir which did not observe any protection for women who may or may not know their partners HIV status (MTN, 2011a, Van Damme, 2012).

A number of possible reasons for the disparity in results have been proposed including differences in the populations, routes of transmission, behaviour based on knowing the partners HIV status, and drug adherence (Cohen, 2012). The Food and Drug Administration (FDA) recently approved Truvada for pre-exposure prophylaxis in the United States of America (USA) (Cohen, 2012). However, licensing in South Africa still appears a long way off given the need to understand more about why Truvada did not prove a viable HIV prevention option for women in the FemPrEP trial. There is evidence that oral administration of tenofovir results in higher drug levels in the rectal tissue than the vaginal tissue (MTN-001, 2011, Anton, 2010). However, given the robustness of the Partners PrEP results among women in serodiscordant partnerships, it is possible that the difference is due to HIV negative women taking the daily drugs more consistently if they know their partner is HIV positive. The VOICE trial is still evaluating the effect of daily oral Truvada among women and is expected to report the results

in 2013. The disparity in the results so far, further highlights the importance of adherence to these drugs and the need to ensure that any new HIV prevention options are easy and convenient for women to use within the context of their daily lives.

1.5.3 Microbicides

Long before the idea of PrEP, there was a recognised need for HIV prevention options that women could use independently of their male partners, such as vaginal microbicides. Vaginal microbicides are experimental products being evaluated to find out if they reduce the risk of infection with HIV and other STIs for women during sexual intercourse. To date, most microbicides have been formulated as a gel, which women can either apply intravaginally before sex or which are contained in a vaginal ring with a slow release mechanism. Although rectal microbicides are also being developed, I exclusively focus on vaginal microbicides in this thesis.

The first call for vaginal microbicides came from South African researchers with experience of the anti-apartheid movement who understood women's sexual health needs from the perspective of a family planning background and feminist public health approach (Stein, 1990). Despite promising results in pre-clinical studies, results of clinical trials were disappointing with six microbicide candidates failing to demonstrate effectiveness from 2000 to 2009. Finally in 2010 the Centre for the AIDS Programme of Research in South Africa (CAPRISA) presented a major breakthrough in microbicide research (Abdool-Karim, 2010b). The CAPRISA 004 trial demonstrated that when used before and after sex, a vaginal microbicide gel containing tenofovir, reduced the risk of HIV infection for women by 39% (95% CI: 6, 60). This was the first ARV based microbicide to be evaluated. Confirmatory results from an independent trial are expected in 2014 which should be sufficient to apply to license tenofovir based microbicide gel for HIV prevention for women if the results support the CAPRISA 004 findings (FACTS, 2012).

CAPRISA 004, iPrEx, Partners PrEP and TDF2 have signalled 'game-changing' results, providing proof for the concept of vaginal microbicides in women and oral PrEP in women and men. There is optimism that ARV-based microbicides and oral PrEP will be approved in South Africa as effective HIV prevention options for women within the next few years. Preferences for vaginal microbicides or oral tablets will differ based on individual, relational, social and cultural determinants. Vaginal microbicides are expected to offer better protection from vaginal acquisition of HIV than oral strategies, while oral strategies are likely to offer better protection from rectal and blood born acquisition (MTN-001, 2011). Preferences for vaginal or oral options are also likely to be influenced by sexual preferences and practices (MTN-001, 2011).

1.6 The context

Preparations for the implementation of new prevention technologies need to take account of the individual, social, cultural and structural influences on HIV transmission. Existing HIV prevention options have been insufficient for many women in the face of gender inequality. African women of reproductive age are the most at risk group in South Africa and new prevention technologies must meet their needs. It is unlikely that we will have a HIV vaccine within the next decade. Vaginal microbicides and oral PrEP appear to be the most optimistic options for women. However, they both present different benefits and challenges for the user. Microbicides have been shown to be highly favoured by women in a range of African countries and could meet the needs of women that may not be met by oral PrEP. In terms of microbicides, their user dependency, vaginal insertion, gel consistency, and partial effectiveness raise real challenges for public health implementation.

To support the implementation of an effective microbicide, we need to understand more about the various ways in which women will incorporate microbicides not only into their sexual health routine, but also their relationships and broader social realities. We need to characterise the ways in which socio-cultural norms could facilitate or impede the use of microbicides. This includes understanding more about women's specific sexual desires and preferences and the ways in which microbicides could be positioned to promote positive messages about both sexual health and pleasure.

1.7 This thesis

From May 2004 to December 2009 I was the principal investigator and lead social scientist on the Microbicides Development Programme (MDP) 301 clinical trial at the Africa Centre for Health and Population Studies (Africa Centre) in KwaZulu-Natal, South Africa. The Africa Centre was one of six research centres in sub-Saharan Africa which conducted the MDP 301 clinical trial. MDP 301 was an international, multi-centre, randomised, double-blind, placebo controlled phase III clinical trial which evaluated the safety and effectiveness of PRO2000 microbicide gel in the prevention of vaginally acquired HIV infection (Nunn, 2009, McCormack, 2010).

As part of the MDP 301 clinical trial, I collected qualitative and quantitative data on trial participant's sexual behaviour and microbicide acceptability, as well as on socio-cultural norms regarding sexuality and sexual health. I also collected qualitative data on socio-cultural norms from male partners of trial participants as well as from women and men in the community who were not enrolled in the MDP 301 clinical trial. For the purpose of this thesis, I developed a

research question that was compatible with the aims of the MDP 301 clinical trial and used the available qualitative and quantitative data to address the objectives of this thesis.

The overarching research question of this PhD is:

Are microbicides compatible with socio-cultural norms regarding sexuality and sexual health in rural KwaZulu-Natal, South Africa?

The objectives of the research are:

- To explore socio-cultural norms regarding: (i) intravaginal cleansing, (ii) intravaginal insertion, (iii) love medicines, and (iv) sexual communication in KwaZulu-Natal.
- To assess the extent to which these socio-cultural norms influence or are influenced by microbicides.
- To evaluate ways in which microbicides impact on sexual norms and practices among women enrolled in the trial.

The research presented in this thesis is submitted in support of a PhD. The thesis contains 9 chapters. In addition to the Introduction presented above, it includes an overview of the relevant literature, the background to the MDP 301 trial, the methods used for the PhD, four empirical chapters, and a final Discussion chapter.

In chapter 2, I present an overview of candidate microbicides tested in effectiveness trials to date and a systematic review of literature relating to microbicide acceptability. I summarise the key gaps in the evidence and describe the approach that I adopt to evaluate microbicide acceptability in this thesis, in terms of compatibility to socio-cultural norms.

In chapter 3, I describe the MDP 301 clinical trial at the Africa Centre on which this thesis is based. I outline the study populations, as well as the methods used for the collection and management of qualitative and quantitative data in the trial.

In chapter 4, I present an outline of the cultural perspective that I adopt for the analysis and the mixed methods approach that I use. I also describe my approach to qualitative and quantitative data analysis in the thesis.

In chapter 5 I examine post-coital intravaginal cleansing practices. Using both qualitative and quantitative data I explore socio-cultural norms of intravaginal cleansing practices and intravaginal cleansing among women using microbicides in the trial.

In chapter 6 I examine intravaginal insertion to enhance sexual pleasure. Using qualitative data I compare the use of intravaginal inserts and microbicides to further understand how sexual practices, preferences and expectations could impact on the use of microbicides.

In chapter 7, I examine love medicines that are used to 'supernaturally' attract or retain male partners. Using qualitative data I explore socio-cultural norms relating to love medicines and compare attitudes towards love medicines with microbicides.

In chapter 8, I examine sexual communication. Using both qualitative and quantitative data I explore socio-cultural norms surrounding sexual communication and the ways in which women communicate with their partners about microbicides.

In the final chapter I summarise my findings, consider the significance of them, and discuss the implications of my findings for future research and for the introduction of microbicides in KwaZulu-Natal.

Appendices are presented in volume 2 of the thesis.

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2 Literature review

Summary

In this chapter, I review the literature relating to vaginal microbicides. Firstly, I provide an overview of candidate microbicides that have been evaluated to date. Secondly, I present the results of a systematic review of the literature pertaining to the acceptability of vaginal microbicides. Finally, I summarise gaps in the evidence and describe the context within which I examine microbicide acceptability in this thesis.

2.1 Microbicide clinical research

In the late 1980's, it became apparent that the impact of HIV was going to be profound for women in Africa. On the basis of evidence from family planning services, it was recognised that as a male controlled method, male condoms were unlikely to meet the HIV prevention needs of women. Women's rights and reproductive health groups highlighted the need for additional HIV prevention options that women could use without requiring male involvement (Stein, 1990, WHO, 1991, Heise, 1999, Heise, 2004). By 1992, the United Kingdom (UK) Medical Research Council (MRC) and the USA National Institutes of Health (NIH) opened their first calls for microbicide research. In the year 2000, scientists, policy makers and advocates held the first international microbicides conference (AIDS, 2001). By then, microbicide development was on the research agendas of many scientific institutions including the MRC, NIH, Family Health International (FHI), the Contraceptive Research And Development Program (CONRAD), and the Population Council (Stone, 2002). For more than a decade, microbicide research has been central to HIV prevention efforts.

Generally speaking, a 'microbicide' is any compound or substance whose purpose is to reduce the infectivity of microbes. For the purpose of this thesis I am exclusively referring to HIV prevention microbicides, defined as any compound that has a mechanism of action against HIV. Most microbicides are not specific to HIV, thereby also having the potential to reduce the risk of acquisition of other STIs. As stated previously, microbicides are being developed for both vaginal and rectal use, although I am exclusively focusing on vaginal microbicides. In the second half of this chapter, I present evidence from a systematic review of literature on microbicide acceptability from hypothetical and surrogate studies, as well as clinical trials of candidate microbicides. Given the experimental and novel nature of microbicides, I firstly present literature on the candidate microbicides tested to date.

2.1.1 First generation microbicides

Initially microbicide compounds were evaluated for their ability to inactivate HIV or inhibit HIV from entering or fusing with human cells. These compounds have been categorised as first generation microbicides[1].

Nonoxynol-9 (N-9) was the first compound evaluated as a microbicide, although it was previously widely used as a spermicide. N-9 was available over the counter in many countries and was available in a variety of forms including vaginal gels, creams, foams, foaming tablets, suppositories, sponges and films. N-9 is a surfactant that damages the outer surface membrane of sperm, preventing conception. It was thought that N-9 might have the potential to damage the outer surface of microorganisms potentially inactivating HIV and other STIs. In the 1980's a series of observational studies (Austin, 1984, Cutler, 1977, Jick, 1982, Quinn, 1985, Roddy, 1993, Rosenberg, 1992, Weir, 1994, Roddy, 2002) and randomised control trials (Barbone, 1990, Rosenberg, 1987, Louv, 1988, Rendon, 1980, Niruthisard, 1992) were conducted, with some suggesting that N-9 could offer protection against Neisseria gonorrhoea (NG) and Chlamydia Trachomatis (CT). *In vitro* studies suggested that N-9 could inactivate HIV (Hicks, 1985) and prevent transmission of the feline immunodeficiency virus (Moench, 1993) and simian immunodeficiency virus (Miller, 1992) in animal models. In an observational study in Cameroon, female sex workers (FSWs) who regularly used N-9 suppositories had 70-80% fewer new HIV infections than women who did not use the suppositories regularly over a year (Zekeng, 1993). Some of the evidence regarding STI prevention was contradictory and most of the findings suggesting N-9 could reduce the risk of HIV acquisition were derived from observational studies. The evidence was therefore not sufficiently rigorous to support the promotion of N-9 for HIV prevention (Cook, 1998).

Consequently, a series of randomised controlled trials were conducted in the 1990's to evaluate whether N-9 could reduce the risk of vaginal HIV acquisition (Kreiss, 1992, Richardson, 2001, Roddy, 1998, Van Damme, 2002, Roddy, 2002). Nonoxynol-9 was evaluated when formulated in gel, film and a vaginal sponge, all inserted prior to sex (entries 1 to 4 in Table 2-1). Another trial evaluated N-9 as a vaginal gel in Cameroon but was insufficiently powered to detect efficacy against HIV acquisition (Roddy, 2002). The other four trials found that N-9 did not reduce the risk of acquisition of HIV, NG or CT (Wilkinson, 2002). The last N-9

[1] In this thesis I refer to two generations of candidate microbicides: first (surfactants and fusion inhibitors) and second (ARVs). However, some researchers refer to three generations of candidate microbicides: first (surfactants), second (fusion inhibitors) and third (ARV) - see for example Ramjee et al; The last decade of microbicide clinical trials in Africa: from hypothesis to facts; 2010.

trial was conducted by CONRAD (COL-1492) among female sex workers in Benin, Côte d'Ivoire, South Africa and Thailand. The results suggested that frequent use of N-9 might actually increase the risk of HIV acquisition for some women, possibly as a result of vaginal irritation (Van Damme, 2002). While disappointing, these results provided important information about the use of N-9 which resulted in recommendations from the World Health Organisation (WHO) not to promote condoms lubricated with N-9 (WHO, 2001).

Table 2-1: Randomised control trials which have evaluated the safety and effectiveness of candidate microbicides

No	Reference	Candidate microbicide	Sponsor (trial name)	Countries involved	Number enrolled	Study conducted from and to	Hazard ratio product: placebo (95% CI)
1	(Kreiss, 1992)	N-9 sponge (unblind)	FHI	Kenya	138	January 1987 to June 1990	1.7 (0.9, 3.0)
2	(Roddy, 1998)	N-9 film	FHI	Cameroon	1,292	March 1994 to December 1996	1.0 (0.7, 1.5)
3	(Richardson, 2001)	N-9 gel	FHI	Kenya	278	July 1996 to February 1998 (discontinued: low recruitment and retention)	0.7 (0.3, 1.5)
4	(Van Damme, 2002)	N-9 gel	CONRAD (COL-1492)	Benin, Côte d'Ivoire, South Africa, Thailand	892	September 1996 to June 2000	1.5 (1.0, 2.2)
5	(Peterson, 2007)	SAVVY (C31G)	FHI	Ghana	2,142	March 2004 to February 2006	0.88 (0.33, 2.27)
6	(Feldblum, 2008)	SAVVY (C31G)	FHI	Nigeria	2,153	September 2004 to December 2006	1.7 (0.9, 3.5)
7	(Skoler-Karpoff, 2008)	Carraguard	Population Council	South Africa	6,202	March 2004 to March 2007	0.87 (0.69, 1.09)
8	(Halpern, 2008)	Cellulose Sulphate (Ushercell)	FHI	Nigeria	1,644	November 2004 to March 2007	0.8 (0.3, 1.8)
9	(Van Damme, 2008)	Cellulose Sulphate (Ushercell)	CONRAD	Benin, India, South Africa, Uganda	1,428	July 2005 to March 2007	1.61 (0.86, 3.01)
10	(Abdool-Karim, 2009)	PRO2000 0.5% & Buffer Gel	HPTN (035)	Malawi, South Africa, Zambia, Zimbabwe, USA	3,099	February 2005 to September 2008	PRO2000 0.5%: 0.7 (0.5, 1.1) Buffer Gel: 1.1 (0.8, 1.6)
11	(McCormack, 2010)	PRO2000 0.5% & PRO2000 2%	MDP (301)	South Africa, Tanzania, Uganda, Zambia	9,385	October 2005 to September 2009 (2% discontinued Feb 2008)	PRO2000 0.5%: 1.05 (0.82, 1.34) PRO2000 2%: 1.21 (0.88, 1.68)
12	(Abdool-Karim, 2010b)	Tenofovir 1%	CAPRISA (004)	South Africa	889	May 2007 to January 2009	0.61 (0.40, 0.94)

It is important to note that Table 2-1 presents trial results in terms of *effectiveness* of the products under evaluation not in terms of *efficacy*. Efficacy can only be reported in trials where adherence can be measured objectively, such as in vaccine trials. To date microbicide trials have evaluated products that are user dependent. Without a reliable biological measure of product adherence it has not been possible to estimate the true biological efficacy of a product. Effectiveness as measured in microbicide trials, accounts for both the efficacy of the product and adherence to the product by the user (Heise, 2011). The challenge for microbicides, and other user dependent prevention methods, is that the observed effectiveness of a product in a clinical trial may differ from the actual effectiveness of a product when introduced as a HIV prevention option in the public health sector. The level of support and adherence counselling offered to trial participants may mean that adherence levels achieved in trial settings cannot be achieved in other settings. Conversely, in a non-trial setting, women may be more motivated to use the products once they know the true protective value of an actual microbicide instead of a test candidate or placebo in clinical trials. In this thesis, I will discuss effectiveness in terms of the effect size observed accounting for efficacy and adherence in clinical trial settings. The user dependent aspect of microbicides underlies the importance of product acceptability.

As shown in Table 2-1 (entries 5 to 11) from 2004 to 2009 seven clinical trials evaluated the safety and effectiveness of five candidate microbicides in 11 countries among over 24,000 women. FHI conducted two trials to evaluate a surfactant microbicide called SAVVY (chemical name C31G) in Ghana and Nigeria (Peterson, 2007, Feldblum, 2008). The trials were prematurely closed in 2005 and 2006 respectively. In Ghana (entry 5 Table 2-1), a general decline in HIV incidence meant that the data and safety monitoring board (DSMB) considered the trial no longer viable. Subsequently, an interim review of the data in the Nigeria trial (entry 6 Table 2-1) recommended closure as it was considered unlikely that the trial would observe a reduction in HIV acquisition.

In 2008 the Population Council (entry 7 Table 2-1) successfully completed a phase III trial evaluating Carraguard, which is a seaweed derivative used in a range of products including a nutritional drink (Skoler-Karpoff, 2008). In laboratory tests Carraguard blocked HIV, the human papillomavirus and herpes simplex infections from entering human cells. In the trial, the Population Council found that there were no differences between women using Carraguard and women using the placebo in terms of safety or risk of HIV acquisition.

Two trials evaluated the safety and effectiveness of Cellulose Sulfate (CS), an entry inhibitor with activity against HIV, CT and NG in laboratory studies. The CONRAD CS trial enrolled

women in Benin, South Africa, Uganda, and India (entry 9 Table 2-1). The FHI CS trial enrolled women in Nigeria (entry 8 Table 2-1). The CONRAD trial was stopped prematurely in 2007 due to concern that there were more HIV infections in the CS group compared to the placebo group in interim analysis (Van Damme, 2008). The FHI trial closed as a precautionary measure even though there were no concerns of increased risk of HIV acquisition in that trial (Halpern, 2008). The final analysis of CONRAD data found that Cellulose Sulfate may have increased the risk of HIV acquisition.

The HIV Prevention Trials Network (HPTN) evaluated two candidate microbicides in their HPTN035 trial (entry 10 Table 2-1), BufferGel and 0.5% PRO2000 (Abdool-Karim, 2011). BufferGel is a buffering agent designed to sustain normal vaginal acidity in the presence of ejaculate which is highly alkaline. *In vitro* evidence suggested that by maintaining the normal vaginal pH, acidic vaginal secretions could inactivate pathogenic microorganisms. PRO2000 is an entry inhibitor designed to attach to receptors on HIV, preventing the virus from fusing and attaching to susceptible cells. The trial measured the effectiveness of both candidates in the prevention of HIV, bacterial vaginosis (BV), CT, genital ulcer disease, NG, herpes simplex virus-2 (HSV2), syphilis, trichomonas vaginalis (TV), and pregnancy. Although the final results reported no significant effect of either candidate, it showed a 30% non-significant reduction in HIV acquisition among women allocated to 0.5% PRO2000 compared to placebo. This raised expectations for 0.5% PRO2000 which was being evaluated in the much larger Microbicides Development Programme 301 (MDP 301) clinical trial that was due to report by the end of the same year (Nunn, 2009).

MDP 301 was the largest HIV prevention trial ever conducted in Africa enrolling 9,385 women in South Africa, Tanzania, Uganda, and Zambia (entry 11 Table 2-1). The trial evaluated the effects of PRO2000 microbicide at 0.5% and 2% concentrations. MDP discontinued 2% PRO2000 in February 2008 on the recommendation of the DSMB on the basis that there was no more than a small chance of showing protection against HIV acquisition. MDP 301 continued evaluating 0.5% PRO2000 and reported its findings at the end of 2009. The trial found that while 0.5% PRO2000 and 2% PRO2000 were well tolerated and liked by women, they did not reduce the risk of infection with HIV, HSV2, CT or NG (McCormack, 2010).

The exclusion of CS, Carraguard and PRO2000 as potential candidate microbicides may well have signalled the end of the evaluation of 'entry inhibitors' (Ramjee, 2010). This is disappointing as an effective entry inhibitor could offer the advantages of protecting against other STIs as well as HIV, offer contraceptive or non-contraceptive options, and could be easily distributed in non-clinical settings due to not being systemically absorbed (Omar, 2011).

Unfortunately it appears that surfactants, buffer products and entry inhibitors are unable to offer the level of protection necessary to be viable HIV prevention options for women. Nonetheless, as I show in section 2.2.3, these clinical trials contributed important evidence to our understanding of microbicide acceptability.

2.1.2 Second generation microbicides

Even before the results of all the first generation microbicide trials were available, the need to investigate alternative modes of action was recognised. As described in chapter 1 section 1.5.2, ARVs have been shown to have both therapeutic and preventive benefits. When used in Africa, ARVs are estimated to at least half the risk of MTCT (Chigwedere, 2008, KeshoBoraStudyGroup., 2011). When used after occupational exposure as PEP, ARVs are estimated to reduce the risk of infection by approximately 80% (Cardo, 1997, Tsai, 1998, Schechter, 2002). Consequently a number of ARVs have been evaluated in preclinical studies as potential 'second generation' candidate microbicides. Tenofovir, which is a nucleotide reverse transcriptase inhibitor (NRTI), was identified as a potential microbicide due to its ability to suppress viral replication, favourable safety profile and long biological half-life.

In May 2007, the CAPRISA 004 trial started evaluating the effectiveness of 1% tenofovir microbicide gel. N-9, SAVVY, CS, Carraguard, BufferGel and PRO2000 were all evaluated as vaginal gels applied from a pre-filled applicator up to one hour before sex. Evidence from all of these studies demonstrated that this was an acceptable mode of application. At that time, while there was preclinical evidence to suggest that dosing with tenofovir gel before and after sex could achieve sufficient drug levels to prevent viral replication, there was insufficient data to support single dose coitally-dependent use of tenofovir gel. Consequently the CAPRISA 004 trial evaluated dual dose coitally dependent use of tenofovir gel, whereby women were asked to insert a first gel applicator up to 12 hours before sex and a second gel applicator up to 12 hours after sex, with no more than two applications in a 24 hour period. This dosing strategy is known as BAT24, an acronym for before-after-two-24.

The CAPRISA 004 trial enrolled 899 women in two sites in KwaZulu-Natal, South Africa (entry 12 Table 2-1). In 2010, CAPRISA reported a major breakthrough in microbicide research by providing proof for the concept of vaginal microbicides. CAPRISA 004 demonstrated that 1% tenofovir gel reduced the risk of HIV infection for women by 39% (95% CI: 6, 60) (Abdool-Karim, 2010b). As expected with user-dependent products such as microbicides, sub-analyses of the data demonstrated higher levels of effectiveness among women who adhered more strictly to microbicide use. Effectiveness peaked at 54% (95% CI: 4, 80) in women who reported using the microbicide in 80% or more sex acts. A collaboration of South African research

institutions called FACTS (Follow-on African Consortium for Tenofovir Studies) are repeating the CAPRISA 004 study design to confirm the effectiveness of the BAT24 dosing strategy in 2,200 women in 9 sites in South Africa (FACTS, 2012). The FACTS 001 trial is expected to report results in 2014 and, if the results of CAPRISA 004 are confirmed, would support an application to licence tenofovir microbicide gel as a coitally dependent HIV prevention option.

In addition to evaluating daily oral PrEP (described in chapter 1 section 1.5.2), the VOICE trial also evaluated *daily* dosing with tenofovir gel. In contrast to the CAPRISA 004 trial, the VOICE trial stopped evaluating tenofovir gel in November 2011 as the DSMB observed no reduction in HIV incidence among women assigned to tenofovir gel compared to women assigned to placebo gel (MTN, 2011b). It is not yet clear why tenofovir gel could offer protection against HIV when used before and after sex, but not daily. It is possible that the BAT24 dosing regimen is more efficient at ensuring sufficient concentrations of drug are in the right place at the right time to prevent viral replication. However, tenofovir has a half-life of 6 days and therefore drug levels should be stable if used on a daily basis. The VOICE trial are due to complete evaluation of daily oral Truvada in early 2013 and only after that will release more details of the findings relating to the daily use of tenofovir gel. Both biological and drug adherence factors are likely to account for the lack of effect of tenofovir gel observed in the trial.

If in the next few years FACTS 001 confirms the effectiveness of tenofovir gel using the BAT24 dosing strategy, additional research will still be necessary to ensure the safety of tenofovir and ensure distribution mechanisms support optimal adherence strategies to provide the best protection possible in communities most in need of additional prevention options. For example, additional evidence will be required on safety in adolescents (MTN-021, 2012, FACTS, 2012), pregnant and lactating women (MTN-008, 2011), post-menopausal women, and in the rectum (MTN-007, 2011). Follow on studies from CAPRISA 004 and VOICE will continue to monitor drug resistance in women who seroconverted when using tenofovir gel (MTN-018, 2011, CAPRISA009, 2011). In an open label study, CAPRISA are evaluating the effectiveness and safety of tenofovir gel when provided to CAPRISA 004 trial participants through family planning services (CAPRISA008, 2012). It may also be necessary to evaluate the effectiveness of coitally dependent single dosing of tenofovir gel, which could be an easier and cheaper dosing option than BAT24 (MDP, 2011). At the same time, we need to further explore the user-acceptability factors that influence adherence in order to better explain the disparity between CAPRISA 004 and VOICE in terms of the effectiveness of tenofovir gel.

Other ARVs are being or will be evaluated in microbicide gels including TMC120 known as Dapivirine (MTN, 2012), Maraviroc (MTN-013/IPM-026, 2011), and MV-150 (PopCouncil,

2011). All three of these products are likely to be evaluated in vaginal rings that can be left in place for a month with a slow release drug mechanism. Hopefully within the next decade women will have a choice of both coitally and non-coitally dependent microbicides. To support microbicide adherence in the future, it is important that we understand as much as possible about factors that influence the acceptability of microbicides.

2.2 Microbicide acceptability research

Microbicides are user dependent and can only offer protection if used consistently at coitus. Microbicides delivered through slow release vaginal rings will be less coitally-dependent, although they will still be user dependent in terms of women needing to insert the ring, keep it in place and replace it as required. In this way, microbicides are similar to condoms in that they are dependent on correct and consistent use. In South Africa today, where condoms are widely available, the low level of acceptability of male condoms remains the biggest barrier to consistent condom use. The acceptability of a microbicide will influence user uptake and adherence to the product. On this basis, acceptability is a central tenet of microbicide research (Morrow, 2008).

Microbicide acceptability has been evaluated in three ways to date; 1) the first has been to evaluate the acceptability of microbicides hypothetically, 2) the second has been to evaluate the acceptability of surrogate products that are used like microbicides, and 3) the third has been to evaluate the acceptability of candidate microbicides in clinical trials. So far, most of the research has taken a *linear perspective* of microbicide acceptability. By this I mean that there has been a clear line from product (hypothetical, surrogate or candidate microbicide) to the measure of acceptability. In the main, microbicide acceptability has been measured by directly asking women or men if they are willing to use a microbicide, if the attributes of a specific microbicide are acceptable, or if the experience of using a microbicide (or surrogate) is acceptable.

Microbicide → willing to use → product characteristics → actual use

This approach has provided valuable insights into both the acceptability of using a vaginal gel for HIV prevention and the acceptability of specific product characteristics. In this thesis, I take an alternative approach to measure acceptability by assessing the **compatibility** of microbicides with socio-cultural norms of sexuality and sexual health. I explain this approach in more detail below in section 2.3. In order to illustrate what we know to date about microbicide acceptability and highlight gaps in the evidence, I firstly present a comprehensive overview of the existing microbicide acceptability literature.

I systemically reviewed the literature on vaginal microbicide acceptability and identified all articles that present primary findings and are published in peer-reviewed journals. I include all literature without any geographical restrictions and include studies with women and men. The criteria used for the systematic literature review are explained in appendix G. The literature review was conducted in November 2011 in two stages: 1) Stage 1 (s1) search relates to articles identified during the systematic review of literature in PubMed, Web of Knowledge and POPLINE search engines; 2) Stage 2 (s2) search relates to articles that were found on review of the articles included in stage 1. Below I present the findings from the systematic review of the microbicide acceptability literature from hypothetical, surrogate and candidate microbicide studies.

2.2.1 Hypothetical studies

The stage 1 systematic literature review identified 23 articles on the hypothetical acceptability of microbicides for the prevention of HIV and STIs (listed in Table 2-2 as s1 studies). The stage 2 review identified an additional 4 articles (listed in Table 2-2 as s2 studies). Studies evaluating the hypothetical acceptability of microbicides have tended to focus on indicators of willingness to use a microbicide. In hypothetical studies the willingness to use a microbicide has been framed in two different ways: firstly, a person's willingness to use a vaginal product as a microbicide if it was proven to reduce the risk of HIV infection; secondly, a person's willingness to use an effective microbicide if they perceived themselves at risk of HIV infection (Woodsong, 2008).

Hypothetical acceptability has mainly been assessed among women and men in the USA, but also in Ghana, Malawi, Rwanda, South Africa, Zimbabwe, Brazil, Mexico, China and India[2]. Studies have included female sex workers (Han, 2009, Wang, 2008), intravenous drug users (McMahon, 2011), adolescent girls and their mothers (Short, 2003, Short, 2004), Muslim women (Hoel, 2011), and health care workers (Hoffman, 2008, Short, 2003). Overall, hypothetical willingness to use vaginal microbicides was influenced by 1) individual characteristics such as age, race and ethnicity, 2) relational issues such as marital status, relationship type, and cohabitation, 3) behavioural factors such as higher risk sexual behaviour, current use of condoms and other contraceptives, and 4) product related factors such as potential ease of use and insertion, cost, side effects, and impact on fertility and conception.

[2] Tolley et al assessed hypothetical acceptability among 30 women, although 8 of them had used a microbicide candidate in a prior 2-week safety study.

Table 2-2: Hypothetical studies

Ref	Countries	Women	Men	Method	Search stage
Auslander, 2007	USA	126	0	Quant	s1
Bisika, 2009	Malawi	32	55	Qual	s1
Coggins, 2000b	Mexico, USA, Zimbabwe	0	90	Qual	s1
Cook, 2009	USA	408	0	Quant	s1
Darroch, 1999	USA	1000	0	Quant	s1
Han, 2009	China	54	0	Quant	s1
Hardy, 1998	Brazil	635	0	Quant	s2
Hoel, 2011	South Africa	29	0	Qual	s1
Hoffman, 2008	South Africa, USA	254		Qual	s1
Holt, 2006	USA	388		Mixed	s1
MacPhail, 2009	South Africa	100	0	Qual	s1
McMahon, 2011	USA	71	0	Quant	s2
Morrow, 2007a	USA	531	0	Quant	s1
Morrow, 2007b	USA	531	0	Quant	s1
Olsen, 2007	USA	401	0	Quant	s1
Orner, 2006	South Africa	213		Qual	s1
Ramjee, 2001	South Africa	0	243	Quant	s1
Reiff, 2008	USA	23	0	Qual	s1
Short, 2004	USA	42	0	Qual	s2
Short, 2003	USA	72	0	Qual	s2
Tanner, 2008b	USA	405	0	Quant	s1
Tanner , 2008a	Ghana	19	0	Qual	s1
Tolley, 2006	India	30	15	Qual	s1
van de Wijgert, 1999	Zimbabwe	0	43	Qual	s1
Veldhuijzen, 2006	Rwanda	±80		Qual	s1
Verguet, 2010	USA	71	0	Mixed	s1
Wang, 2008	China	400	200	Mixed	s1

In addition there were a range of social and cultural issues that specifically influenced hypothetical willingness to use microbicides in Africa. Self-perceived risk of HIV was a major factor increasing women's and men's willingness to use microbicides in South Africa (Ramjee, 2001, Orner, 2006). Hypothetically, vaginal microbicides were perceived as highly acceptable, except among men in Malawi who thought that women would find it easier to be unfaithful with a microbicide that protected them from HIV and STI infection (Bisika, 2009). Acceptability was generally premised on the need for women to discuss microbicides with men prior to use (Veldhuijzen, 2006, Ramjee, 2001, van de Wijgert, 1999, Coggins, 2000b, Bisika, 2009, Tanner, 2008a), except in South Africa where women's use without the male partner's knowledge was considered acceptable in some circumstances (Orner, 2006, MacPhail, 2009). For men in Rwanda the potential lubrication offered by microbicides increased their willingness to use the products (Veldhuijzen, 2006), whereas men in Malawi, South Africa and Zimbabwe were concerned that the added lubrication could negatively impact on their sexual enjoyment (van de Wijgert, 1999, Orner, 2006, Bisika, 2009, Ramjee, 2001).

Finally, one article compared studies among health care providers in South Africa and the USA and found support for microbicides but concern about promoting a partially effective product (Hoffman, 2008). Evidence from hypothetical studies illustrates high levels of willingness to use microbicides whilst highlighting that there will be different individual and socio-cultural preferences that influence acceptability. In Africa, different socio-cultural expectations regarding a woman's need to discuss microbicides with her partner and the potential impact of lubrication on sexual pleasure, were particularly pronounced.

2.2.2 Surrogate studies

The stage 1 systematic literature review identified 14 articles on the acceptability of microbicides based on the evaluation of surrogate products (listed in Table 2-3 as s1 studies). The stage 2 review identified an additional 9 articles although 4 of these related to a single study (listed in Table 2-3 as s2 studies). Multiple articles from other single studies were included and are identified as such in the table. Studies evaluating the acceptability of surrogate products have been able to expand upon the hypothetical willingness to use a product if one was available. These studies have been able to assess the extent to which specific product related characteristics influence women's willingness to use a product and how the use of the product impacts on other factors, such as sexual activity.

Most of the studies involved women using surrogate products during sex, except one which involved women applying the products without having sex (Schwartz, 2007) and two in which surrogate products were compared *ex vivo* (Mahan, 2011, Mason, 2003). A range of surrogate products have been used including vaginal moisturisers, treatments for bacterial vaginosis, lubricants, contraceptives, and placebos, in a variety of formulations including gels, films, tablets, capsules, foams, suppositories and vaginal sponges.

The majority of the studies evaluating acceptability of surrogate products have been conducted in the USA. Studies in the USA have offered insights into acceptability among specific groups of women such as injecting drug users (Mason, 2003, Hammett, 2000b, Mosack, 2005, Hammett, 2000a), commercial sex workers (Mosack, 2005) and adolescents (Short, 2009, Zubowicz, 2006, Short, 2007b, Short, 2008, Short, 2007a, Sunder, 2006). The rest of the surrogate studies have been conducted in Africa, with one in Malawi, Zambia, South Africa, Uganda, a multi-centre study in Burkina Faso, Tanzania and Zambia and among couples in the MDP multi-centre pilot study in South Africa, Tanzania, Uganda and Zambia.

Table 2-3: Surrogate studies

Ref	Surrogate	Countries	Women	Men	Method	Search stage
Coetzee, 2001	Methyl cellulose placebo	South Africa	28	0	Quant	s1
Green, 2001*1	Female condom, foaming tablets, contraceptive sponge, Delfen foam, film and gel	Uganda	131	21	Qual	s2
Hammett, 2000a	Replens gel, Lubrin suppository, Moist Again gel	USA, Puerto Rico	83	0	Qual	s1
Hammett, 2000b	Replens gel, Lubrin suppository, Moist Again gel	USA, Puerto Rico	743	0	Quant	s1
Jones, 2008	Astroglide Silken Secret (high-viscosity gel), KY Jelly (low-viscosity gel), Lubrin (suppository)	Zambia	301	0	Quant	s1
Koo, 2005	Replens gel, Lubrin suppository	USA	100	85	Mixed	s2
Mahan, 2011	KY Jelly, Pre-Seed, Astroglide, Replens, RepHresh, Options Gynol II	USA	10	10	Quant	s1
Mason, 2003	Female condom, vaginal spermicides, lubricants, including suppositiories, film, foam, creams and gels	USA, Puerto Rico	66	0	Qual -	s2
Montgomery, 2008	HEC placebo	South Africa, Tanzania, Uganda, Zambia	45	45	Qual	s1
Mosack, 2005*2	Replens gel	USA	96	0	Quant	s1
Nel, 2011	Placebo tablet, film, soft-gel capsule	Bukino Faso, Tanzania, Zambia	526	0	Quant	s1
Pool, 2000*1	Female condom, foaming tablets, contraceptive sponge, Delfen foam, film and gel	Uganda	138	42	Qual	s2
Salter, 2008	Metronidozole vaginal gel (BV treatment)	Malawi	1686	21	Mixed	s1
Schwartz, 2007	HEC and polystyrene sulfonate placebos	USA	30	0	Quant	s1
Short, 2009	Replens gel, Lubrin suppository	USA	166	0	Quant	s1
Short, 2007b*4	Replens gel, Lubrin suppository	USA	208	0	Quant	s2
Short, 2008*4	Replens gel, Lubrin suppository	USA	208	0	Quant	s2
Short, 2007a*4	Replens gel, Lubrin suppository	USA	70	0	Quant	s2
Sunder, 2006*4	Replens gel, Lubrin suppository	USA	208	0	Mixed	s2
Tanner, 2010*3	Silken Secret vaginal moisturiser	USA	40	0	Qual	s1
Tanner, 2009*3	Silken Secret vaginal moisturiser	USA	40	0	Qual	s1
Weeks, 2004*2	Vaginal moisturiser	USA	94	0	Quant	s1
Zubowicz, 2006	Replens gel, Lubrin suppository	USA	175	0	Qual	s2

*1-4 identify multiple articles that refer to a single study

Studies of surrogate products mainly reinforced findings from the hypothetical studies regarding the importance of individual, relational, behavioural and product characteristics on willingness to use microbicides. In addition, women's willingness to use microbicides was found to be influenced by a history of male violence (Weeks, 2004, Hammett, 2000b) and women's perception of their partner's acceptance of the products (Salter, 2008, Jones, 2008, Green, 2001, Tanner, 2010). In some of the African studies, although the products were used

by women, the influence of male partners on women's willingness to use products was considerable (Montgomery, 2008).

A number of studies specifically compared different vaginal products and found that preferences differed considerably across populations (Hammett, 2000a, Mahan, 2011, Nel, 2011, Jones, 2008, Salter, 2008). For example, women in Burkina Faso and Tanzania preferred gel capsules to vaginal tablets or film, whereas women in Zambia preferred a film formulation of the same product (Nel, 2011). The authors concluded that different preferences were probably influenced by cultural factors as there were no discernible differences in individual or relational characteristics.

In surrogate studies, the willingness to use the products was highly influenced by the impact of the products on sex. The studies highlighted the importance of a microbicide not interfering with preferred sexual activity in terms of the timing of insertion, visibility of the product and impact on sexual pleasure. In the USA, additional lubrication during sex was generally viewed as enhancing sexual pleasure. Only in one study in which women did not use the products during sex did they express concern that the additional lubrication may be perceived by male partners as a sign of infection, improper hygiene, or evidence of infidelity (Mason, 2003). The impact on sexual pleasure was more complex in Africa, with women in South Africa reporting no impact of a vaginal gel on sexual pleasure (Coetzee, 2001), men in Malawi finding a vaginal gel enhanced sexual pleasure by tightening the vagina (Salter, 2008), women and men in Uganda reporting enhanced sexual pleasure due to added lubrication from a range of products (Pool, 2000) but women in Zambia preferring drier products with less lubrication (Jones, 2008).

The studies with surrogate products, especially in Africa, highlight that while willingness to use microbicides was dependent on product characteristics, overall acceptability was highly influenced by the views of male partners and the impact of product use on sexual activity. In line with the findings from hypothetical studies, this evidence highlights the importance of socio-cultural factors relating to sexual preferences and gender dynamics for microbicide acceptability.

2.2.3 Candidate microbicides

The stage 1 systematic literature review identified 43 articles on the acceptability of candidate microbicides as evaluated in clinical trials (listed in Table 2-5 as s1 studies). The stage 2 review identified an additional 15 articles (listed in Table 2-5 as s2 studies). A Population Council report is included in the stage 2 search despite not being peer-reviewed as it offers a unique contribution to understanding formulation preferences of a candidate microbicide in different countries (Coggins, 1998). Although the criteria included all candidate microbicides, I excluded

5 articles from studies which only evaluated microbicide gels in a diaphragm as the acceptability related to the diaphragm not to the microbicide gel itself (Guest, 2007, Montgomery, 2010c, von Mollendorf, 2010, Anderson, 2009, Williams, 2007). However I included 3 other articles (2 stage 1 and 1 stage 2) from 2 diaphragm trials which had microbicide gel only arms and therefore reported on gel acceptability as well as diaphragm acceptability (Behets, 2008a, van der Straten, 2008, Turner, 2009).

Thirteen articles (6 stage 1 and 7 stage 2 articles) are not included in Table 2-4 or Table 2-5 as they involved an assessment of the products in the absence of sex (Ballagh, 2002, Coggins, 2000a, Holmes, 2008, Jespers, 2007, Joshi, 2003, Mauck, 2001b, Mauck, 2001a, Mauck, 2004b, Mauck, 2004c, Mauck, 2004a, Schwartz, 2005, Tabet, 2003, Van Damme, 2000). In these studies, the majority of abstinent women found the products acceptable and commented on the physical sensation caused by the products (mainly heat or irritation) and impact of different volumes of gel being inserted (leakage and messiness). The majority of abstinent men were also content with the products when applied to their penis, commenting on the physical sensations (mainly tingling or stinging) and gel consistency (sticky and slow drying).

As shown in Table 2-4 the systematic literature review identified a total of 45 manuscripts (37 stage 1 and 8 stage 2) relating to 36 studies of candidate microbicides assessed during sexual activity. There are 4 articles from pilot studies, 25 from phase I trials, 9 from phase II trials, 2 from phase IIb trials and 5 from phase III trials.

Table 2-4: Number of studies and related manuscripts included in the systematic literature review of candidate microbicide acceptability

Candidate microbicide	Studies	Articles	Pilot	Phase I	Phase II	Phase IIB	Phase III
ACIDFORM™	1	2	2				
Buffer Gel	2	2		2			
Buffer Gel /PRO2000	1	1				1	
Carraguard	5	8		5	3		
Cellulose Sulphate	6	6		4	1		1
Dextrin Sulphate	2	2		1	1		
Invisible Condom	3	3		1	2		
N-9	6	6	2	2			2
Praneem polyherbal	2	2		1	1		
PRO2000	4	6		3	1		2
Tenofovir	3	4		3		1	
VivaGel®	1	3		3			
TOTAL STUDIES	**36**		**3**	**19**	**8**	**2**	**4**
TOTAL ARTICLES		**45**	**4**	**25**	**9**	**2**	**5**

I present summary data from each of the 45 articles on microbicide acceptability in Table 2-5. In the table, the articles are organised by study phase, microbicide type and then by author's name in alphabetical order. In the table I identify multiple articles that refer to a single study. In addition, I list the countries in which the testing has taken place and the size of the cohorts included in the analyses, although the number of women and men in the presented analyses may differ from the total number of people in the actual trial. In the table I also indicate the maximum period of time women were assigned to use the trial products and the dosing schedule of the study. Many of the trials included matched placebo controls, but, as is convention in microbicide acceptability research, I only distinguish between the microbicide and placebo products if distinctions are noteworthy. Otherwise trial participant's experiences of both the candidate microbicide and placebo are considered of relevance to the evaluation of microbicide acceptability. In the table I also note in the methods column whether the acceptability data was collected using quantitative techniques which include case report forms (CRFs), coital diaries (CD), computer-assisted self-interview (CASI) or audio CASI (ACASI), or using qualitative techniques which include in-depth interviews (IDIs), focus group discussions (FGDs) or participant observation (PO) methods.

The subsequent columns in Table 2-5 indicate whether the study assessed acceptability on the basis of satisfaction with product characteristics (product features), satisfaction with the mode of application (apply), or a willingness to use the product if shown to be effective or willingness to recommend the product to others (willingness to use). The review identified three dominant themes of acceptability which I have listed in the table as 1) the impact of using the product on sexual activity (impact on sex), 2) using the product with or without prior discussion with a partner (discuss use) and 3) the women's perception of their partners acceptance of the product (partner response). Additional issues relating to acceptability are noted in the 'other' column. The final column notes if the manuscripts were identified during the primary literature search (stage 1 search) or on secondary review of the literature (stage 2 search).

Table 2-5: Systematic literature review extraction table

Ref	Phase	Product	Countries	Cohort: female (male)	Duration on product	Dosing schedule	Methods	Product features	Apply	Willing-ness to use	Impact on sex	Discuss Use	Partner response	Other	Search stage
Behets 2008a*1	Pilot	Acidform: gel, diaphragm	Madagascar	192	4 weeks	pre-sex	CRF	√	√			√	√		s1
Turner 2009*1	Pilot	Acidform: gel, diaphragm	Madagascar	192	4 weeks	pre-sex	CRF	√				√			s2
Coggins 1998	Pilot	N-9: gel, film, suppository	Côte d'Ivoire, Thailand, USA, Zimbabwe	145	12 weeks	pre-sex	CRF/FGD	√				√			s2
Hira 1995	Pilot	N-9: foam, suppository, tablets	Zambia	85 (128)	28 days	pre-sex	CRF	√			√	√			s2
Bentley 2000	1	BufferGel	USA	27 (2)	14/28 days	1-2 daily	CRF/ CD/ IDI/FGD	√	√	√	√		√		s1
Bentley 2004	1	BufferGel	India, Malawi, Thailand, Zimbabwe	98 (FGDs)	14 days	2 daily	CRF/FGD	√	√		√	√	√		s1
Kilmarx 2008*2	1	Carraguard	Thailand	55 couples	6 months	pre-sex	CRF/CD	√	√		√	√			s1
Martin 2010*2	1	Carraguard	Thailand	55 couples	6 months	pre-sex	FGD	√	√	√	√	√	√	Impact on risk behaviour	s1
Ramjee 2007	1	Carraguard	South Africa	40 (20)	14 days	pre-sex or daily	CRF/IDI	√	√	√	√	√			s1
Whitehead 2006*2	1	Carraguard	Thailand	55 couples	6 months	pre-sex	CRF	√			√	√		Views of couples compared	s1
Whitehead 2011	1	Carraguard	Thailand	60	14 days	daily	CRF	√				√			s1
Doh 2007	1	CS	Cameroon	54	14 days	4 daily	CRF	√		√					s2
El-Sadr 2006	1	CS	USA	59 (11)	14 days	1-2 daily	CRF	√		√	√	√			s1
Malonza 2005	1	CS	India, Nigeria, Uganda	180	7 days	2 daily	CRF	√		√		√			s1

Ref	Phase	Products	Countries	Cohort: female (male)	Duration on product	Dosing schedule	Methods	Product features	Apply	Willing-ness to use	Impact on sex	Discuss use	Partner response	Other	Search stage
Schwartz 2006	1	CS	Dominican Republic, USA	60	14 days	2 daily	CRF	√	√	√					s2
Low-beer 2002	1	Dextrin Sulphate	UK	73 (10)	28 days	pre-sex or daily	CRF	√	√	√					s1
Trottier 2007	1	Invisible condom	Canada	41 (23)	14 days	once or twice daily	CRF	√	√		√				s1
Ramjee 1999	1	N-9 gel	South Africa	20	2 months	daily	CRF	√							s1
Rustomjee 1999	1	N-9 film	South Africa	20	2 months	daily	CRF	√				√	√	Vaginal practices	s1
Joglekar 2006	1	Praneem polyherbal	India	20 (5)	14 days	daily	CRF/IDI/ FGD	√		√	√	√	√		s1
Joglekar 2007	1	PRO2000	India	42	14 days	2 daily	CRF/FGD	√	√			√			s1
Mayer 2003*3	1	PRO2000	South Africa, USA	63	14 days	2 daily	CRF	√		√					s2
Morrow 2003 *3	1	PRO2000	South Africa, USA	63	14 days	2 daily	CRF/CD/ IDI/FGD	√		√	√	√		Vaginal hygiene	s1
Carballo-Diéguez 2007	1	Tenofovir	USA	0 (24)	14 days	2 daily	CRF/IDI	√			√	√			s1
Hoffman 2010*4	1	Tenofovir	USA	79	14 days	pre-sex or 1-2 daily	CRF/FGD	√			√	√			s1
Rosen 2008*4	1	Tenofovir	USA	84	14 days	pre-sex or 1-2 daily	CRF/FGD	√		√	√	√	√		s1
Carballo-Diéguez 2011*5	1	VivaGel® (SPL7013)	Puerto Rico, USA	61	14 days	2 daily	IDI/ phone CD/ internet CASI	√	√	√	√	√	√	Impact intimacy	s1
Giguere 2012*5	1	VivaGel® (SPL7013)	Puerto Rico, USA	59	14 days	2 daily	CRF/IDI	√		√	√		√	Vaginal practices	s1
McGowan 2011*5	1	VivaGel® (SPL7013)	Puerto Rico, USA	61	14 days	2 daily	Internet CASI	√		√					s1
Altini 2010	2	Carraguard	South Africa	400	6-12 months	pre-sex	CRF	√	√	√	√	√	√		s1

Ref	Phase	Products	Countries	Cohort: female (male)	Duration on product	Dosing schedule	Methods	Product features	Apply	Willing-ness to use	Impact on sex	Discuss Use	Partner response	Other	Search stage
Jones 2009*6	2	Carraguard	Thailand	165	12 months	pre-sex	CRF	√	√		√	√	√	Accepted long term	s1
Kilmarx 2006*6	2	Carraguard	Thailand	165	12 months	pre-sex	CRF/CD	√	√		√				s1
van der Straten, 2008	2	CS: gel, diaphragm	Zimbabwe	117	6 months	pre-sex	CRF/ ACASI	√		√	√	√	√		s1
Bakobaki 2005	2	Dextrin Sulphate	Uganda	109	28 days	pre-sex or 2 daily	CRF	√	√	√	√				s1
Mbopi-Keou 2009	2	Invisible Condom	Cameroon	260	14 days	1-2-3 daily	CRF	√	√						s1
Mbopi-Keou 2010	2	Invisible Condom	Cameroon	194	8 weeks	2 daily	CRF	√	√		√				s1
Joglekar 2010	2	Praneem polyherbal	India	100	6 months	pre-sex	CRF	√			√		√		s1
Kamali 2010	2	PRO2000	Uganda	180	28 days	2 daily	CRF	√	√	√					s1
Woodsong 2008	2B	BufferGel, PRO2000	Malawi, Zimbabwe	301 (109)	30 months	pre-sex	IDI/FGD	√			√	√	√	Gender	s1
Abdool-Karim 2010	2B	Tenofovir	South Africa	889	30 months	BAT24	CRF	√		√					s2
Greene 2010	3	CS	Benin, India, Uganda	53	12 months	pre-sex	IDI	√	√		√	√	√	Vaginal practices	s1
Visness 1998	3	N-9 film	Cameroon	520	12 months	pre-sex	CRF	√		√		√			s2
Vandebosch 2004	3	N-9 gel	Benin, Côte d'Ivoire, South Africa, Thailand	658	Up to 2 years	pre-sex	CRF	√			√	√			s1
Montgomery 2010b*7	3	PRO2000	South Africa, Tanzania, Uganda, Zambia	464	12-24 months	pre-sex	IDI	√			√	√	√	Vaginal practices	s1
Stadler 2011*7	3	PRO2000	South Africa	179 (18)	12 months	pre-sex	IDI/FGD/ PO						√	Body fluids	s1

*1-7 identify multiple articles that refer to a single study

The assessment of acceptability at every stage of the development phase of microbicides is critical in order to understand the broader issues that influence the use of microbicides in clinical trials as well as potential use of effective products in the future (Morrow, 2008). Unlike in hypothetical and surrogate studies, clinical trials have been able to assess acceptability of specific candidate microbicides. As products progress from phase I trials to phase III trials, more women use the products for longer periods of time. Overall the levels of acceptability in the various phases of testing have been high. Below I briefly present some key findings that contributed to our understanding of microbicide acceptability.

Pilot studies

ACIDFORM™ and N-9 were both initially evaluated in pilot studies as they were licensed spermicides before being considered as potential candidate microbicides. Women were asked to use these products for only short periods of time, between 28 days to 12 weeks. Despite evidence from surrogate studies regarding the impact of male violence on women's willingness to use microbicides, the ACIDFORM™ pilot was the only study of a candidate microbicide to evaluate the impact of partner violence on acceptability. This study found a positive association between adherence and a history of partner violence among women assigned to use gel in a diaphragm, but no such association among women assigned to use gel alone (Turner, 2009). The N-9 pilot studies were unique in that they conducted head-to-head evaluation of different product formulations and, as in surrogate studies, found that preferences differed considerably between populations (Hira, 1995, Coggins, 1998). Women preferred film in Thailand and Zimbabwe, gel in Côte d'Ivoire, tablets in Zambia, and all formulations equally in the USA. The formulations that were considered the most 'messy' to use were the ones least favoured in both studies, although ideas of which formulations were messy differed between populations as it was predominantly the foam in the Hira study and the suppositories in the Coggins study.

Phase I studies

The vast majority of the evidence regarding the acceptability of candidate microbicides has come from early phase I safety studies. One phase I trial evaluated the use of Carraguard over a six month period, but the remainder evaluated microbicide use over an average of just 16 days, ranging from 7 to 28 days (Table 2-5). Phase I trials have included small cohorts, typically with less than 100 women. Some phase I trials included HIV-positive as well as HIV-negative women (El-Sadr, 2006, Ramjee, 2007, Rosen, 2008, Whitehead, 2011, Mayer, 2003) and men (Carballo-Diéguez, 2007, Ramjee, 2007). Twelve phase I trials, and one phase II trial, included sexually abstinent as well as sexually active women (Bentley, 2000, Bentley, 2004, El-Sadr,

2006, Hoffman, 2010, Malonza, 2005, Mbopi-Keou, 2009, Morrow, 2003, Ramjee, 2007, Rosen, 2008, Schwartz, 2006, Trottier, 2007, Whitehead, 2011, Mayer, 2003). Most studies evaluated the acceptability of using the microbicides every day, although 4 studies evaluated pericoital (before or/and after sex) use. Phase I acceptability studies were conducted in over a dozen countries in Africa, the Americas, Asia and Europe.

The primary focus of phase I trials has been the acceptability both of a specific candidate microbicide and mode of application. Measuring acceptability of specific product characteristics in phase I trials has been important in ensuring that only the most acceptable products and formulations progressed into phase II and III trials. Overall, product acceptability has been high, although concerns regarding gel leakage (Carballo-Diéguez, 2011, El-Sadr, 2006, Giguere, 2012, Morrow, 2003, Rosen, 2008, Schwartz, 2006), bad odour (Carballo-Diéguez, 2011, Joglekar, 2007, Ramjee, 2007, Rustomjee, 1999, Low-Beer, 2002) or not liking the colour of specific products (Ramjee, 2007) have been identified. As in the pilot studies, the messiness of some products caused concern. In one study, products were reported to be more messy the more frequently they were used in a day (Bentley, 2000). However, products being messy to use was also reported in studies that required pre-coital (Kilmarx, 2008, Martin, 2010) as well as daily insertion (Bentley, 2004, Carballo-Diéguez, 2011, McGowan, 2011).

The evaluation of the acceptability of modes of application is also critical, as ease, comfort and convenience of insertion have important implications for product usage. Product applicators have been found acceptable except in a few cases such as when women have found the applicators difficult to assemble (Carballo-Diéguez, 2011), the plastic too hard (Martin, 2010) or concern about the cleanliness of re-useable applicators (Morrow, 2003). The acceptability of various microbicide gel applicators and other gel delivery devices such as diaphragms and vaginal rings have also been assessed independently of trials evaluating candidate microbicides (Hardy, 1998, Brache, 2006, Coetzee, 2001, Cohen, 2004, Cohen, 2007, Vail, 2004, Hardy, 2007, LePage, 1988, Malcolm, 2010, Behets, 2008a, Ballagh, 2008, Montgomery, 2010c, Sahin-Hodoglugil, 2011, Nel, 2011, Smith, 2008, Frezieres, 2012).

Over time, phase I trials have incorporated broader questions of acceptability, specifically with respect of the impact of the product on sex and the views of male partners. More recent phase I trials have included qualitative evaluations of product acceptability at this early stage of development. These evaluations have provided insights into the potential for microbicide characteristics that improve sex to increase sexual frequency, and microbicide characteristics that increase messiness to diminish intimacy in relationships (Carballo-Diéguez, 2011, Martin, 2010, Whitehead, 2006). They have also highlighted that couples' views and priorities

regarding acceptability of microbicides often differ, for example with men placing higher priority on the taste and smell of products than women (Whitehead, 2006). Overall, the impact on sexual pleasure has either been neutral or positive, although there were a few studies in which women and men reported decreased sexual pleasure (Carballo-Diéguez, 2011, Joglekar, 2006). Concerns regarding microbicides impacting on oral sex only emerged in the United States (Morrow, 2003, Carballo-Diéguez, 2011). A few phase I studies have considered the implications of vaginal practices on acceptability. These studies found that some women felt the need to increase external and internal intravaginal cleansing when using the microbicide, others found microbicides highly acceptable despite regular intravaginal cleansing or the insertion of products during commercial sex, while others reported that the microbicide made them feel like they were menstruating, which they associated with feeling unclean (Morrow, 2003, Rustomjee, 1999, Giguere, 2012).

Overall, most phase I trials found the candidate microbicides and applicators to be highly acceptable in diverse populations of women and men in all 4 continents. Only one study recommended that the gel formulation should be improved prior to further testing (Carballo-Diéguez, 2011). In most cases the volume of gel used and frequency of use was reduced after phase I trials, thereby addressing some of the concerns related to product consistency, such as leakage or messiness. In most cases, the extent to which women perceived themselves at risk of HIV acquisition appeared to influence the extent to which they were willing to tolerate inconvenient or unpleasant effects of microbicides (Bentley, 2000, Bentley, 2004, Carballo-Diéguez, 2011, Doh, 2007, Giguere, 2012, Joglekar, 2006, Martin, 2010, Morrow, 2003). In line with findings from surrogate studies, in phase I trials it was evident that preferences for product characteristics were influenced by social and cultural factors. The evidence also highlights the importance of vaginal practices for microbicide acceptability.

Phase II studies

In phase II trials, larger cohorts of women were typically expected to use candidate microbicides for a longer duration, on average for more than 4 months, ranging from 14 days to 12 months. Over half of the phase II trials evaluated pre-coital use of candidate microbicides. Articles on all the phase II trials have referred to studies conducted only in Africa and Asia.

Phase II studies have predominantly focused on the acceptability of product-specific characteristics, the ease of application, and the impact on sexual experiences. These trials have been able to assess acceptability over longer periods of use. Most studies found that women continued to find products acceptable over time, although one study found a decline in

positive reporting about ease of insertion, timing of insertion and gel volume (Jones, 2009). Interestingly qualitative methods have not been used in any of the phase II studies. This has been criticised as a missed opportunity as the expanded sample size and extended duration of microbicide use in phase II trials offers an important opportunity to garner a more in-depth understanding of acceptability (Morrow, 2008). Nonetheless the Carraguard trial in South Africa took a broader view of vaginal practices than had been considered previously in phase II trials. They found significant differences in intravaginal practices between ethnic groups, although they did not explore how this may impact on microbicide acceptability (Altini, 2010).

Phase IIb and III studies

In phase IIb and III trials, considerably larger cohorts of women used candidate microbicides for a minimum of 12 months up to a maximum of 30 months. In these trials all candidate microbicides have been gel formulations mostly inserted up to one hour before sex, but one inserted both before and after sex (BAT24). All the articles refer to evidence from either Africa or Asia. Given that there have been 12 phase IIb or III trials in 15 countries with almost 28,000 women using candidate microbicides (or placebo) (Table 2-1), it is surprising that there are only 7 articles from these trials reporting on acceptability. From a typically linear perspective, acceptability over the longer term was very high in most studies, with 97-98% of women reporting liking the product attributes and 80-98% of women reporting a willingness to use an effective microbicide in the future (Abdool-Karim, 2010a, Visness, 1998, Vandebosch, 2004).

However, phase IIb and III trials offer the most important opportunity to move beyond a purely linear perspective of acceptability and have typically evaluated a broader and more complex range of acceptability parameters. Four of the articles from phase IIb/III trials are based on more in-depth qualitative measures of acceptability. Two of these articles relate to data collected in the MDP 301 clinical trial. The first, which includes data from the Africa Centre used in this thesis, adopts an **emic approach** to the measurement of acceptability in order to evaluate the range of meanings that women attribute to microbicides (Montgomery, 2010b). This analysis provides a richer, ethnographic and cross-cultural perspective of women's views regarding the purpose of microbicides, the use of microbicides with or without partner knowledge, and the impact of microbicides on sexual pleasure. The findings highlight that microbicides have a much wider significance for users than is generally captured with linear perspectives of acceptability as women position microbicides within the broader context of their overall sexuality and sexual health. The authors conclude that "we need to move beyond seeing microbicides in the narrow sense of a 'new prevention technology' and consider how

they might fit in with and influence existing socio-cultural practices and how this fits with a broader public health agenda of women's sexual health" (Montgomery, 2010b;658).

The second MDP article, which only uses data from the Johannesburg MDP 301 centre, evaluates the extent to which cultural beliefs regarding the role of bodily fluids in maintaining good health influence the acceptability of microbicides (Stadler, 2011). In this context, the study found that microbicides are compatible with cultural beliefs relating to the flow of bodily fluids, whereas condoms are not. This paper again highlights that women assign significance to microbicides beyond merely HIV prevention, for example perceiving microbicides as improving their reproductive health and intimacy in their relationships. An article by Greene et al (2010) still looked at acceptability from a linear perspective although they adopted qualitative methods and used a 'socio-ecological model' to evaluate the influences of the product, individual, partner, provider and culture on acceptability. They found that in Uganda and Benin, the socio-cultural familiarity with traditional products to increase vaginal lubrication positively influenced attitudes towards microbicides. The article by Woodsong and Alleman (2008) most closely resembles the 'compatibility' model of acceptability that I adopt in this thesis. They interviewed trial participants, male partners, health professionals and community stakeholders in Malawi and Zimbabwe about socio-cultural norms relating to sexual decision–making, sexual pleasure and intravaginal practices, and then considered the acceptability of microbicides in light of these findings. The authors concluded that although acceptability of microbicides was high (in the typically linear sense), socio-cultural norms prioritising male decision making and male sexual pleasure could impede women's ability to use microbicides in the longer term.

Overall the evidence from phase IIb and III trials demonstrates that although product characteristics are highly acceptable to women in a variety of settings, consistent use of a microbicide may depend on socio-cultural, contextual and partner-related factors that are not always measured adequately by traditional linear perspectives of acceptability.

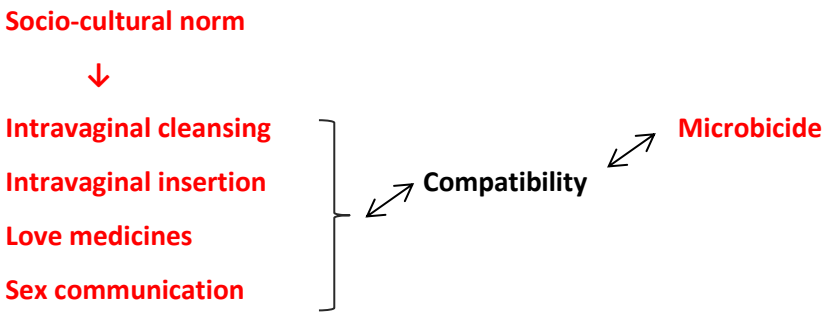
2.3 Compatibility as a measure of acceptability

As shown above, there is a vast body of evidence about microbicide acceptability. However, to date most of the evidence is based on hypothetical or surrogate studies where women are not using microbicides, or phase I trials were women are using microbicides for short periods of time under restricted circumstances. The majority of the evidence from trials testing candidate microbicides is quantitative and takes a strictly linear approach to microbicide acceptability. This evidence has provided important insights into the individual, relational, behavioural and cultural factors that influence microbicide acceptability. However, a number of key articles

from larger phase IIb and III trials have demonstrated that a linear perspective of acceptability does not capture the multiple ways in which women perceive microbicides more generally.

Consequently I intend to take an alternative approach to evaluating the acceptability of microbicides. I evaluate the **compatibility** of microbicides with socio-cultural norms of sexuality and sexual health. As such I explore specific socio-cultural norms, explore women's experiences of microbicides, and then compare and contrast the two in order to assess their compatibility. In this way I aim to gain insight into additional factors affecting how women incorporate microbicides into their broader lives.

Evidence from hypothetical, surrogate and candidate microbicide studies have all highlighted the importance of socio-cultural norms for microbicide acceptability. The importance of socio-cultural issues relating to sexual preferences, sexual practices and gender dynamics has been particularly pronounced in the literature from Africa. However, there are still significant gaps in our understanding of how these socio-cultural norms could influence the acceptability of microbicides (Mantell, 2005, Coly, 2008). In order to address these gaps, I intend to assess the compatibility of microbicides with a range of socio-cultural norms related to women's sexuality and sexual health in KwaZulu-Natal. Specifically I will consider 1) intravaginal cleansing, 2) intravaginal insertion, 3) love medicines and 4) sexual communication. We need to understand all four of these topics for a range of reasons which I briefly describe below, and present in greater detail in chapters 5 to 8.



Firstly, to date women in microbicide trials have been instructed to insert the microbicide before sex (and also after with tenofovir gel) and refrain from intravaginal cleansing for at least an hour after sex as it is thought that microbicides need to remain *in situ* post-ejaculation to prevent HIV infection. However, we still know very little about how vaginal cleansing practices, as well as the symbolic significance of intravaginal cleansing after sexual intercourse, could influence or be influenced by, the use of microbicides (Mantell, 2005).

Secondly, while there is evidence regarding the impact of microbicide use on sexual pleasure, there are substantial gaps in our understanding of how sexual practices and preferences could

influence or be influenced by the use of microbicides (Braunstein, 2003). For example, while the use of intravaginal insertions has been well described in some parts of Africa, we don't know whether the desired effects of using intravaginal insertions will be in conflict with the introduction of microbicides (Mantell, 2005).

Thirdly, acceptability and adherence research relating to anti-retroviral therapy has taken account of the pluralistic health care system in South Africa whereby people rely on both biomedical and traditional medicine (Dahab, 2010). However, the influence of traditional medicines has been largely neglected in microbicide acceptability research. Only one hypothetical microbicide acceptability study considered traditional medicines and found that Zimbabwean men believed that side effects from traditional and Western medicine could take up to 30 years to appear, and this influenced their concern about the impact of microbicides on fertility (van de Wijgert, 1999). The use of traditional medicines as 'love medicines' has been reported within the context of vaginal practices in KwaZulu-Natal (Scorgie, 2009). However, the purpose and use of love medicines is described very differently in the ethnographic literature of KwaZulu-Natal than that of vaginal practices such as intravaginal insertion (Parle, 2012, Wickström, 2008a, Berglund, 1976). There is currently no information regarding the ways in which traditional love medicines could influence or be influenced by the use of microbicides.

Finally, there is a considerable amount of evidence regarding the influence of male partners' views on women's acceptability of microbicides. The evidence suggests that the ability to use microbicides without a male partner's prior knowledge is of less relevance to women in Africa than was previously thought (Woodsong, 2004, Montgomery, 2010c). However, we still do not fully understand the process or timing of the negotiations that take place between women and men regarding the use of a microbicide. It will be important to understand how communication in relationships about microbicide use influence women's ability to use microbicides (Coly, 2008).

While we know that in the main women support the use of microbicides and find vaginal gels an appropriate method for HIV prevention, we need to more fully understand how women will incorporate microbicide use into their everyday lives to achieve adherence in the longer term and to understand what factors could impede sustained usage. Our knowledge relating to the interplay between socio-cultural norms of intravaginal cleansing, intravaginal insertion, love medicines and sexual communication and the use of microbicides is limited. As we move towards the introduction of microbicides as HIV prevention options, understanding how

microbicides will be positioned in relation to these social and culturally specific topics will become increasingly important.

In this thesis I focus on socio-cultural norms relating to intravaginal cleansing, intravaginal insertions, love medicines, and sexual communication, and evaluate their compatibility with microbicides. This approach will help me identify multidimensional contextual issues which are likely to impact on long term acceptability of microbicides in KwaZulu-Natal. I explain the socio-cultural perspective used for this thesis in more detail in the methods chapter (chapter 4). In the next chapter I describe the MDP 301 clinical trial.

3 Background to MDP 301

Summary

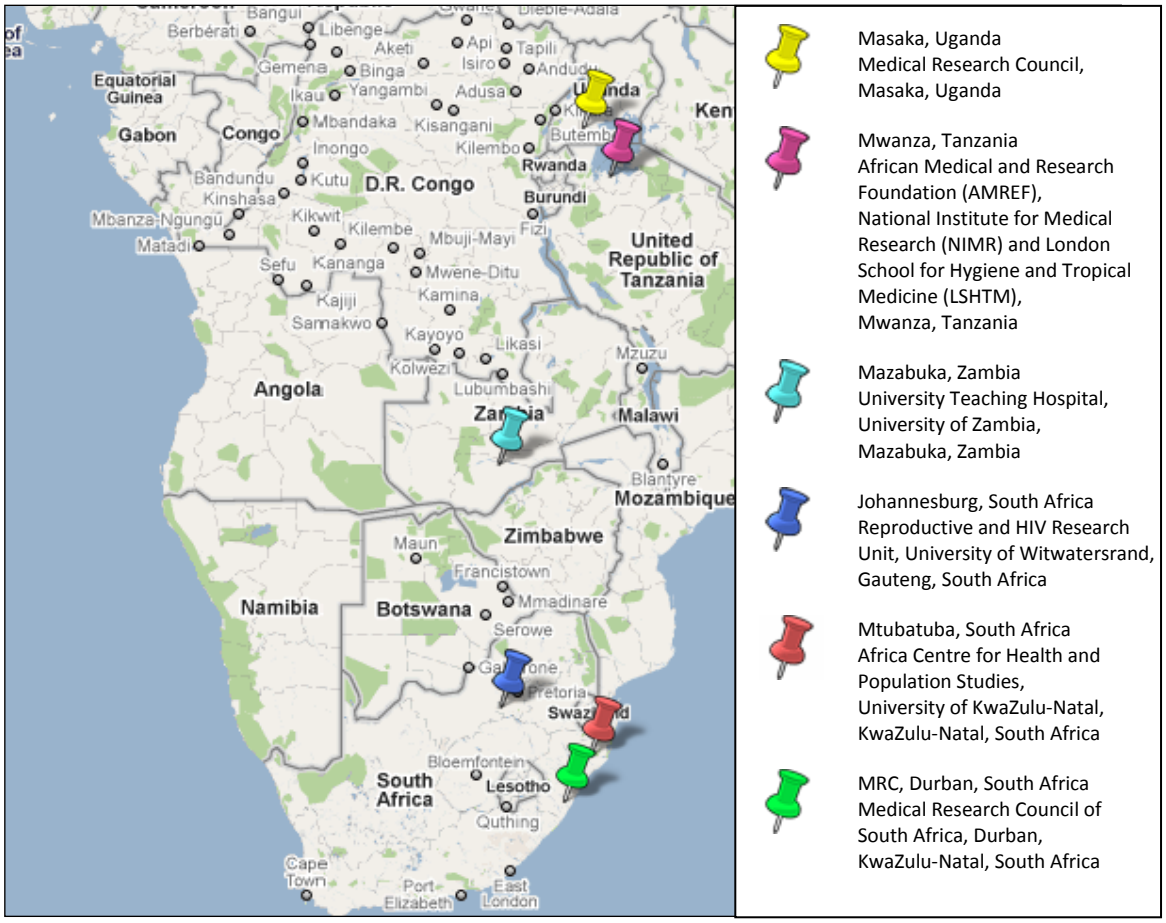
This thesis is based on an analysis of qualitative and quantitative data collected as part of the Microbicides Development Programme MDP 301 clinical trial at the Africa Centre for Health and Population Studies in KwaZulu-Natal, South Africa. In this chapter I provide a background to the MDP 301 clinical trial at the Africa Centre before going on to describe the methods I used for my PhD in the next chapter. I describe here the MDP 301 study design and the study population at the Africa Centre. I provide an overview of how the qualitative and quantitative data that I use in this thesis were collected in the MDP 301 trial. In addition I outline the ethical issues and review procedures of the trial. Finally I describe my role in the MDP 301 clinical trial at the Africa Centre.

3.1 Microbicides Development Programme

The Microbicides Development Programme was established in 2000 by the UK MRC. MDP was funded by the UK government through its Department for International Development (DFID) and MRC. MDP was a not-for-profit partnership of 16 research institutions in Africa and Europe. It was jointly coordinated by the MRC Clinical Trials Unit and Imperial College in London, who were directly responsible to DFID and MRC for the conduct of the programme. The ultimate goal of MDP was to develop safe, effective, acceptable and affordable microbicides. The MDP 301 trial was conducted by six research institutions in Africa (Figure 3-1). Feasibility and pilot studies were completed in preparation for the clinical trial. Further information about MDP is available on the MRC website (http://www.mdp.mrc.ac.uk/).

This thesis exclusively focuses on data collected as part of the MDP 301 clinical trial at the Africa Centre for Health and Population Studies, Mtubatuba, South Africa (see the red pin 📌 in Figure 3-1 for the geographic location of the Africa Centre).

Figure 3-1: MDP 301 clinical trial research institutions



3.1.1 The Africa Centre for Health and Population Studies

The Africa Centre for Health and Population Studies is part of the University of KwaZulu-Natal (www.africacentre.ac.za). It is located in Somkhele, near Mtubatuba, in the Umkhanyakude District of KwaZulu-Natal, South Africa. The centre was established with grants from the Wellcome Trust in partnership with the South African Medical Research Council in 1998. The aim of the centre was to carry out research on population and health issues affecting a rural population with one of the highest burdens of HIV in the world. The cornerstone of the Africa Centre's research programme is a biannual household demographic survey that commenced in 2000 and an annual HIV surveillance study that commenced in 2003 (Tanser, 2008). The Africa Centre conducts a host of additional clinical and social studies, but MDP 301 was the Centre's first phase III clinical trial.

I joined the Africa Centre MDP team in May 2004 as co-investigator and social scientist on the feasibility study. I was then co-investigator and senior social scientist on the pilot study. Following the departure of the principal investigator I assumed full responsibility for the pilot study in 2005. Subsequently I was principal investigator and senior social scientist on the MDP 301 clinical trial. I was named as sole principal investigator for the registration of the trial with

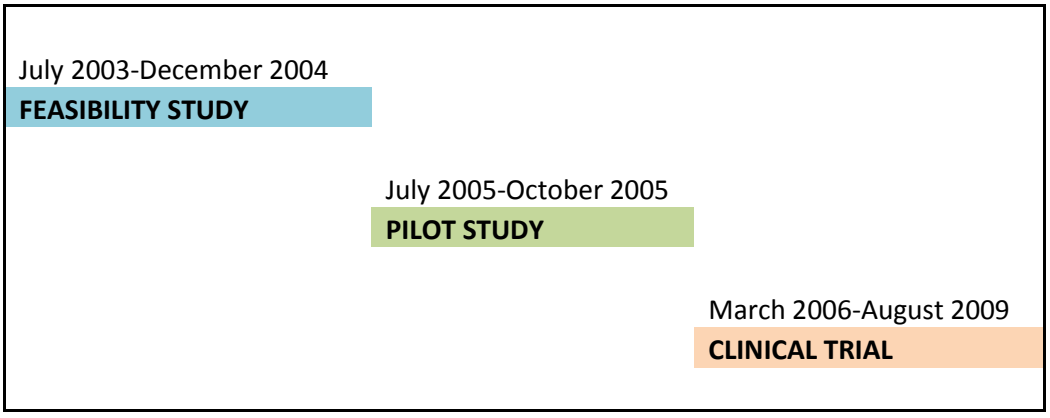
the US FDA but as co-principal investigator for registration of the trial with the South Africa MCC, due to different requirements between the drug regulators. I describe my role in MDP 301 at the end of this chapter in section 3.7.

3.1.2 Feasibility and pilot studies

In preparation for the MDP 301 phase III clinical trial, the Africa Centre conducted a microbicide ***feasibility*** study from July 2003 to December 2004 (Figure 3-2). We enrolled 449 women who visited the study clinics quarterly for up to 12 months. The study assessed the feasibility of identifying populations with high HIV incidence and community preparedness for phase III microbicide trials. During the feasibility study we tested a range of data collection tools, assessed the feasibility of using a mixed methods data collection approach, and reviewed specific terminology to see if it would be comparable across research populations in future clinical trials.

Based on the experiences of the feasibility studies, all MDP partners contributed to the development of a ***pilot*** study protocol, with uniform data collection tools and a unified database. At the Africa Centre we conducted a microbicide ***pilot*** study from July 2005 to October 2005 (Figure 3-2). We enrolled 51 HIV negative women who used a vaginal placebo gel during sex for 12 weeks. The pilot study was designed to optimise study procedures in preparation for the clinical trial by ensuring informed consent, data, laboratory and pharmacy management were compliant with international standards of Good Clinical Practice (GCP), Good Clinical Laboratory Practice (GCLP) and Good Pharmacy Practice (GPP) guidelines. We also tested gel adherence and acceptability measurement tools.

Figure 3-2: Timelines of Africa Centre MDP studies



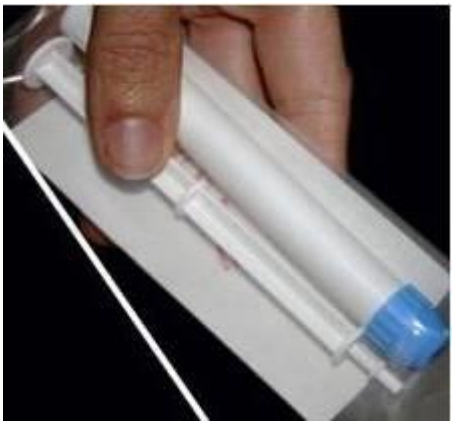
3.2 MDP 301 study design

MDP 301 was an international multi-centre, randomised, double-blind, placebo-controlled phase III trial. It was designed to evaluate the safety and effectiveness of 0.5% and 2% PRO2000 candidate microbicide gels compared to placebo in preventing vaginally acquired HIV infection. The MDP 301 trial protocol is available on the MRC website (http://www.mdp.mrc.ac.uk/mdpstudy.html). The trial design (Nunn, 2009), social science methodology (Pool, 2010a) and trial results (McCormack, 2010) of MDP 301 have been reported elsewhere. Below I summarise aspects of the trial design of relevance for this thesis.

3.2.1 Intervention

PRO2000 gel is a naphthalene sulphonate polymer, designed to protect against HIV and STI infection by inhibiting viral attachment and entry into susceptible cells. PRO2000 was administered in a clear, water-based vehicle gel and dispensed in prefilled applicators (Figure 3-3) containing two-grams of gel at either 0.5% or 2% concentration of PRO2000.

Figure 3-3: Gel applicator



The control gel was the universal hydroxyethylcellulose (HEC) placebo used in most microbicide trials. The HEC placebo was a clear, water-based formulation designed to serve as an inert comparator in clinical trials of active vaginal candidate microbicides (Moench, 2004). It was administered in the same prefilled applicators as PRO2000 and was not obviously distinguishable from the active gel.

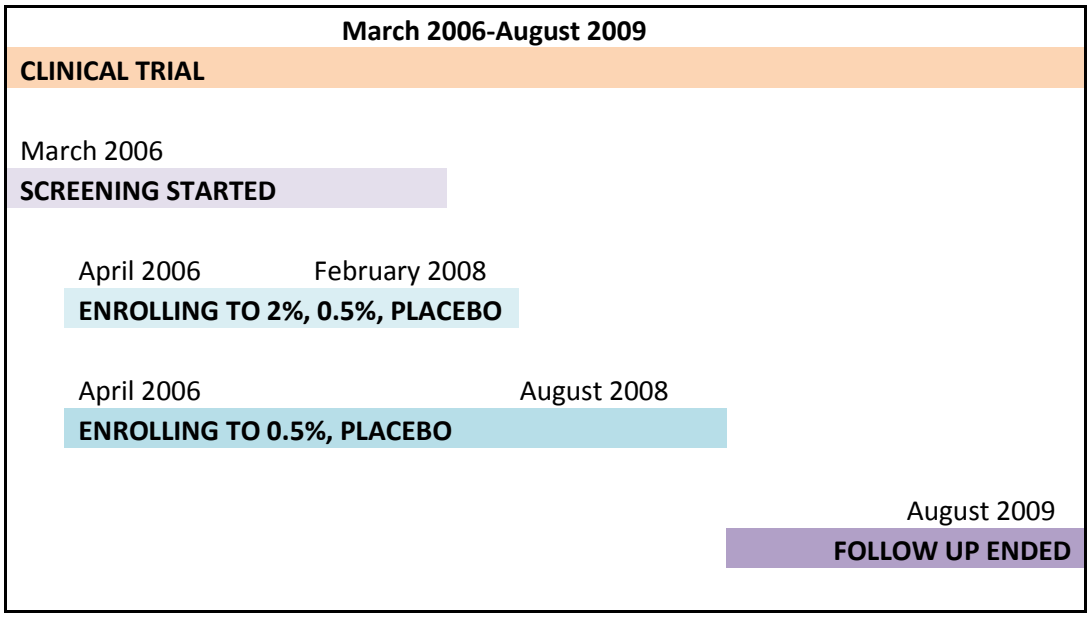
At enrolment, participants were trained on how and when to insert the gel. Participants were provided with pictorial instructions. They were asked to practice insertion by inserting their first applicator at the enrolment visit and discussing the experience with a study nurse. Participants were asked to insert one dose of gel vaginally up to 1 hour before each act of vaginal sexual intercourse and not to remove the gel by cleaning inside their vagina up to 1 hour after sex. Participants were asked to return all used applicators in clear plastic bags

provided with the gel. They were also asked to bring all unused gel applicators to each visit to allow full reconciliation of dispensed product. Participants were regularly counselled that consistent use of condoms is the only known way to prevent sexual transmission of HIV for women. Both male and female condoms were freely available to participants throughout the trial.

3.2.2 Randomization

At the Africa Centre screening commenced in March 2006 and enrolment commenced a month later (Figure 3-4). From April 2006 to February 2008, eligible participants who provided informed consent were randomized in a 1:1:1 schedule to receive pre-filled vaginal applicators containing 0.5% PRO2000 gel, 2% PRO2000 gel or placebo gel. Evaluation of 2% PRO2000 gel was discontinued due to futility in February 2008 following recommendations by the DSMB and Trial Steering Committee. Women randomized to 2% PRO2000 gel were discontinued from gel use but encouraged to continue to attend the quarterly clinical visits until their scheduled end of follow up. The experiences of women discontinued from 2% PRO2000 gel at the Africa Centre have been described elsewhere (Gafos, 2011). From February 2008 to the end of enrolment in August 2008, eligible participants who provided informed consent were randomized in a 1:1 schedule to receive 0.5% PRO2000 gel or placebo gel. Women were follow-up for a total of 52 weeks therefore follow up was completed in August 2009.

Figure 3-4: Timelines of MDP 301



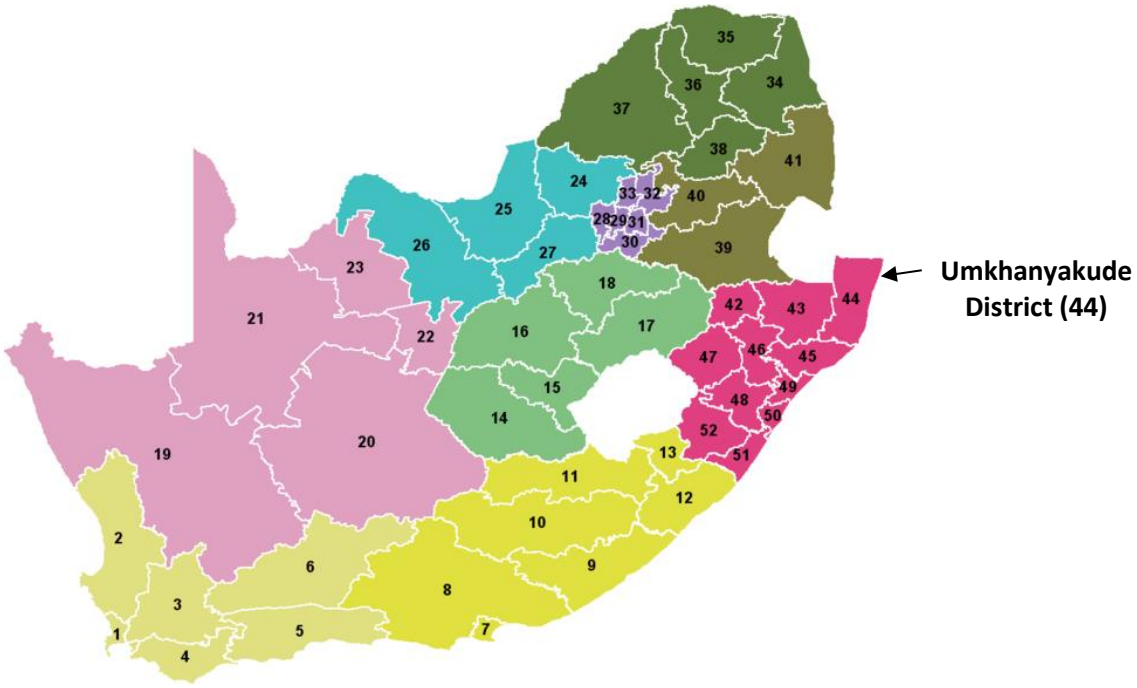
3.2.3 Social science component

The MDP 301 clinical trial protocol included integrated social science components designed to investigate individual, social and cultural issues that could affect the acceptability of a vaginal microbicide gel. Social science methodologies were also used to enhance the accuracy with which gel adherence was measured and to identify barriers to adherence (Pool, 2010a, Pool, 2010b).

3.3 Study population and recruitment

The Africa Centre is in the Umkhanyakude District of the KwaZulu-Natal Province of South Africa (Figure 3-5).

Figure 3-5: Map of South Africa showing the 9 provinces and 52 districts



**Provinces (districts): Western Cape (1-6); Eastern Cape (7-13); Free State (14-18); Northern Cape (19-23); North West (24-27); Gauteng (28-33); Limpopo (34-38); Mpumalanga (39-41); KwaZulu-Natal (42-52).*

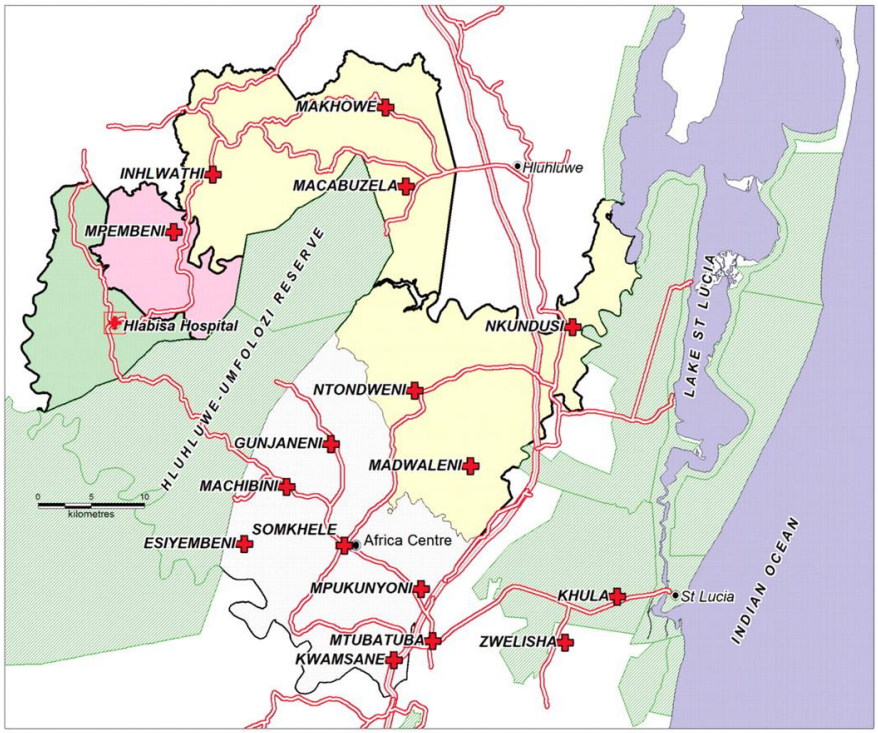
The Africa Centre is located in a rural area called Somkhele (Figure 3-6). The MDP pharmacy, specimen management facilities, data centre and management team were all based at the Africa Centre. MDP study procedures were conducted at dedicated research clinics established in 3 of 16 Department of Health primary health care clinics in the Hlabisa health sub-district of Umkhanyakude (Figure 3-6). Recruitment activities were conducted at the MDP clinics and in the surrounding municipality areas of Hlabisa and Mtubatuba.

The three MDP clinics were located at:

1. ***Mtubatuba***: Mtubatuba is a small urban trading town and shopping hub. The clinic predominantly services rural populations that live outside of Mtubatuba town.
2. ***KwaMsane***: KwaMsane is an urban and peri-urban residential area defined in South Africa as a township. The clinic services urban and peri-urban populations from the township as well as rural populations from neighbouring areas.
3. ***Madwaleni***: Madwaleni is a rural area under traditional authority. The clinic services the local rural population.

Figure 3-6: Map of Hlabisa health sub-district

(Showing the Africa Centre and the 16 primary health care clinics of Hlabisa including the 3 MDP clinics at Mtubatuba, KwaMsane and Madwaleni)

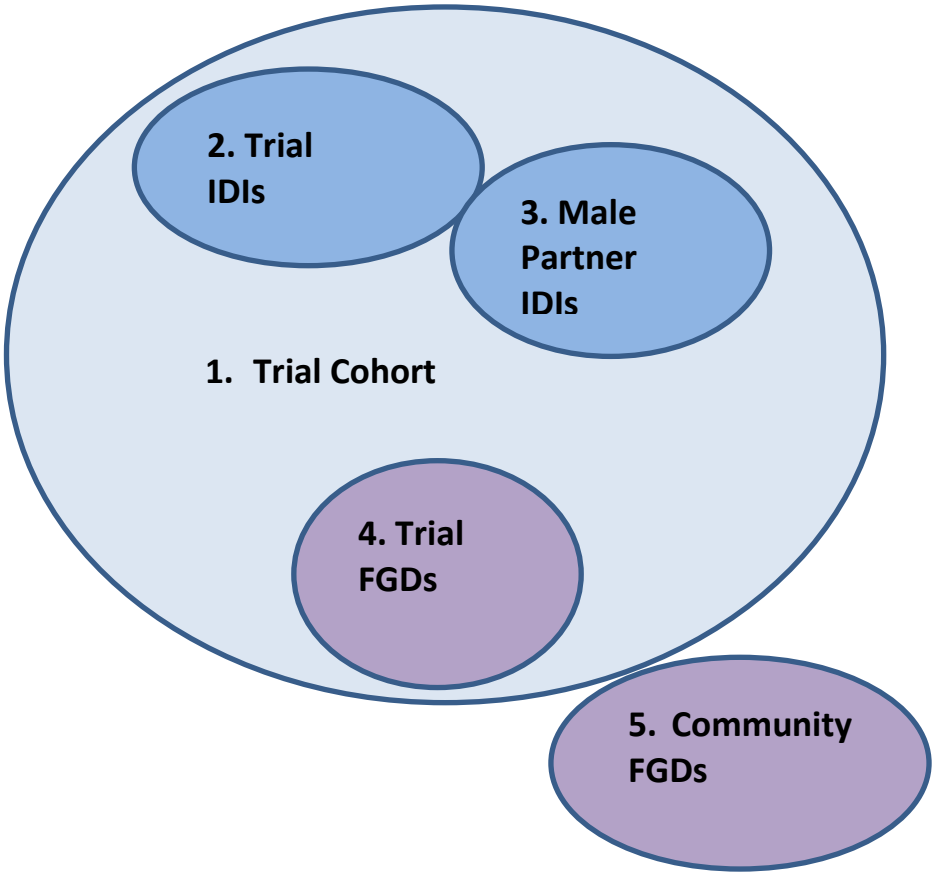


Recruitment activities took place regularly in the Hlabisa and Mtubatuba municipality's at all primary health care clinics, community meetings, on local radio stations, and during Africa Centre MDP sponsored community events such as roadshows, public health awareness days, football tournaments and fun runs. The talks were supported by a variety of multi-media resources developed by the Africa Centre MDP team including posters, songs, plays and interactive participant learning activities. During recruitment staff discussed HIV, the need for additional HIV prevention options, microbicides and the aims of the MDP 301 clinical trial. The eligibility criteria for trial participation were explained and other ways to get involved with the

study were described. Women and men interested in learning more about the MDP 301 trial were advised to visit one of the three MDP clinics.

The MDP study population can be sub-divided into 5 study groups, as depicted in Figure 3-7 and described below:

Figure 3-7: MDP 301 study groups



** IDIs = in-depth interviews; FGDs = focus group discussions*

All study procedures were conducted in Zulu. In KwaZulu-Natal, Zulu is the most frequently spoken of the 11 official languages in South Africa. Approximately 98% of people in Umkhanyakude speak Zulu as their first language (Lehohl, 2003). In Zulu, the language is referred to as *isiZulu* and the people are referred to as *amaZulu*. In this thesis I use the English grammatical version of the word 'Zulu' to refer to the language and the people.

3.3.1 Trial cohort

During community presentations, women from the general community were invited to visit the MDP clinics to find out more about the trial and their eligibility to participate. The eligibility of volunteers was assessed at both ***initial screening visits*** and ***subsequent enrolment visits***. The screening eligibility assessment included providing informed consent, HIV counselling and

testing, pregnancy testing and a series of questionnaires. The enrolment eligibility assessment included informed consent, pregnancy testing, general and genital examinations and a series of questionnaires.

The inclusion criteria were as follows:

- Women aged 18 years of age and above at enrolment
- Likely to be sexually active at entry and during follow-up
- Willing to undergo HIV counselling and testing at screening and at approximately 12 weekly intervals, and additionally if required
- HIV negative at screening according to the local HIV testing algorithm
- Willing to receive HIV test result before randomisation
- Willing to use study gel as instructed
- Willing to undergo regular speculum examinations and genital infection screens
- Willing to have regular urine pregnancy tests
- Willing to receive health education about condoms
- Willing and able to give informed consent

The exclusion criteria were as follows:

- Unable or unwilling to provide a reliable method of contact for the research team
- Likely to move permanently out of the area within the year
- Likely to have sex more than 14 times a week on a regular basis during the course of follow-up
- Using spermicides regularly
- Pregnant or within 6 weeks postpartum at enrolment
- Had grade 3 clinical or laboratory abnormalities which were considered by the clinician or the Trial Management Group to make enrolment inadvisable
- Required referral for assessment of a clinically suspicious cervical lesion
- Had treatment to the cervix, or to the womb through the cervix, within 30 days of enrolment
- Known latex allergy
- Participating, or having participated within 30 days of enrolment, in a clinical trial of an unlicensed product, microbicide, barrier method or any other intervention likely to impact on the outcome of this trial
- Considered unlikely to be able to comply with the protocol

A total of 1,775 women volunteered to be screened for the study at the Africa Centre. Eligible volunteers were invited to return for enrolment within 6 weeks of screening. If they returned beyond the 6 week window they were re-screened. As a result 21 women were screened twice and 1 was screened 3 times. Only data collected during the last screening visit was used for analysis.

Table 3-1: Trial cohort – number of women screened and enrolled

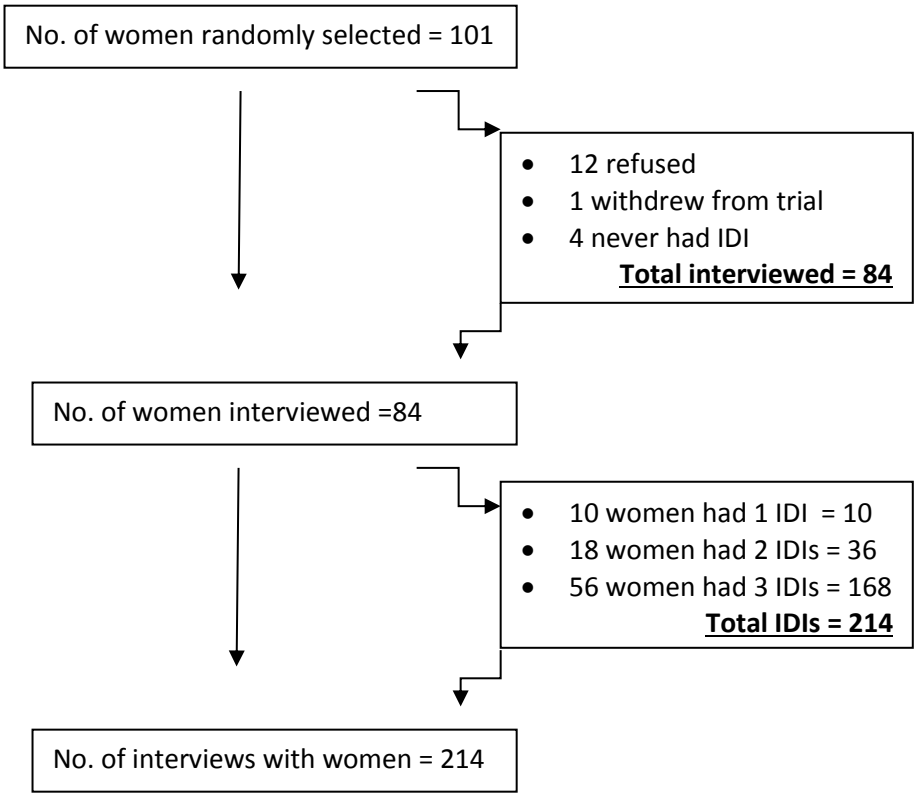
Eligibility	Number (% of screened)	Reasons not enrolled
Screened	1775 (100%)	
Ineligible	531 (30%)	
HIV+		495
Pregnant		20
Not sexually active in last 4 weeks		8
Clinical abnormalities		6
Choose not to consent		1
Wanted to conceive in next year		1
Eligible	1244 (70%)	
Never returned for enrolment		67
Enrolled	1177 (66%)	

Table 3-1 shows the number of women screened and enrolled at the Africa Centre and the reasons for ineligibility. Of the 1775 women screened, 531 (30%) were ineligible; 519 at screening and 12 at enrolment. The main reason for ineligibility was HIV status with 495 of those screened being HIV positive (28% of all those who were screened). A total of 41 screened women were pregnant, but pregnancy was the primary reason for ineligibility for only 20 women as the other 21 were also HIV positive. An additional 16 women were ineligible for other reasons as listed in Table 3-1. Of the 1,244 eligible volunteers, 67 (5% of eligible women) chose not to return for enrolment. These volunteers were not contacted after screening as the decision not to return for enrolment was viewed as a latent refusal to consent. In total 1,177 women consented to participate and were randomised into the trial.

3.3.2 Trial in-depth interviews (IDIs)

Each clinical trial site randomly assigned a subset of women enrolled in the trial to participate in up to 3 IDIs at 4, 24 and 52 weeks after enrolment. The target sample size for this subset was at least 100 women per centre. This number was small enough to enable the collection of detailed qualitative data and yet large enough to generate results that could be generalised to the whole trial population.

Table 3-2: Trial IDIs



At the Africa Centre, 101 women in the trial cohort were randomly selected at enrolment to participate in IDIs. In total 84 women were interviewed during 214 interviews at various time (Table 3-2 and Table 3-3 column 1). We were not able to complete all 3 IDIs with each participant, mainly due to participants not having the time to attend the IDI at certain week schedules. In total, 79 women were interviewed at week 4, 72 at week 24 and 63 at week 52. The IDIs with these women are referred to as "Trial IDIs". Refusal to participate or withdrawal from the social science cohort did not affect a participant's enrolment in the trial.

3.3.3 Male partner in-depth interviews (IDIs)

Each clinical trial site was expected to interview male partners of the women in the Trial IDI subset in up to 3 IDIs corresponding to the participants' week 4, 24 and 52 visits. The target was to enrol approximately a fifth of the trial IDI women's male partners, so the sample size was at least 20 male partners per centre. Again this number was considered reasonable based on the experiences of interviewing male partners in the feasibility study and sufficient to collect detailed qualitative data that would be generalizable to the whole trial population.

All trial participants who had an in-depth interview were asked to invite their male partners to participate in in-depth interviews. However, at the Africa Centre we were unable to interview

our target of 20 male partners of trial participants who were randomly selected for IDIs. Consequently on an ad hoc basis we asked trial participants who were not selected for IDIs to invite their male partners for in-depth interviews. In total, 17 male partners of trial participants were interviewed during 21 interviews, as 15 men had 1 IDI and 2 men had 3 IDIs (Table 3-3, column 2). Out of the 17 male partners interviewed, 7 were partners of women who had an IDI and 10 were partners of women in the trial who did not.

3.3.4 Trial focus group discussions (FGDs)

Each clinical trial site was expected to conduct 1 FGD per month for the duration of the trial. These were supposed to switch between trial participant's one month and community members the next month. This monthly schedule was agreed in order to ensure that we identified any changing perspectives and identified any emerging concerns. At the Africa Centre we conducted the trial for 41 months and therefore the target was for approximately 20 trial FGDs and 20 community FGDs.

Trial participants not randomly selected for IDIs were invited to participate in FGDs on an ad hoc basis. The FGDs were advertised at the MDP clinics. Participants were not able to participate in more than one FGD during the trial. During the course of the trial 17 FGDs were conducted with trial participants but 7 of these were to address specific topics not related to this PhD. Therefore 10 trial FGDs with 77 women enrolled in the trial are included in this PhD Table 3-3, column 3). Refusal to participate in an FGD did not affect a participant's enrolment in the trial.

3.3.5 Community focus group discussions (FGDs)

FGDs were also advertised at community events and conducted with women and men who were resident in the trial catchment area but not enrolled in the trial. During the course of the trial 20 FGDs were conducted with community members but 3 of these were to address specific topics not related to this PhD. Therefore 17 community FGDs are included in this PhD with 54 women from the community participating in 6 FGDs and 103 men from the community participating in 11 FGDs (Table 3-3, columns 4 and 5 respectively). There are more male than female FGDs because we prioritised FGDs with men from the community over FGDs with women from the community due to the challenges we faced in terms of interviewing male partners of trial participants.

Table 3-3: Number of IDIs and FGDs

	Col 1	Col 2	Col 3	Col 4	Col 5
	Trial IDIs	**Male partner IDIs**	**Trial FGDs**	**Community FGDs (female)**	**Community FGDs (male)**
No of people	84	17	77	54	103
No of IDIs	214	21	-	-	-
No. of FGDs	-	-	10	6	11
Mean age (range)	34 (19-64)	42 (26-68)	36 (19-65)	37 (21-63)	30 (17-67)
Employed	19%	46%	21%	13%	5%
Married	24%	31%	27%	41%	14%

NB: Additional key informant or topic specific interviews and FGDs were conducted for this thesis and these will be described as necessary in the empirical chapters.

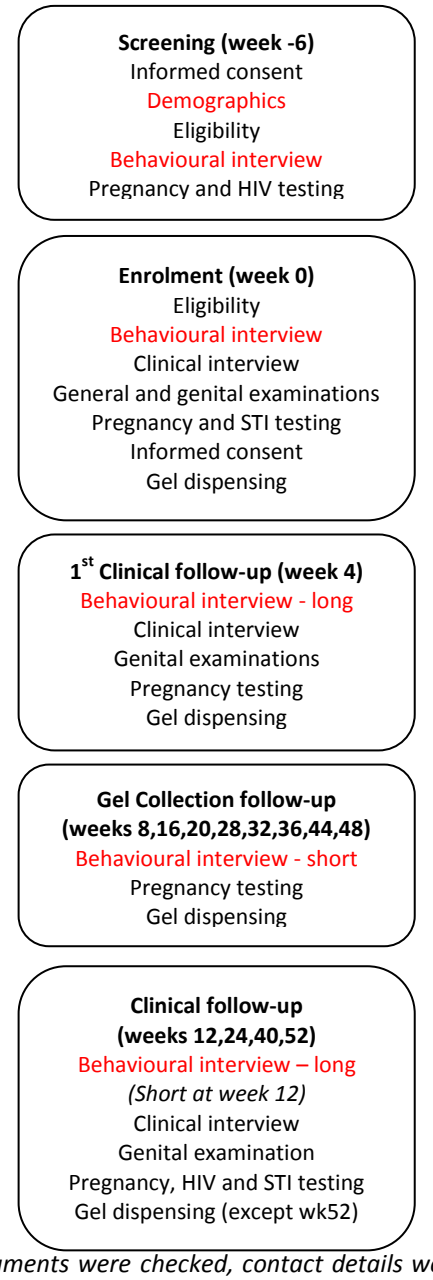
3.4 Data collection

Each clinic team included a clinical manager (who was a senior nurse), 3 or 4 nurses, 4 or 5 counsellors and a clinic assistant. Research doctors, pharmacists, laboratory technicians and social science research assistants were based at the Africa Centre and rotated around the three clinics as necessary. All staff received extensive training prior to being delegated protocol-related responsibilities. Data were collected in line with GCP data collection and quality control procedures.

3.4.1 Trial cohort

For the trial cohort, there were 15 scheduled clinic visits which included screening, enrolment, then visits every 4 weeks for 52 weeks (Figure 3-8). The follow-up visits were divided into long clinical visits (weeks 4, 12, 24, 40, 52) or short gel collection visits (weeks 8, 16, 20, 28, 32, 36, 44, 48). The long clinical visits included clinical examinations as well as the completion of questionnaires. The short gel collection visits did not include clinical examinations but included health related questions which could trigger a clinical assessment as necessary. Participants were able to visit the clinic at other times as necessary.

Figure 3-8: Summary of visit schedule for MDP 301 trial participants



**At every study visit, identity documents were checked, contact details were confirmed, condoms were dispensed and reimbursement provided.*

3.4.2 Trial IDIs

The in-depth interviews followed a semi-structured interview guide but were open and in-depth, allowing the interviewer to probe and follow-up on issues as they arose. The discussion topics were developed in advance of the trial following a review of the relevant literature and findings from formative research conducted during the earlier feasibility and pilot studies. During the course of the trial, adjustments were made to the interview guide, primarily to add new topics in order to better investigate inconsistencies in the trial data.

The IDI guide (appendix E) for the trial IDIs included the following topics:

- Gel acceptability,
- Gel and condom use,
- Partnership types,
- Partner involvement in gel use,
- Vaginal practices including washing and insertion,
- Sexual practices including sex during menstruation and anal sex,
- Comprehension and acceptability of study procedures, and
- Risk perception.

3.4.3 Male partner IDIs

The male interview guides were similar to the female trial interview guides and included the following topics:

- Gel acceptability,
- Gel and condom use,
- Partner involvement in gel use,
- Sexual practices including sex during menstruation and anal sex,
- Comprehension and acceptability of study procedures, and
- Risk perception.

The female and male interviews were usually conducted at one of the MDP clinics, although they could also be conducted at the participant's or male partner's home or place of work if the interviewee preferred.

3.4.4 Trial FGDs

Trial participant FGDs were stratified by age and clinic of enrolment. The FGDs included an average of 9 women ranging from 5 to 20 women per group. The trial FGD guides for trial participants included the same topics as the trial IDI guides.

Unlike IDIs where women were asked about socio-cultural norms as well as their personal experiences in relation to each of the discussion topics, in FGDs women were only asked about socio-cultural norms, not about their own personal experiences. However, women were not prevented from sharing personal experiences if they wanted to in the group setting.

3.4.5 Community FGDs

Community FGDs were stratified by sex, age and area of residence. The FGDs included an average of 9 women or men ranging from 5 to 13 per group. The community FGD guide included the following topics:

- MDP trial,
- Theoretical gel acceptability,
- Partner involvement in gel use,
- Vaginal practices including washing and insertion, and
- Sexual practices including sex during menstruation and anal sex.

The trial participant and community FGDs were held in locations convenient to the group, which could be at the Africa Centre, local church hall, meeting room or village hall.

3.4.6 Quantitative data

Quantitative data were collected on questionnaires at every long and short clinic visit. Structured questionnaires used in clinical trials are most frequently referred to as case report forms (CRF). The CRFs were completed by trained counsellors. In this thesis, I mainly use the demographic data collected at screening and the behavioural data collected at each visit – which are highlighted in red in Figure 3-8.

In chapter 5 I also use the results of rapid pregnancy and HIV tests which were conducted by counsellors. I also use the results of STI tests, the samples for which were collected by nurses and tested in laboratories in Durban. The quantitative data that I use in this thesis will be described in more detail in chapter 4 section 4.5.

3.5 Data management

Data transfer, entry, filing and archiving were compliant with the international conference on harmonisation of GCP requirements. In this section I explain the management of only the qualitative and quantitative data used for this thesis.

3.5.1 Qualitative data

IDIs and FGDs

IDIs and FGDs were conducted by trained social science research assistants. Research assistants also served as note takers in FGDs, documenting additional verbal and non-verbal cues of interest. IDIs and FGDs were recorded on two digital recorders. Both recordings were downloaded onto a secure password protected computer drive within 24 hours of the IDI or

FGD and then deleted from the recorders. The primary recording was transcribed in Zulu into a Word document. If the primary recording failed or was inaudible, the secondary recording was used for the transcription. The Zulu transcription was translated into English, in the same Word document. The final transcript used for coding generally included text in both Zulu and English. Interviewer and note taker observations were also included in the transcripts.

All qualitative transcripts were imported into NVivo 2.0 software for coding. For the purpose of the trial, a predefined coding framework was used that had been developed at the same time as the IDI and FGD guides, again following a review of the relevant literature and findings from formative research. The qualitative data analysis that I used for this thesis will be described in chapter 4 section 4.4.

Quality Control

Approximately 5% of the IDI and FGD transcripts were re-transcribed, re-translated or back-translated for quality control. Approximately another 5% of transcripts were compared to the audio recordings. The coded transcriptions were quality controlled every month to ensure that coding was consistent across transcripts and coders. On a monthly basis, the site NVivo project was sent to the international social science coordination team in London and Barcelona. Coding was assessed for consistency within and across sites and quality control issues were fed back to the site social science team. Coding categories were discussed and refined between the site teams and social science coordinators both via email and during workshops specifically designed for this purpose.

3.5.2 Quantitative data

Case Report Form (CRFs)

All quantitative data collected at the clinics were recorded on carbonised pre-printed CRFs. The original CRFs were transferred to the Africa Centre data centre, under full chain of custody procedures. Carbonised copies of the CRFs were filed in the clinic participant file.

Data entry

The CRFs were double-data entered in the MDP 301 database using an Access application with a SQL Server database. After data capturing, the CRFs were filed on the data centre participant file. The database automatically checked for consistency between the 2 blinded entries and detected missing data and data inconsistencies in defined fields. Data quality reports were printed from the database and investigated regularly. A copy of the database was transferred to the MRC clinical trials unit in London fortnightly.

Monitoring

Independent data monitors visited the Africa Centre at least every two months. They checked a random sample of participant files against the database to ensure data accuracy. They also reviewed source documents that were not data captured including informed consent documentation.

3.6 Ethical issues

The trial was conducted in accordance with the international conference on harmonisation of GCP guidelines, the national guidelines for good practice in the conduct of clinical trials in human participants in South Africa and the South African National Health Bill.

3.6.1 Informed consent

The purpose of the MDP 301 trial was explained to volunteers in Zulu by trained counsellors using trial participant information sheets (PIS) supported by the use of audio recordings of frequently asked questions and pictorial flip charts. Open ended questioning techniques were used throughout the information sessions and at various follow-up visits to assess volunteers understanding of the key trial messages. At screening, eligible women were encouraged to carefully consider the implications of participation and discuss the trial with their partners or other family members prior to enrolling.

Prior to screening, after receiving HIV counselling and again prior to enrolment, volunteers were asked to complete written informed consent forms (appendix D). Volunteers were required to indicate their consent by a signature or, if illiterate, a thumbprint. Illiterate women were required to have an independent witness of their choice present during the consent to enrol in the trial.

Before enrolment, formal assessments of understanding were administered to ensure volunteers fully understood the following three critical messages:

a) the gel might not protect women from HIV;
b) condoms do prevent HIV; and
c) women had to stop using gel if they became pregnant.

Information about the IDIs or FGDs was explained to women and men using one of the following participant information sheets (PIS) (appendix C):

- Female participant IDI PIS ("Trial IDIs")
- Male partner IDI PIS ("Male partner IDIs")
- Female participant FGD PIS ("Trial FGD")
- Community member (female and male) FGD PIS ("Community FGD")

All IDI and FGD participants were required to indicate their consent by a signature or, if illiterate, a thumbprint on dedicated informed consent forms. A single consent form was sufficient for multiple interviews. Verbal consent to record the IDIs was confirmed on the tape recordings.

All volunteers were reimbursed for travel costs and inconvenience. The reimbursement policy was agreed in line with the requirements of the South African Medicines Control Council (MCC) and in consultation with the community advisory board. Trial participants were reimbursed at a rate of R150 (South African Rand - equivalent to approximately £10) per scheduled clinic visit. Additionally trial participants and community members were reimbursed at a rate of R80 (equivalent to approximately £5) per IDI or FGD. Trial participants who attended the clinic for a study visit and an IDI or FGD on the same day were reimbursed at the single rate of R150.

3.6.2 Standard of care and prevention

The standard of care package provided to enrolled participants and their partners, as well as volunteers screened out due to ineligibility, was defined in negotiation with local stakeholders and care providers.

At screening, ineligible volunteers who were found to be HIV-positive were offered a structured counselling programme that included 3 counselling sessions, HIV counselling and testing for male partners, and couple counselling. HIV-positive women were offered CD4 tests and referred to local services for HIV treatment and care. Ineligible volunteers who were found to be pregnant were provided with pregnancy options counselling and referred to local services, which included prevention of mother-to-child transmission services for HIV-positive women.

The Africa Centre MDP standard of care package for enrolled participants included:

- Safer sex counselling,
- Unlimited supply of free male and female condoms,
- HIV counselling and testing - also available for participant's male partners and children,
- Seroconverters were provided with CD4 tests and referred to local services for HIV treatment and care,
- Treatment for curable STIs - also available for participant's male partners,
- Cervical cancer screening – with referral for further investigation or treatment,
- Family planning services which included oral and injectable contraceptives, as well as referrals for sterilization,
- Pregnancy options counselling which included referrals to antenatal services which included prevention of mother-to-child transmission services, emergency contraceptives and referrals to pregnancy termination services,
- HIV and STI post exposure prophylaxes were available for victims of sexual assault, and
- Referral systems were in place for cases of physical or sexual assault.

3.6.3 Ethical review

At the Africa Centre the trial was reviewed by the institutional Community Advisory Board (CAB) which comprised representatives from each traditional authority area and municipality area around the Africa Centre. The CAB members were already trained on the principals of research and good clinical practice, and I provided additional training on clinical trial designs, ethical considerations of HIV prevention research, and microbicides. The CAB reviewed the initial study design and data collection tools; consulted on the standard of care, standard of prevention, reimbursement, and dissemination policies; and commented on trial progress and summary findings at monthly meetings.

The MDP 301 trial protocol was reviewed and approved for implementation at the Africa Centre by the University of KwaZulu-Natal Biomedical Ethics Committee (T111/05) (appendix A) and the South African MCC (N2/19/8/2) (appendix B). The protocol was also reviewed by two ethics committees in the UK and the FDA in the USA where the PRO2000 and placebo gels were manufactured. The trial was registered with the International Standard Randomised Controlled Trial Registry (ISRCTN64716212) and the South African Clinical Trial Registry (DOH-27-0207-1669). From trial commencement at the first multinational MDP clinical trial research site in October 2005 to completion in the last MDP clinical trial research site in September 2009, 4 protocol revisions were submitted. Only 2 protocol versions were implemented at the Africa Centre (version 1.2 and version 2.0).

3.7 My role in MDP 301

As principal investigator of the MDP 301 clinical trial at the Africa Centre, I was responsible for managing the budget (£3.6m), work plans, sub-studies, scientific output and public relations. I sat on the MDP's Trial Management Group, Trial Steering Committee, Programme Liaison Group, Programme Management Board and Programme Management Board Executive. I was responsible for managing regulatory and ethics body requirements, developing and implementing standard operating procedures (SOPs), and developing and delivering comprehensive staff training and development programmes. I managed the heads of each of the 9 disciplinary groups which included clinical, counselling, laboratory, pharmacy, data, recruitment, retention, social science and community liaison. In turn the disciplinary heads managed staff in the respective disciplinary groups. During the course of the trial I was responsible for the employment of approximately 120 staff for the MDP studies. The staff complement peaked in mid-2008 at around 65 employees. At monthly team meetings, I gave updates on trial progress against targets and feedback on data quality. In addition, I provided scientific training to senior staff in statistics, STATA, End Note and NVivo.

My role as principal investigator provided me with an in-depth understanding of the data I use in this thesis. Of most relevance for this thesis, I was responsible for developing qualitative and quantitative data collection SOPs, training staff in the collection and management of data, quality controlling data, coding and analysing qualitative and quantitative data during the course of the trial. In the next chapter I describe the methods I used to analyse the MDP 301 data – both qualitative and quantitative - for this PhD thesis.

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4 Methods

Summary

In the last chapter I described how the qualitative and quantitative data that underpin my thesis were collected as part of the MDP 301 clinical trial at the Africa Centre. In this chapter I present the methods I use in this thesis. I start by describing the cultural perspective underlying my analysis of the data. Next I describe and reflect on the mixed methods design of the MDP 301 trial and the mixed methods approach I have adopted for my data analysis. To conclude, I describe how I prepared and analysed the qualitative and quantitative data.

4.1 Cultural perspective

In this thesis I consider whether microbicides are compatible with socio-cultural norms regarding sexuality and sexual health in rural KwaZulu-Natal, South Africa. I examine the cultural norms attached to intravaginal cleansing, intravaginal insertion, love medicines, and sexual communication for women in KwaZulu-Natal. I then explore the ways in which these norms could influence, and be influenced by, the introduction of vaginal microbicides.

4.1.1 Defining 'Culture'

I use the term 'culture' in the anthropological sense of the word. Over the centuries, anthropologists have wrestled with philosophers in order to distinguish culture from civilisation, battled with sociologists and psychologists to keep the definition sufficiently broad, and social anthropologists and cultural anthropologists have struggled to keep the definition sufficiently focused and sharp (Barnard, 2000, Just, 2000, Keesing, 1998). Nonetheless, 'culture' is still considered an ambiguous term with no standard definition. In fact in his book on 'Redefining Culture', Baldwin lists over 300 different definitions of culture (2006). The term remains highly contested by anthropologists. Indeed Kuper argues that we should "avoid the hyper-referential word altogether, and... talk more precisely of knowledge, or belief, or art, or technology, or tradition, or even of ideology" (Kuper, 2000). However, attempts to replace the word 'culture' have largely failed due to the lack of other terms to describe not only knowledge or belief, but the other less tangible commonalities of established norms and values that underlie our understanding of social realities.

4.1.2 Socio-cultural anthropology

The discipline of *social anthropology* originated in the United Kingdom and was primarily concerned with the study of social structures, social groups, individual identities and roles within social groups, and relationships between individuals and among social groups. The

discipline of *cultural anthropology* originated in North America and some parts of continental Europe and was primarily concerned with the meanings, norms, beliefs, values and symbols that are assigned to everyday aspects of life. Socio-cultural anthropology was born out of the recognition that the two approaches are "complementary ways of looking at the same reality, each illuminating a different side" (Keesing, 1998;23). Together, they enable an interpretative view of cultural norms within the historical and political context of social relations (Barnard, 2000). I am using this socio-cultural anthropological understanding of culture in order to evaluate cultural norms as they apply to women's sexuality and sexual health. As such I am interested in how the *social* position of women and the *cultural* meanings regarding intravaginal cleansing, intravaginal insertion, love medicines and sexual communication interact in the production of *socio-cultural* norms.

4.1.3 Conceptual inventory

Given the complex and contested nature of what makes up culture, I will define below the aspects of culture that are of relevance to this thesis, in other words the conceptual inventory of how I am applying 'culture' (Keesing, 1998).

Culture as learned

Keesing and Strathern describe culture as an 'ideational system', a construct within the realm of ideas: "Culture in this sense comprises systems of shared ideas, systems of concepts and rules and meanings that underlie and are expressed in the ways that humans live. Culture, so defined, refers to what humans *learn*, not what they do and make" (1998;16). In this sense, cultural norms are learned representations of what is 'normal' behaviour and reflect socially agreed-upon expectations that guide behaviour. Normative behaviour is guarded by formal and informal rules and expectations that serve as social sanctions and taboos. However, while cultural norms inform and influence expectations regarding sexual practices they do not determine them (Bock, 1964). Individuals accept, reject and amend cultural norms in their everyday lives. While a belief, value or action may conform to, or reject, the cultural norm, it is often measured in relation to the norm or norms that are dominant at that time. On this basis, I am interested in exploring the continuum from what is considered 'normal' and sanctioned to what is considered 'abnormal' and taboo in terms of intravaginal cleansing, intravaginal insertion, love medicines and sexual communication for women in KwaZulu-Natal.

We learn culture as a combination of both external and internal norms (Weaver, 1994). External norms are explicitly learnt and form part of a person's conscious and objective knowledge such as the things people see, hear and touch. Internal norms are implicitly learnt and form part of a person's unconscious and subjective knowledge such as beliefs, values,

thought patterns and myths. Practices relating to sexuality and sexual health are informed by both external and internal norms. Women observe and are instructed in ways to manage their sexuality and sexual health, at the same time as learning the meanings attached to these practices. As such, I examine sexuality and sexual health as culturally constructed concepts imbued with meanings that are passed from generation to generation through explicit and implicit learning (Vance, 1984, Foucault, 1978, Butler, 1990).

Culture as multiple norms

In this thesis, I am interested in Zulu cultural norms. Therefore the parameters of the cultural norms that I am interested in, are defined by ethnicity. However, cultural norms are historically situated and as such change over time. Fox describes cultural norms as being continuous, in that they are informed by the past and they inform the future (2008). The ethnically bound historical memory can result in the co-existence of both traditional and modern norms at a single point in time (Rapport, 2000). Similarly, cultural norms are not bounded and nonporous. Zulu culture emerged from Bantu-speaking cultures and continues to be influenced and changed by surrounding cultures as well as changing ideas of South African identity more broadly. As such, external influences can produce multiple versions of a single cultural norm at any one time and place. Neither are cultural norms learned, applied, or informed equally by all individuals in a given time and space. As such cultural norms are *distributed* unevenly across a society. Keesing and Strathern argue that "such a distributive view of culture can take into account the different perspectives on a way of life of women and men, young and old, specialists and nonspecialists" (1998;19). Consequently while there may be a number of shared norms, many will be specific to our sex, for example, and may change over our life course. As Rapport states, culture is not "a coherent, bounded and stable system of shared beliefs and actions" (2000;95). As such, I am interested in understanding the different versions of cultural norms that relate to intravaginal cleansing, intravaginal insertion, love medicines and sexual communication for women in KwaZulu-Natal.

Cultural meanings of new technology

In addition to exploring established cultural norms, I am also interested in the ways in which microbicides, as a novel technology, are ascribed with social and cultural meaning. As van Oost explains: "an essential element in embedding a new technology in society is the development of conceptual frameworks for giving meaning to the new phenomenon" (1998;182). I explore the extent to which existing socio-cultural meanings relating to sexuality and sexual health are used to give meaning to microbicides as a new sexual health technologies. This is important to

understand as microbicides will be positioned at the intersection of sexuality and sexual health which are imbued with layers of socio-cultural meaning and expectations.

In summary, I view cultural norms as learned, normative but not deterministic, historically situated, dynamic and unevenly distributed. I view cultural norms as both continuous in terms of reifying existing meanings, and adaptive in terms of ascribing meaning to new technologies. The cultural meanings attached to the sexuality and sexual health of women, are at all times informed by the social meanings attached to being a women. I use the concept of culture to understand how women give meaning to microbicides in a rural part of KwaZulu-Natal.

4.2 Mixed methods

In this thesis I adopted a mixed methods research approach that combines multiple qualitative methods with quantitative methods. In all four of the empirical chapters I use qualitative data collected during both in-depth interviews and focus group discussions. In two of the four empirical chapters I use quantitative as well as qualitative data. Below I introduce the literature on mixed methods research before describing the mixed methods design used for the MDP 301 trial and discussing the mixed methods approach I adopted for the data analysis and interpretation in my thesis.

4.2.1 Mixed methods research

The debate regarding the different epistemological and ontological assumptions underpinning qualitative and quantitative research is extensive (Brannen, 2005). However, mixed methods research is often described as offering a third methodological approach that allows researchers to draw on both qualitative and quantitative data simultaneously (Tashakkori, 2003). Mixed methods research has gained recognition over the last few decades with the publication of two principle text books (Creswell, 2007, Tashakkori, 2003), the establishment of a dedicated conference on mixed methods, a dedicated Journal of Mixed Methods Research and an increasing number of peer-reviewed journal articles.

There is on-going debate about whether mixed methods research is a research methodology, research design, or research data collection method. I use the broadest possible description, as proposed by Creswell and Planto Clark, of mixed methods as a “research design with philosophical assumptions… as well as quantitative and qualitative methods” (2007;5).

There are various definitions of mixed methods research, although this definition by Johnson, Onwuegbuzie and Turner is now widely accepted:

> "Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative approaches (e.g. use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the purpose of breadth and depth of understanding and corroboration" (Johnson, 2007;123).

The above definition allows for a variety of mixed methods research designs which can determine the level of interaction between qualitative and quantitative methods, whether they are used sequentially or consecutively, the ways in which the different methods are combined, and the priority given to the different epistemological methodologies (Creswell, 2011).

4.2.2 Mixed methods: MDP 301 trial

In MDP we used an integrated mixed methods approach. MDP used mixed methods research in a number of ways. Before the trial we collected qualitative and quantitative data during the feasibility and pilot studies and used the findings to develop the trial protocol and data collection tools. A qualitative component was embedded within the trial with subsamples of the cohort selected to participate in either IDs or FGDs. Also during the trial, qualitative data were collected in parallel during FGDs with community members not enrolled in the trial. These various applications of mixed methods research have been well described in the literature (Caracelli, 1997, Creswell, 2003, Creswell, 2007, Creswell, 2011).

MDP 301 was the first microbicide clinical trial to use qualitative and quantitative data in a combined sequential (before the trial), embedded (subsample of cohort) and parallel (community) mixed methods design. However, mixed method designs have been successfully used in a number of other microbicide clinical trials as well as other randomised control trials (Brady, 2009, Rogers, 2003, Flemming, 2008, Victor, 2004, MTN-003, 2011). The main rational for the mixed methods approach in MDP 301 was to assess and improve the accuracy of self-reported sexual behaviour data (Pool, 2010a). The collection of accurate sexual behaviour data was particularly important in the trial in order to monitor gel adherence. It is inherently difficult to collect accurate data on sensitive topics using self-reporting methods. In MDP we used a 'triangulation' approach which entailed comparing self-reported sexual behaviour data from multiple quantitative and qualitative sources in an effort to move "toward developing a more composite and holistic picture, while at the same time accepting a necessary degree of

uncertainty in the result" (Pool, 2010a). The MDP 301 triangulation design and results of the triangulation process have been published elsewhere (Pool, 2010a, Pool, 2010b).

In addition, the collection of more in-depth data on vaginal and anal sex, gel and condom use, and intravaginal cleansing and insertion were also considered critical to the interpretation of the trial result. In the COL 1492 trial of N-9 microbicide gel, the results differed across different study populations in the various clinical trial sites but these differences could not be sufficiently explained (Van Damme, 2002). Consequently, a thorough qualitative understanding of sexual behaviour and practices in the research centres was considered of particular importance to help explain any such differences in results if they were observed in MDP 301.

A major advantage of the MDP 301 mixed methods design for qualitative researchers was the ability to link qualitative data to a much larger quantitative dataset. The main advantage for quantitative researchers was the ability to get a more in-depth understanding from the qualitative dataset. As such, this model allowed the use of interpretive, rich and emergent analytic approaches within the constraints of a randomised control trial. However, the challenges included ensuring the internal validity of the quantitative data, ensuring that the qualitative data were sufficiently rich, and balancing the often opposing paradigms. The strengths and weaknesses of using the mixed methods approach for the MDP 301 trial have been discussed elsewhere (Pool, 2008).

4.2.3 Mixed methods: PhD

For my thesis, I built on the mixed methods research approach by utilising the qualitative and quantitative data in the MDP 301 trial. In order to address my overarching research question about the compatibility of microbicides with socio-cultural norms regarding sexuality and sexual health, I defined 3 main research objectives. Based on the data collected in MDP 301 I identified the most appropriate data sources to address each objective.

My first objective was to explore socio-cultural norms regarding intravaginal cleansing, intravaginal insertion, love medicines, and sexual communication. For this purpose I used data collected during FGDs with women and men from the local community. In the FGDs women and men were asked to describe these socio-cultural norms and explain the reason for them.

My second objective was to assess the extent to which these norms would be considered compatible with microbicides. Again I used data collected during FGDs with women and men from the local community. In some cases, women and men were asked to consider how, hypothetically, these socio-cultural norms could impact on the use of microbicides.

My third objective was to investigate the impact of these norms on the actual use of microbicides. For this I used data collected during IDIs and FGDs with trial participants and, in some cases, IDIs with their male partners. In the IDIs and FGDs women, and sometimes men, were asked to describe the socio-cultural norms and explain the reason for them. I could therefore compare trial participant's perceptions of socio-cultural norms with those of women and men from the community. In some cases they were also asked to consider how, hypothetically, these socio-cultural norms could impact on the use of microbicides for other women and men in the community. Again this allowed me to compare trial participant's perceptions of the impact of socio-cultural norms on microbicides with those of women and men from the community. Finally, in the IDIs and FGDs women were asked to describe their experiences of using the microbicide and, in some cases, how the socio-cultural norms had impacted on their own use of microbicides in the trial. This allowed me to explore the actual use of microbicides within the context of these socio-cultural norms.

To some extent, addressing these three objectives would have been sufficient to answer my PhD question regarding the compatibility of microbicides with socio-cultural norms of sexuality and sexual health. However, qualitative data alone would not have been able to quantify the impact of cultural norms on actual practice. Through MDP 301 I had access to quantitative data on intravaginal cleansing and communication about the gel among trial participants. This provided an opportunity to quantify these practices. While the qualitative data provided a rich and in-depth understanding of these phenomena, the quantitative data measured the behaviour and, as such, provided insight into the impact of socio-cultural norms on the acceptability of microbicides.

Although quantitative data were available on intravaginal insertion, the practice was discouraged during the trial and the prevalence was so low that a description of the quantitative data was not informative. We did not collect quantitative data on love medicines as the topic only emerged as being of interest in the IDIs and FGDs during the trial; it had not emerged during the prior feasibility or pilot studies.

Therefore in order to best address my research objectives I use IDI and FGD qualitative data in all four empirical chapters and qualitative and quantitative data in two of the empirical chapters (5 and 8). As described in section 4.2.2, qualitative and quantitative data were collected concurrently during the trial. I analysed the qualitative IDI and FGD data, and quantitative data, separately but concurrently. I compared and contrasted the similarities and differences between the datasets. This allowed me to take a second look at the IDI data after considering the FGD findings and vice versa, as well as taking a second look at the quantitative

data after considering the qualitative findings and vice versa. Finally I merged or mixed the results during the interpretation stage.

4.3 A critical reflection on my methodology

The advantages and limitations of IDIs, FGDs and CRFs as data collection methods have been extensively described (Collumbien, 2012). In this section I critically reflect on using a mixed method approach to address the specific aims of my PhD.

4.3.1 Mixed qualitative methods

As described above in section 4.2.3, I use mixed qualitative methods (IDIs and FGDs) in all 4 empirical chapters. It is well established that IDIs are the most appropriate way of collecting data on individual behaviour while FGDs are the most appropriate way of collecting data on cultural norms and attitudes (Ulin, 2002). This was equally true in the MDP study.

Although we collected data on cultural norms in both IDIs and FGDs, the FGDs were the most valuable source of information about cultural norms as the group environment moderated exaggerated or extreme opinions. The FGDs facilitated the collection of respondent-independent data in terms of people reporting on other people's behaviour, within an informal and relaxed group environment (Ulin, 2002). However, the FGDs were also a valuable source of indirect self-reported data in terms of respondents talking about themselves in the guise of talking about what 'others' do (Pool, 2010a). The FGDs, even more so than IDIs, tapped into cultural norms of using storytelling to describe social realities and experiences (Seal, 2007).

The IDIs, on the other hand, were the most valuable source of information on individual behaviour. The in-depth interviews provided more time and space for the interviewer to build rapport with participants and probe about their individual sexual behaviour and experiences, in a private environment. Although IDIs are subject to social desirability bias, evidence suggests that they can be a more proficient way of eliciting sensitive information than using CRFs (Pool, 2010b).

The mix of IDI and FGD qualitative methods was the most appropriate for exploring both socio-cultural norms and behaviour relating to intravaginal cleansing, intravaginal insertion, love medicines and sexual communication. Collumbien has argued that the use of data from *both* IDIs and FGDs is particularly useful for research on sexuality and sexual health (2012;57). By using mixed qualitative methods I was able to compare and contrast opinions regarding socio-cultural norms between women enrolled in the trial and women not enrolled in the trial, and between women and men, as well as compare and contrast opinions regarding cultural norms and individual experience and practice. While this did not overcome the challenge of women

providing socially desirable responses in reporting sensitive sexual behaviours, it did allow me to couch individual practice within the broader context of socio-cultural expectations.

Both the in-depth interviews and focus group discussions were semi-structured. This meant that each topic was systematically discussed in every IDI and FGD. It also meant that the IDIs and FGDs were formatted so that less sensitive topics were discussed first and more sensitive topics could be addressed later when rapport with the interviewer had been established. Semi-structured formats do not allow for completely free flowing conversation in the way that unstructured formats do. However, the fact that the IDIs and FGDs were only semi and not completely structured did facilitate flexibility in exploring the complex and dynamic nature of the specific phenomena of interest.

In addition, the regularity with which IDIs and FGDs were conducted allowed emerging topics and themes to be fed back into subsequent discussions. The topic of love medicines is a prime example. Love medicine was not a pre-defined topic but emerged during discussions about vaginal practices. The longitudinal nature of the IDIs and the frequency of the FGDs, allowed me to have the topic probed in subsequent discussions in addition to arranging an interview and FGD with key informants, as described in chapter 7. A limitation of FGD data is that it can be difficult to verify. However in this study, the frequency with which FGDs were conducted meant that dominant themes could be verified in terms of the regularity with which they emerged, and these themes could be fed back into group discussions thereby providing an opportunity to test assumptions about specific cultural norms.

Another frequently reported limitation of IDIs and FGDs is that the cost and capacity needs generally only make it feasible to interview a sub-sample of the trial cohort. Although this was true of the MDP trial, the number of IDIs and FGDs that were conducted was far beyond the number required to address the questions of interest or the number needed to reach data saturation (Kielmann, 2011).

To explore the compatibility of microbicides within the context of socio-cultural norms of sexuality and sexual health, I also need to understand how women perceived the gel. As such I was particularly interested in understanding the experience of using a microbicide from the perspective of women using microbicides in clinical trials (Montgomery, 2010b). IDIs with women using microbicides provide the best way to achieve this and enabled me to adopt an *emic* approach to women's acceptability of microbicides. In this context I use the term emic to refer to the local concepts and factors that are meaningful to the women using the gel, i.e. the 'insider view'. I use this in contrast to an ***etic perspective*** based on what is meaningful to the researcher and the scientific community, i.e. the 'outsider view'. This approach has been used

in other areas of public health research and is a useful way of applying anthropological methods to applied questions (Boyce, 1988, Clark, 2001, Collumbien, 2004). By approaching acceptability from an ***emic perspective***, I was able to take account of cultural concepts and factors that are meaningful to women in relation to how they incorporate microbicides into their sexual lives. The counterbalance to this advantage of IDIs is that the interpretations are very specific to the local community and are unlikely to be generalizable beyond the area. Nonetheless, the results can highlight issues for exploration in other settings.

4.3.2 Mixed qualitative and quantitative methods

As described above in section 4.2.3, I use mixed qualitative and quantitative methods (IDIs, FGDs, and CRFs) in 2 empirical chapters. Unlike the qualitative data, the quantitative data provide generalizable and representative findings from the entire cohort. The use of CRFs facilitated the systematic collection of data on intravaginal cleansing and communication about the gel. The CRFs were administered in the clinic by counsellors who the participants were familiar with due to their monthly visits. As such there was more rapport between the interviewer and interviewee than is typical in the collection of questionnaire data. The flip side of this relationship between the interviewer and interviewee is that the data were collected by staff members who counselled women about safer sex and gel adherence. CRFs are already prone to desirability bias, and the role of the CRF interviewer as a counsellor could have exacerbated this even further as respondents may have provided answers that avoided embarrassment and projected their actions in a favourable light (Fisher, 1993).

By CRFs being administered, instead of self-completed, interviewers were able to probe and ask follow-up questions, and clarify inconsistencies in responses in a single CRF (internal consistency) and across other CRFs (external consistency). The vast majority of the questions were closed as CRFs are not an efficient way to collect responses to open questions. As such the main disadvantage of collecting data on practices that are socially constructed using CRFs was that they were inflexible and required a fixed answer (Pool, 2010a). Although the CRF questions were informed by qualitative research in the feasibility and pilot studies, they still reflected a predominantly etic approach. The main advantage of the quantitative data, was that it helped to put the qualitative findings into perspective and to a lesser extent, helped to validate the qualitative findings on the impact of socio-cultural norms on gel use (Collumbien, 2012).

Although qualitative data are often considered by quantitative researchers more prone to being influenced by the researcher's personal biases and idiosyncrasies (Hammersley, 1997), the inclusion/exclusion of variables, categorisations of variables and interpretations of

quantitative data are also prone to manipulation. As such I was conscious of considering my own cultural frames of reference and biases throughout the analyses.

The main benefit of the mixed qualitative and quantitative methods research approach is that collectively the various data types provide a more complete understanding of the phenomena of interest than either data type could do individually. I combine the various data methods "to capture different dimensions of the same phenomenon" (Ulin, 2002;16). The qualitative data elucidate the reasons behind specific phenomena, and the quantitative data quantify the phenomena within the trial cohort. The use of mixed methods allowed me to compare textual and numerical findings for convergence and divergence (Morrow, 2008). Individually the qualitative or quantitative data would not be able to both characterise and situate the findings within the cultural context.

The major challenge of using multiple data methods is that it can be difficult to merge findings at the interpretation stage as each set of findings are addressing a single topic but from a different perspective. It can be equally challenging to explain divergent evidence from findings. I discuss the implications of these challenges in the empirical chapters.

4.3.3 Working with translated data

Both the qualitative and quantitative data were collected in Zulu. I am not proficient in Zulu and therefore analysed all of the data in English. There are multiple challenges to working with translated data. There are three issues that I want to reflect on here: 1) collecting data in Zulu; 2) translating language; and 3) translating meaning.

Collecting data in Zulu

I did not personally collect the qualitative or quantitative data. This is a limitation as I was not able to directly pursue leads and seek clarifications during interviews. However, there are substantial benefits in matching the characteristics of interviewer-interviewee, especially when discussing sensitive and culturally relative topics (Seidman, 2006). During the feasibility study I found that interviewees expressed a preference for interviewers to be the same sex, age and local to the area. The issue of being 'local' was related to linguistics. Although Zulu is the dominant language in KwaZulu-Natal, there are substantial differences between what is called 'deep Zulu' (*isiZulu esijulile*) used in the more rural areas and 'urban Zulu' (*isiZulu sasedolobheni*) used in the cities. The main difference is the extent to which urban Zulu incorporates words from other South African languages. However, the dialects are distinct enough so that people who are raised speaking urban Zulu would not understand certain words used in deep Zulu. I therefore placed great emphasis on the fact that all research

assistants and counsellors were Zulu and from the local area of Umkhanyakude. I also attempted to match the sex and age of the interviewer (research assistant or counsellor) with the respondent where possible. In terms of my PhD analysis, the benefits of matching interviewer and interviewee outweighed the limitations of not personally collecting the data.

Translating language

English to Zulu: The IDI and FGD guides and CRFs were translated from English to Zulu. A series of workshops were conducted to identify, and then test, the most appropriate Zulu words, especially for behaviour which could be considered culturally sensitive, such as intravaginal insertion. The Zulu words were tested during the feasibility and pilot studies. The agreed upon Zulu words were used consistently in both qualitative and quantitative data collection. In my analysis, this meant I was able to distinguish between standard terms used by the research staff and terms introduced by the respondents.

Zulu to English: As described in chapter 3 section 3.5.1, the IDIs and FGDs were transcribed in Zulu and translated into English with extensive quality control checks. Although I am not proficient in Zulu, by retaining the Zulu text in the transcript I was able to list the Zulu words used to describe particular phenomena of interest during my analysis. I was then able to rank these words in order of use frequency and consider the implications of using one word as opposed to another in the text.

Translating meaning

Although I could feel confident in the quality of the translated language, extrapolating meaning around cultural norms from translated data is a particular challenge. As Keesing and Strathern argue, the analysis of well translated text is not a "shortcut to cultural understanding" (1998;33). It is necessary to explore the meanings attached to words in order to capture the nuance of local understandings (Collumbien, 2012). Keesing and Strathern have argued that cultural differences are often exaggerated when anthropologists try to interpret conventional ways of talking about experiences too literally (1998). In an effort to grasp the meanings expressed in the textual data and not exaggerate interpretation through literal translation, I conducted regular workshops with the social science team up until I left the area in December 2009.

As an example, I conducted a workshop to discuss the nuances of the language used in relation to sex and intravaginal insertions that I present in chapter 6. I identified the key Zulu words and phrases used in relation to sex, and then during the workshop interrogated the vernacular

meanings and the contexts within which the words were used. Five social science staff members who were born in the area and were primary Zulu speakers attended the workshop. The interrogation of the vernacular terms included listing all words used in the study to describe sexual experiences, discussing alternative uses of each word in sentences not related to sex, listing alternative words that could have been used to describe the same experiences but were not, cross referencing words used to describe intravaginal insertion and gel usage, and, finally, categorising the words into associated experiences. These workshops enabled me to thoroughly challenge my interpretations of not only the Zulu words but also the meanings attached to them.

Although my command of Zulu is very limited, my knowledge of South African society is substantial. From 1996 to 1999 I studied African history and politics for my Bachelor's degree focusing on South Africa. I conducted secondary research in Johannesburg for my bachelors' thesis in 1999. From 2001 to 2003 I studied reproductive and sexual health research for my Master's degree again focusing specifically on South Africa. I conducted primary research in Umkhanyakude for 4 months in 2003 which included conducting 15 semi-structured interviews with the assistance of a Zulu speaking interpreter. During the course of the MDP trial, I lived in the rural community of Umkhanyakude for almost 6 years (2004 to 2009) and participated in all aspects of social life. This long term and in-depth relationship with South Africa provided great insight into the social and cultural dynamics of the area. This familiarity with Zulu society greatly enhanced my understanding of cultural meanings and my interpretation of the data.

However there were also advantages to my analysis of me not being Zulu. As a foreigner my 'outsider' status meant that I observed cultural norms without being consumed by them (Just, 2000). One example was in the interpretation of the qualitative data in chapter 6. I presented preliminary interpretations to the social science team suggesting that the use of microbicide gel enhanced women's sexual pleasure. The social science team all acknowledged that women talked about sexual pleasure yet they rejected my interpretation of the data. They stated that sexual pleasure in Zulu society was the prerogative of the male and therefore when women were talking about 'pleasure' they were referring to their partner's pleasure or their pleasure in sexually satisfying their partner. I subsequently presented textual data from approximately 20 interviews which I believed reflected examples of women talking about sexual pleasure for their male partner, themselves, or both themselves and their partners. Two research assistants and I independently coded the text against these 3 categories i.e. male pleasure, female pleasure, pleasure for both. On comparison we had 100% concordance with the categories and the social science team agreed that women were describing their own sexual pleasure despite

this being against cultural convention. In this way, my interpretation of the data was not influenced or constrained by dominant cultural norms.

4.4 Qualitative data

4.4.1 Qualitative data preparation

During the trial I quality controlled English translations of IDIs and FGDs for completeness and comprehension, as well as re-translations of Zulu transcriptions for accuracy. I coded the qualitative data and trained the social science coordinator (Misiwe Mzimela) and social science supervisor (Sizakele Sukazi) to code data in NVivo 2. For MDP 301 the data were coded according to broad and fine coding categories that were predefined in trial guidelines, while also allowing for open coding for emerging themes and concepts (Boyatzis, 1998). During coding each qualitative coder completed coding memos in NVivo to document observations relating to the quality of the interview or FGD, as well as the quality of the transcription and translation. In addition, each qualitative coder was assigned a specific topic to fine code, for example gel acceptability, condom use or vaginal practices. During fine coding each qualitative coder completed a topic journal in NVivo to document points of interest such as emerging themes, consistent and inconsistent opinions, or the use of particular words or descriptions.

I met with the other 2 qualitative coders (Misiwe and Sizakele) on a monthly basis to discuss coding. This included operational issues such as the quality of the interviews and staff training needs, as well as analytical issues such as coding newly emerging themes and consistency of coding across coders. We reviewed each other's coding memos and discussed the topic journals. Both Misiwe and Sizakele coded the data in Zulu and English, whereas I coded the data in English. We discussed the nuances in the translations from Zulu to English during the monthly meetings.

During the trial, I continually analysed and interpreted the qualitative data and discussed interpretations of the findings at the monthly meetings. Alternative interpretations or understandings of the data were discussed in great detail. Findings from sub-analyses were presented to MDP staff as well as the broader Africa Centre staff, MDP trial participants, and Africa Centre CAB members to gauge the credibility and trustworthiness of themes and interpretations. If there were any surprises or disagreements about interpretations, I revisited the data and reviewed the coding and interpretation. Where necessary, I sought clarity from the interviewee, key informants, or discussed the findings in FGDs or workshops until we reached agreement that the interpretations were accurate.

For the purpose of my PhD thesis I returned to the original transcripts and applied a separate coding schema specific to my PhD. I did this because during the trial the coding process focused exclusively on the main trial outcome measures, such as gel adherence. By returning to the original transcripts I was able to approach the data purely from the perspective of my PhD research question. Despite coding the data separately for my PhD, the iterative process of data coding and interpretation during the trial greatly enhanced my understanding of the data, as well as ensuring that data were collected to a very high standard of quality.

4.4.2 Qualitative data analysis

There are now a number of guides to qualitative data analysis that focus on applied field research and draw on experiences from HIV-prevention research (Ulin, 2002, Kielmann, 2011, Collumbien, 2012). I use a thematic analysis approach adapted from Ulin et al (2002;135-166) and use the Kielmann and Collumbien guides to illustrate the analysis process I used.

Terminology

During my analysis I applied operational categories to the data to help me group the data and explore it systematically. I distinguished between what I categorised as topics, themes and concepts. Below I describe how I defined these operational categories during my analysis:

Topics: these are the overarching phenomena of interest. For this analysis the topics are gel acceptability, intravaginal cleansing, intravaginal insertion, love medicines, and sexual communication.

Themes: these emerged from each topic and explained certain aspects of the topic. For example within the topic of intravaginal insertion, themes included knowledge of insertion, products used for insertion, reasons for insertion etc. In many cases there could be multiple layers of themes, for example within reasons for insertion there were sub-themes of hot, tight and dry sex.

Concepts: these emanated from topics or themes but I distinguished them from themes or sub-themes. In the main a concept would be relevant across topics or themes. For example, in the intravaginal insertion analysis, 'sexual pleasure' emerged as a concept that was applied to gel acceptability and intravaginal insertion (topics), as well as reasons for insertion and experiences of gel use (themes). I handled concepts in the same way as I handled themes during the analysis, which I explain below.

Process of analysis

I coded the IDIs and FGDs for the trial from May 2006 to December 2009. I first conducted analysis specifically for my PhD in late 2008 and completed the last analysis in May 2012. The coding process has been iterative and pragmatic due to 1) the duration over which I have been immersed in the data, 2) the large quantity of qualitative data included in this analysis, and 3) the fact that I am exploring 5 distinct yet overlapping topics. I describe the topic specific analysis in the relevant empirical chapters. However, below I describe the basic principles of reading, coding, displaying, reducing and interpreting that I applied to each analysis (Ulin, 2002).

Reading: This is often referred to as familiarisation or immersion. By reading through each transcript in NVivo I immersed myself in the data. I also read both the coding memos and topic journals. While reading the IDI transcripts I created what I called a case history spread sheet. I prepared an Excel spread sheet with a row per individual woman interviewed. I used the spread sheet to make notes for my own reference, to both help my recall of the textual data as well as aid my own thought process. I could add, hide, delete, copy, paste and sort columns as necessary as my thinking progressed. I found it easier to collate and reference my notes about individual women on a spread sheet than in an NVivo journal. Given the vast number of interviews included in this analysis, this process allowed me to make notes on the context of women's lives and retain individual stories of the women across different analyses.

Coding: My first coding approach was deductive as I coded predefined 'topics' that were noted as relevant in the existing literature (Kielmann, 2011). I read through each transcript and broad coded all text relating to each topic. I dealt with one topic at a time, eventually broad coding all data relating to gel acceptability, intravaginal cleansing, intravaginal insertion, love medicines, and sexual communication. During this first stage of coding, I noted emerging themes. My second coding approach was inductive as I developed codes on the basis of the textual data. I conducted a coding sort for each topic thereby collating all text relating to the topic in a single file (Ulin, 2002;138). I organised the themes and sub-themes that I had identified so far and assigned tentative codes. As I read through the topic I fine coded the data with the codes I had identified, and noted possible new codes, the potential to merge codes, and evidence that challenged existing codes. I usually interspersed broad and fine coding, for example I would broad and fine code all IDIs from Mtubatuba clinic before moving onto the IDIs from KwaMsane clinic. If subsequent coding resulted in changes to the coding scheme, I revisited the previously coded transcripts to look again at the data and if necessary revise the codes. I constructed the coding schemes for IDIs and FGDs separately so as not to superimpose

themes from one data collection source onto another data collection source. However I did compare and contrast themes across the two data sources and adjust the coding scheme for each when appropriate. As such the coding scheme continuously evolved (Ulin, 2002;147). By allowing the themes to emerge from the data and conducting the broad and fine coding intermittently, I allowed the data to 'speak' to me, as Kielmann et al recommend, rather than pre-defining coding for sub-themes (2011;65). This process of data-driven coding is based on grounded theory methods (Glaser, 1967).

While coding I noted issues that could affect data credibility or impact on the weight given to certain opinions. For example, I noted if a theme emerged in response to discussions introduced by the interviewer or emerged spontaneously, when questions were leading or loaded, whether responses were based on first or second hand accounts, and whether an individual had contradictory opinions (Ulin, 2002;158). In FGDs I also particularly noted which participants were unresponsive, which participants were very vocal, and when opinions of the group were influenced or swayed by particular individuals.

Displaying: Ulin describes displaying data as "laying out or taking an inventory of what you know related to a theme" in order to "turn your attention to capturing the variation, or richness, of each theme, separating qualitative and quantitative aspects and noting differences between individuals or among subgroups" (Ulin, 2002;156). As such, I looked at each theme individually and mapped patterns in the textual data. I started by looking at the frequency distribution of thematic codes and ranked opinions from the majority to the minority perspectives, thereby giving weight to the dominant opinions but retaining the marginal opinions. This reduces the risk in qualitative analysis of using data selectively to support interpretation (Collumbien, 2012;73). I proceeded by mapping out the richness and variation in each sub-theme, for example, by differentiating between discussions that were lively versus stagnant, descriptions that were detailed versus general, and opinions that were emotive versus dispassionate. I identified patterns in the data and subsequently dissected these patterns, for example, by comparing and contrasting opinions of younger to older respondents, females to males, rural to urban residents, and trial participants to community members. In addition I looked for consistent or contradictory opinions of individuals within interviews or across multiple interviews, as well as exploring factors that influenced consistent or contradictory options between individuals such as traditional or modern perspectives. I regularly tested and challenged the emerging patterns, often using the search options in NVivo for this purpose. I consistently considered the credibility of the data when assigning priority to differing opinions. Displaying the data and looking for patterns facilitated a process of constant comparison within a single theme across transcripts (Kielmann, 2011;65). This allowed me to

crystalize the thematic coding scheme and start interpreting the data. Again, this is a familiar technique in grounded theory (Glaser, 1967).

Interpreting: At the stage of interpretation, I continuously returned to the main research question that I posed for this PhD: Are microbicides compatible with socio-cultural norms regarding sexuality and sexual health in rural KwaZulu-Natal, South Africa? I attempted to identify and explain the core meanings of each topic in relation to their relevance for microbicides. During the trial, I was able to check the credibility and trustworthiness of my PhD interpretations with the MDP team, participants and CAB. From January 2010 onwards, when I relocated to London, I presented my interpretations to Misiwe Mzimela (the social science coordinator and co-investigator) and Hlengiwe Ndlovu (the clinic coordinator and co-investigator) during regular emails and Skype calls. I met both Misiwe and Hlengiwe in person in 2012 and discussed my interpretations in their entirety. I also had feedback on written material from Sizakele Sukazi. In addition, I discussed my interpretations with two anthropologists who had worked in KwaZulu-Natal on love medicines and/or vaginal practices, Annete Wickström (Wickström, 2010, Wickström, 2008a) and Fiona Scorgie (Scorgie, 2009, Scorgie, 2011, Scorgie, 2010, Scorgie, 2002). I was able to compare and contrast my interpretations with their own and discuss similarities and differences. These review processes ensured I felt confident about the credibility and trustworthiness of my interpretations.

In the main I present my interpretations in the thesis by theme and sub-theme. I usually present the sub-themes in a weighted fashion, presenting the most frequently reported themes first and the least reported last. I note when a comment is atypical or contradictory. I use exemplary and representative quotes to illustrate specific themes, norms and shared perspectives (Ulin, 2002;182-4). I also use provocative quotes to highlight more marginal or extreme perspectives. I source all quotes documenting whether they were recorded in an IDI or FGD, by a woman or a man, and, where available, report the age of the respondent. Throughout the thesis I have tracked my use of quotes to ensure that a good distribution of IDI and FGDs participant's voices are included.

4.4.3 Analytical considerations

There are two analytical considerations of note that I discuss below, these are the issue of data saturation in qualitative analysis and the use of software for qualitative data analysis. In section 4.3.3 I have already discussed the challenges of working with translated data.

Data Saturation

In MDP 301 trial participants were selected for in-depth interviews randomly in order to be able to interview a representative sample of the trial cohort and make inferences about the whole trial cohort. For my PhD, I did not necessarily need a random sample or data that would be generalizable. In trying to understand the socio-cultural norms relating to sexuality and sexual health, I wanted to be able to capture the breadth and variations in perspectives. As such, I could have stopped analysis when I had reached data saturation. Ulin describes data saturation as being reached when "no new or relevant data seem to emerge regarding a category under study, the category is well developed in terms of its properties and dimensions demonstrating variation, and the relationships among categories are well established and validate new data" (2002;22). Indeed, I completed the analysis and interpretation of data on intravaginal insertion (chapter 6) before the end of data collection but after data saturation had been achieved. These findings were published in support of my PhD (Gafos, 2010). Although I did not extend the analysis for the thesis I did review the data that was subsequently collected to ensure the findings were not contradictory. However, given that I had access to such a vast quantity of qualitative data, except for chapter 6, I decided to continue analysis beyond the point of data saturation. I felt that the sheer volume of the qualitative data, the fact that it was collected in IDIs as well as FGDs, and the consistency with which themes recurred, helped to maximise the rigour of my interpretation (Collumbien, 2012, Kielmann, 2011). The inclusion of all IDIs and FGDs increased the strength of my interpretation but did not decrease the depth or breath with which I explored the topics.

Qualitative data analysis software

During this analysis I used NVivo version 2.0 and later version 8.0. NVivo is a very useful data management tool but does not have analysis functions (Collumbien, 2012;72). The advantages of using NVivo for data management have been well documented (see Di Gregorio for a case study of MDP) (2008;196-210). These include the ability to manage data, manage ideas, query data, graphically model data, and report from the data (Bazeley, 2007). However, there have been methodological concerns raised about the use of software in qualitative analysis, for example that it might distance the researcher from their data (Kelle, 1995, Ulin, 2002). However, for my PhD analysis, I utilised NVivo as a data management tool while remaining immersed in the data. I specifically benefited from the ability to file and code large quantities of qualitative data, link data to journals, look at data longitudinally across interviews or inter-relationally across couples, sort data by individual or group attributes, and search textual data systematically by codes, matrices or text words.

4.5 Quantitative data

I use quantitative data in two chapters: chapter 5 on intravaginal cleansing and chapter 8 on sexual communication. In both chapters I conduct univariate and multivariate analyses. I describe the dependent variables used for these analyses in the relevant empirical chapters. In this section I describe the independent demographic, socio-economic, sexual behaviour and trial related variables used in these analyses.

4.5.1 Demographic and socio-economic variables

At screening individual demographic, household demographic and household socio-economic data were collected by counsellors on CRFs. The demographic CRF is attached at appendix F. I use the following variables in my analyses:

Individual demographics (Table 4-1):

- Age
- Education
- Employment
- Religion

In categorising religion, I was particularly interested in the impact of the Shembe religion in the analyses as Shembe promotes traditionalist Zulu values and beliefs, such as polygamy, the role of the ancestors and the use of faith healing (Hexham, 1996).

Table 4-1: Individual demographic variables

Variable	CRF question (s)	CRF responses	Analytical categories
Age	Date of visit Date of birth	[Dates (or age if date of birth unknown)]	• 18 to 24 • 25 to 34 • 35 to 44 • 45 or older
Education	What is the highest level of education you gained?	• None • Incomplete primary • Complete primary • Incomplete secondary • Complete secondary • Incomplete tertiary • Complete tertiary • Incomplete secondary with some vocational training	• Primary or lower • Any secondary • Any tertiary.
Employment	How would you define your employment status?	• Employed full-time • Employed part-time • Student • Work seeker • Unemployed • Housewife • Retired • Other (free text)	• Employed (part or full time) • Unemployed
Religion	What religion do you belong to?	• Christian (protestant) • Christian (catholic), • Christian (unspecified) • Traditional African • Seventh day Adventist • Born again Christian • Muslim • Hindu • Zionist • Shembe • Jehovah's Witness, • None • Other (free text)	• Christian • Zionist • Shembe • Other • No religion

Household demographics and socio-economics (Table 4-2):

- Head of household
- Household size
- Water source
- Fuel source
- Assets

Table 4-2: Household demographic and socio-economic variables

Variable	CRF question (s)	CRF responses	Analytical categories
Head of household	Who would you say is the head of your household?	• Self • Partner • Sibling • Child • Daughter/Son in law • Parent • Mother/Father in law • Other relative • Niece/Nephew • Other (free text)	• Self • Partner • Parent/parent-in-law • Other
Household size	How many people usually sleep in your household? How many rooms in your household are used for sleeping?	[List number]	Number of people per room used for sleeping • 4 people or more • 3 people per room • 2 people per room • 1 person per room
Water source	What is currently the most often used source of drinking water in your household?	[Free text]	• Inside house • Public tap • Community source • Free flowing
Fuel source	What is the main fuel you use for cooking?	[Free text]	• Electricity, • Gas • Paraffin, • Wood
Assets	Does your household have:	• Electricity • A radio • A television • A telephone • A refrigerator	Binary: yes/no
Assets	Does any member of you household own:	• A bicycle • Sheet or cattle	Binary: yes/no

We did not collect data on marital status or cohabitation with partners in the trial and therefore I use the head of household category primarily as a proxy indicator for women's relationship status. I assume that reporting a partner as a head of the household is a good proxy measure for co-habitation and reporting the self as a head of household is a good proxy measure for non-co-habitation. However, reports that the head of the household is a parent or another family member does not preclude co-habitation with a partner.

I manually coded the free text water and fuel source variables and categorised them sequentially from the most expensive to the least expensive sources (Martins, 2005).

4.5.2 Sexual behaviour variables

Sexual behaviour data were collected at every visit by counsellors on CRFs. The contents of the CRFs differed at screening, enrolment and during short (weeks 8, 12, 16, 20, 28, 32, 36, 44, 48) or long (weeks 4, 24, 40, 52) behavioural interviews. The Sexual Behaviour CRFs 1 (screening), 2 (enrolment) and 4 (long behavioural interviews) are attached at appendix F.

I use the following sexual behaviour variables in my analyses (Table 4-3):

- Age at first sex
- Contraceptive use (reported at enrolment)
- Multiple partners
- Sex during menstruation
- Clinical biomarkers

Table 4-3: Sexual behaviour variables

Variable	CRF question (s)	CRF responses	Analytical categories
Age at first sex (SB1 CRF)	How old were you the first time you had sexual intercourse?	• Less than 15 years • 15 to 19 years • 20 years of older • Never had sexual intercourse	• Less than 15 years • 15 to 19 years • 20 years of older
Contraceptive use (SB2 CRF)	Are you currently using any method of family planning? If yes, which of the following methods are you using? [Taken from the enrolment visit]	Yes or No • Pills • Diaphragm • Injectable Nur-Isterate • Injectable Depo-Provera • Injectable other • IUCD • Norplant implant • Sterilisation • Condom (male or female) • Natural/rhythm • Foam/jelly/spermicide • Traditional vaginal • Traditional oral • Traditional other • Other (free text)	• Oral pill • Injectable • Sterilised • No reliable form of contraceptive [NB: condom categorised as not a reliable method]
Multiple partners (SB4 CRFs)	How many different people have you had sex with in the last week?" (weeks 4, 24, 40 and 52) Did you have more than one sexual partner during the course of the trial? (week 52)	[List number] Yes or no	Binary: yes/no
Sex during menstruation (SB4 CRF)	In the last 4 weeks have you had sex whilst you were menstruating? (weeks 4, 24, 40 and 52)	Yes or no	Binary: yes/no
Clinical biomarkers	• Pregnancy (every visit) • HIV (weeks 12, 24, 40 and 52) • Syphilis (weeks 24 and 52) • Trichomonas Vaginalis (week 24) • Neisseria gonorrhoea (week 24) • chlamydia trachomatis (week 24)	Positive or negative	Binary: yes/no

At the long behavioural interviews, more detailed information was collected about each sex act in the last week, or if the woman had not had sex in the last week, then each sex act in the last four weeks. For each sex act women were asked a series of questions, including if they used a condom and if they used gel.

I created the following variables using this per sex act data (Table 4-4):

- Average sexual frequency in last week at week 4
- Sexual frequency in last week on average during the trial
- Condom use at week 4
- Condom use on average during the trial
- Gel use on average during the trial

Table 4-4: Sexual behaviour variables based on per sex act data

Variable	CRF question (s)	CRF responses	Analytical categories
Average sexual frequency in last week at week 4	• Describe each sex acts in the last week (week 4) [total number summed]	[List details of each act]	• 0 • 1-3 • 4-6 • 7-9 • 10 or more
Sexual frequency in last week on average during the trial	• Describe each sex acts in the last week (week 4, 24, 40, 52) [total number summed and divided by the number of long visits attended]	[List details of each act]	• 1-3 • 4-6 • 7-9 • 10 or more
Condom use at week 4	• Did you use a condom during this sex act? (week 4) (asked for every sex act listed in the last week/4 weeks) [total number summed and divided by the number of sex acts]	[Yes or no per sex act]	• Every sex act • Not every sex act (sometimes or never)
Condom use on average during the trial	• Did you use a condom during this sex act? (week 4, 24, 40, 52) (asked for every sex act listed in the last week/4 weeks) [total number summed and divided by the number of sex acts divided by number of long visits attended]	[[Yes or no per sex act]	• Always • Sometimes • Never
Gel use on average during the trial	• Did you use gel before this sex act? (week 4, 24, 40, 52) (asked for every sex act listed in the last week/4 weeks) [total number summed and divided by the number of sex acts divided by number of long visits attended]	[Yes or no per sex act]	• Every sex act • Not every sex act (sometimes or never)

4.5.3 Trial participant variables

In addition to data collected on CRFs, I included the following variables in relation to trial participation:

- ***Clinic of enrolment:*** I included a variable to indicate enrolment at KwaMsane, Mtubatuba, or Madwaleni clinics.
- ***Gel allocation****:* I included a variable to indicate randomisation to either PRO2000 0.5%. PRO2000 2%, or placebo gel. It is important to note that although women in the trial could have been using 0.5% PRO2000, 2% PRO2000 or a placebo gel, throughout the thesis I refer to all the gels used in the trial as 'microbicides' or simply as 'gels'.
- ***Previous participation*****:** I included a binary variable that defined if women had participated in the MDP feasibility or pilot studies prior to the trial.
- ***Area of residency****:* For the purpose of my PhD analysis, I collected additional data on the area of residency of each participant. The area of residency was categorized as urban, peri-urban or rural on the basis of the residential density of the traditional or municipal area (Tanser, 2008).

4.5.4 Quantitative data analysis

Data from each CRF were stored separately in the database. I extracted individual datasets from the Africa Centre MDP 301 database as text files and imported them initially into STATA 10.0 and later STATA 11.0 (STATA Corporation, College Station, Texas, USA). I personally conducted all quantitative data analysis presented in this thesis. The specific statistical methods used for each analysis will be presented in the relevant empirical chapters.

4.6 Conclusion

In this chapter I have explained how I explore microbicide acceptability from a cultural perspective and outlined the conceptual inventory of how I apply 'culture' in this thesis. I have laid out the mixed methods research approach as it applied to the MDP 301 trial and my PhD. All four empirical chapters are based on mixed qualitative methods and two of these four chapters are also based on mixed qualitative and quantitative methods. In the mixed qualitative methods chapters, I use IDI and FGD data to explore specific phenomena from different perspectives i.e. socio-cultural norms regarding intravaginal cleansing and individual intravaginal cleansing practices. The main advantage of this approach is that I can examine the multiplicity of socio-cultural norms and explore individual behaviour within this context. In the mixed qualitative and quantitative methods chapters, quantitative data are principally used to describe specific phenomena, i.e. intravaginal cleansing and communication about the gel.

Qualitative data are then used to elucidate the reasons behind specific phenomena, i.e. the reasons for intravaginal cleansing. The main advantage of this approach is that behaviours are both characterised and the rationale for that behaviour is explored. I use thematic coding for the qualitative analysis which allows me to explore the acceptability of microbicides from the emic perspective of women using this novel technology. I have critically reflected on the mixed methods research approach in this chapter and will expand on the advantages and limitations of these mixed methods approaches in the subsequent empirical chapters.

5 Intravaginal cleansing in KwaZulu-Natal

Summary

As described in chapter 0, there is evidence that microbicides need to remain *in situ* post-ejaculation to prevent HIV infection. Concerns regarding the compatibility of intravaginal cleansing and microbicides have been repeatedly raised over the years. However, there are substantial gaps in our knowledge about post-coital intravaginal cleansing practices among women using microbicides. In this chapter, I present results of a systematic review of the literature on intravaginal cleansing in Africa. Using the MDP 301 data I then explore intravaginal cleansing practices after sex in the Umkhanyakude District, consider socio-cultural norms regarding intravaginal cleansing and assess intravaginal cleansing among women in the clinical trial. This analysis is based on quantitative data collected during the trial as well as qualitative data collected during focus-group discussions and in-depth-interviews. The analyses aim to understand the individual and socio-cultural norms regarding intravaginal cleansing after sex in KwaZulu-Natal, in the context of microbicide gel use. By quantifying and qualifying intravaginal cleansing practices, I explore whether the need for microbicides to remain *in situ* after sex runs counter to local post-coital cleansing practices in a rural part of KwaZulu-Natal.

5.1 Literature review

5.1.1 Intravaginal cleansing

As demonstrated from the literature review in chapter 2, one of the gaps in our understanding of microbicide acceptability is in relation to the interface between vaginal practices and vaginal microbicides (Mantell, 2005). Vaginal practices include a broad range of different practices that women use to manage their health, hygiene and sexuality (Hull, 2011). Recently a WHO multi-country study on gender, sexuality and vaginal practices (GSVP) identified seven distinct classifications of vaginal practices (Hilber, 2007). The classifications are described in Table 5-1 which is reproduced from Hull et al (2011). For the purpose of this thesis, I focus exclusively on intravaginal cleansing (internal cleansing or washing inside the vagina) in this chapter and intravaginal insertion (pushing or placing something inside the vagina) in the next chapter.

I conducted a systematic review of literature pertaining to vaginal practices in Africa. At the point of search it was not possible to distinguish between different classifications of vaginal practices and therefore I manually excluded studies that did not relate to intravaginal cleansing or insertion.

Table 5-1: Classification of vaginal practices in the World Health Organization Gender, Sexuality and Vaginal Practices study

1. **External washing**: cleaning of the external area around the vagina and genitalia using a product or substance with or without water, normally using your hand. This excludes washing which occurs as part of general bodily hygiene. 2. **Intravaginal cleansing**: internal cleansing or washing inside the vagina includes wiping the internal genitalia with fingers and other substances (e.g., cotton, cloths, paper) for the purpose of removing fluids. It also includes douching, which is the pressurised shooting or pumping of water or solution (including douching gel) into the vagina. 3. **External application**: placing or rubbing various substances or products to the external genitalia—that is the labia, clitoris, vulva. 4**. Intravaginal insertion**: pushing or placing something inside the vagina (including powders, creams, herbs, tablets, sticks, stones, leaves, cotton, paper, tampons, tissue, etc.) regardless of the duration it is left inside. 5. **Oral ingestion**: ingesting (drinking, swallowing) substances perceived to affect the vagina and uterus. This includes the ingestion of substances/medicines to dry or lubricate the vagina. 6. **Vaginal streaming or smoking**: the ''steaming'' or ''smoking'' of the vagina, by sitting above a source of heat (fire, coals, hot rocks) on which water, herbs, or oils are placed to create steam or smoke. 7. **Anatomical modification**: (''cutting'' and ''pulling''), surgical procedures used for modifying the vagina, or restoration of the hymen; includes female genital circumcision, incision with insertion of substance into the lesion (scarification process, tattoos of the vulva or labia); excludes episiotomies or operations to repair a protruding uterus. In some countries, elongation or pulling of the labia minora is practiced from early childhood.

I identified all articles that present primary findings and are published in peer-reviewed journals. I restricted the review to studies in Africa at the point of search but included multi-country studies that included a single African country. The criteria used for the systematic literature review are explained in appendix G. The literature review was conducted in January 2012 in two stages: 1) Stage 1 (s1) search relates to articles identified during the systematic review of literature in PubMed, Web of Knowledge and POPLINE search engines; 2) Stage 2 (s2) search relates to articles that were found on review of the articles reviewed in stage 1.

The systemic literature review identified 76 articles on intravaginal practices relating to research in 21 Sub-Saharan African countries (Table 5-2). Of these, 72 articles addressed intravaginal cleansing and 51 addressed intravaginal insertion, 47 of which addressed both. In this section I present evidence from the systematic review of the literature on intravaginal cleansing in Africa. Table 5-2 presents the manuscripts included in the review, lists the country or countries where the study was conducted. The table notes if the paper reported specifically on intravaginal cleansing (indicated with an X) or if the report included intravaginal cleansing but reports of it did not clearly exclude other vaginal practices (indicated with an O) and lists the prevalence of intravaginal cleansing when reported in the manuscript.

Table 5-2: Systematic literature review of intravaginal cleansing in Africa

No	Reference	Country	IV Cleansing	IV Cleansing Prevalence
1	Allen 2010	Tanzania	X	75%
2	Allen 2007	Tanzania	X	36-53%
3	Baeten 2009	Kenya (FSW)	X	94%
4	Bagnol 2008	Mozambique	X	
5	Baisley 2009	Tanzania	X	65%
6	Banda 2007	Zambia	O	
7	Bayo 2002	Mali	X	18%
8	Behets 2008b	Madagascar (FSW)	X	
9	Behets 2008a	Madagascar (FSW)	X	88%
10	Beksinska 1999	South Africa	O	
11	Beksinska 2010	South Africa	X	Treatment 49%
12	Braunstein 2005	Brazil, Burkina Faso, Senegal, India, Kenya, South Africa, Thailand, USA, Zimbabwe	X	
13	Braunstein 2011	Rwanda	X	
14	Brown 1993	DRC	X	
15	Civic 1996	Zimbabwe	O	
16	Dallabetta 1995	Malawi	O	
17	Demba 2005	The Gambia	X	38%
18	Fonck 2001	Kenya (FSW)	X	72%
19	Gallo 2010	Kenya (FSW)	X	99%
20	Gausset 2001	Zambia	X	
21	Gresenguet 1997	CAR	X	21-35%
22	Guest 2007	South Africa	X	26%
23	Hassan 2007	Kenya (FSW)	X	87%
24	Hilber 2010a	META: Burkina Faso, Kenya, Ivory Coast, Malawi, South Africa, Tanzania, Uganda, USA, Zambia, Zimbabwe	X	
25	Hilber 2010b	WHO GSVP: Mozambique, South Africa, Indonesia, Thailand	X	
26	Hira 1990	Zambia	O	
27	Hull 2011	WHO GSVP: Mozambique, South Africa, Indonesia, Thailand	X	Mozambique=92%, South Africa=64%
28	Imade 2008	Nigeria (FSW)	X	50%
29	Imade 2005	Nigeria (FSW)	X	4-81%
30	La Ruche 1999	Ivory Coast	X	97%
31	Lees 2010	Tanzania	X	74-99%
32	Low 2010	Burkina Faso	X	8%
33	Low 2011	META: Kenya, Malawi, South Africa, Tanzania, Uganda, Zimbabwe	X	6-89%
34	Mayaud 2008	Burkina Faso	X	90%
35	Mbizvo 2004	Zimbabwe	X	51%
36	McClelland 2008	Kenya (FSW)	X	86%
37	McClelland 2006	Kenya (FSW)	X	94%
38	McFarland 2009	Botswana	X	

No	Reference	Country	IV Cleansing	IV Cleansing Prevalence
39	Montgomery 2009	South Africa, Zimbabwe	X	83%
40	Morar 1998	South Africa (FSW)	X	
41	Morar 2003	South Africa (FSW)	X	97%
42	Myer 2006	South Africa	X	13%
43	Myer 2005b	META: CAR, DRC, Kenya, Ivory Coast, Malawi, South Africa, Thailand, Zambia, Zimbabwe	X	6-98%
44	Myer 2004	South Africa	X	29%
45	Nwadioha 2011	Nigeria	X	85%
46	Okal 2008	Kenya	X	
47	Pitts 1994	Zimbabwe	O	
48	Priddy 2011	Kenya (FSW)	X	100%
49	Ramjee 1999	South Africa (FSW)	O	[100%]
50	Ray 1996	Zimbabwe (men)	X	
51	Reddy 2009	South Africa	X	19%
52	Roddy 1998	Cameroon (FSW)	X	26%
53	Runganga 1992	Zimbabwe	O	
54	Runganga 1995	Zimbabwe	X	
55	Rustomjee 1999	South Africa (FSW)	O	
56	Sagay 2010	Nigeria (FSW)	X	20%
57	Sandala 1995	Zambia	O	[33%]
58	Sandøy 2007	Zambia	O	
59	Schwandt 2006	Kenya (FSW)	O	
60	Scorgie 2011	South Africa	X	63%
61	Scorgie 2008	South Africa	X	
62	Sharma 2006	Kenya (FSW)	X	
63	Sallam 2001	Egypt	X	
64	Smit 2011	South Africa	X	63%
65	Tevi-Bénissan 1997	CAR	X	
66	Turner 2010	Zimbabwe	X	84%
67	van de Wijgert 2000	Zimbabwe	X	59%
68	van de Wijgert 2008	Uganda, Zimbabwe	X	Uganda=68%, Zimbabwe=63%
69	van der Straten 2010a	South Africa, Zimbabwe	X	SA Gauteng=87%, SA KZN=78%, Zimbabwe=83%
70	van der Straten 2010b	Zimbabwe	X	84%
71	Veldhuijzen 2006	Rwanda	X	
72	Watson-Jones 2007	Tanzania	X	60%

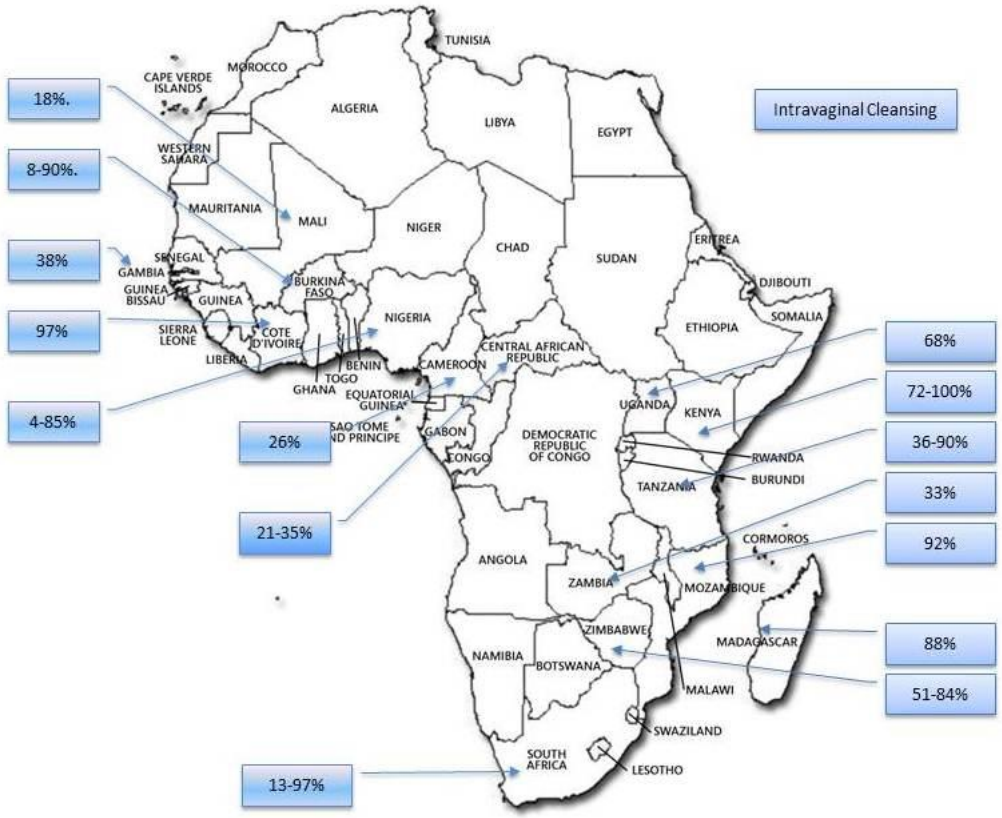
NB: META =meta-analysis; WHO GSVP=refers to the World Health Organisation multi-country study on Gender Sexuality and vaginal practices; FSW=Female Sex Worker; DRC=Democratic Republic of Congo; CAR=Central African Republic; SA=South Africa; KZN=KwaZulu-Natal; In the column entitled 'IV Cleansing' 'X' is used to show that the article reported on intravaginal cleansing, and 'O' is used to show that the article reported on intravaginal cleansing but it was not possible to exclude other vaginal practices. In the column entitled 'IV Cleansing Prevalence' brackets [] are used when it is not possible to exclude other vaginal practices.

5.1.2 Prevalence of intravaginal cleansing

Out of the 72 papers identified in the systematic literature review, 42 provided primary data on the prevalence of intravaginal cleansing. Two meta-analysis articles provided secondary data, some of which had not been previously published. The minimum and maximum

prevalence reported for each country is illustrated in Figure 5-1. The reported prevalence of intravaginal cleansing ranged from 8% in Burkina Faso to 100% in Kenya. Despite there being a substantial body of evidence on intravaginal practices, comparing the prevalence of specific intravaginal practices was hindered by a number of factors. Below I highlight some of the key factors that emerged during the review of the literature that need to be considered when comparing the prevalence of intravaginal practices across studies.

Figure 5-1: Prevalence of intravaginal cleansing in Africa as reported in the literature



Problems with comparing prevalence of intravaginal practices

Prior to the WHO classifications, various types of vaginal practices were often conflated making it difficult to compare the types and prevalence of practices across different settings. For example, research in Zimbabwe reported that 88% of the 63 women interviewed reported using “herbs and other agents regularly as a preparation for sexual intercourse” (Runganga, 1992). This practice would generally be defined as intravaginal insertion. However on further reading it is evident that the definition included washing with cold water prior to sex, which would now be defined by the WHO classification as intravaginal cleansing. In fact, around 42% of the women reported what is now defined as intravaginal insertion and 46% reported intravaginal cleansing. On a similar note, it is not always possible from the articles to distinguish between the measurement of external washing and intravaginal cleansing. I have

only included cleansing practices that are more likely to be internal than external in the systematic review. Misclassification of practices could both over and under-estimate the prevalence of specific practices. It is worth noting that although it is useful for researchers to distinguish between the classifications of vaginal practices, women themselves are unlikely to consider the differences of practices beyond using a practice to serve a particular purpose.

Secondly, in some communities intravaginal practices are highly stigmatized or have been measured in studies that have discouraged the practices, such as microbicide trials, thereby increasing the risk of social desirability bias. For example, in a study in Tanzania, women reported significantly more intravaginal cleansing in self-completed diaries than they did in administered questionnaires (53% compared to 36%; $p<0.005$) (Allen, 2007). Reporting bias is likely to under-estimate the prevalence of some practices more than others depending on the socio-cultural attitudes to specific practices, or study requirements.

Thirdly, it is important to note that the prevalence of intravaginal practices is likely to change over time. For example, one study in Zambia which used repeated measures of intravaginal practices over three population-based surveys found that the use of traditional agents before sex (although it is not clear if this was cleansing or insertion) decreased from 36% in 1995, to 20% in 1999, to 16% in 2005 among rural women (Sandøy, 2007). However, data on time trends of intravaginal practices are rare and therefore in this chapter prevalence is presented without consideration of longitudinal changes. The cross sectional view of prevalence which I have adopted for Figure 5-1, could therefore both over and under-estimate the prevalence of specific practices.

Fourthly, studies that include distinct populations within the same country illustrate that the prevalence of practices differs dramatically within countries. For example, in a study in South Africa, 80% of women who described themselves as not religious practiced intravaginal cleansing, compared to only 53% who described themselves as very religious (Scorgie, 2011). Similarly, a study in Nigeria found that while 81% of female sex workers reported intravaginal cleansing, only 4% of women recruited in family planning clinics reported this practice in the same area (Imade, 2005). The majority of the studies in Kenya, Madagascar and Nigeria have included female sex workers and their reporting of intravaginal cleansing has been consistently high (McClelland, 2008, McClelland, 2006, Priddy, 2011, Schwandt, 2006, Baeten, 2009, Fonck, 2001, Gallo, 2010, Behets, 2008a, Hassan, 2007, Imade, 2008, Imade, 2005, Sagay, 2010). Data from female sex worker populations is not representative of other women in the same communities. Some of the South African studies have also included female sex workers, but I will discuss the South African studies in more detail below.

Prevalence in South Africa

In South Africa initial studies in the 1990's among female sex-workers in KwaZulu-Natal suggested that intravaginal cleansing was virtually universally practiced (Morar, 1998, Morar, 2003, Ramjee, 1999, Rustomjee, 1999). However, subsequent studies among women not engaged in sex work found that the prevalence of intravaginal practices is relatively low in South Africa when compared to many other African countries. For example, the meta-analysis conducted by Low et al including data from studies in Kenya, Malawi, South Africa, Tanzania, Uganda and Zimbabwe, found that studies in South Africa had the lowest overall prevalence of current intravaginal practices (18%-27%) while studies in Zimbabwe had the highest (69-92%) (Low, 2011).

As shown in Table 5-2, other studies in South Africa have reported intravaginal cleansing practices ranging from 13% to 29% in the Western Cape, 87% in Gauteng, and 63% to 78% in KwaZulu-Natal (Myer, 2006, Myer, 2004, Reddy, 2009, van der Straten, 2010a, Montgomery, 2009, Hull, 2011, Smit, 2011, Guest, 2007, Scorgie, 2011). Another study in KwaZulu-Natal among women with symptoms of reproductive tract infections and STIs, found that approximately half of the women practiced intravaginal cleansing to treat the symptoms (Beksinska, 2010).

The WHO GSVP study included a household survey of vaginal practices in KwaZulu-Natal. This study addressed most of the limitations listed above in that it clearly distinguished between the various vaginal practices, the data were not collected in a trial setting that prohibited certain practices, it presents relatively recent data which was collected in 2007 and 2008, and it was a population based survey not limited to specific sub-groups. Of course, social desirability may still have affected responses if certain practices were socially frowned upon. The systematic literature review identified 2 articles from this study that reported the prevalence of intravaginal practices in KwaZulu-Natal. Both articles are methodologically sound (NICE, 2006) and provide the most robust evidence on intravaginal practices in KwaZulu-Natal. The WHO household survey found 64% (95% CI: 59, 69%) of women reported ever practicing intravaginal cleansing and 63% (95% CI: 58, 69%) reported currently practicing intravaginal cleansing (Hull, 2011, Smit, 2011).

As Figure 5-1 illustrates, the prevalence of intravaginal cleansing varies dramatically by country, as well as by population group, partner type, and time. Overall, intravaginal cleansing is common in South Africa although there are vast differences in prevalence across communities suggesting that intravaginal cleansing practices are influenced by socio-cultural norms regarding sexuality and sexual health.

The WHO GSVP study is one of the only studies to have characterized women who cleanse intravaginally in KwaZulu-Natal. Among the women surveyed, intravaginal practices (including internal cleansing and/or insertion practices) were associated with higher sexual activity, transactional sex, not using condoms consistently and having an STI (Smit, 2011). In the same cohort where 63% of women reported intravaginal cleansing, cleansing was higher among women who were aged 30 to 44 years old, less educated, not religious, engaged in transactional sex, concerned about STIs, didn't have access to media, and thought their male partners' didn't have other female partners (Scorgie, 2011).

5.1.3 Motivation for intravaginal cleansing

In order to identify the motivation for intravaginal cleansing (and insertion), I considered two reviews of literature pertaining to vaginal practices (Brown, 2000, Braunstein, 2003), an ethnographic study from KwaZulu-Natal (Berglund, 1976) and a meta-ethnography of vaginal practices in Sub-Saharan Africa published after the systematic literature review was conducted (Hilber, 2012), in addition to the articles identified in the systematic review.

It is evident from the literature that the motivation for practicing intravaginal cleansing and intravaginal insertion overlap extensively. Six main motives for both intravaginal cleansing and intravaginal insertion have been identified in the literature:

- ***Vaginal hygiene*** – either as part of daily bodily cleaning or specifically to remove undesirable discharge or odour before or after sex, and during menstruation;
- ***Vaginal health*** – to reduce the risk of sexually transmitted infections;
- ***Contraception*** – to reduce the risk of pregnancy or induce abortion;
- ***Treatment*** – to treat sexually transmitted infections or vaginal discharge;
- ***Post-partum*** – to restore and tighten the vagina after child birth;
- ***Sexual preparation*** – to tighten, dry, warm or lubricate the vagina in order to enhance the sexual experience for the male partner, the female, or both.

There are a number of ways of dividing intravaginal practices when looking at the motivation for these practices. Scorgie has argued that vaginal practices can be looked at in terms of "those undertaken for purposes of 'hygiene' (genital washing, douching and application) and those for 'sexual motivations' (application, insertion, ingestion and incisions)" (Scorgie, 2011). This is a useful distinction although it is important to recognise that the separation of practices based on motivation for use is not always so clear, particularly in relation to vaginal hygiene. For example, the WHO survey in KwaZulu-Natal found that of the women who reported intravaginal cleansing, 95% said they practiced it for hygiene purposes, and of the women who

reported intravaginal insertion, 33% said they practiced it for hygiene purposes (Hull, 2011). The cross-over between intravaginal cleansing and insertion for hygiene purposes is reflected in the literature and can be seen in Table 5-2 which indicates which studies were ambiguous about this distinction (shown by use of O instead of X). While it is clear that women practice both intravaginal cleansing and insertion for hygiene purposes, of the women who reported intravaginal cleansing, only 2% said they practiced it to improve male sexual pleasure (Hull, 2011).

While acknowledging this ambiguity, it is still the fact that intravaginal cleansing is most frequently reported in relation to vaginal hygiene and intravaginal insertion is most commonly reported in relation to enhancing sexual pleasure. Consequently in this thesis I focus on intravaginal cleansing practices for vaginal hygiene and intravaginal insertion practices for sexual preparation. Of the 63% of women who reported practicing intravaginal cleansing in KwaZulu-Natal, 95% said the main reason was for hygiene purposes (Smit, 2011). The main outcomes of intravaginal cleansing were cleanliness (90%) and odour reduction (61%).

Above I have presented evidence from the literature that describes the reasons women give for practicing intravaginal cleansing and/or insertion. Only a few of the manuscripts included in the literature review looked beyond the functional reason for these practices in an attempt to explore the social contexts that inform intravaginal practices. Very recently, Hilber et al explored the social contexts of all vaginal practices in a meta-ethnography that draws on texts relating to vaginal practices in Africa from the 1950's onwards (2012). By analysing (or re-analysing) the views of research informants and interpretations of the anthropologists expressed in the literature, the authors developed a conceptual framework to describe the rationale behind the use of intravaginal practices (Figure 5-2).

The conceptual framework is premised on 4 layers of influence; 1) ethno-medical and cosmological beliefs about the body, 2) social and cultural norms of womanhood, 3) socially normative vaginal practices, and 4) social and economic expectations and pressures. This conceptual framework accounts for the historical, political, religious, economic, social and cultural factors that influence women's vaginal practices in an array of contemporary African societies. The authors contend that "vaginal practices are used to negotiate social, economic and relationship challenges in women's lives" (Hilber, 2012;30). As such they describe vaginal practices as ways in which women exert agency over their roles within society.

Figure 5-2: Vaginal practices contextualised

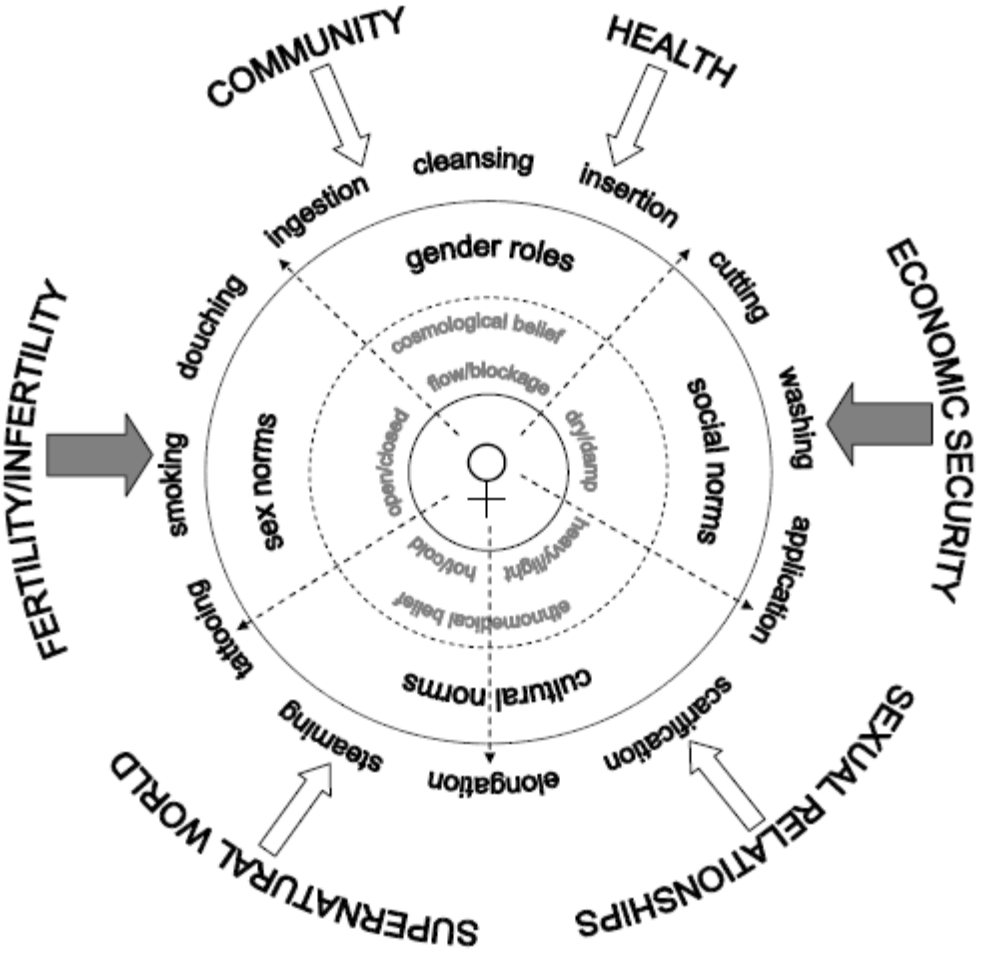
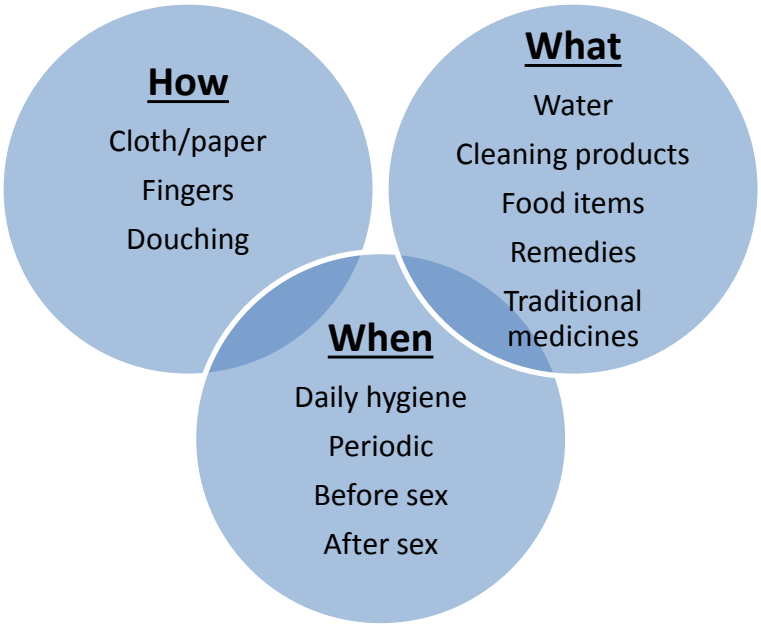


*Figure copied from (Hilber, 2012;29)

5.1.4 Intravaginal cleansing as part of vaginal hygiene

In the systematic literature review, 72 articles addressed the issue of intravaginal cleansing and the vast majority described some form of hygiene practice. Intravaginal cleansing can best be explained by describing how it is performed, what products are used and when it is performed (Figure 5-3).

Figure 5-3: The how, what and when of intravaginal cleansing



How intravaginal cleansing is performed

Intravaginal cleansing is performed in a number of ways. Probably the most common form of intravaginal cleansing is with a cloth or paper towel (Runganga, 1995, Ray, 1996, Van de Wijgert, 2008, Brown, 1993, Hassan, 2007, Myer, 2004, Sandala, 1995, McClelland, 2008, McClelland, 2006, Demba, 2005, Turner, 2010, Hilber, 2010b). In the WHO survey, 52% of women in KwaZulu-Natal used cloth during intravaginal cleansing and 9% used paper (Smit, 2011). Cloths and paper towels are sometimes used dry but are more commonly wet before use and used to wipe inside the vagina. They may be wet in water or a range of soluble products discussed below.

A number of studies have reported the use of finger cleaning (McFarland, 2009, McClelland, 2008, Allen, 2010, McClelland, 2006, Hassan, 2007, van de Wijgert, 2000, Brown, 1993, Scorgie, 2011, Behets, 2008b, Myer, 2006, Braunstein, 2005). This involves inserting a finger or fingers into the vagina in order to clean out the cavity. Prior to insertion, the finger may be wet in water or another solution or even wrapped in a cloth or paper towel to assist the cleansing process. One of the review articles found that fingers were the most commonly used way of applying liquids during intravaginal cleansing (Hilber, 2010a).

The final way in which intravaginal cleansing is performed is as vaginal douching. Douching is the use of pressurized water or another solution used to clean the vagina. The term douching comes from the French word ‘douche’ which translates as ‘shower’. As such, douching infers the use of fast flowing water that flushes out the vaginal cavity. Vaginal douching is more

prevalent in the USA (Diclemente, 2012) than in the African sub-continent where intravaginal cleansing usually refers to the use of unpressurized water (Hilber, 2010a). Some studies in Africa clearly indicate the use of douche bags to force water or other solutions into the vagina (McClelland, 2006) or specifically asked women whether they forced water or liquid into the vagina (Bayo, 2002). However, other studies incorrectly use the term douching to refer to any use of water or solution in the vagina. The WHO study found that intravaginal cleansing in Africa predominantly referred to the use of fingers, cloth and paper, but rarely included the use of pressurized water as a douche (Hilber, 2010b).

What products are used for intravaginal cleansing

A variety of products are used in the process of intravaginal cleansing. The WHO survey reported that in KwaZulu-Natal, products were used by the vast majority of women who reported intravaginal cleansing, with only the minority using water alone (Smit, 2011). However, interestingly, this definition included the use of cloth and paper. In this section I describe products that are used for intravaginal cleansing in addition to cloth and paper.

In the main, products are diluted in water or other solutions and then used for intravaginal cleansing. As described above, these solutions are often applied on a cloth or with fingers. The products reported in the literature include:

- ***Water:*** on its own without any other substances
- ***Cleaning or hygiene products***: soap, liquid soap, caustic soda, bath salts, antiseptics, disinfectants, detergents;
- ***Food items****:* limes, lemons, tea leaves, vinegar, salt;
- ***Over the counter remedies****:* Alum (hydrated aluminium potassium sulphate – also called Alone in Botswana), soluble pain killers such as Aspirin;
- ***Traditional medicines***: herbs, minerals.

Some of the products used for intravaginal cleansing are also used for intravaginal insertion. Similarly, although these products are used for intravaginal cleansing as part of vaginal hygiene, many are also used to reduce the risk of STIs and pregnancy, to treat STIs, to tighten the vagina after child birth and in preparation for sex. In KwaZulu-Natal, the main products used for intravaginal cleansing were soap and household disinfectants (Smit, 2011).

When intravaginal cleansing is performed

The timing of intravaginal cleansing can offer insights into the specific purpose of the practice. There are four specific timings of intravaginal cleansing reported in the literature, although they are not exclusive.

Firstly, intravaginal cleansing is practiced as part of the daily bodily cleaning routine. During a bath, shower, or basin wash, women clean inside the vagina while cleaning the rest of the body. In this sense, intravaginal cleansing is a usual part of vaginal hygiene practices along with washing the genitals externally and changing underpants regularly (Runganga, 1995).

Secondly, intravaginal cleansing can be periodic. In these instances intravaginal cleansing is either practiced or increased during menstruation or when women experience unpleasant vaginal symptoms such as during infection with candida, BV or STIs (Veldhuijzen, 2006, Bagnol, 2008).

Thirdly, intravaginal cleansing is specifically performed before sex. Some studies show that women perform intravaginal cleansing every night before going to bed to be prepared in case their partner wants sex (Gausset, 2001). Most of the studies with female sex workers describe how women perform intravaginal cleansing between clients to ensure the vagina is clean and appealing for the next client (Behets, 2008b). Some studies have shown how women cleanse intravaginally between acts of sex with their partners to ensure the vagina is in an optimal state of cleanliness (Hilber, 2010b, Brown, 1993). The pre-sex intravaginal cleansing practices generally reflect local expectations regarding the optimal state of the vagina, with a dominance of the need for a clean and tight vagina prior to sex (McFarland, 2009). In some countries, including South Africa, women report intravaginal cleansing prior to sex to avoid accusations of promiscuity or infidelity (Beksinska, 1999, Braunstein, 2005, Scorgie, 2009). It is pre-coital intravaginal cleansing practices that often have multiple purposes of vaginal hygiene and sexual preparation, as well as overlapping with intravaginal insertion practices.

Finally, in addition to cleansing between acts of sexual intercourse, the literature specifically describes post-sex cleansing practices. Some studies highlight that socio-cultural beliefs regarding semen and post-coital vaginal secretions being dirty or even polluting encourage women to remove these secretions after sex (Allen, 2010, Scorgie, 2011, Brown, 1993, Runganga, 1995, Berglund, 1976). Post-coital secretions are often described as generating a bad odour that can be smelt by others and therefore must be removed (Ray, 1996). Few studies have reported on how long after sex intravaginal cleansing is performed, but one study in Tanzania found that half of the women who cleansed inside their vagina after sex did so

within 2 hours (Allen, 2010). It is post-coital intravaginal cleansing practices that often have multiple purposes of vaginal hygiene, vaginal health and contraception.

In the WHO survey, in KwaZulu-Natal 92% of women reported intravaginal cleansing as part of their general hygiene routine, 17% around the time of menstruation, 10% in preparation for sex, and 19% after sex (Smit, 2011).

5.1.5 Intravaginal practices and HIV acquisition

To date the main interest in intravaginal practices has been in relation to the potential link with HIV acquisition. The links between HIV acquisition and prevalent BV (Atashili, 2008, Myer, 2005a) or other STIs (McClelland, 2007, Van Der Pol, 2008, Freeman, 2006) are well established. Consequently the association between intravaginal practices and BV or other STIs has also been investigated as mediators to HIV acquisition.

The systematic literature review identified 30 articles that dealt specifically with intravaginal practices as potential risk factors for either HIV (Mbizvo, 2004, Fonck, 2001, Imade, 2008, Dallabetta, 1995, Gresenguet, 1997, Hira, 1990, Myer, 2006, Myer, 2004, McClelland, 2006, Priddy, 2011, Sandala, 1995, Watson-Jones, 2007, Van de Wijgert, 2008, Braunstein, 2011), BV (Baisley, 2009, Demba, 2005, McClelland, 2008, Nwadioha, 2011, Mbizvo, 2004, Fonck, 2001, Imade, 2008, Baeten, 2009, Hassan, 2007, Sallam, 2001, van de Wijgert, 2000, La Ruche, 1999), or other STIs (Fonck, 2001, Imade, 2008, La Ruche, 1999, Sallam, 2001, van de Wijgert, 2000, Myer, 2004, Reddy, 2009, Mehta, 2008, Mehta, 2007, Low, 2010, Mayaud, 2008, Watson-Jones, 2007, Turner, 2010, Schwandt, 2006). However, the results to date have often been contradictory and few studies have demonstrated a temporal association between intravaginal practices and either HIV, BV or other STIs.

The literature review also identified 3 meta-analyses of the data. The first meta-analysis included data presented in the literature up to 2004 from 9 cross sectional and 3 prospective studies (Myer, 2005b). This analysis found an overall association between intravaginal practices (cleansing and insertion) and prevalent HIV in unadjusted but not adjusted analyses, and no evidence of any association with incident HIV. A subsequent meta-analysis included data presented in the literature up to 2008 from 15 prospective studies (Hilber, 2010a). This analysis found some evidence of an association between intravaginal practices (cleansing and insertion) with both BV and HIV in unadjusted but not in adjusted analyses. The same review found no association between intravaginal practices and TV, but some evidence of an association with candida. Finally, a meta-analysis of pooled individual participant data from 10 prospective longitudinal studies found that the intravaginal use of cloth or paper, intravaginal cleansing with soap, and intravaginal insertion of products to dry or tighten the vagina was

significantly associated with HIV acquisition after controlling for age, marital status, and number of sex partners in the previous 3 months (Low, 2011). However the use of household cleaners, vinegar or lime juice, was not associated with HIV acquisition. The meta-analysis also found that intravaginal cleansing with soap was associated with the development of intermediate vaginal flora and BV. Intermediate vaginal flora and BV were both associated with HIV acquisition in multivariable models.

While the meta-analysis by Low et al has gone some way to clarify the associations between specific intravaginal practices and HIV acquisition, additional prospective studies are still necessary to further understand the temporal relationship between HIV infection and other intravaginal cleansing and insertion practices (Hilber, 2007, Hilber, 2010a). Evidently some intravaginal practices increase the risk of infection with HIV and BV, but not all. It is critical that clear and concise messages about the risks associated with specific practices can be disseminated as part of HIV prevention packages. A blanket rejection of what are clearly well established practices could run counter to the implementation of culturally relevant HIV prevention programmes. As Hilber et al contend based on the findings of the meta-ethnography described above in section 5.1.3: “efforts to change potentially harmful practices will require attention to their role as a survival strategy for women” (2012;30).

5.1.6 Intravaginal cleansing and microbicides

In addition to concerns about the HIV risks associated with intravaginal practices, concerns regarding the compatibility of intravaginal practices and HIV prevention options have been repeatedly raised over the years (Baleta, 1998). These concerns have related to the compatibility of intravaginal practices with condom use, male circumcision, the diaphragm and microbicides (Priddy, 2011, Smit, 2011, Low, 2011).

There are two key concerns that have been raised with regard to intravaginal cleansing and microbicides. Firstly, that the use of products during pre-sex intravaginal cleansing or insertion could interact with the active ingredients in microbicides and render them ineffective or unsafe (Low, 2011). Secondly, that post-sex intravaginal cleansing could remove the microbicide too soon after male ejaculation and either prevent or dilute the protective effect of the microbicide (Hilber, 2007). Whilst I am unable to investigate the first concern as it would require pharmacological evaluation, I am able to explore the second concern in this thesis.

The literature highlights that the prevalence of intravaginal cleansing differs dramatically by country, population group, partner type, and over time. However, to date there is hardly any evidence regarding post-coital intravaginal cleansing practices in the presence of microbicides. Of the 12 microbicide effectiveness trials conducted to date only two have reported post-coital

intravaginal cleansing at baseline (Abdool-Karim, 2009, Halpern, 2008) and only one of these has measured intravaginal cleansing during follow up (Table 5-3).

Table 5-3: Microbicide trials reporting of intravaginal cleansing

No	Reference	Microbicide Candidate	Countries involved	Cleansing
1	(Kreiss, 1992)	N-9 sponge (unblind)	Kenya	Not reported
2	(Roddy, 1998)	N-9 film	Cameroon	Baseline: Douching 25-27% Other vaginal substances 43-47%
3	(Richardson, 2001)	N-9 gel	Kenya	Baseline: Douching (cloth most likely form) 86% Douch with water 32-34% Douch with detergent or soap 50-55%
4	(Van Damme, 2002)	N-9 gel	Benin, Côte d'Ivoire, South Africa, Thailand	Baseline: Routine washing of the vagina 100% Mean times per day 3 (IQR 2-3)
5	(Peterson, 2007)	SAVVY (C31G)	Ghana	Baseline: Douching 52-54%
6	(Feldblum, 2008)	SAVVY (C31G)	Nigeria	Baseline: Douching 61%
7	(Skoler-Karpoff, 2008)	Carraguard	South Africa	Not reported
8	(Halpern, 2008)	Cellulose Sulphate (Ushercell)	Nigeria	Baseline: Douch after sex 71-72% **During follow-up = 6%**
9	(Van Damme, 2008)	Cellulose Sulphate (Ushercell)	Benin, India, South Africa, Uganda	Not reported
10	(Abdool-Karim, 2009)	PRO2000 0.5% & Buffer Gel	Malawi, South Africa, Zambia, Zimbabwe, USA	Baseline: Douching before sex 24-27% Douching after sex 26-30%
11	(McCormack, 2010)	PRO2000 0.5% & PRO2000 2%	South Africa, Tanzania, Uganda, Zambia	Not reported
12	(Abdool-Karim, 2010b)	Tenofovir 1%	South Africa	Not reported

The compatibility between post-coital intravaginal cleansing practices and microbicide use need to be understood within the context of the socio-cultural factors that influence women's vaginal practices. In this chapter I use qualitative and quantitative data to explore the compatibility of socio-cultural norms regarding intravaginal cleansing and user-requirements of microbicides. In order to contextualise the topic, I use qualitative data to examine socio-cultural norms relating to vaginal hygiene generally and intravaginal cleansing specifically. In order to ground the topic in the practices used locally, I use quantitative data to investigate patterns of post-coital intravaginal cleansing during the course of the trial and characterize women who practice intravaginal cleansing. By using qualitative and quantitative data, I assess whether the need for microbicides to remain *in situ* after sex runs counter to local post-coital cleansing practices in a rural part of KwaZulu-Natal, South Africa.

5.2 Methods

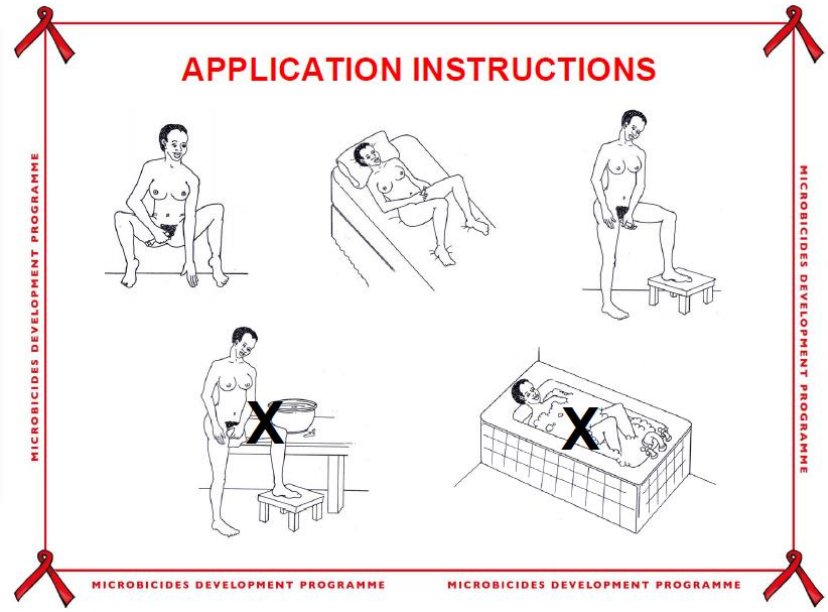
5.2.1 Instructions regarding intravaginal cleansing

As part of the MDP 301 clinical trial protocol, women were advised not to clean inside their vagina for at least one hour after sex. As described in chapter 3 section 3.6.1, the participant information sheet (PIS) was read out to participants at screening and they were provided with a written copy. The PIS stated:

> "Once the gel has been inserted you should not wash inside your vagina, or put anything else in your vagina, for at least one hour after sex."

The PIS was discussed in combination with a visual flipchart to help reinforce key messages. Figure 5-4 shows the visual flipchart page on 'application instructions'. The images on the top line were used to describe the different gel application positions that women could use. The images on the bottom line were used to discourage intravaginal cleansing or bathing up to one hour after sex.

Figure 5-4: Participant information visual flipchart: gel application instructions



Key messages were reinforced throughout the trial using 'frequently asked questions' (FAQ) crib sheets. The crib sheet included the following FAQ on intravaginal cleansing:

Q18: How long after sex can I clean my vagina?

A: It is not necessary to clean your vagina. Your vagina works on its own to clean itself, and this is healthier for you than using water, soap, or other substances to clean the vagina, since soap and other substances can damage the inside of the vagina. If you feel you must clean your vagina after sex, please wait at least one hour after having sex before cleaning.

Although women were discouraged from intravaginal cleansing up to an hour after sex, interviewers were trained to encourage participants to report all behaviour as accurately as possible.

As described in the PIS quote above, in the trial we referred to all trial products simply as 'gels'. We used the Zulu word *isigcobisi* which was the closest available translation to 'gel' and strictly speaking mainly refers to gel-like ointments. During the trial relatively equal proportions of women were assigned to the different gel allocation groups of 0.5% PRO2000, 2% PRO2000 or placebo. Through this thesis I repeatedly refer to microbicide gels merely as gels and do not distinguish between women's experiences of the different gels unless it is noteworthy. Otherwise I use women's experience of using any of the 3 gels as an assessment of microbicide acceptability.

5.2.2 Quantitative data

Dependent variables

As described in chapter 4 section 4.5.2, long sexual behaviour CRFs were completed routinely at each clinical visit at weeks 4, 24, 40 and 52 after enrolment. Long sexual behaviour CRFs were also completed at other visits if the participant had missed a clinical visit or was discontinuing gel use for any reason and therefore some women completed more than 4 of these CRFs during the course of the trial.

Data were collected about each sex act in the last week, or the last 4 weeks if the women had not had sex in the last week. For each sex act, women were asked the following question "Did you clean inside your vagina after sex?" Staff clarified that intravaginal cleansing included the use of a dry cloth. If a participant reported cleansing inside her vagina after sex, she was asked how long after sex she had cleansed. Responses were recorded as either less than 1 hour, between 1 to 2 hours or more than 2 hours after sex. The outcome measure for this analysis is cleansing inside the vagina up to one hour after sex at any time during the trial.

Independent demographic, sexual behaviour and socio-economic variables

In the literature, age, educational level, marital status and cohabitation, occupation, religiosity, coital frequency, contraceptive use, condom use and STIs have been shown to be associated with vaginal hygiene practices (Scorgie, 2011, Penman-Aguilar, 2011, Smit, 2011).

To assess the impact of these factors on intravaginal cleansing, the following variables described in chapter 4 sections 4.5.1 and 4.5.2 are included in this analysis: age, educational

level, relationship to the head of household, employment status, religious affiliation, sexual behaviour, and incidence of HIV, STIs or pregnancy.

I created a variable for occupation based on the categories used in the WHO household survey in KwaZulu-Natal (unemployed, housewife, unskilled manual work, salaried sales work, self-employed sales work) but found that it was no better a predictor of intravaginal cleansing than employment status and therefore did not include it in this analysis (Scorgie, 2011). Data on religiosity were not available but I included religious affiliation. I included variables on average sexual frequency over the course of the trial and contraceptive use as reported at enrolment.

I included clinical variables on HIV and STI infection at any point during the trial. I was also interested to find out if intravaginal cleansing practices were associated with pregnancy and therefore included a variable that identified all women who had a positive pregnancy test during the trial.

Given that I was specifically interested in intravaginal cleansing in relation to sexual activity, I included a range of sexual behaviour variables including variables on age at first sex, multiple partners, consistent condom use, and consistent gel use described in chapter 4 section 4.5.2. There is some evidence of increased intravaginal cleansing during menstruation (Allen, 2010, Veldhuijzen, 2006). I was not able to distinguish between menses related and unrelated cleansing, but did include a variable that identified women who had sex during menstruation at any time during the trial.

In order to control for any potential differences between clinics, clinic of enrolment was included as a variable. Gel group was also included in case gel consistency affected cleansing practices. In addition I included variables relating to household socio-economic status as described in chapter 4 section 4.5.1, including residential area, household size, and access to electricity.

Quantitative analysis

In STATA, I compared women who reported intravaginal cleansing (IVC) up to one hour after sex at some time during the trial to those who did not. I also consider changes in intravaginal cleansing up to one hour after sex by comparing the proportions of women who intravaginally cleansed in the first six months of the trial to the proportion in the last six months of the trial. Univariate associations were assessed using the Pearson Chi2 test. I tested the contribution to the multivariable model of each variable that was significant in univariate analysis at the 0.10 level using likelihood ratio tests (LRT) (Kirkwood, 2003). Multivariate associations were

assessed at the 0.05 level, after controlling for potential confounding factors, through multiple logistic regression analyses.

5.2.3 Qualitative data

For the qualitative analysis I used data from the focus group discussions with community members and trial participants, as well as from the in-depth interviews with female trial participants, as described in chapter 3 section 3.4. There were two stages to the qualitative data analysis for this chapter.

Firstly, I analysed the 17 community FGDs and 10 trial participant FGDs, coding all text that addressed issues relating to intravaginal cleansing. Three main themes emerged from the data: motivation for intravaginal cleansing, classifications of intravaginal cleansing, and implications of intravaginal cleansing. I present the qualitative findings from the FGDs for each of these themes. The FGD data provide insights into norms and expectations regarding intravaginal cleansing in the community.

Secondly, I analysed data from 214 in-depth interviews conducted over the duration of the trial with 84 trial participants. I coded the IDIs for all text relating to vaginal cleansing. Three main themes emerged from the data: intravaginal cleansing practices generally, intravaginal cleansing in relation to gel use, and circumstances that influence intravaginal cleansing. I present the IDI findings for each of these themes. The IDI data provide insights into women's intravaginal cleansing practices within the context of using microbicides.

5.3 Results – quantitative analysis

In this section I assess the characteristics of women who intravaginally cleansed up to one hour after sex during the trial and consider changes in intravaginal cleansing practices over the course of the trial. In total, 1,177 women enrolled in the Africa Centre MDP 301 clinical trial. Thirty-four women were dropped from this analysis as they never completed a long sexual behaviour questionnaire. Of these, 3 were discontinued by the investigator as they had been randomised in error, 15 were lost to follow up, 12 withdrew from the trial, and 4 did not report sexual activity prior to a clinical visit. Consequently data from 1,143 women were included in this analysis. Women provided data on the long behavioural questionnaires a mean of 3.71 times (range 1 to 6; standard deviation 0.88).

5.3.1 Univariate analysis

Of the 1143 women included in the analysis, 464 (41%) reported cleansing inside their vagina sometime after sex at some point during the trial (with no linear correlation to age; odds ratio

[OR] 0.99; CI: 0.98, 1.00) while 336 (29%) reported cleansing inside their vagina **up to one hour** after sex at some point during the trial. Women who intravaginally cleansed up to one hour after sex were younger than women who did not, with a mean age of 33 compared to 35 years of age (t test p-value=0.02) and there was a linear correlation with age (OR: 0.987; p-value 0.02).

As shown in Table 5-4, Table 5-5 and Table 5-6, the following variables were significantly associated with intravaginal cleansing up to one hour after sex in univariate analysis at a 10% level: age group, employment status, area of residence, clinic of enrolment, household size, having multiple partners, consistency of gel use, consistency of condom use, frequency of sex, becoming pregnant during the trial, and having a positive gonorrhoea test. All of these variables contributed to the model in likelihood ratio tests except for condom use (LRT p-value 0.53), pregnancy (LRT p-value 0.15), and gonorrhoea (LRT p-value 0.11) which were not included in the multivariate model.

There were no statistically significant differences between women who intravaginally cleansed up to one hour after sex and women who did not in terms of education level, relationship to the head of household, religion, access to electricity, age at first sex, contraceptive use at enrolment, having sex during menstruation, gel allocation, or positive tests for HIV, CT, TV or syphilis.

Table 5-4: Individual and household characteristics of women who intravaginally cleansed up to one hour after sex compared to women who did not

	Never IVC in hour	Ever IVC in hour	Chi2 p-value
	807 (71%)	336 (29%)	
Age group			0.08
18-24	216 (66%)	110 (34%)	
25-34	175 (72%)	68 (28%)	
35-44	190 (69%)	84 (31%)	
45+	226 (75%)	74 (25%)	
Educational level			0.12
Primary or lower	398 (71%)	159 (29%)	
Incomplete secondary	262 (71%)	105 (29%)	
Complete secondary	125 (65%)	68 (35%)	
Tertiary	22 (85%)	4 (15%)	
Employment status			0.01
Unemployed	442 (68%)	208 (32%)	
Housewife	230 (77%)	68 (23%)	
Employed	135 (69%)	60 (31%)	
Head of household			0.35
Partner	351 (73%)	133 (27%)	
Parent	265 (67%)	129 (33%)	
Self	88 (72%)	35 (28%)	
Other	103 (73%)	39 (27%)	
Area of residency			<0.01
Rural	618 (69%)	281 (31%)	
Peri-urban/urban	189 (77%)	55 (23%)	
Religion			0.31
Christian	181 (72%)	69 (28%)	
Zionist	369 (70%)	159 (30%)	
Shembe	190 (68%)	89 (32%)	
None or Other	67 (78%)	19 (22%)	
Clinic of enrolment			<0.01
KwaMsane	369 (84%)	69 (16%)	
Mtubatuba	239 (65%)	130 (35%)	
Madwaleni	199 (59%)	137 (41%)	
Access to electricity			0.11
No	390 (68%)	180 (32%)	
Yes	417 (73%)	156 (27%)	
Household size			0.03
4 people or more	164 (65%)	90 (35%)	
3 people per room	262 (69%)	116 (31%)	
2 people per room	317 (74%)	110 (26%)	
1 person per room	64 (76%)	20 (24%)	

Table 5-5: Sexual behaviour characteristics of women who intravaginally cleansed up to one hour after sex compared to women who did not

	Never IVC in hour	Ever IVC in hour	Chi2 p-value
	807 (71%)	336 (29%)	
Age at first sex			0.24
Less than 15	44 (62%)	27 (38%)	
15-19 years old	645 (71%)	258 (29%)	
20 years or older	118 (70%)	51 (30%)	
Contraceptive use			0.41
None	406 (72%)	161 (28%)	
Pill	51 (67%)	25 (33%)	
Injectable	264 (68%)	122 (32%)	
Sterilised	86 (75%)	28 (25%)	
Multiple partners			0.07
No	717 (70%)	305 (30%)	
Yes	7 (50%)	7 (50%)	
Missing	83 (78%)	24 (22%)	
Gel use			0.03
Always	483 (68%)	224 (32%)	
Sometimes or never	324 (74%)	112 (26%)	
Condom use			0.08
Always	340 (69%)	154 (31%)	
Never	171 (77%)	52 (23%)	
Sometimes	296 (69%)	130 (31%)	
Average number of sex acts			<0.01
1 to 3 acts	179 (74%)	63 (26%)	
4 to 6 acts	467 (74%)	163 (26%)	
7 to 9 acts	138 (60%)	93 (40%)	
10 or more acts	23 (58%)	17 (42%)	
Had sex during menstruation			0.7
No	759 (71%)	314 (29%)	
Yes	48 (69%)	22 (31%)	
Gel group			0.19
Placebo	271 (69%)	123 (31%)	
0.5%	281 (69%)	125 (31%)	
2%	255 (74%)	88 (26%)	

Table 5-6: Clinical characteristics of women who intravaginally cleansed up to one hour after sex compared to women who did not

	Never IVC in hour	Ever IVC in hour	Chi2 p-value
	807 (71%)	336 (29%)	
HIV			0.12
Negative	768 (71%)	312 (29%)	
Positive	39 (62%)	24 (38%)	
Pregnant			0.04
No	747 (70%)	322 (30%)	
Yes	60 (81%)	14 (19%)	
NG			0.02
No	770 (71%)	309 (29%)	
Yes	37 (58%)	27 (42%)	
CT			0.55
No	766 (71%)	316 (29%)	
Yes	41 (67%)	20 (33%)	
TV			0.95
No	763 (71%)	318 (29%)	
Yes	44 (71%)	18 (29%)	
Syphilis			0.12
No	782 (70%)	331 (30%)	
Yes	25 (83%)	5 (17%)	

5.3.2 Multivariate analysis

Table 5-7 presents the output from the final multivariate model. Women were more likely to intravaginally cleanse up to one hour after sex if they were 18 to 24 years old, consistently used gel during sex, and enrolled at Mtubatuba or Madwaleni clinics. Women who lived in smaller households were less likely to cleanse. Surprisingly, sexual activity and multiple partners were not independently associated with intravaginal cleansing in the multivariate model. Neither was intravaginal cleansing associated with area of residence or employment status.

In summary, women who intravaginally cleansed up to one hour after sex were younger, lived in crowded households, consistently used gel and were more likely to have enrolled at Mtubatuba or Madwaleni clinics.

Table 5-7: Multivariate model comparing women who intravaginal cleansed up to one hour after sex compared to women who did not

	Adjusted OR	95% CI	P-value
Age group			
18-24	1.00		
25-34	0.73	(0.50-1.08)	0.12
35-44	0.76	(0.52-1.12)	0.17
45+	0.60	(0.40-0.89)	0.01
Employment status			
Unemployed	1.00		
Housewife	0.96	(0.67-1.38)	0.83
Employed	1.10	(0.74-1.64)	0.63
Household size			
4 people or more	1.00		
3 people per room	0.73	(0.51-1.05)	0.09
2 people per room	0.62	(0.43-0.88)	0.01
1 person per room	0.55	(0.30-1.00)	0.05
Residency			
Rural	1.00		
Peri-urban/urban	1.10	(0.75-1.62)	0.64
Clinic of enrolment			
KwaMsane	1.00		
Mtubatuba	3.03	(2.10-4.37)	0.00
Madwaleni	3.72	(2.50-5.53)	0.00
Multiple partners			
No	1.00		
Yes	2.92	(0.95-8.98)	0.06
Missing	0.63	(0.38-1.05)	0.08
Gel use			
Always	1.00		
Sometimes or never	0.63	(0.48-0.85)	0.00
Average number of sex acts			
1 to 3 acts	1.00		
4 to 6 acts	0.81	(0.57-1.17)	0.26
7 to 9 acts	1.29	(0.85-1.96)	0.24
10 or more acts	1.21	(0.58-2.55)	0.61

5.3.3 Changes over time

Of the 1143 women included in this analysis, 1065 provided data on intravaginal cleansing practices in both the first and second half of the trial. In the first half of the trial, from week 4 to week 24, 277 (26%) women reported intravaginal cleansing up to one hour after sex. In the second half of the trial, from week 28 to week 52, this had fallen to 138 (13%). One hundred and ninety eight (198) women reported intravaginal cleansing in the first half of the trial but not the second half. The only independent association with decreased cleansing was clinic of

enrolment. With KwaMsane clinic as the reference, women at Mtubatuba were twice as likely to stop cleansing (OR: 2.27; CI: 1.51, 3.41) and women at Madwaleni were almost 3 times more likely to stop cleansing (OR: 2.73; CI: 1.82, 4.10) (data not presented).

5.4 Results – qualitative analysis of community FGDs

5.4.1 Motivation

Vaginal cleansing after sex, both internal and external, was described as a regular part of woman's general hygiene routine. The vagina was described as requiring specific cleaning because, as this woman explained:

> "We were given a smelly piece of organ" (Community FGD, 59 year old woman).

Semen was also described as being dirty and smelly. The combination of semen, vaginal discharge and sweat required that women clean themselves after sex. This woman's description of why women clean internally after sex was typical:

> **"**You cannot sleep, you can't relax, you are wet and there is a bad smell" (Trial FGD, 33 year old woman)

Removing the smell of sexual fluids was described as a necessary part of having self-respect. One woman explained that women wash after sex "if one is a woman who loves herself" but also explained that:

> "There are women who do not love themselves: she does not wash and wipe after sex even during the day. She would have a bad smell because sperm or discharge keeps on coming out" (Community FGD, 31 year old woman).

Similarly, vaginal cleansing was frequently described as a necessary part of respecting your partner and others in the household:

> "The expectation is that the woman brings water in her bedroom so that she washes (vaginally) first before meeting people and making tea for them" (Community FGD, 59 year old woman).

However, there were half a dozen women and men who claimed that a woman washing after sex could be considered a sign of disrespect to the man:

> "I noticed that my partner might think that I do not love him, because after I have sex with him I wash" (Trial FGD, 20 year old woman).

"Some men will say don't wash because it will disturb or lower their dignity" (Community FGD, 19 year old man).

There were also descriptions of men needing to clean themselves after sex or being cleaned by their female partner, however this topic was not probed in these discussions.

Perceptions of cleansing practices in the community were consistent across the various FGDs with female community members, male community members and female trial participants. There were no obvious differences between group discussions with younger versus older people, or rural versus peri-urban respondents. Women were clearly better informed about vaginal cleansing practices, but this was to be expected. There was clear agreement that it was necessary to clean after sex in order to remove both female and male sexual fluids.

5.4.2 Classification

All discussants agreed that women used one of two vaginal cleansing practices after sex and there were examples of both classification types provided in every FGD.

External

Approximately two-thirds of FGD discussants said women wiped outside their vagina after sex. Women reportedly wiped with a dry or damp cloth, towel, tissue or toilet paper, or, less commonly, with their underwear. Some respondents even said that many women had a specific towel for this purpose that they kept at the head of their bed.

This quote exemplifies a common theme regarding different cleansing practices (wiping externally versus washing internally) depending on whether a woman had sex in the day or in the night:

"If you have sex during the day you wash because you still have to go outside, so you cannot wipe with a towel. (At night) you wipe because you are going to sleep and you wash in the morning" (Community FGD, young woman)

Internal

Approximately a third of FGD discussants said women washed inside their vagina after sex, even during the night. The respondents explained that women would get up after sex to go and wash. However there were also frequent reports of women placing a basin of water next to the bed at night in order to wash after sex:

> "I do not know what the other people do but with me I put my water next to me when I sleep so that immediately after sex I take it and wash myself because I hate the sperm"(Community FGD, 35 year old woman).

Discussants reported that women used plain, usually cold, water to intravaginally cleanse after sex. Only a few women and men mentioned the use of disinfectants (liquid Dettol or Savlon) in the water. Intravaginal cleansing involved the insertion of either cloth or fingers, and generally included the use of water. One woman explained why it is better to use a damp rather than a dry towel:

> "What is normal is to use a damp thing, the dry one scrubs, the damp one is better" (Community FGD, young woman).

The use of fingers to clean intravaginally after sex was described in 4 out of 10 FGDs with trial participants and 2 out of 6 community FGDs with women. However, finger cleansing was not mentioned in any of the 11 community FGDs with men, suggesting that women practice this privately. This woman described how she intravaginally cleansed:

> "I do it when I am wiping with a wet towel, I insert the fingers all around my womb to take out the dirt" (Trial FGD, 35 year old woman).

One woman who used her fingers to intravaginally cleanse as part of her regular hygiene routine explained:

> "If I did not insert fingers it will be like I did not wash" (Trial FGD, 42 year old woman).

The discussants said that many women in the community use fingers as part of their general hygiene routine and especially during menstruation.

5.4.3 Implication

There were a few unprompted conversations about the health implications and health benefits of intravaginal cleansing. In a community FGD, one woman stated that it was not necessary to wash after sex as women were not advised to do so at the primary health centres. Another woman, in the same FGD, stated that it was dangerous to use tissue to clean intravaginally:

> "It is dangerous because it could be left in the vagina because it is soft (Community FGD, 30 year old woman).

The most frequently mentioned benefit of washing after sex was what was called "*isisholozi*". This referred to washing after sex in order to reduce the risk of HIV infection:

> "I think that by washing I can say that s/he thinks that s/he is doing *isisholozi*" (Community FGD, young man).

The term '*isisholozi*' is a reference to the clan name of President Jacob Gedleyihlekisa Zuma, which is Msholozi. Before becoming president of South Africa, Jacob Zuma stood trial in 2006 accused of raping Fezeka Kuzwayo. Zuma admitted to having unprotected sex with Fezeka knowing that she was HIV positive, but claimed to have showered after sex to avoid becoming infected with HIV. The details of the case were highly published in the national media. After the criminal trial, the idea of showering after sex to reduce the risk of HIV was regularly repeated in the study area. This myth was repeated in 4 out of 11 community FGDs with men and 1 out of 6 community FGDs with women, but none with trial participants. This is possibly because the benefits of showering after sex were viewed as more pertinent to men than to women, as this FGD exchange demonstrates:

> "I heard another sister saying that after sex it is important to wash but using moving water like in the shower because if one does not wash after sex one might get HIV infection but washing immediately after sex helps to avoid HIV infection"(Community FGD, 26 year old woman).

> "I hear that but I do not believe it. May be it is better for men but the (female) abdominal structure allows things to enter inside, so even washing will not help me" (Community FGD, 30 year old woman).

It was noteworthy that only one focus group discussed condom use in the context of intravaginal cleansing and stated that using a condom did not reduce the need to wash:

> "It is the same even if you can use a condom" (Community FGD, 25 year old man).

5.5 Results – qualitative analysis of trial IDIs

In the in-depth interviews the motivation provided for vaginal cleansing mirrored those provided in the FGDs. However, women in the IDIs thought intravaginal cleansing was more common in the community than the FGD discussants did. Approximately half of the trial participants thought that women in the community usually externally wipe the vagina after sex and the other half thought women usually internally cleanse the vagina.

5.5.1 Intravaginal cleansing

During the IDIs, women's comprehension of many of the key trial messages was tested – for example their understanding that the gel was investigational and that the gel could not be

used when pregnant. However, their comprehension of the advice not to intravaginally cleanse up to one hour after sex was not evaluated thoroughly in the interviews. It was obvious that some women clearly understood this requirement, but it was often not clear whether women who continued to intravaginally cleanse up to one hour after sex understood that this could limit the effectiveness of the gel.

Of the 84 women interviewed, 33 reported intravaginally cleansing immediately after sex in at least one in-depth interview. Approximately half of these women reported inserting either a single finger or multiple fingers in order to clean inside the vagina after sex. Some reported just using their fingers to clean whilst other women reported using a cloth over the fingers:

> "It is the towel which gets inside together with the finger too, though the finger is in the towel" (Trial IDI, 39 year old woman).

Other women reported just using water to wash internally, although no-one reported using a douching device of any sort. A few women reported using soapy water, specifically referring to the use of 'Sunlight' which is a popular soap brand in South Africa. Other women reported using face cloths or towels to clean intravaginally:

> "I wipe internal and external… with a towel" (Trial IDI, 26 year old woman).

5.5.2 Microbicide gel use

Two women thought that they were *supposed* to clean after sex in order to remove the gel. Others continued to clean despite knowing they were advised not to, as it was their usual practice. This woman refers to her 'sperm' which is a term commonly used to refer to female sexual fluids in this community:

> "I like cleaning myself, so as to remove gel and my sperms, because it's not easy for his dirt to get into me because we would have used a condom. I just wash to clean my dirt" (Trial IDI, 39 year old woman).

Other women specifically cleaned intravaginally between sex acts. This woman was asked why she intravaginally cleansed between sex:

> "To remove the old gel because it will not work…. I insert fingers wipe with a towel and insert the gel….After we had sex I wash to remove the old gel because I don't want him to want sex again before I have inserted the gel again" (Trial IDI, 46 year old woman).

Approximately half a dozen women explained that they used to wash intravaginally after sex, but since joining the trial and being advised not to, no longer wash intravaginally if they used gel:

> "I know that I should wash after having sex. But if I used the gel I don't wash because it was said that I shouldn't wash (internally), I should wipe (externally)" (Trial IDI, 26 year old woman).

> "I do not wash because I was taught….. if I do not use the gel I wash" (Trial IDI, 32 year old woman).

Interestingly there were no reports of women waiting for more than an hour after sex to cleanse based on the advice of the research staff.

5.5.3 Factors that influence intravaginal cleansing

There were a number of circumstances under which women said they were more inclined to intravaginally cleanse after sex. One woman claimed that she cleansed intravaginally after sex more often when she was pregnant (37 year old trial participant). A number of women reported that they only intravaginally cleanse after sex if they have sex whilst menstruating.

> "You can usually wash only when you have been doing sex whilst menstruating, then you could maybe wash because of that reason" (Trial IDI, 33 year old woman).

Sex during menstruation was considered to be rare in the community. One woman described it as:

> "Culturally and religiously unacceptable" (Trial IDI, 33 year old woman).

Indeed contact between a woman who is menstruating and any male is expressly forbidden by the Shembe religion. Among the trial participants interviewed, Shembe was the third largest religious categorisation reported as their main religion by 14 of the 84 women. Menstruating women are not supposed to have any contact with men, as this woman explains:

> "I don't prepare him food when I am menstruating. Food for him is prepared by the children, I don't even sleep in his bedroom, I leave his bedroom" (Trial IDI, 48 year old woman).

In the IDIs, sex during menstruation was described as dirty (*ngcolile*), smelly (*nuka*), shameful (*amahloni*), disgraceful or disgusting (*ihlazo*), embarrassing (*ukuhlaziswa*) and as a sign of a

lack of self-respect (*ukuzenyanya* – does not love oneself). Some women believed that having sex during menstruation increased the chance of getting pregnant, as this woman explains:

> "It is said if you want a child you should try during menstruation" (Trial IDI, 51 year old woman).

Others believed that the body was weak during menstruation and therefore more prone to infection. Having sex during menstruation was most frequently attributed to migrant labourers, whereby if the couple were only together for a short period of time while the migrant labourer was home and the women was menstruating the whole time, then they would not forego sex.

Despite the objections to sex during menstruation, in the quantitative data 9% (100/1143) of women reported ever having sex during menstruation and 6% (70/1143) reported it during the trial. In the IDIs 14 of the 84 women reported having sex during menstruation while in the trial. Eighty-seven per cent (61/70) of women in the quantitative data and over half in the qualitative data reported usually using gel when having sex during menstruation. In the qualitative data over half reported intravaginal cleansing after sex during menstruation.

Unlike in the FGDs, the impact of condom use on intravaginal cleansing was broached regularly in the IDIs. For the majority, the use of a condom did not alter their need to cleanse after sex as they still found it necessary to remove their own vaginal fluids. However, a few women reported that they were less inclined to intravaginally cleanse after sex if their partners had worn condoms:

> "Before I started using condoms I used to wash…..Now there is no dirtiness because I am using condoms" (Trial IDI, 46 year old woman).

5.6 Discussion

In this chapter, I set out to investigate post-coital intravaginal cleansing practices. Using quantitative data I compared women who intravaginally cleansed up to one hour after sex with those who did not. Using qualitative data I examined community perceptions regarding motivations, classifications, and implications of intravaginal cleansing. Finally, I explored intravaginal cleansing among women using microbicide gel who had been advised not to intravaginally cleanse up to one hour after sex.

By drawing on both the quantitative and qualitative data, I found that the prevalence of post-coital intravaginal cleansing was higher in this community than previously reported. Although

the majority of women did not report post-coital intravaginal cleansing, approximately one third of the women did report this at some time during the trial. In this population, younger age and household crowding are associated with intravaginal cleansing practices, although condom use is not. The quantitative analysis also highlighted an association between intravaginal cleansing and gel use which was supported by the qualitative data. In addition, both the quantitative and qualitative data suggest that intravaginal cleansing practices are amenable to change. The main strengths of these analyses are that the findings are consistent across the quantitative and qualitative data, and the qualitative data helps explain some of the quantitative findings.

5.6.1 Prevalence and factors associated with intravaginal cleansing

It is striking that approximately a third of women reported intravaginal cleansing up to one hour after sex in both the quantitative and qualitative data. In the WHO household survey among women who reported practising intravaginal cleansing at the time of the survey, 19% reported cleansing after sex (Scorgie, 2011). If the WHO survey had measured post-coital cleansing among all women who had intravaginally cleansed *in the last year,* as I have, it is likely that the prevalence would have been closer to that observed in this MDP analysis. I believe that the different measurements explain the differences in prevalence between the studies. There is no other evidence relating specifically to **post-coital** intravaginal cleansing in KwaZulu-Natal.

The main strength of this analysis is that it is the first to measure intravaginal cleansing up to one hour after sex, which is the period of greatest relevance for microbicide gel use. It is concerning that a third of women continued to cleanse intravaginally up to one hour after sex despite being explicitly advised not to. If the efficacy of a microbicide is reduced by post-coital cleansing, the high prevalence of intravaginal cleansing after sex could negatively impact on the feasibility of vaginal microbicides in KwaZulu-Natal.

One limitation of the quantitative analysis is that I rely solely on self-reported intravaginal cleansing data from the CRF. A previous study found that compared to administered questionnaires, pictorial daily self-completed diaries can improve collection of data on cleansing frequency and cleansing in proximity to sex (Francis, 2012, Lees, 2010). However, in MDP 301 IDIs were more efficient for the collection of sensitive information than CRFs or coital diaries (Pool, 2010b). As such, the fact that the quantitative data are remarkably consistent with the qualitative IDI data, increases confidence in the estimated prevalence of post-coital intravaginal cleansing in this cohort.

Age

The quantitative data indicates that younger women were more likely to intravaginally cleanse up to one hour after sex than older women. As this is the first study to characterise women who intravaginally cleanse **up to one hour after sex**, it is difficult to compare this finding to previous studies. Two other studies in the Western Cape Province of South Africa found an association between younger age and intravaginal cleansing generally, although the cohort was substantially older (35 to 65 year olds) (Myer, 2006, Myer, 2004). However, these MDP findings are comparable to the WHO household survey which found that intravaginal cleansing was lower among 30 to 44 year old women, although there was no linear correlation with age (Smit, 2011).

There were no suggestions in the qualitative data that intravaginal cleansing was a new practice or that practices might differ by age. The qualitative data did suggest that in some circumstances intravaginal cleansing immediately after sex could be interpreted as disrespectful to a partner. Other studies have found that married women are less likely to intravaginally cleanse (Myer, 2006, Myer, 2004). It may be the case that older women were in more stable relationships and were less likely to intravaginally cleanse after sex in case it offends their partner or alternatively merely felt less of a need to intravaginal cleanse with a stable partner. It is a limitation of this analysis that I was not able to control for marital status in the quantitative data and am therefore unable to test these hypotheses. Either way, this finding suggests that the need to intravaginally cleanse after sex declines as women age and highlights the need to target younger women with messages about intravaginal cleansing.

Crowding

The quantitative findings demonstrated that women in larger households were more likely to intravaginally cleanse after sex. The qualitative data offers a possible explanation for this finding. Households in KwaZulu-Natal are often multi-generational and there were frequent references to the need to be 'clean' before greeting other people in the household as a sign of respect. As such, in the IDIs women often talked about placing a bowl of water next to their bed in order to wash after sex. Household crowding was inversely associated with intravaginal cleansing in the microbicide-diaphragm trial in Madagascar (Penman-Aguilar, 2011). Madagascar is very ethnically diverse and intravaginal cleansing practices varied widely by region. The qualitative data from this MDP analysis illustrates the extent to which socio-cultural norms inform intravaginal cleansing practices. This would suggest that the disparity between studies in the influence of household crowding is highly likely to relate to differences in household structures and socio-cultural norms regarding intravaginal cleansing between

KwaZulu-Natal and Madagascar. Crowding has been shown to reduce adherence to microbicides in Uganda (Abaasa, 2012) although not in South Africa (Crook, 2010). The impact of household size on both intravaginal cleansing practices and microbicide use should be considered in future studies.

Condom Use

In this study both the quantitative and qualitative data suggest that intravaginal cleansing after sex is not influenced by condom use. Only a few women stated that a condom reduced the need to clean internally after sex. This finding differs from other studies in South Africa which have found that intravaginal practices, although not specifically post-coital intravaginal cleansing, are lower among women who use condoms (van der Straten, 2010a, Smit, 2011, Myer, 2006). Van der Straten suggests that "the use of male condoms should prevent any post-coital discharge, and hence, this may in part explain lower vaginal practices" (2010b;597). However in this analysis, the qualitative data clearly demonstrated that intravaginal cleansing is influenced equally by the need to remove semen as well as vaginal sexual fluids and sweat. This may explain why condom use does not influence post-coital intravaginal cleansing in this cohort.

Menstruation

The qualitative findings reiterate previous descriptions of sex during menstruation as not culturally acceptable in KwaZulu-Natal (Berglund, 1976). However, both the quantitative and qualitative findings confirm that a minority of women do have sex during menstruation in this community. The qualitative findings suggest that during menstruation women may be more inclined to clean intravaginally after sex. Increased intravaginal cleansing during menstruation has been well documented (Veldhuijzen, 2006, Scorgie, 2011). However, there has been little attention to intravaginal cleansing specifically in relation to sex during menstruation. In the quantitative analysis, ever having sex during menstruation was not associated with intravaginal cleansing after sex. Nonetheless, collectively the quantitative and qualitative analyses show that some women have sex during menstruation and use gel when having sex during menstruation. This finding highlights the need to understand more about gel use during menstruation and intravaginal cleansing after sex during menstruation.

Other associations

Other studies in South Africa have found associations between intravaginal practices (although not specifically post-coital intravaginal cleansing) and educational level, sexual activity, and

HIV/STI prevalence (Myer, 2006, Myer, 2004, Scorgie, 2011). These characteristics were not associated with intravaginal cleansing up to one hour after sex in this MDP cohort. The differences in the findings can most likely be attributed to the fact that in this analysis I focus exclusively on post-coital intravaginal cleansing, as opposed to intravaginal cleansing practices more generally. However, it is also worth noting that this analysis is the only one to exclude HIV positive women. Therefore we cannot exclude the fact that the disparity in the findings could also be reflective of different post-coital cleansing practices among HIV negative and positive women.

Cleansing practices

Although we did not ask women what they used during intravaginal cleansing in the sexual behaviour questionnaires, it is clear from the qualitative data that intravaginal cleansing mainly involves water, fingers and/or a cloth. One of the systematic reviews of intravaginal practices and HIV found that fingers were the most commonly used way of applying liquids during intravaginal cleansing (Hilber, 2010a). Conversely the WHO household survey in KwaZulu-Natal found that most women who intravaginally cleansed used a product, with cloth being the most frequently used although not necessarily after sex (Smit, 2011). The use of water and fingers may be preferable to the use of cloth because, as described in section 5.1.5, the meta-analysis of participant data found an association with HIV in terms of intravaginal cleansing with soap, cloth or paper (Low, 2011). It is also promising that, unlike in other studies (Scorgie, 2011), there were few reports in this analysis of commercial or other products being used for intravaginal cleansing. It would still be useful to understand the impact that each of these different cleansing practices (water, fingers and cloth) has on the removal of gel after sex to find out if the concern about post-coital cleansing is justified.

5.6.2 Intravaginal cleansing when using microbicide gel

In the quantitative analysis there were no differences in intravaginal cleansing between women in the product or placebo groups. Only 1 of the 12 microbicide trials described in Table 5-3 reported on intravaginal cleansing during trial follow-up and they did not observe differences between gel groups either (Halpern, 2008).

It is of particular interest that intravaginal cleansing up to one hour after sex was higher among women who consistently used gel throughout the trial compared to women who were less consistent users. This quantitative evidence suggests that the presence of the gel may increase some women's desire to intravaginally cleanse after sex. The qualitative data supports this finding with a number of women talking about the need to cleanse intravaginally to specifically remove the gel between sex acts or after sex.

Interestingly a diaphragm trial in South Africa and Zimbabwe found the opposite results (van der Straten, 2010a). They found that in the intervention arm, women who intravaginally cleansed were less likely to report consistent use of gel when administered in a diaphragm (Replens gel). The authors suggest that intravaginal cleansing may interfere with the use of the diaphragm, which has been shown elsewhere (Sharma, 2006, Montgomery, 2009). The fact that the van der Straten study attributed the differences in intravaginal cleansing to the diaphragm rather than the gel, may explain the differences in our findings. However it is important to note that the diaphragm trial measured intravaginal cleansing unrelated to sex and this may also have influenced the difference with our findings. Neither the CS microbicide trial, nor a phase II microbicide trial, which measured intravaginal practices during follow up, measured the differences in intravaginal cleansing in relation to consistency of product use (Altini, 2010, Halpern, 2008).

Evidence from MDP 301 and other microbicide trials has shown that many women describe microbicides as being cleansing and hygienic (Mantell, 2006b, Saethre, 2010, Gafos, 2008, Montgomery, 2010b). The gel has been described as treating vaginal discharge and itching, cleansing the body in terms of purifying the blood, getting rid of unpleasant bodily secretions and odours, and protecting against disease (Montgomery, 2010b). However, to date the impact of women perceiving the gel as having cleansing properties has not been considered in terms of intravaginal cleansing. If women think the gel is cleansing, it is feasible to think that they may want to leave the gel *in situ* after sex in order for it to absorb impurities which can then be discarded in the gel as post-sexual discharge. However, the fact that in this analysis the prevalence of intravaginal cleansing was higher among women who consistently used gel, could suggest the opposite. This is to say, for some women the idea that the gel absorbs impurities could exacerbate the need to remove the gel after sex. A diaphragm trial that observed higher levels in intravaginal cleansing with HEC placebo gel compared to the less viscous Acidform gel concluded that: “gels may have been sensed as moisture or wetness, and vaginal cleansing may have been motivated by the volume of gel that was present; that is, as more gel accumulated in the vagina, women may have experienced a greater compulsion to cleanse despite having been instructed not to do so” (Penman-Aguilar, 2011;193).

Despite the difference in results in terms of whether intravaginal cleansing is associated with higher or lower product adherence, the finding that product use (microbicide or diaphragm) is impacted by intravaginal cleansing practices, or vice versa, is critically important for the future of HIV prevention and requires far more focused attention in future research. It is vital that we understand more about the impact of post-coital intravaginal cleansing on the effectiveness of microbicides and the association between the use of microbicides and intravaginal cleansing.

We should not lose sight of the fact that the majority of women did not report post-coital intravaginal cleansing. However these findings are especially important in the context of the current tenofovir microbicide trials which are evaluating both pre and post coital gel application. If the efficacy of a microbicide is reduced by post-coital cleansing and if, for some women, the presence of the gel increases the desire to intravaginally cleanse after sex, we may need to consider alternative delivery mechanisms that limit the volume of gel left in the vagina after sex. In the meantime it is vital that the impact of the vaginal ring on intravaginal cleansing is also evaluated.

5.6.3 Changing intravaginal cleansing practices

Although the prevalence of intravaginal cleansing up to an hour after sex in this study was not optimal for microbicide use, it is evident from both the quantitative and qualitative data that some women were willing to change their behaviour when using microbicides. In the quantitative data there was a marked decrease in intravaginal cleansing after sex from the first to the second half of the trial. In the qualitative data it was clear that some women were willing to stop intravaginal cleansing when using the gel after being counselled to do so. However, the qualitative data also highlighted that some women misunderstood the messaging and assumed they *should* remove the gel after sex. These findings illustrate the need for consistent counselling regarding intravaginal cleansing.

Another finding supporting the need for effective counselling is the fact that the prevalence of post-coital intravaginal cleansing was higher among women enrolled at Mtubatuba and Madwaleni clinics than KwaMsane clinic. Area of residency was not associated with cleansing practices, suggesting that the differences observed by clinic of enrolment are most likely to do with differences in counselling. The fact that women enrolled at Mtubatuba and Madwaleni clinics were most likely to stop intravaginal cleansing in the second half of the trial suggests that counselling against intravaginal cleansing after sex at these clinics had an impact.

Counselling has been shown to decrease intravaginal cleansing among women in other microbicide and diaphragm trials (Penman-Aguilar, 2011, van der Straten, 2010a, Halpern, 2008, Altini, 2010). However, in the diaphragm trial in Zimbabwe and South Africa, the counselling messages were more successful at decreasing intravaginal insertion than intravaginal cleansing (van der Straten, 2010a). There are certainly counselling models that have been used successfully in the USA to reduce intravaginal cleansing practices (Grimley, 2005). Prior to microbicide roll out, processes should be developed to identify women who require intervention and standardised counselling techniques should be evaluated in South Africa to assist in the reduction of intravaginal cleansing after sex.

The delivery of messages about the public health risks of vaginal practices has been hindered by the lack of sufficient evidence associating vaginal practices to HIV acquisition. Similarly, evidence supporting the need to avoid post-coital intravaginal cleansing when using microbicides is insufficient. Given that intravaginal cleansing is clearly an important socio-cultural norm for women in terms of sexuality and sexual health, it is not advisable to discourage the practices without an evidence base. Even then, messaging to discourage the practices must be sensitive to local motives for intravaginal cleansing and under what circumstances these may be waived by women. These factors highlight the need for the development and delivery of clear and consistent public health messages about the risks of intravaginal cleansing in relation to both HIV and microbicide use. Inconsistent or inaccurate messaging could have a major impact on intravaginal cleansing and ultimately the feasibility of microbicides in this community.

5.7 Conclusion

The majority of women did not report post coital intravaginal cleansing. However, one third of women did intravaginally cleanse up to one hour after sex at some time during the trial, despite repeatedly being advised not to. Discouraging post-coital intravaginal cleansing clearly runs counter to local vaginal hygiene practices for a substantial minority of women in this community. However, the analysis demonstrates that it is a practice amenable to change. In order to develop effective messages and counselling practices, it is vital that we understand more about the impact of post-coital intravaginal cleansing on product effectiveness, establish definitive public health messages regarding the HIV and STI risks associated with intravaginal cleansing, and explore further the association between post-coital intravaginal cleansing and gel adherence. If post-coital intravaginal cleansing significantly reduces the efficacy of microbicides, whether delivered before and after sex or in a vaginal ring, then cleansing practices could undermine the feasibility of microbicides for some women in the absence of effective behaviour change programmes.

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6 Intravaginal insertion in KwaZulu-Natal

Summary

As described in chapter 2, there are substantial gaps in our understanding of how socio-cultural norms relating to intravaginal insertion may influence the use of vaginal microbicides. Intravaginal insertion is practiced in many parts of Africa. It is often associated with a preference for 'dry' sex. All HIV prevention microbicides tested to date have been vaginally applied lubricant-based gels. Consequently the acceptability of microbicides among women who engage in intravaginal insertion to achieve 'dry' sex has been questioned. In this chapter, I present results of a systematic review of the literature on intravaginal insertion in Africa. To better understand whether a lubricant-based vaginal microbicide would be acceptable in communities where intravaginal insertions are used, I use the MDP 301 data to investigate the desired effects of intravaginal insertion. I then investigate how women experienced the use of microbicides in the clinical trial. I compared these findings to further understand how sexual practices, preferences and expectations could impact on the use of microbicides. This analysis is based on qualitative data collected during in-depth-interviews and focus-group discussions with women enrolled in the trial as well as women and men from the community. It focuses on people's knowledge of intravaginal insertion in the community and trial participants' experience of using microbicides. This analysis aims to examine whether the traditional use of intravaginal insertions could be in conflict with the use of vaginal microbicides.

6.1 Literature review

As described in the last chapter, the systematic review of literature on intravaginal practices in Africa identified 51 articles on intravaginal insertion. In this section I present evidence from the systematic review of the literature on intravaginal insertion in Africa. Table 6-1 presents the manuscripts included in the review, lists the country or countries where the study was conducted, notes if the paper reported specifically on intravaginal insertion (indicated with an X) or if the report included intravaginal insertion but did not exclude other vaginal practices (indicated with an O) and lists the prevalence of intravaginal insertion when reported in the manuscript.

Table 6-1: Systematic literature review of intravaginal insertion in Africa

No.	Reference	Country	IV Insert	IV Insertion Prevalence
1	Allen 2010	Tanzania	X	5%
2	Allen 2007	Tanzania	X	low
3	Bagnol 2008	Mozambique	X	
4	Baisley 2009	Tanzania	X	5-10%
5	Banda 2007	Zambia	X	[45%]
6	Beksinska 1999	South Africa	X	[46%]
7	Beksinska 2010	South Africa	X	Treatment 24%
8	Braunstein 2005	Brazil, Burkina Faso, Senegal, India, Kenya, South Africa, Thailand, USA, Zimbabwe	X	
9	Brown 1993	DRC	X	33%
10	Civic 1996	Zimbabwe	O	
11	Dallabetta 1995	Malawi	X	[47%]
12	Guest 2007	South Africa	X	13%
13	Hilber 2010a	META: Burkina Faso, Kenya, Ivory Coast, Malawi, South Africa, Tanzania, Uganda, USA, Zambia, Zimbabwe	X	
14	Hilber 2010b	WHO GSVP: Mozambique, South Africa, Indonesia, Thailand	X	
15	Hira 1990	Zambia	O	
16	Hull 2011	WHO GSVP: Mozambique, South Africa, Indonesia, Thailand	X	Moz=72%, SA=17%
17	La Ruche 1999	Ivory Coast	X	10%
18	Lees 2010	Tanzania	X	0%
19	Low 2011	META: Kenya, Malawi, South Africa, Tanzania, Uganda, Zimbabwe	X	1-20%
20	Mbikusita-Lewanika 2009	Zambia	X	75%
21	Mbizvo 2004	Zimbabwe	X	28%
22	McClelland 2008	Kenya (FSW)	X	10%
23	McClelland 2006	Kenya (FSW)	X	1%
24	McFarland 2009	Botswana	X	
25	Mehta 2007	Kenya (men)	X	
26	Mehta 2008	Kenya (men)	X	
27	Morar 1998	South Africa (FSW)	X	91%
28	Morar 2003	South Africa (FSW)	X	94%
29	Myer 2005b	META: CAR, DRC, Kenya, Ivory Coast, Malawi, South Africa, Thailand, Zambia, Zimbabwe	X	26-99%
30	Pitts 1994	Zimbabwe	X	
31	Ramjee 1999	South Africa (FSW)	O	
32	Ray 1996	Zimbabwe (men)	X	
33	Reddy 2009	South Africa	X	37% prefer dry sex
34	Roddy 1998	Cameroon (FSW)	X	45%
35	Runganga 1992	Zimbabwe	X	[87%]
36	Runganga 1995	Zimbabwe	X	99%
37	Rustomjee 1999	South Africa (FSW)	O	[80%]
38	Sandala 1995	Zambia	O	
39	Sandøy 2007	Zambia	O	[5-20%]
40	Schwandt 2006	Kenya (FSW)	X	[13-36%]
41	Scorgie 2011	South Africa	X	12%
42	Scorgie 2008	South Africa	X	
43	Scorgie 2010	South Africa	X	
44	Smit 2011	South Africa	X	12%

No	Reference	Country	IV Insert	IV Insertion Prevalence
45	Turner 2010	Zimbabwe	X	40%
46	van de Wijgert 2000	Zimbabwe	X	96%
47	van de Wijgert 2008	Uganda, Zimbabwe	X	Uganda=2%, Zimbabwe=12%
48	van der Straten 2010a	South Africa, Zimbabwe	X	SA Gauteng=19%, SA KZN=13%, Zimbabwe=21%
49	van der Straten 2010b	Zimbabwe	X	67%
50	Veldhuijzen 2006	Rwanda	X	
51	Watson-Jones 2007	Tanzania	X	4-9%

NB: META=meta-analysis; WHO GSVP=refers to the World Health Organisation multi-country study on Gender Sexuality and Vaginal Practices; FSW=Female Sex Worker; DRC=Democratic Republic of Congo; CAR=Central African Republic; SA=South Africa; KZN=KwaZulu-Natal; In the column entitled 'IV Insert' 'X' is used to show that the article reported on intravaginal insertions, and 'O' is used to show that the article reported on intravaginal insertion but it was not possible to exclude other vaginal practices. In the column entitled 'IV Insertion Prevalence' brackets [] are used when it was not possible to exclude other vaginal practices.

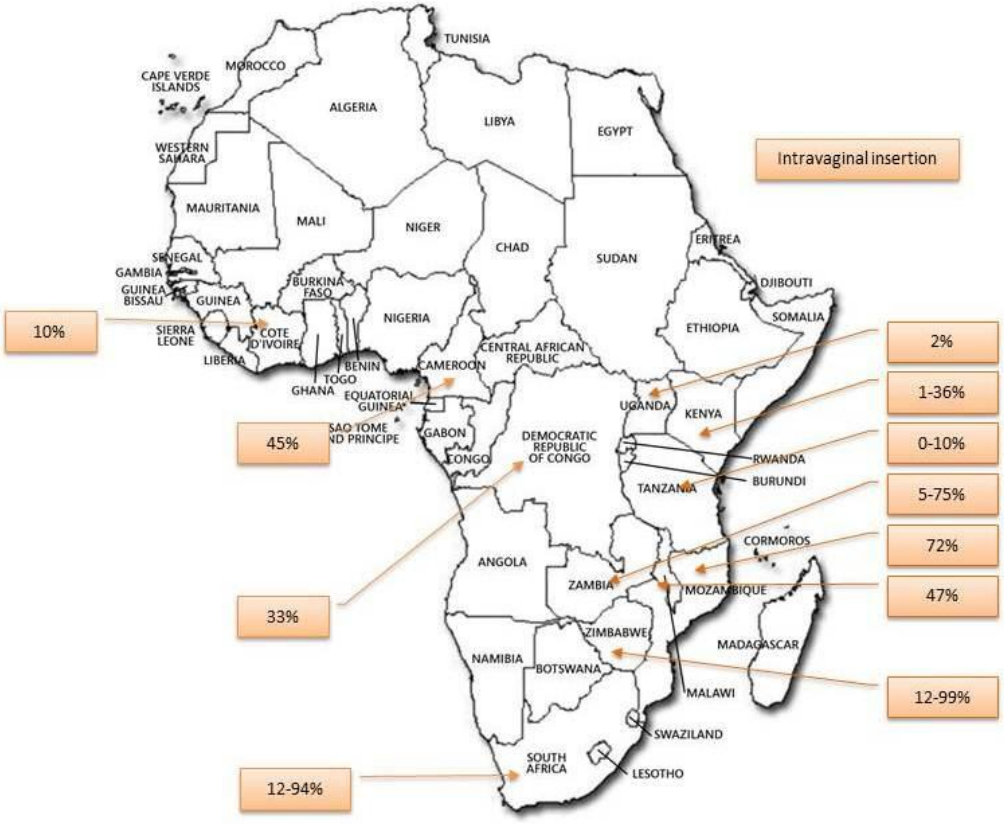
6.1.1 Prevalence of intravaginal insertion

Out of the 51 papers identified in the systematic literature review, 33 provided primary data on the prevalence of intravaginal insertion. Two meta-analysis articles provided secondary data, some of which had not been previously published. The minimum and maximum prevalence reported for each country is illustrated in Figure 6-1. The reported prevalence of intravaginal insertion ranged from 0% in Tanzania to 99% in Zimbabwe. Comparing the prevalence of intravaginal insertion across studies was subject to the same problems as those outlined for intravaginal cleansing described in chapter 5 section 5.1.2.

Prevalence in South Africa

Although initial studies in South Africa among female sex-workers suggested that intravaginal insertion was commonly practiced (Morar, 1998, Morar, 2003, Ramjee, 1999, Rustomjee, 1999), subsequent studies among women not engaged in sex work found that the prevalence is relatively low. For example, a multi-country survey found that intravaginal insertion practices were substantially lower in South Africa than in Mozambique (17% compared to 72%) (Hull, 2011).

Figure 6-1: Prevalence of intravaginal insertion in Africa as reported in the literature



As shown in Table 6-1, among women not engaged in sex work intravaginal insertion has been reported as ranging from 13% to 46% in Gauteng, although the latter study reported on all practices designed to 'dry' the vagina and therefore may include both intravaginal cleansing and insertion practices (Beksinska, 1999, van der Straten, 2010a, Guest, 2007). The only evidence from the Western Cape is based on women's preference for dry sex as opposed to the use of intravaginal insertions. The study found that 37% of women reported a preference for dry sex which again could indicate intravaginal cleansing as well as insertion (Reddy, 2009). In KwaZulu-Natal, reports of intravaginal insertion have ranged from 94% among sex workers to 13% among women not involved with sex work (van der Straten, 2010a, Morar, 2003). Another study in KwaZulu-Natal among women with symptoms of reproductive tract infections and STIs, found that a quarter of women practiced intravaginal insertion to treat the symptoms (Beksinska, 2010).

The 2 articles from the WHO GSVP household survey identified in the systematic literature review, found that in KwaZulu-Natal 17% (95% CI: 12, 23%) of women reported ever practicing intravaginal insertion and 12% (95% CI: 8, 17%) reported currently practicing it (Hull, 2011, Smit, 2011). Overall, intravaginal insertion in South Africa is low among women not engaged in sex work. As with intravaginal cleansing, the vast differences in prevalence across countries

and population groups suggests that intravaginal insertion practices are influenced by socio-cultural norms regarding sexuality and sexual health.

6.1.2 Motivation for intravaginal insertion

As described in the last chapter, the motivation for intravaginal insertion overlap with the motivation for intravaginal cleansing and include vaginal hygiene, vaginal health, contraception, treatment of sexually transmitted infections or vaginal discharge, post-partum vaginal restoration, and sexual preparation. A seventh motivation for the use of intravaginal insertions was as a 'love potion' to attract or retain partners. I will return to this topic in chapter 7. As explained in the last chapter, despite the overlap of motivation for intravaginal practices, in this chapter I focus on intravaginal insertion practices for sexual preparation.

6.1.3 Intravaginal insertion as part of sexual preparation

The most frequently reported motivation for intravaginal insertion is to enhance sexual pleasure (Morar, 2003, Brown, 1993, Civic, 1996, Sandala, 1995, Runganga, 1992, Smit, 2011, Hull, 2011, Reddy, 2009, La Ruche, 1999, Veldhuijzen, 2006, Beksinska, 1999, Bagnol, 2008, Scorgie, 2009, Mehta, 2008, Scorgie, 2011, Hilber, 2010b). The WHO study found that the main reasons women in KwaZulu-Natal reported using intravaginal insertions were to increase their partners' sexual pleasure (32%), their own sexual pleasure (30%), and/or to keep their partner committed to the relationship (41%) (Hull, 2011). This said, it is important to stress that many women reported multiple reasons for intravaginal insertion and the desire for sexual pleasure often overlapped with the desire for vaginal hygiene.

A wide range of products have been reported to be used as intravaginal insertions in Africa. There are a number of regional variations although a surprising amount of consistency between the types of products used. They can be grouped into 7 main categories (Brown, 2000):

- ***Traditional medicines:*** roots, bark, leaves, herbs, minerals, and animal parts;
- ***Food items****:* cassava, kapok, nuts, kola, mango, root ginger, chilli pepper sauce, tomatoes, salt, vinegar, berries, lemon juice, sugar, tea, food seasoning, ice cubes, and Coke;
- ***Cleaning or hygiene products****:* soap powder, talcum powder, toothpaste, detergents, caustic soda, antiseptics, and bath salts;
- ***Commercial products****:* tobacco or snuff (finely-ground tobacco), aspirin tablets, antibiotics, and perfumed oils;

- ***Over the counter remedies**:* Tiger Balm (a menthol-based anodyne and anti-itching remedy used for colds, headaches or insect bites), Blue Stone (copper sulphate: used locally to clean wounds), alum (hydrated aluminium potassium sulphate), Entressdruppels (oral remedy to relieve nervousness, restlessness, and sleeplessness. Locally believed to protect a baby from evil when placed on the fontanella), and Staaldruppels (an oral liquid treatment for iron deficiency anaemia's and stopping bleeding resulting from minor cuts);
- ***Items marketed as aphrodisiacs**:* tablets, ointments and powders, such as Tong Yong tablets, pau-yuen-tong Chinese balm, Love Drops and China Fruit (dried Chinese plums) or granules sold in plastic straws and sucked like a sweet;
- ***Absorbing materials**:* paper, tampons, cotton wool, cloth, gauze, flannel, tissue paper, and newspaper.

Items are reportedly either diluted in water and then inserted, or inserted as they are and left to 'dissolve', or inserted and then removed prior to sex (Scorgie, 2009). In Mozambique there are additional examples of traditional medicines merely being put in the woman's underpants or the powder being moulded into balls called 'vaginal eggs' and inserted (Bagnol, 2008). In KwaZulu-Natal there are examples of women using what are referred to as 'pantyhose', which is tying traditional medicines into small pieces of nylon tights and inserting it for a few hours, removing it before sex (Scorgie, 2009).

In the literature, the use of intravaginal insertions to enhance sexual pleasure is often referred to as 'dry' sex. However, the WHO study found that practices to enhance sexual pleasure "are not always aimed at 'drying' the vagina; women focused more on 'closing, warming and tightening'" the vagina (WHO, 2007). In fact, the prioritisation of vaginal 'tightening' in the use of intravaginal products is evident in most of the literature even if it is not explicitly differentiated from vaginal 'drying'. For example, while Civic's article is entitled 'dry sex' and women were asked about their use of 'vaginal drying agents', she explains that 'drying' and 'tightening' were equally desirable effects of product use, in addition to vaginal 'warming' (Civic, 1996).

Brown's research in the Democratic Republic of Congo demonstrated that when referring to 'drying' the vagina, women's aim was to remove watery, messy, dirty excessive amounts of secretions, as opposed to the removal of small amounts of normal secretions caused by sexual excitement, or unusual vaginal discharge caused by infection (Brown, 1993). Similarly research in South Africa found that ideally the vagina was expected to be clean, not too wet or dry, tight, closed and warm in preparation for sex (Hilber, 2010b). This idea of the removal of

unusual excessive amounts of watery secretions or a vagina that is neither too wet nor too dry, differs from the definition of 'dry' sex that is often proposed in terms of the removal of all vaginal secretions (Braunstein, 2003). In contrast to the idea of dry sex, a number of studies have highlighted the use of intravaginal insertions to increase vaginal lubrication. Although there is some evidence from South Africa (Guest, 2007), the majority of the evidence is from the Great Lakes region of East Africa (Baisley, 2009, Watson-Jones, 2007, McClelland, 2008, Mehta, 2008, Veldhuijzen, 2006, Hassan, 2007, Priddy, 2011, Sharma, 2006, Braunstein, 2005). The nuances between the 'drying', 'tightening' and 'heating' effects of product use have been relatively unimportant in public health research that has been concerned about the desiccant, irritant and astringent effect of intravaginal insertions on the vaginal mucosa and flora in terms of increasing the risk of HIV acquisition. However, these nuances become critical in terms of considering the acceptability of lubricant based vaginal microbicides in the future.

The WHO study found that in KwaZulu-Natal the intended physical effects of using intravaginal insertions were to tighten (43%), heat (30%) or dry (23%) the vagina (Hull, 2011). In addition to 'warming' the vagina (Beksinska, 1999, Brown, 1993, Civic, 1996), references to intravaginal insertion making a woman 'hot' during sex, in terms of being sexually aroused, have been noted in KwaZulu-Natal (Scorgie, 2009, Berglund, 1976, Morar, 1998) Mozambique (Bagnol, 2008) and Zimbabwe (Runganga, 1992).

6.1.4 Intravaginal insertion and microbicides

In addition to concerns about the HIV risks associated with intravaginal practices, a number of authors have questioned whether microbicides will be acceptable among women who engage in vaginal practices to achieve 'dry' sex (Beksinska, 1999). The main concern is that lubricant based microbicides will not be acceptable to women who engage in intravaginal insertion, especially where socio-cultural norms prioritise a preference for dry sex (Beksinska, 1999, Kun, 1998). This concern is fuelled in South Africa by the fact that research has shown both women and men associate the use of progestogen injectable contraceptives with vaginal wetness and consider this an unacceptable side effect (Smit, 2002, Beksinska, 2001).

As with intravaginal cleansing, the compatibility between the desired effects of intravaginal insertion and microbicide use need to be understood within the context of the socio-cultural factors that influence women's vaginal practices. In this chapter, I use qualitative data to compare and contrast the impact of microbicides and intravaginal insertions on sexual pleasure. To better understand whether a lubricant-based vaginal microbicide gel would be acceptable in communities where intravaginal insertions are used, I investigate the desired effects of intravaginal insertion and socio-cultural norms of sexual pleasure. I then investigate

how women experienced the use of vaginal gels in a microbicide clinical trial in KwaZulu-Natal. I compared these findings to further understand socio-cultural norms relating to sexual practices, preferences and expectations and to examine whether the use of intravaginal insertions conflicts with the use of microbicides in a rural part of KwaZulu-Natal. These findings were published in the Journal of Culture Health and Sexuality in 2010 (Gafos, 2010).

6.2 Methods

The analysis is based on accounts of trial participants' and their partners' personal experience of using gels, trial participants' as well as community members' knowledge of intravaginal insertion in the community, and in a minority of cases, respondents' personal experience of using intravaginal insertions.

In total, data from 118 IDIs with 63 women and 8 men, and 15 FGDs with 73 women and 53 men, are included in the analysis. The composition of the IDI samples is presented in Table 6-2 and of the FGD samples in Table 6-3. The overall management and analysis of the qualitative data have been described in chapter 4 section 4.4. For this chapter there were two stages to the analysis. Firstly, I analysed data from the 15 FGDs with trial participants and community members and 110 IDIs with trial participants coding all text that addressed issues relating to intravaginal insertion. Three main themes emerged from the data: motivation for intravaginal insertion, types of intravaginal insertions, and desired outcomes of using intravaginal insertions. Secondly, I analysed data from the 6 FGDs with trial participants, 110 IDIs with trial participants and 8 IDIs with male partners. I coded all text relating to the impact of the gel on sexual experience. I compared and contrasted the expected outcomes of using intravaginal insertions with the actual experiences of using microbicide gels.

The analysis was completed prior to the end of the trial as data saturation had been achieved in relation to the topics of interest (Dahlgren, 2007). Transcripts of IDIs with the subsequent 21 women and 9 men as well as the subsequent 12 FGDs were reviewed after the end of the trial. The data in these transcripts supported the findings of this analysis and there were no contradictory findings.

Table 6-2: Description of the IDI sample

	Female participant IDIs	Male partner IDIs
Week 4	63	8
Week 24	38*	
Week 52	9*	
Total number of IDIs	110	8
Number of respondents	63	8
Mean age	33	41
Age range	19-64	26-60

***** The 38 women interviewed at week 24 and the 9 interviewed at week 52 were initially interviewed at week 4

Table 6-3: Description of the FGD sample

	Female participant FGDs	Female community FGDs	Male community FGDs
Total number of FGDs	6	3	6
Number. of respondents	47	26	53
Mean age	35	29	25
Age range	19-65	18-59	18-45

As described in chapter 4 section 4.3.3, during a workshop with study staff I interrogated the meanings of the words used to describe the expected outcomes of using intravaginal insertions and the actual experiences of using microbicides. This involved listing all words used in the study to describe sexual experiences, discussing alternative uses of each word in sentences not related to sex, listing alternative words that could have been used to describe the same experiences but were not, cross referencing words used to describe intravaginal insertion and gel usage, and, finally, categorising the words into associated experiences. This resulted in the three categorisations of hot, tight and dry sex which I present below.

6.3 Results

6.3.1 Intravaginal insertion

In both the in-depth-interviews and FGDs, women and men widely acknowledged the intravaginal use of a variety of products. In their first interview, 47 of the 63 trial participants said they knew that women in the community used intravaginal insertions. The majority of participants in 14 of the 15 FGDs were also familiar with the topic. Knowledge about the use of insertions was based on rumours in the community, seeing products sold on the street, stories from neighbours, friends or female family members using products and, occasionally, personal

experience. Respondents said that women used intravaginal insertions predominantly to enhance sexual pleasure, although other reasons were also reported such as vaginal hygiene and maintaining good health.

Of the 63 trial participants interviewed, only 7 reported ever using intravaginal insertions themselves for sexual pleasure before joining the trial. None of the participants reported use during the trial. Female community members not enrolled in the trial were not asked directly about their own personal use of insertions because this information was not collected in FGDs, but a similar proportion spontaneously described using insertions themselves. There was no age differentiation in women's knowledge of product use. The majority of all female and male respondents said this was an age-old practice as articulated by this woman who had experience of selling and using intravaginal insertions:

> "We were using them (insertions) a long time ago, even our mothers were using them" (Community FGD, 50 year old woman).

Respondents said they were aware of a number of products that were used as intravaginal insertions to increase sexual pleasure (Figure 6-2). These included a range of commercial, hygiene or food products, such as snuff, Disprin (Aspirin), Inza (Ibuprofen), Colgate toothpaste, bath salts, and Knorrox cubes (South African food seasoning), as well as over the counter remedies such as Tiger Balm, alum, Blue Stone, Entressdruppels and Staaldruppels. There was a range of sexual stimulants that were designed to be taken orally, but were sometimes inserted vaginally, such as Silver Bullets (tablets crushed before insertion) and Love Drops (liquid). In addition there was a range of traditional medicines (locally called *umuthi* [singular] or *imithi* [plural]). Generally respondents were unaware of the actual names or contents of the *imithi*, but some were mentioned such as *imbulu* oil (oil and fat of a water monitor), snake oil, hippopotamus fat, and *umganu* tree bark (soaked and then water inserted vaginally). Other general items infrequently reported to be inserted vaginally included whisky, newspaper after being softened by rubbing, water after boiling rice in it and water after soaking a type of jelly fish (also renowned for treating asthma and arthritis when taken orally). Overall, the most commonly reported intravaginal insertions were snuff, alum and a range of *imithi*.

Figure 6-2: Intravaginal insertions

Intravaginal insertions were reportedly used in a variety of ways to enhance sexual pleasure. Some products were diluted in water and then applied intravaginally (particularly alum), or inserted and either left to 'dissolve' (e.g. Tiger Balm or Blue Stone), or inserted and the remnants removed prior to sex (e.g. traditional herbs and snuff). There were no reports of *umuthi* being inserted in pantyhose. Respondents reported that these products were readily available from pharmacies, shops, and traditional healers. I purchased most of the products at the local pharmacy, including *Imbulu* oil. The pharmacy staff were clearly aware of the intravaginal use of the products and even specified that only the pure white Colgate toothpaste was used vaginally, not the multi-coloured Colgate containing breath freshener. A male customer in the pharmacy assisted in identifying the English name of the *Imbulu* animal, and when asked what the oil was used for he said women use it, pointing towards the genital area, and was obviously embarrassed. Knowledge of intravaginal product use is clearly commonplace, but because of its sexual and personal nature it is a subject addressed with embarrassment and often humour.

Many respondents referred to a state of sexual preparedness that a woman was expected to achieve and this was most regularly described as a woman being 'alright' in advance of sex. For example, this participant said that women use intravaginal insertions:

> "So that should her lover arrive he would find her in a good condition" (Trial IDI, 24 year old woman).

In order of reporting frequency, the desired outcome of using intravaginal insertions was to make a woman 'hot', 'tight' or 'dry' during sex and these concepts are explored below.

'Hot' Sex

Intravaginal insertions have previously been described as increasing the 'warmth' of the vagina. However, in this study when respondents referred to using insertions to be 'hot' (*shisa*), only on a few occasions did this relate to the vagina itself being 'hot'. Instead it predominantly related to sexual arousal. Similarly references to a woman being 'cold' (*banda* or *qanda*) related to women not being sexually attractive, not being aroused, or being sexually unresponsive.

When asked to define the difference between 'hot' and 'cold' sex, one participant explained:

> If sex was not hot: "I don't care if he stops (sex)"
>
> Whereas if sex is hot: "I will hold on to him" (Trial IDI, 22 year old woman).

The quotes below illustrate the use of the word 'hot' to describe sexual desirability:

> "Snuff brings that heat into your blood (*uku<u>shisa</u> kwegazi*)" (Trial IDI, 31 year old woman).
>
> "Snuff makes you … more enjoyable and hot (*shisa*) during sex" (Trial IDI, 33 year old woman).

The idea of hot sex was often combined with references to increasing male sex drive (*langazele* meaning 'to long for' or 'desire') or making the woman 'strong' during sex in terms of being physically active during penetration. The words translated as strong included *uqine* ('making strong'), *khuthale* ('active', 'diligent' or 'industrious'), and *simame* ('to get strong', especially after illness). The word *simame* is also used to refer to 'success' in terms of someone who is hard working and has elevated their social status.

The following quotes explain the use of intravaginal insertions in terms of increasing libido:

> "You may end up experiencing difficulty, maybe your partner is not eager (*akasaku<u>langazeleli</u>*) for sex.… You insert Zulu things (traditional medicines) in order for your partner to find you right, so that he is eager (*aku<u>langazele</u>*) for sex" (Trial IDI, 33 year old woman).
>
> "Some say you must insert, maybe it will help you to be strong (*usimame*) when you are having sex" (Trial IDI, 46 year old woman).

Snuff was the most commonly reported intravaginal insertion used to achieve 'hot' sex. There are references in the literature to the intravaginal use of snuff by women on their own for personal sexual satisfaction (Scorgie, 2009). Similar reports did emerge in this investigation although they were rare and generally described in terms of women becoming addicted to using snuff vaginally and "craving it" (*qaleka*):

> "I know of an old woman who can no longer stop inserting snuff even in front of us she inserts because she used to do it when she was young" (Trial FGD, 35 year old woman).

There were a few reports of snuff increasing the risk of cervical cancer which may be informed by public health messages regarding the risks of smoking tobacco.

'Tight' Sex

Increased sexual pleasure was also reported when the woman was 'tight'. The Zulu words to explain this included *buyisa*: 'cause to return' or 'restore'; *qoqa:* 'gather together' or 'collect' generally after being dismantled; *buyisana:* 'return' or 'become reunited'; *shwaqa:* 'collect together'; or *bamba:* to 'grasp'. All these terms referred to bringing the vagina 'back together', implying a return to the 'natural' and optimal state of a contracted and tight vagina. These conditions were regularly described as 'being like a virgin' (*intombinto* meaning 'young girl who has not been touched' or *itshitshi* referring to the age set of young virgin girls) or not being 'loose' (*xega*). The term loose is viewed as a negative attribute and is associated with promiscuity and infidelity, as well as older age.

There was another interpretation of being tight, as described by the Zulu word *shuba* (or -*shubisa*). This means becoming thick in terms of food, literally describing the process of 'precipitation' from fluid to solid, for example when jelly sets or milk curdles. Closely associated is the word *qinisa* which also means to tighten but more specifically is translated as to 'make firm' or 'strengthen'. When respondents referred to being 'wet', they were generally referring to the presence of 'water' in the vagina. So this idea of 'thickening' results in the transformation of watery secretions into thick mucus. Being tight or thick during sex was viewed as representing youth, virginity, desirability, and as an optimum state for the partner's sexual pleasure. Alum, Blue Stone, Tiger Balm and Disprin were most regularly associated with tight sex, although Staaldruppels and Entressdruppels were also mentioned.

”It is usual (to use insertions) because sometimes you find that you are loose (*uyaxega*) and you want to tighten (*ezizokuginisa*) yourself” (Trial IDI, 46 year old woman).

“I have heard ladies say that they insert. I do not know whether it is those things that thicken (*bayazishubisa*) their vagina” (Trial IDI, 19 year old woman).

‘Dry’ Sex

Respondents were far less likely to refer to the use of insertions for vaginal dryness compared with their ‘hot’ or ‘tight’ attributes. The Zulu word for ‘dry’ is *oma* and describes becoming dry, being thirsty, or the weather being dry such as in a drought. Bad sex was described as being ‘cold’ and ‘wet’. It would be easy to assume that ‘good’ sex must be ‘hot’ and ‘dry’, but in these interviews there was a distinct meaning to being ‘wet’. Wet was seen as an unhealthy state for the vagina, generally associated with watery secretions or STI related discharge. It was sometimes said that if a woman had been cursed by an evil spell her vagina would be ‘full of water’. Hence the desire to be dry was often related to the removal of excessive water or discharge in the vagina, and a need to ‘drain the water’:

“They insert to become dry (*yomile*) because maybe a woman feels that she is wet or there is water (discharge) coming out, then she needs things to insert to make her dry” (Trial IDI, 28 year old woman).

None of the references to becoming dry referred to the absence of secretions or abrasive penetrative sex. Women clearly distinguished between lubrication and excessive wetness as the following description of good and bad sex demonstrates:

Good Sex: “It is when sex is slippery (*uyashelela*) then it is more enjoyable”.

Bad Sex: “It’s when you feel pain ….or if you are too wet (*umanzi*) you do not enjoy sex” (Trial IDI, 22 year old woman).

6.3.2 Microbicide gel

There was an unexpected positive impact of gel use on sexual pleasure. Of the trial participants and their partners interviewed, 49 of the 63 women and 4 of the 8 men said the gel enhanced their sexual pleasure. Only one male reported a decrease in sexual pleasure. The remainder reported that gel did not affect their sexual experience. A number of women discussed the use of gel in the context of their knowledge of intravaginal insertions:

> "It has happened for a long time that there are things you insert just for a day and not informing your partner about such things. Now that there is gel, there is no need to look for other things" (Trial IDI, 42 year old woman).

Trial participants said that the gel increased their sexual pleasure by making sex 'hot', 'tight', 'smooth' and 'dry'. The hot, tight and dry outcomes and the frequency with which they were reported were consistent with the desired outcome of using intravaginal insertions. In addition women enjoyed the lubricating effect of the gel which made sex 'smooth'. The reports of these experiences did not change across the IDIs at different time points. The pattern of reporting was also similar across the three different vaginal gels dispensed in the trial. The concepts of hot, tight, smooth and dry sex in relation to gel use are explored below.

'Hot' sex

Trial participants were familiar with the idea of both intravaginal insertions and gel making sex 'hot' and at times compared gel use to other women's use of local insertions:

> "They say they do it (intravaginal insertion) for them to be alright. Some other things (insertions) make someone to be alright, others become hot during sex, others become pleasant during sex… I usually tell them that I have got the gel... that it makes me to be alright" (Trial IDI, 41 year old woman).

The trial participant quoted below is one of three wives in a polygamous marriage and states that she receives more attention from her husband than the other wives since she started using the gel:

> "It shows there is a difference that the gel makes; he craves that heat (*kushisa*) that rises, and it means he can see that it is love that rises, and it's hot (*ukushisa*)" (Trial IDI, 54 year old woman).

Male partners also referred to the gel making sex hot and increasing women's libido:

> "It (gel) makes you feel hot, and makes sex more enjoyable" (Male IDI, partner of 39 year old trial participant).

> "You see, it happens that if we start having sex, I reach climax and then I sleep. But when my partner inserts gel, there is encouragement in our lives…. there is no laziness (during sex)" (Male IDI, partner of 37 year old trial participant).

'Tight' sex

References to the gel tightening the vagina also reflect how respondents described intravaginal insertions. As the quote below demonstrates, women often used intravaginal insertions as a reference point:

> "What I have noticed with the gel is that when I inserted it, it was like I had used the traditional herbs (*imithi*) because it tightened (*buyisa*) my vagina… It feels tight like that of a child (*itshitshi*)" (Trial IDI, 29 year old woman).

The presence of the gel, which is viscous in consistency, was often described in the same way as the use of intravaginal insertions, as 'thickening' the vaginal secretions. This woman describes the gel as having a thickening effect, like hair gel:

> "(Gel) thickens (*shubisa*) the vagina, I will compare it to the styling gel that is used in hair … It works perfectly and I think it would help those people who have discharge because it thickens the vagina" (Trial IDI, 34 year old woman).

In terms of gel use, women used *simame* to describe the gel being 'successful' in enhancing sexual pleasure thereby having a positive impact on the relationship overall.

'Smooth' Sex

After describing the gel as making sex hot and tight, its lubricating impact was the third most commonly reported positive attribute. This reference to a preference for 'slippery' or lubricated sex only emerged in relation to gel use, and yet was not divorced from the ideal of sex being tight or dry. The quotes below highlight the reasons why some women liked the lubricating effect of the gel:

> "Eh I can say that after having sex I experienced pains, but since I have been using the gel I have been okay and sex is not painful. I even felt like after having sex I could have more because it was not painful, [because] it is slippery" (Trial IDI, 22 year old woman).

> "If I have inserted the gel and by the time we are having sex, he usually feels it being very hot in a pleasant way and that nice slipperiness. Everything is just nice for him. That is why he would just say, 'my darling, insert your thing' (gel)" (Trial IDI, 26 year old woman).

The desire for lubrication was not universal, and the potential lubricating effect of the gel had caused concern for some participants who ended up being pleasantly surprised that the gel was not 'too slippery':

> "I was expecting the gel to be slippery (*kuyashelela*) as it is like Vaseline, but only to find out that this gel tightens (*kuyabamba*)" (Trial IDI, 43 year old woman).

'Dry' Sex

The gel is lubricant in texture, yet the fact that the gel 'dried' the vagina was the fourth most frequently reported positive attribute, after hot, tight and lubricating:

> "When I did not use the gel I got wet, but when I used the gel it made me dry…It was more enjoyable" (Trial IDI, 19 year old woman).

> "(Before) there was just water coming out of the vagina, but now that I'm using the gel I feel alright and dry (*ngizomele*)" (Trial IDI, 26 year old woman).

Only one of the eight male partners interviewed commented that he preferred sex without the gel, because of the increased wetness. He described the gel as being like 'water' and stated that a woman using the gel is:

> "Like a person who is using contraception (injectable), you have one sex act and the next she is not the same (becomes too wet)" (Male IDI, partner of 40 year old trial participant).

6.3.3 Social acceptability

Respondents stated that intravaginal insertions were generally used secretively without the knowledge of the male partner. The majority of female respondents talked about women using products for sexual enhancement without expressing either positive or negative attitudes. However, the majority of the male respondents viewed the use of insertions negatively and were suspicious of women who used them. There were a number of negative connotations associated with the use of intravaginal insertions. These included assumptions of sexual inadequacy, infidelity and promiscuity if a woman had to use a product for her or her partner to enjoy sex:

> "There is my friend, who inserts (intravaginal insertions). She says that she does that because she wants to be enjoyed during sex. Maybe her partner told her that she is not great at sex" (Trial IDI, 23 year old woman).

> "I have heard people at school saying that snuff is useful when one has been cheating so that the real partner does not feel that you have been cheating" (Community FGD, 21 year old woman).

Conversely, the majority of trial participants discussed gel use with their partners. Gel use was viewed positively by both women and men, although men from the general community were adamant that they would want to know if their partner was using the gel. There was a common belief that men could 'feel' if a woman had had sex with someone else, as this man stated;

> "As I have explained, I know her (his partner), sometimes it happens that when you start to have sex you feel that she is wet, and I wonder how come she is so wet early? She will be shy, I will then ask her where she was before and ask her to leave, she will then tell the truth that she cheated" (Community FGD, 25 year old man).

This assumption made some men suspicious of the gel. One male partner of a trial participant reported that the only thing he did not like about the gel was that he could not tell if his partner had been unfaithful:

> "I can say if you are having sex with someone there is a difference between if you had sex with her many days ago or if you had sex with her yesterday. There is a difference that feels like this person has been having sex with another person. The difference is (when using gel) you cannot differentiate whether she has been with another person" (Male IDI, partner of 37 year old trial participant).

One woman was forced to stop using the gel due to her partner hearing rumours in a bar that women were using the gel to hide infidelity.

6.3.4 Sexual pleasure

Although the conversations about the use of intravaginal insertions related to increasing sexual pleasure, it was often unclear as to whether they were considered to increase the males' sexual pleasure or that of the woman. When this topic was probed, it was often difficult to distinguish between a women being sexually satisfied versus her being satisfied that she had sexually satisfied her partner. This discussion was infused with the expectation that a woman was supposed to satisfy her partner and failure to do so could result in the partner taking an additional girlfriend or the complete dissolution of the relationship.

However, the discussion relating to gel use and sexual pleasure was far less ambiguous. One third of the women who reported that gel increased sexual pleasure claimed that the

increased pleasure was predominantly experienced by the men and another third claimed it was predominantly experienced by the women. In these discussions there was a far stronger emphasis on female sexual desire and pleasure. This often related to the lubrication of the gel reducing pain during sex, as well as increasing sexual stimulation and consequently, female satisfaction:

> "I was feeling pain before I used gel, but now because it (gel) softens (lubricates), now I am enjoying sex as a woman" (Trial IDI, 39 year old woman).

While many women reported experiencing pain during sex, it was clear that pain was not a necessary aspect of sex and was not desired by women. This differs from recent findings in Mozambique where good sex was expected to be painful and involve friction (Bagnol, 2008).

In addition to sex being less painful with gel, female sexual pleasure was described in terms of sex being longer in duration, 'hot', 'tight', 'smooth' and 'dry', and explicitly in terms of women achieving orgasm. The Zulu word used for orgasm was *kuvuthondaba* which means 'climax', although this was described in a variety of ways in terms of the woman 'becoming alright' (*kulunge*), being 'satisfied' (*usuwenele*), 'spilling out' or 'passing out' (*echithe*) in terms of vaginal fluids flowing during orgasm, 'feeling free' (*ukhululeke*) or sex 'going well' (*kuhambe kahle*). There were also multiple descriptions of 'reaching the end' almost like finishing or winning a race or completing the task. These references included *ushaye kuqala* meaning to *'*beat/finish first', *ofika kuqala* meaning to 'reach first' and *nifikisane la nifikisana* meaning to 'make you get to where you are supposed to get to'. When probed about the terms used to describe reaching orgasm, women generally compared it to the male orgasm resulting in ejaculation ('*umuntu weslisa uma esechitha lamanzi akhe'* meaning 'when a male spills out his male secretions').

The quotes below also demonstrate the impact that women felt gel use had on their sexual pleasure:

> "I enjoy sex because we take longer before we orgasm if we use the gel" (Trial IDI, 28 year old woman).

> "It didn't happen that I lag behind when we are having sex (with gel). … It does happen that the woman reaches orgasm first, or the partner first, this time since I used your thing (the gel) it is me who came first like when you reach first and the man later" (Trial IDI, 56 year old woman).

Women's desire for sexual pleasure was also demonstrated by their expectation of foreplay. Foreplay was only specifically mentioned by 9 female interviewees and discussed in 5 FGDs, although this was not a topic explicitly probed. Additionally women stated the need to be 'ready' for sex which may have been a less explicit reference to foreplay in the absence of intravaginal inserts. Foreplay was generally described as 'romancing' each other and the English word was usually used in the context of Zulu grammar (*romansana*) or explained as 'preparing' the partner (*lungisa).* This participant explained that she did not like it when her partner "catches me off guard" because:

> "He has to romance me so that I will be *isizwa* ('getting the feeling' in terms of being sexually aroused) because I have to be aroused so that by the time he comes to me (starts intercourse) I will be warm and right" (Trial IDI, 48 year old woman).

This view was expressed by other women and this woman describes the foreplay she expects:

> "If he just forces himself (on you) you don't enjoy it, he must first touch and play with you" (Trial IDI, 36 year old woman).

Unlike intravaginal insertions, the use of which was rarely disclosed to male partners, the use of gel was at times incorporated into the process of sexual preparation, as this quote demonstrates:

> "When he starts romancing me he sees that we are ready for sex, he would then say, 'my partner, take your gel and insert'. He also enjoys the gel a lot because he is comfortable with it" (Trial IDI, 47 year old woman).

Another related theme only reported on two occasions was that because gel reduced pain during sex, women could enjoy a wider range of sexual positions, as this woman explained:

> "It means I can have sex in many ways, before I couldn't because it hurt before I was using the gel. I would do it the same way, but now I can do it other ways… I can now have sex looking down, sideways or on bended knees" (Trial IDI, 22 year old woman).

6.4 Discussion

In this chapter, I set out to examine whether the use of intravaginal insertions could be in conflict with the use of microbicide gels in a predominantly rural part of KwaZulu-Natal. I have described the types of intravaginal insertions used in the community and their desired effects. I found that the experience of using gels – which made sex hot, tight and dry – precisely matched the desired outcomes of intravaginal insertion. This study provides evidence that

vaginal microbicide gels may be more socio-culturally acceptable in communities where intravaginal insertion is practiced than previously thought.

The validity of these findings is supported by the evidence from the WHO GSVP study which was also conducted in KwaZulu-Natal while the MDP 301 trial was on-going (Scorgie, 2011, Smit, 2011). In the trial we prohibited the use of intravaginal insertions and therefore did not attempt to measure the prevalence of intravaginal insertion. The fact that only 7 out of the 63 trial participants reported ever using intravaginal insertions is more believable in comparison to the prevalence reported in the WHO household survey than in comparison to previous studies among sex workers. Findings in this study are consistent with the WHO study in terms of reported motivation for using intravaginal insertions, the products used and the ways in which they are used. The desired effects of using intravaginal insertions were similar across the two studies, although sexual arousal and increased libido were evidently more important in this study than the WHO study. Nonetheless, these findings support the WHO study in arguing that intravaginal insertions are not exclusively associated with a desire for dry sex.

There are two reasons why the association between intravaginal insertion and dry sex may have been previously overstated. Firstly, there has been research into intravaginal insertion for almost six decades with insertions being reported to tighten, dry and warm the vagina. However the advent of the HIV epidemic reignited interest in intravaginal insertion and raised concern about a link between the drying effect of various vaginal practices and HIV infection (Dallabetta, 1995, Fonck, 2001, Gresenguet, 1997, Mann, 1988, Myer, 2006, Myer, 2005b, Runganga, 1995, van de Wijgert, 2000). Consequently researchers focused on dry sex and often phrased questions about vaginal practices to explicitly ask about the use of vaginal drying agents (Banda, 2007).

Secondly, the desire for dry sex is atypical in terms of western concepts of sexual pleasure and therefore became a ‘cultural practice of interest’. Conversely, it is not unusual for women in Western countries to desire a tight vagina (Braun, 2001), evidenced by a growing demand for vaginal laser treatment and cosmetic surgery to tighten the vagina and vulvar structures. The idea of heat stimulation is also not uncommon in Western countries; a well-known condom brand markets a heat lubricant, described as creating ‘a warming sensation that will immediately heighten sensitivity’.

The main strength of this study is my ability to investigate in depth the concept of dry sex among a cohort of women using lubricant-based vaginal gels. When respondents discussed the use of insertions to dry the vagina, it might have been assumed that vaginal secretions were being removed to reduce lubrication and increase friction. However, the same respondents

described the lubricating gel as drying the vagina. The comparison between traditional intravaginal insertions and the gel has allowed me to critically review the idea of vaginal 'dryness'. These trial participants could have been using one of three gels; 0.5% PRO2000, 2% PRO2000 or placebo. While there were no obvious differences in reports between the gel groups, it will be important to evaluate the impact of other gel compounds, such as tenofovir gel, on the sexual experiences of women in terms of making sex hot, tight or dry in KwaZulu-Natal and elsewhere in Africa.

A limitation of this study is that only a minority of the respondents reported using intravaginal insertions themselves, and only the women enrolled in the trial and their male partners had used the gels. This limited my ability to directly compare the experience of using intravaginal insertions with the use of microbicide gels. In addition, given that the use of intravaginal insertion was prohibited when using the microbicide gels and given the higher prevalence of intravaginal insertion reported in the WHO study, it is probable that women who regularly use insertions were discouraged from joining the trial and possible that women in the trial underreported intravaginal insertion. Finally, in this chapter I focused exclusively on intravaginal insertions. However, intravaginal cleansing, external application and oral ingestion of products are also associated with increasing sexual pleasure in KwaZulu-Natal. It will be important to also investigate the desired effects of these practices in order to evaluate a possible conflict with microbicide gel use in terms of socio-cultural norms of sexual expectations and pleasure.

These findings also highlight issues that need to be considered before the introduction of an effective microbicide. There were some reports of negative associations with intravaginal insertion relating to sexual inadequacy and promiscuity. In this study, trial participants often explained their use of gel in terms of their knowledge of intravaginal insertion. Given this cross fertilisation of language, the potential risk of these limited negative connotations being transferred to an effective microbicide gel need to be considered in the development of future microbicide marketing strategies.

A major difference between intravaginal insertion and gel use was the focus on female sexual pleasure in relation to the gel. The ambiguity regarding whether intravaginal insertions increase sexual pleasure for women or men may be because only a minority of the respondents had used intravaginal insertions themselves. Certainly female sexual pleasure was a more dominant reason for intravaginal insertion in the WHO study than in this study (Hull, 2011). In addition, the stronger emphasis on female sexual pleasure in relation to microbicides may be the result of the gel itself. However, it is important to note that women enrolled in the

microbicide trial were encouraged to talk about their sexual experiences regularly. Therefore, women enrolled in the trial may have been more forthcoming in discussing sexuality and pleasure in terms of gel use. These findings do not negate the gender imbalances of sexual encounters in this population, but they do present an image of female sexual desire and sexual expectation that has often been absent in discussions about intravaginal insertion.

Women were eager to use a product that could reduce pain and discomfort during sex and increase sexual pleasure for both themselves and their partners. The gel offered both relief and satisfaction. Local familiarity with the idea of physically inserting products vaginally appeared to demystify the vaginal insertion of a microbicide gel. In terms of microbicide acceptability it is importance that women are comfortable touching their genitals (van der Straten, 2010b). In addition, the discourse surrounding intravaginal insertion has provided clear terms of reference for women to explain their use of a novel vaginal product. This not only counters the fear that microbicide gels may be less acceptable in communities where intravaginal insertions are used for sexual enhancement, but suggests that local knowledge, language and understanding of using products vaginally may actually facilitate the introduction of microbicide gels.

6.5 Conclusion

Regardless of whether or not an effective microbicide is eventually formulated in a lubricant gel or another formulation applied vaginally, marketing strategies will have to take account of socio-cultural norms regarding intravaginal insertion as well as sexual practices, preferences and expectations. There is evidence to date that microbicide gels are acceptable among trial cohorts. In this chapter I have demonstrated that a desire for dry sex does not preclude a desire for lubrication. I have also demonstrated that microbicides meet socio-cultural expectations regarding intravaginal insertion and sexual pleasure in KwaZulu-Natal. These findings provide optimism regarding the acceptability of a lubricant-based microbicide in the broader community if a microbicide gel is made available for HIV prevention in the future.

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7 'The things we do for love': Love medicines

Summary

As described in chapter 6, intravaginal practices include the use of love potions. Love potions are a common form of traditional medicine in many parts of Africa. In the microbicide acceptability literature the role of traditional medicine has been largely ignored, as highlighted in chapter 2. The literature describes the use of love potions as being similar to many other intravaginal practices designed to enhance sexual pleasure. In KwaZulu-Natal love potions are referred to as *imithi yenthando* (love medicines) and some are believed to work through supernatural forces. In the last chapter I demonstrated that the traditional use of intravaginal insertions does not conflict with the introduction of microbicides. In this chapter I explore whether the concept of supernatural love medicines could influence the acceptability of vaginal microbicide gels in KwaZulu-Natal. I present evidence regarding love potions that is available in the vaginal practices literature and explain the ethno-medical and cosmological beliefs that underlie the concept of love medicines in KwaZulu-Natal. I compare the narratives people use to discuss love medicines to the narratives used to describe the microbicide gel. This analysis is based on qualitative data collected during in-depth-interviews and focus-group discussions with women enrolled in the trial as well as women and men from the community. This analysis explores whether the concept of love medicines could be in conflict with the use of vaginal microbicide gels.

7.1 Literature review

In chapter 2 I highlighted that the role of traditional medicine has been largely neglected in microbicide acceptability research. In South Africa the majority of the population access both biomedical and traditional health practitioners (WHO, 2002, Dickenson, 2008, Pefile, 2005). There is an abundance of literature on traditional health practitioners and traditional medicine in South Africa. The contemporary role of traditional health practitioners and traditional medicine in public health programmes has been extensively described (Colvin, 2001, Munk, 1997, Peltzer, 2006, Freeman, 1992, Louw, 1995, Wilkinson, 1998, Peltzer, 1998, Peltzer, 2000, Peltzer, 2001, Peltzer, 2003, Colvin, 2003, Richter, 2003, Green, 1995). Traditional Zulu culture and practices relating to health and well-being have been particularly well documented (Ngubane, 1977, Berglund, 1976, Jolles, 2000, Flint, 2008, Wickström, 2008a). However, to date, microbicides have not been described within the context of traditional health culture. Mantell highlighted a gap in our knowledge regarding the role of traditional health practitioners in shaping opinions about the acceptability of microbicides (2005). Similarly, there is a gap in our understanding about the extent to which traditional medical culture could

impact on microbicide acceptability. While there is a need to explore how microbicides may be understood in relation to a range of traditional medicines, in this chapter I focus specifically on the use of love medicines in KwaZulu-Natal as one form of traditional medicine (Flint, 2008).

In chapters 5 and 6 I explained that intravaginal cleansing and intravaginal insertion practices are used by women to manage vaginal hygiene, vaginal health, contraception, treatment of STIs, post-partum vaginal restoration, and in preparation for sex. A seventh motivation for the use of intravaginal insertions was as 'love potions' to attract or retain partners. Love potions are a common form of traditional medicine in many parts of Africa. Certainly each South African language has a term for love potions. In Zulu, they are called *imithi yenthando (*singular*: umuthi wenthando*) which translates as 'love medicines'. In addition to being used as intravaginal insertions, the literature also reports the use of love potions during other vaginal practices including external application, oral ingestion, and incisions with insertion of substances into the lesion (see Table 5-1 for definitions of vaginal practices).

As shown in Table 7-1, the systematic review of literature on vaginal practices in Africa identified 7 papers that included references to love potions or love medicines. However, four of these relate to research conducted as part of the WHO GSVP study (Bagnol, 2008, Hilber, 2010b, Scorgie, 2009, Scorgie, 2010). In addition to the search criteria used for vaginal practices (appendix G) I conducted key word searches for 'love medicine', 'love' AND 'medicine', 'love potion' and 'love' AND 'potion' in PubMed, Web of Knowledge and POPLINE which yielded 102 citations. However, only 1 citation related to the use of love potions in Africa (Morocco) although this did not meet the inclusion criteria as it was a French language article (Akhmisse, 2000).

Most of the discussion of love potions is to be found in anthropological studies on witchcraft. I wanted to look specifically at love potions within the context of vaginal practices and therefore did not conduct an extensive literature review on witchcraft in South Africa. However, I did draw on key ethnographic texts on Zulu traditional health practitioners and medicines. Before describing love medicines, it is necessary to describe the ethno-medical and cosmological beliefs that underlie the concept of love medicines in KwaZulu-Natal.

Table 7-1: Literature on love medicines within the systematic literature review of vaginal practices in Sub-Saharan Africa

No.	Reference	Country	Love medicines
1	Bagnol 2008	Mozambique	X
2	Brown 1993	DRC	X
3	Civic 1996	Zimbabwe	X
4	Hilber 2010	WHO GSVP: Mozambique, South Africa, Indonesia, Thailand	X
5	Morar 1998	South Africa (FSW)	X
6	Scorgie 2008	South Africa	X
7	Scorgie 2010	South Africa	X

7.1.1 Zulu cosmology

Zulu cosmology is premised on the role of both the creator and of ancestors. There are a number of different Zulu narratives that describe the creation of human beings by the creator, called *Nkosi* in Zulu (Berglund, 1976, Ngubane, 1977, Carton, 2008a, Carton, 2008b). However, in contemporary Zulu society, *Nkosi* most frequently refers to the Christian God as creator of all things (Carton, 2008b). God is praised with names such as *Nkulunkulu* (the one above or the Great-Great), *Mvelingqangi* (the one who was there before all else or the maker of the world), *Mdali* (referring to origin and creation), *Jehovah* (from the Old Testament) and *Thixo* (or *Tikxo* from the Xhosa word for Supreme Being). God is distinct from other spiritual beings such as the ancestors. In some interpretations of the creation narrative, God is attributed with bestowing powers to the ancestors (Berglund, 1976, Carton, 2008b).

The ancestors are family members who are deceased but are able to influence, and provide guidance and direction, to their own family members on earth. Ancestors are known as *Amadlozi* (ancestors), *Abangasekho (*souls that have passed on*) or Abantu abadala* (elders of the family). In traditional Zulu culture, the interface between the world of the living and the world of the ancestors is fluid and the ancestors are ever present (Berglund, 1976). Within this worldview, ancestors play an important role in maintaining harmony among their liking kin, and as such, provide the foundation for many traditional medical practices.

7.1.2 Traditional health practitioners in South Africa

The South African government is attempting to register, regulate and integrate traditional health practitioners into the National Health Services under the 2004 Traditional Health Practitioners Act (RSA, 2004). However, integration has proved challenging for a number of reasons, not least because of the various definitions of traditional health practitioners and

traditional medicine (Ashforth, 2005). The Act defines four types of traditional health practitioners: herbalist, diviner, traditional birth attendant and traditional surgeon (i.e. for circumcision). Birth attendants and traditional surgeons do not play a role in love medicines and as a result I will only focus on herbalists and diviners. The Act describes both herbalists and diviners as "a person who engages in traditional health practice and is registered [as an herbalist or diviner] under this Act". However, the Act does not attempt to distinguish between different traditional health practitioners nor define the different uses of traditional medicines.

Herbalists

In Zulu, a herbalist is known as an *inyanga* (plural: *izinyanga*). *Inyanga* has been translated as doctor, herbal doctor, medicine man/woman, herbal specialist, or man/woman of the trees. *Izinyanga* use *imithi* (traditional medicines) which directly translates as 'trees'. *Imithi* are generally made from tree parts, shrubs, herbs, roots, minerals from soil and stones, and animal parts, as well as contemporary commercial and pharmaceutical products. *Izinyanga* treat illnesses based on two distinct causative principles: those caused by nature and those caused by pollution (Ngubane, 1977;22-29). Natural illnesses can be caused by genetic predisposition such as epilepsy, seasonal changes such as hay fever, or infections such as colds. In the case of natural illnesses, somatic symptoms are treated using *imithi*. It is accepted that natural illnesses can be treated by biomedical health practitioners as effectively as traditional health practitioners. However, other illnesses can be caused by 'pollution' from within the supernatural realm. The underlying causes of illnesses caused by pollution can only be treated by traditional health practitioners. Pollution can be the result of the environment, for example, if a vulnerable person walked over the track were a dangerous snake had crossed, the person may pick up the evil elements left behind by the snake. Alternatively pollution can be the result of inharmonious relationships with the ancestors or as a result of other supernatural forces. As such an *inyanga* can use *imithi* to either strengthen a person against pollution or remove pollution by correcting that person's relationship with the environment, the ancestors or other supernatural forces. *Imithi* can be administered in a variety of ways, including *ukudlisa* (oral) *ukuchata* (enema), *ukuphalaza* (purging), *ukugquma* (steam inhalation), *ukuncinda* (licking) or *ukugcaba* (incisions). The most important issue to stress for this discussion of love medicines is that *imithi* are understood to treat ailments from both the natural and the supernatural realm. It is also important to note that *imithi* can be used to either heal or harm a person, depending on the substances used and depending on the motives behind their use (Ngubane, 1977, Flint, 2008, Berglund, 1976).

Diviners

In Zulu a diviner is called an *isangoma* (plural: *izangoma*). *Izangoma* are called to practice by their ancestors and from them, derive their knowledge and power. As such, *izangoma* function through their power of divination and their ability to communicate with the ancestors and other spiritual beings via specific 'languages', dreams, trances or symbols such as throwing of bones. Eunice Nomusa Sihoto described how she was called upon to be a *isangoma* during a dream in which her deceased great-grandfather instructed her on where to go to train and, via her unconscious state, instructed her teachers on what and how to train her (Naidoo, 2006). *Izangoma* play a vital role in Zulu society in terms of advising traditional leaders, resolving Ancestral or familial disagreements, and identifying and reversing witchcraft (Flint, 2008). Another type of diviner less frequently mentioned in the literature is a*bathandazi* (singular: *umthandazi* – *thandaza* meaning to pray) who are known as either water diviners or faith healers (Ashforth, 2005, Peltzer, 2006). *Abathandazi* use prayer, candles and holy water (*isiwasho*) to diagnose and treat medical and social ailments. In 1998, a Government Select Committee on Social Services on Traditional Healers refused to include *abathandazi* into the review as they were not considered traditional in South Africa (SelectCommittee, 1998). Regardless of their South African authenticity, *abathandazi* are now an integrated part of traditional medicine in contemporary KwaZulu-Natal (Ashforth, 2005).

The ways in which *izinyanga, izangoma* and *abathandazi* prevent, diagnose or treat health and social problems differs considerably. However, their practices are premised on a common understanding of the relationships between people on earth with the ancestors and other supernatural forces. As such they tap into both natural and supernatural aspects of the world. Referrals between different types of traditional health practitioners are common so a client's problem can be treated with both *imithi* and divination. The combination of training as an *inyanga*, *isangoma and umthandazi* is also common in contemporary Zulu society. Traditionally *izinyanga* were male and *izangoma* were female, but this gender distinction has waned over time. As such traditional health practitioners and traditional medicine continue to adapt to changing social circumstances and the 'traditional' continues to be redefined and reinvented (Wright, 2008). Nonetheless, the essential link between the natural and the supernatural aspects of traditional medicine have remained constant (Petrus, 2011, Niehaus, 2003).

7.1.3 Witchcraft

The Traditional Health Practitioners Act specifically excludes *abathakathi (*witches or evil-doers; singular: *umthakathi*) whose practice is illegal under the Witchcraft Suppression Act

(RSA, 1957). During British colonial rule, the roles of traditional healers where often confused with the roles of *abathakathi*. However, in Zulu culture these roles are very distinct and diametrically opposed. Some Zulu narratives describe an *umthakathi* as someone who was born with supernatural powers (Flint, 2008). However other narratives describe *umthakathi* as anyone trained to use *imithi* and who uses them to bewitch (*thakatha*) others using witchcraft (*uyathakatha*) for purely malevolent reasons. One role of *izinyanga* and *izangoma* is to identify when the work of *abathakathi* is at play and to reverse the evil done by them. As such, the entire function of *abathakathi* is for evil purposes. The role of the *abathakathi* is often provided as an explanation for a range of misfortunes in South Africa, especially unexplained death (Fottrell, 2011).

There are many different interpretations of witchcraft in African societies. Witchcraft has been described as a way of explaining and maintaining the social and moral framework of societies (Evans-Pritchard, 1937), as a response to political socio-economic changes (Comaroff, 1993), and as a function of micro-politics such as those relating to familial relationships, sexuality and morality (Niehaus, 2002). Cross cutting these explanations, is the association between social inequalities and witchcraft. Misfortune and fortune are often viewed as the result of witchcraft (Petrus, 2011, Niehaus, 2003). Whatever the rationale for witchcraft in society, the belief in the use of the supernatural for both benevolent and malevolent aims remains entrenched in many societies, including KwaZulu-Natal.

7.1.4 Types of love medicines

In contemporary Zulu society the term *imithi yenthando* is used to describe a broad range of traditional and commercial products that are designed to make someone attractive to others. This can be for the purpose of attracting friends or business acquaintances (Bagnol, 2008). However the main reason for using *imithi yenthando* is to attract or retain a sexual partner (Scorgie, 2009). Some of the products used as intravaginal insertions to enhance sexual pleasure described in the previous chapter are sometimes called *imithi yenthando*. However, *imithi yenthando* also refer to the use of traditional medicines as love potions that tap into the supernatural in order to force or compel someone to love another. The idea is not dissimilar to the European concept of Cupid in that once under the spell, the recipient is uncontrollably in love with a specific person (Cotterell, 2008). The use of love potions has been described for centuries in European literature and theatrical presentations such as Shakespeare's 'A Midsummer Night's Dream' and Wagner's 'Tristan und Isolde' (Aronson, 2003).

The use of love potions has also been described extensively across Africa (Vontress, 2005, Keller, 1978). As illustrated in Table 7-1, within the vaginal practices literature the use of love

potions has been described in the Democratic Republic of Congo, South Africa, Mozambique and Zimbabwe (Brown, 1993, Civic, 1996, Bagnol, 2008, Hilber, 2010b, Scorgie, 2009, Scorgie, 2010, Morar, 1998). In English, *imithi yenthando* are most frequently described as operating through 'sorcery' (Scorgie, 2009). However, there is no Zulu word for 'sorcery'. The English word 'sorcery' comes from the Latin word *sors* which means 'spell' although it is often conflated with the French word *sorcier* which means 'witch' (Vontress, 2005). As such in English sorcery in commonly thought of in terms of witchcraft. It is therefore important to highlight that in Zulu tradition, *imithi yenthando* are not considered the purview of *abathakathi*. Some love medicines are manipulated for evil purposes, can be administered by witches, and have at times been blamed for the death of the recipient (Parle, 2012). There have also been reports of women describing how they have been 'bewitched' by other women in a love triangle out of jealousy or spite (Scorgie, 2009, Brown, 1993). However, in the main *imithi yenthando* are considered more likely to be used for benevolent aims to promote love and intimacy, than for malevolent reasons (Wickström, 2008a). As such, *imithi yenthando* are more likely to be sought from an *inyanga or isangoma,* than from an *umthakathi.* The rationale for *imithi yenthando* is not based on a concept of witchcraft but rather premised on the belief in the interface between the natural and supernatural worlds that, as explained above, is the basis of traditional Zulu cosmology.

As described above, traditional medicines (*imithi)* can be made from a range of traditional and commercial products, and love *imithi* are no different in this way. Love medicines can be directly administered in food or drink. They can also be placed strategically on the body of the user so as they come into contact with the lover during intimate encounters. One example of this involves making small incisions in the skin and placing traditional medicines inside the cuts (Civic, 1996). In KwaZulu-Natal this is a regular form of administering traditional medicine and is called *ukugcaba* (Ngubane, 1977, Jolles, 2000, Henderson, 2005). More recently, this form of administration appears to have been adopted as a way of applying love medicines around the vagina as well as other areas that will come into contact with the partner during sexual intercourse (Morar, 1998, Scorgie, 2010). The WHO survey found that almost half of the women in KwaZulu-Natal were aware of the use of *ukugcaba* in the genital area (although not just for the administration of love medicines) and 3% reported applying traditional medicines to the genital area by way of *ukugcaba* (Scorgie, 2010).

As with other forms of traditional medicine, love medicines can also be activated by being blown in the air, burnt and sent in the smoke, chewed and spat out while speaking the name of the intended lover, buried in an area the intended lover will walk over, or sown into animate objects that are strategically placed in positions to call the intended lover to that place (Civic,

1996, Bagnol, 2008, Scorgie, 2009, Keller, 1978, Berglund, 1976, Ngubane, 1977, Akhmisse, 2000). In some cases, love medicines need to be mixed with the bodily fluids of the intended lover in order to be activated. In addition to being used to attract a partner or maintain a relationship, love medicines can also be administered to a third partner via a lover to make the third party appear sexually unappealing (Hilber, 2010b, Scorgie, 2009, Bagnol, 2008).

In Zulu society, historically love medicines were only used by men, never by women (Ngubane, 1977, Parle, 2012, Flint, 2008). However, more recent studies in KwaZulu-Natal show that both women and men now use love medicines to actively take control of and influence the course of relationships (Scorgie, 2009, Wickström, 2008a, Scorgie, 2010, Parle, 2012). As such, when used by women they have been interpreted as subversive of gender norms and considered a threat to the social moral order of society as well as male hegemony (Wood, 2007, Niehaus, 2002). For example, Figure 7-1 is taken from the South African feminist journal, Agenda, and depicts how the manipulative use of love medicines by women can be blamed for any challenge to traditionalist gender roles (Madlala, 1995).

Figure 7-1: Picture from an Agenda journal article entitled 'Male Feminist Experience'

Love potion in food...

"Gossip is thick and strong about any man who shares chores with his wife. 'He is described as *wamdlisa umuthi ukuba abe yisilima sakhe*': there is talk about how his wife has used a special love potion in his food to turn him into a domestic puppet"

7.1.5 Love medicines and microbicides

The introduction of a new HIV intervention on a mass scale is bound to be interpreted in the context of local understandings of the world, health and medicine. This has been true in South Africa in terms of both condoms and ARVs (Munk, 1997, Niehaus, 2005, Stadler, 2003, Ashforth, 2000). The ways in which microbicides are interpreted locally could have a major impact on women's ability and desire to use them. Microbicides have already been described in trial communities as a way to 'improve relationships' (Montgomery, 2010b, Gafos, 2011). However, to date there has been no evaluation of how microbicides might be related to love

medicines that are also viewed in KwaZulu-Natal as a way to 'improve relationships'. Therefore there is a need to understand how the socio-cultural meanings attached to love medicines could influence the reception of microbicides by both women and men. This analysis is of particular importance given the suspicion that surrounds the use of love medicines to subvert gender norms and findings presented in chapter 6 regarding the crossover of language between intravaginal insertions and microbicides.

7.2 Methods

As described in chapter 3 section 3.4, intravaginal cleansing and insertion practices were included as a standard topic for discussion in the MDP in-depth interview and focus group discussions. Love medicines were not a standard topic for discussion. While investigating intravaginal insertions, narratives emerged describing the use of traditional medicines as love potions to influence the course of love and relationships by drawing on supernatural forces. This topic was not discussed systematically in every IDI or FGD and therefore this analysis is based on narratives that were spontaneously introduced by the respondents.

Data from all of the 235 IDIs and 27 FGDs described in chapter 3 Table 3-3 were interrogated for this analysis. Data are also included from an additional key informant IDI and an additional FGD with traditional healers. The additional IDI and FGD were conducted in order to seek clarity on issues that emerged in the other IDIs and FGDs in relation to traditional medicines. I conducted the key informant in-depth interview with a male trainer of traditional health practitioners who practiced as an *inyanga* (herbalist), *isangoma* (spiritualist) and *umthandazi* (water diviner), with the assistance of a Zulu speaking translator (Misiwe) and a Zulu speaking note taker (Sizakele). Misiwe conducted the additional FGD with traditional health practitioners, with the assistance of 3 research assistants. She informed the Mtubatuba Traditional Health Practitioners Council of the planned FGD and practitioners contacted Misiwe if they wanted to participate. Fourteen traditional health practitioners attended the FGD; 8 *izangoma*, 3 *abathandazi*, and 3 practitioners who were both *izangoma* and *abathandazi*. The Council also represent *izinyanga* although none volunteered for the FGD. Of the 14 practitioners, 11 were female and 3 were male. The FGD addressed a number of topics including the range of issues the traditional healers were consulted on, the management of HIV and STIs, the use of intravaginal insertions and love medicines, and the diagnosis, treatment and referral processes of different traditional health practitioners.

This analysis draws on the narratives that trial participants' and community members' used to describe love medicines and the use of love medicines in the community, as well as the narratives that trial participants' and their partners' used to describe their personal experience

of using microbicide gels. I first identified all data that related to the use of love medicines that operate through the supernatural and analysed the data, building themes and concepts during the analysis. I then interrogated the data that I had already coded as relating to the use of microbicides for any of the themes or concepts that I had identified in the narratives on love medicines. I compared and contrasted the narratives of women's descriptions of using a novel vaginal microbicide gel with their descriptions of love medicines. In comparing these narratives, I consider how the social concept of love medicines could influence the introduction of microbicide gels in the future. These narratives provide insight into how women position microbicides in relation to love medicines that operate through the supernatural. This evaluation also offers a glimpse into socially constructed ideas of 'love' and how microbicides fit within the broader socio-cultural notions of love and relationships.

7.3 Results

7.3.1 Love

The only Zulu word used for love was '*uthando'*. In the transcripts *uthando* was always translated as love, although its use would often be more akin to the word 'like' in English. For example this woman used the word *uthando* to explain that her partner:

> "…does not love condoms" (Trial IDI, 22 year old woman).

Nonetheless, in reference to partnerships the translation of *uthando* as 'love' usually seemed more appropriate than 'like'.

In this study love could best be described as encompassing sexual satisfaction, commitment, respect and financial security. As described in the last chapter, sex was discussed in the broader terms of sexuality. Sex in and of itself was not confused with love – for example women described their male partners as having meaningless or noncommittal sex with other women. However, the expression of sexual desire and intimacy within a relationship were the most commonly reported expressions of love.

Commitment to a relationship was most commonly measured in terms of marriage, cohabitation and joint child rearing. Although marriage rates are very low in the area, marriage is idealised in the community and viewed as a symbol of status. However, other examples of commitment to a relationship are fidelity and the duration of a relationship.

Respect (*hlonipho*: respect or reverence) is another important demonstration of love for both women and men, as this quote illustrates:

> "I would not love you if you did not respect me. Do you see? As the Bible says, the men should love their wives because that is good in the eyes of the Lord, because the woman should be precious to her husband" (Male IDI, partner of 37 year old trial participant).

Respect within a relationship was also described as abiding by social norms. These included sexual norms such as intravaginal cleansing (described in chapter 5) or avoiding contact during menstruation (described in chapter 6), as well as other norms such as avoiding sexual contact immediately after childbirth or the death of a family member.

Financial support and security were also important features of love. Financial symbols of love included providing for the household, buying gifts, sharing information about a salary, or sharing bank accounts. As such, when women and men spoke of love they most frequently referred to some aspects of sexual satisfaction, commitment, respect or financial security. These components of love were demonstrated by actions such as marriage, complying with sexual norms, and sharing a bank account. This concept of love is compatible with other descriptions of love in KwaZulu-Natal (Wickström, 2008a, Hunter, 2010).

Despite most women enrolled in the trial being in long-term stable relationships, approximately a third suspected that their partner had other female partners. As such, women described an overt competition between women for 'good' men who could provide love. In this context, there was a prevailing sense that women needed to work at actively retaining their partners. This was informed both by the idea of competition for men and by the social expectation that both partners need to work at a relationship. There were a number of ways women could 'work' at a relationship, such as making themselves look beautiful, cleansing themselves both physically as well as spiritually to be free of any pollution, and in extreme cases, by using love medicines.

7.3.2 Love medicines

Women used the term *imithi yenthando (love medicines*) to refer to an array of products used to make them more attractive or sexually stimulating, including some of the products described in chapters 5 and 6. In Zulu, there is no linguistic distinction between *imithi yenthando* that work to physically enhance sexual pleasure and *imithi yenthando* which work on the basis of supernatural force. However, the descriptions of how love medicines work make it very clear when people are referring to love medicines that draw on the supernatural to 'force' love. In this chapter all mention of love medicines refers exclusively to love medicines that presuppose a supernatural effect.

Love medicines were not introduced as a topic for discussion by the research staff, but they emerged when talking about sexual norms, relationship issues and intravaginal practices more generally. Love medicines were spontaneously mentioned by 5 out of 84 trial participants and 2 out of 17 male partners. The topic was also raised by respondents in 4 out of 14 FGDs with trial participants and 4 out of 19 FGDs with community members (3 female and 1 male FGD). The topic of love medicines most frequently arose when the individuals or groups were asked about vaginal practices. Once the topic was raised in FGDs, it was evident that the majority of respondents in each FGD were familiar with the concept of love medicines. Certainly, throughout the IDIs and FGDs, the role of supernatural forces was spoken of as commonplace and accepted as a normal part of Zulu traditional cosmology and contemporary social reality. As such, when love medicines were discussed no-one ever doubted that when used they impacted on the relationship supernaturally. It was frequently noted that love medicines were readily available on traditional medicine market stalls throughout the town. While a few women and men reported that love medicines had been used on them, no-one admitted to using love medicines on others. This suggests that while the existence of love medicines was widely accepted, their use was subject to social stigma or to use under prescribed circumstances.

Traditional health practitioners in the FGD reported that they were consulted to diagnose, prevent and treat a broad range of health, social and spiritual issues. They ranked love related concerns within the top five major issues that they dealt with. Love related issues included problems with infidelity or domestic violence, as well as the desire for love, marriage and children. All the practitioners were familiar with love medicines and discussed them as a form of traditional medicine that can be used to resolve problems in relationships.

Love medicines were explained within the context of there being competition between women for ‘good’ men. In this context, it was expected that women would employ a range of techniques to attract and retain a partner. However, there was a sense that the use of love medicines to ‘force’ love was frowned upon as it was used to gain an unfair advantage over other women and restrict the free will of men. The degree to which love medicines were stigmatised depended on the reasons behind using the love medicines. Two main reasons for using love medicines emerged from the data. I have described these as productive and destructive and discuss each below.

Productive use of love medicines

Love medicines were described as being used in a productive sense, to help form or consolidate a relationship. In this context they were described as making a man pursue a woman, desire her exclusively, and achieve sexual satisfaction only with her.

These types of love medicines could be sent in dreams, burnt and sent in the smoke, smeared on the body, administered via razor cuts made in the skin (*ukugcaba*), added to food or drinks, or used intravaginally. The intravaginal use of these types of love medicines was rare but was considered the most potent. This respondent explained why love medicines were sometimes used in this way:

> "*Inthando* is a mixture that is put in a man's food but if the man suspects that you want to do that to him, he will not eat the food when he comes to visit. A woman will then decide to look for *inthando* that is inserted in the vagina and will not want the man to put a condom on during sex so as he gets in touch with the *inthando*. It is not easy for a man to get rid of the *inthando* that was inserted but the one given with food is easy to get rid of by vomiting…. **It (the vagina) is a useful organ"** (Community FGD, 35 year old woman - emphasis added).

This quote also highlights men's suspicion of, and resistance to, love medicines that was regularly reported in both IDIs and FGDs. It also hints at the 'power' or control that women can assume by using love medicines. Love medicines could be used by either women or men, although use by women dominated these conversations, possibly because the microbicide trial focused on female sexuality. Similarly love medicines could be used on anyone, yet the prominent assumption was that they were used by women to steal men from an existing partner or wife. These assumptions were reflected in most of the examples of how love medicines worked, such as below:

> "(When with his wife) the male partner will fall asleep if the other partner uses Zulu love medicine. There will be no sex. In the morning he will return to the other partner who used the love medicine and have sex with her" (Trial FGD, older woman)

This quote demonstrates the complexity of love medicines. While some love medicines will 'force' a man to be infatuated with the women who has used the love medicine, others render the affected man unable to have an affair with any women other than the one who has used the love medicine. Ultimately, both of these responses are designed to achieve fidelity.

Love medicines were clearly blamed for a range of relationship problems including infidelity, men bearing children with other partners, the dissolution of relationships or divorce. Equally, love medicines were evidently used as an excuse for infidelity. This woman explained her partner's response when she challenged his infidelity:

> "He says that he is not serious about loving her (his casual partner) but it is not easy for him to dump her because she has used a love medicine on him because she wants my partner to marry her" (Trial IDI, 47 year old woman).

Some descriptions hinted at love medicines being used as a rationale for the breakdown of relationships – whether people believed that they had been used or not.

However, in a society where masculinity is often linked to a man's ability to attract many partners, love medicines were also used as an excuse for fidelity:

> "I am not cheating anymore. I am sitting still, maybe she did something to me [used love medicines on him]" (Male IDI, partner of 26 year old trial participant).

The duration for which a love medicine would take affect depended on the types of love medicines used. The effects were generally thought to last for long periods of time with women sometimes explaining that they only needed repeating every few years or if you could see the effect wearing off.

Destructive use of love medicines

Love medicines could also be used destructively to acquire love by destroying a person's relationship with another partner. In this sense, the love medicine would be cast on the other partner, generally via the man. The most successful way to do this was to insert the love medicine vaginally before sex and transfer it to the man's penis during unprotected sex, so as he would transfer it to his other partner when he had sex with her. Despite the obvious comparisons, no-one ever compared this with the transmission of HIV.

This use of love medicines resulted in a range of negative consequences for the affected woman making sex with her undesirable. For example, women who were affected by destructive love medicines were reported to be unappealing to their male partner due to menstruation, having excessive vaginal wetness or discharge, her vagina having a bad odour, sores or ulcers, or being 'cold' in the sense of not being sexually stimulated or stimulating.

Many of these symptoms were related to socio-cultural norms regarding sexual expectations. For example, as outlined in chapter 5 sex during menses was described as being socially taboo

and therefore menses would be likely to prevent sex from occurring. Similarly, as described in chapter 6 the dominant social expectation of good sex for both women and men was that a woman was 'hot', 'tight' and 'dry', therefore making sex in the presence of excessive vaginal wetness unappealing and unsatisfying. Many of the symptoms described were concomitant with STI related symptoms although again no comparisons were made with STIs other than *umhlume*, which is described below.

The trial participant below describes her knowledge of the ramifications of using love medicines for destructive purposes. She refers to a *tokoloshe* which is a familiar concept in Southern African mythology and is similar to the mythical figures of the Roman faun or Greek satyrs. There are many different descriptions of the *tokoloshe.* The most frequent description is of a dwarf-like water-spirit that can be utilized by sorcerers to perform mischievous or evil acts on others (Berglund, 1976, Lillejord, 2005, McNab, 2007, Mkhize, 1996, Scholtz, 2004, Zadok, 2006).

> "There are traditional healers who sometimes use herbs to destroy families. They give those herbs to people to drink or wash with. Then you become wet and that sex is not God's (*Nkulunkulu*) will (not natural). It is altered and you find yourself wet like you've been having sex with a *tokoloshe* (bad spirit). You dream that you are with your man while he is not there. You can wait for your man while he is in Johannesburg and by the time he comes back it will be like he came with a tin full of water and poured it in your vagina. That is what people can do to you. I know this thing is problematic, I once had the same problem" (Trial IDI, 54 year old woman).

Cost of using love medicines

There were also implications of being the one to use love medicines. The most common of which was the risk of getting *umhlume*. *Umhlume* was variably described as 1) watery vaginal secretions, 2) foul smelling discharge, 3) itchy genital rash, or 4) small blisters or warts around the vagina, anus or in the perineum area. *Umhlume* could infect women and men, and could be transmitted from mother-to-child prenatally. All of the traditional health practitioners reported treating *umhlume* regularly. There were three main causes of u*mhlume*: natural, pollution or sorcery. Firstly, in its natural form *umhlume* was an STI which could generally be treated by either biomedical or traditional medicines. However, all the practitioners stated that they could not treat 'big' *umhlume* which only occurred in HIV positive patients. These patients were referred to biomedical practitioners. Secondly, *umhlume* could manifest as a result of pollution especially if a woman used love medicines, intravaginal insertions or even contraceptives. The trainer of traditional health practitioners described how his ancestors had

ordered him to stop prescribing intravaginal insertions because they did not appreciate him causing pollution which often resulted in *umhlume*. Thirdly, *umhlume* was a very common ramification of being inflicted by destructive love medicines. The traditional health practitioners explained that the reversal of *umhlume* caused by love medicines required powerful divination.

This description of a single ailment with multiple causes is not uncommon in African traditional medicine and has also been applied to HIV in South Africa (Stadler, 2003, Ashforth, 2001). The traditional treatment of *umhlume* differed depending on whether it was the result of nature, pollution or sorcery. However, regardless of whether it was caused by an STI, the use of love medicines or sorcery, *umhlume* was generally associated with social transgression of some sort. Everyone who talked about love medicines confirmed that the ramifications of using love medicines or being afflicted by destructive love medicines could only be reversed by traditional health practitioners. As such, while *umhlume* as an STI could be treated by biomedicine, *umhlume* relating to other underlying causes, including love medicines, could not.

7.3.3 Microbicides

From the narratives discussing love medicines, three key themes emerged: 1) productive use of love medicines in terms of attracting or retaining a male partner who was or was not in another relationship, 2) destructive use of love medicines in terms of attracting or retaining a male partner who was in another relationship by making his existing female partner repulsive to him, and 3) *umhlume* as a ramification of using love medicines or being afflicted by love medicines. In order to find out if the language used in relation to love medicines was used in relation to microbicides, I interrogated the narratives relating to microbicides for concepts relating to each of these 3 themes. However, first I describe the impact of microbicides on love.

Gel's impact on love

In chapter 6, I demonstrated how women in this trial drew on their familiarity with intravaginal insertions used to enhance sexual pleasure to explain their use of microbicide gel as a novel HIV prevention option. Consequently, it was striking in this analysis that trial participants avoided using language that related microbicides to the use of love medicines. Only one person out of the 404 included in this analysis made reference to the gel being like love medicines. The gel was viewed as having a productive impact on relationships but was never viewed as having a destructive impact or associated with negatively affecting someone else's relationship to further your own.

Approximately half of the trial participants described their partnerships as loving relationships, mainly in terms of being committed and respectful. As described above, sex was not the most important aspect of a relationship, but it was viewed as a tangible demonstration of intimacy, desire and passion, as this quote demonstrates:

> "I enjoy sex [with the gel]…years ago it happened that we had sex once but now there is always love, comforting between mother and father [wife and husband] sitting in the bedroom" (Trial IDI, 56 year old woman).

The gel improved the sexual experiences of the majority of trial participants and their partners. Within the first month of using gel, 60 out of the 84 women said that the gel made sex more enjoyable. This increased to 71 out of the 84 women after almost a year of using the gel. The reports were similar across the different gel groups; 23/26 on 0.5% gel; 22/27 on 2% gel; and 26/31 on placebo gel (based on reports after a year of gel use). As reported in chapter 6, the main reasons that gel increased sexual pleasure were because it made sex 'hot' in terms of increasing sexual desire and libido, tightened the vagina partially because it was cold on insertion thereby stimulating the vagina, added lubrication thereby reducing pain during sex, or dried the vagina by removing excessive wetness.

Many trial participants believed that the gel gave them a competitive edge in terms of retaining their partners by improving their sex lives. One participant even described how she avoided mentioning the gel to her co-wife in a polygamous marriage as the husband was showing her preferential treatment over the other wife since she started using the gel.

By improving sexual pleasure, the gel was viewed as improving the overall state of the relationship. The gel was often described as reigniting the passion in a relationship, as this woman describes:

> "It has changed because my partner enjoys having sex with me now and it makes me happy to know that my partner loves me and his feelings are working (*sebenza* – to work or treat with medicine)" (Trial IDI, 46 year old woman).

Women did not talk about microbicides within the context of the supernatural aspects of love medicines, although they strongly believed that gel had a positive effect on their relationships. They often talked about the male partner 'loving them more' as a result of the gel. Women described how their partners respected them for bringing the gel into the relationships. Respect within relationships was demonstrated in terms of the male partner being monogamous, stopping an affair, agreeing to have a HIV test or agreeing to use condoms. The

participant quoted below believed that the gel had a positive impact on their sexual pleasure and consequently their relationship:

> "My partner has been a womanizer. He sometimes didn't sleep at home and only came back the next morning but now he has stopped that habit. He is no longer doing that. He is now always at home. .... I think that has been caused by this gel" (trial IDI, 34 year old woman).

Some women also reported that the effect gel had on sex facilitated improved communication within their relationships. This was generally presented in terms of making the couple feel closer and more intimate, thereby facilitating open and honest discussion. This quote is an extreme example of this impact on open communication:

> "This thing (gel) is really nice. You turn to tell him everything, without being asked by your partner. You just say it yourself: 'Oh, my partner, I did this and that on such and such a day, oh, I am so sorry for what I did, oh, my love, it was just because of this and that', and again vice versa, with him too, he also talks. He would just say: 'Hey, my love, I am so sorry because I did this and that on such and such a day, hey, it was because of this and that'. Not that he is the one who is talking, but he is made to talk because of this thing (gel). This gel is number one" (Trial IDI, 26 year old woman).

Trial participants gave examples of what they took as 'proof' that the gel had made their partners ***love*** them more. Examples included a partner demonstrating love by holding hands in public places, accompanying her to social events, providing financial support and security for the household, and even trusting her with his bank card as this quote illustrates:

> "It (the gel) is working for me because I even get his bank cards to go and get the groceries. That was no longer happening… You must continue to give me this thing after completion (of trial follow-up). What am I going to do? My relationship will be dysfunctional" (Trial FGD, 46 year old woman).

Women reported other positive impacts on their relationships, such as being commended for taking the initiative to seek additional ways of being 'healthy'. This was both in terms of using the gel as a potential HIV prevention option and in terms of testing for HIV and STIs regularly as part of the trial requirements.

Gel in comparison to love medicines

In the main, women placed microbicides in opposition to supernatural love medicines by describing microbicides as 'natural' (*imvelo*) as opposed to 'supernatural'. The woman quoted below presents the gel as natural by viewing it as being sent by God (*Nkosi*):

> "We are inserting nothing except God's gel……God gave it to me to do it" (Trial FGD, older woman).

Similarly women located microbicides in a strictly biomedical sphere, again contrasting them with the supernatural aspects of traditional medicine. The woman quoted below distances microbicides from the supernatural by distinguishing it from the role of a *tokoloshe*.

> "Whatever I do I do it naturally. I took this (the gel) because it is a doctor's thing and there is no problem with it. There are those who use animal oils and they say it turns to the *tokoloshe* (bad spirit) and that is why I don't want to use many things I just want to have the goodness that God (*Jehova*) put in" (Trial IDI, 54 year old woman).

It was only this woman that referred to the *tokoloshe,* as above. However, it is indicative of the ways in which the discourse about microbicides was positioned in relation to local concepts of the natural and supernatural.

Similarly, FGD participants confirmed that the rumours in the community said that the gel improved sex, much like certain intravaginal insertions. However, they never made reference to the gel being like love medicines and when asked about this, distanced the gel from the supernatural effect of love medicines.

Gel as a cure for umhlume

There was only one theme to transverse the dialogue about both love medicines and microbicides, and that was *umhlume*. Approximately a fifth of trial participants included in this analysis claimed that the gel treated their *umhlume.* However, they did not clarify the source of their *umhlume*, in terms of it being the result of natural, pollutant or supernatural causes. Nonetheless most of these same respondents described *umhlume* as a Zulu illness that should be treated by Zulu traditional medicine. In addition, women talked of the presence of other STIs distinct from *umhlume* and the treatment of those STIs by the clinic nurses. Women often described the gel as having cleansing properties. This was most regularly reported in terms of the removal of vaginal discharge or 'drying' of excessive vaginal wetness. The 'treatment' of *umhlume* that women assigned to the gel, is highly likely to be the result of STI screening and

treatment that took place during the study. In fact the vast majority of women who claimed the gel treated their *umhlume* had been diagnosed, and where appropriate treated, for HSV2, BV or TV. Nonetheless, women attributed the 'treatment' effect of *umhlume* to the gel thereby merging the concepts of the biomedical gel with the ethno-medical causes of *umhlume*.

7.4 Discussion

In this chapter, I set out to explore whether the cross fertilisation of language from intravaginal insertion to microbicides identified in chapter 6, also applied to love medicines and microbicides. I have described the different ways in which love medicines are used to 'force' love and have categorised the narratives as relating to either a productive or destructive use of love medicines. I identified narratives that describe the gel as 'productive' in terms of its impact on love and relationships, but none that describe the gel as 'destructive'. I found that women in the trial distanced microbicides from love medicines by using language that defined microbicides as both 'natural' and 'biological'. Cross-fertilisation of language between microbicides with the 'supernatural' or 'traditional ethno-medical' was avoided and at times resisted. These findings are in stark contrast to the ways in which women drew on the local knowledge, language and understanding of using intravaginal insertions to explain their use of the gel described in chapter 6. These findings suggest that while the compatibility of microbicides and intravaginal insertion may actually facilitate the introduction of microbicide gels, the incompatibility of microbicides and love medicines may actually be advantageous for the introduction of microbicides.

In this study I have used the term 'love medicines' to apply to only one type of *imithi yenthand*o – the type that work through supernatural forces. The ways in which community members and trial participants describe the supernatural love medicines in this study are compatible with descriptions in other ethnographic studies in KwaZulu-Natal (Scorgie, 2009, Scorgie, 2010, Wickström, 2008a). However, the ethnographic component of the WHO GSVP study in KwaZulu-Natal explored love medicines purely within the context of vaginal practices. As such, no discernible distinction was made between the social acceptability of love medicines designed to enhance sexual desirability through physical properties, and love medicines designed to operate through supernatural forces (Scorgie, 2010, Scorgie, 2009). The difference in my analysis is that in comparing socio-cultural norms about intravaginal practices to microbicides, comparisons between the use of *imithi* to physically enhance sexual desirability with microbicides was acceptable to respondents, whereas comparisons between the use of *imithi* to supernaturally enhance love with microbicides was not acceptable.

Microbicides were obviously introduced as a biomedical intervention, provided by health care practitioners and delivered from primary health care clinics. However, in the last chapter I demonstrated how women still compared microbicides with traditional intravaginal insertions. In this chapter I have demonstrated that women did not compare microbicides with love medicines. The reason women specifically distance microbicides from love medicines appears to be to distinguish microbicides from the supernatural and from the use of 'force' to achieve love. While there were some negative associations with the use of intravaginal insertions, described in the last chapter, overall the idea of using products to make sex more enjoyable was generally accepted at least by women. Conversely, in this chapter I have demonstrated that the use of love medicines supernaturally is perceived as a violation of a man's choice. As such, by taking control away from men love medicines are viewed as a transgression of the dynamics of relationships in which male control dominates. If a women uses *imithi* to tighten her vagina, then the man is likely to choose to have sex with her. This is very different to a circumstance whereby the use of a love medicine removes the man's choice of whether or not to have sex with her.

The ethnographic work in KwaZulu-Natal describes the ways in which love medicines can be used to 'poison' or 'bewitch', both concepts associated with envy, jealously and evil (Wickström, 2008a, Scorgie, 2009). In this analysis I avoided using the word 'bewitchment' because when it is written in English it is extremely difficult to detach it from the role of a 'witch'. In this study, the main references to the use of love medicines, even for destructive purposes, were not associated with witches but rather with traditional healers, traders in traditional medicine or ordinary people using *imithi* for malevolent purposes. In this study love medicines were not described as being used to kill someone out of jealousy, as they have been in other contexts when witchcraft is at play (Parle, 2012). However the use of love medicines to cause negative afflictions on another woman was still born out of jealousy and by tapping into the evil aspects of the supernatural. As the interview with the trainer of traditional healers highlighted, creating pollution or interfering with the good-evil nexus of the supernatural, is believed to antagonise the ancestors. It is within this context that the use of the supernatural to 'force' love was frowned upon. It was clear from both women and men, that people, and especially men, were wary of others using love medicines. The potential for love medicines to be used is cause for suspicion and mistrust within relationships. It is therefore not at all surprising that women did not want to associate microbicides with the use of the supernatural forces of love medicines.

Socially it is not unusual that people do not want to be afflicted by supernatural forces, especially ones with the potential for evil intent. However, we also need to consider the extent

to which some of the disapproval is about women taking control of the course of a relationship, in a society with entrenched patriarchal views of relationships and marriage. The ethnographic work in KwaZulu-Natal has described the use of love medicines as a way that women can exert some control over relationships in an environment of high competition for partners (Scorgie, 2010, Parle, 2012, Wickström, 2008a). This is consistent with much of the literature which describes community responses to women's use of love medicines as subversive of gender roles (Wood, 2007, Niehaus, 2002).

In this analysis and other studies of love medicines, vaginal wetness has been associated with being 'cursed' or polluted. Scorgie described how excessive vaginal discharge can be interpreted as a "sign of having had illicit sexual intercourse with an '*isilwane'* (literally, animal: in this context, a witch's familiar) while asleep" (2009;275). A similar concept emerged in my analysis in terms of love medicines resulting in women being wet as if they had sex with a *tokoloshe*. The issue of vaginal wetness is also associated with infidelity in KwaZulu-Natal, as well as elsewhere in Africa (Scorgie, 2009, Ray, 1996). As mentioned earlier, there is evidence in KwaZulu-Natal of male resistance to women using injectable contraceptives due to them increasing vaginal wetness and decreasing sexual pleasure for men (Smit, 2002, Beksinska, 2001). It is striking that accusations of vaginal wetness emerge when women are suspected of taking control of their sexual conduct, be it through sexual affairs, the use of love medicines, or contraceptives. Women's distancing of microbicides from love medicines may be important not only in terms of separating microbicides from the supernatural, but also potentially separating microbicides from women's actions that are stigmatised as subversive of gender norms.

Although women distanced microbicides from love medicines, a few women did describe microbicides as giving them a competitive edge over other women. The competitive edge that microbicides provided was strictly in relation to the physical properties enhancing sexual pleasure, and as such far more comparable to the intravaginal insertions described in the last chapter than the 'forced' love described in this chapter. Nonetheless, none of the other ethnographic studies in KwaZulu-Natal have distinguished between natural and supernatural love medicines and the WHO categorisation of vaginal practices does not distinguish products that work on the basis of the physical versus the supernatural. Indeed even in this chapter I have used the term love medicines on the proviso that I am only talking about the types of *imithi* that work through the supernatural. In Zulu traditional medicine it is not unusual to have a single word for something that works through different sources depending on the intended outcome. However, this ambiguity of the term *imithi yenthando* as including the natural and supernatural, creates the potential for confusion if microbicides are compared to love

medicines and perceived as providing a competitive edge. This analysis suggests that if microbicides are compared with the 'forced' love of *imithi yenthando*, it could potentially be a barrier for women who want to use them.

As described above, in this analysis I found that love medicines are generally frowned upon and perceived as a way for women to exert power or enact control in their relationships. This interpretation is consistent with other descriptions of love medicines as described in the literature on vaginal practices (Scorgie, 2009). However, it is in contrast to findings from an ethnographic study which was also conducted in the Umkhanyakude district of KwaZulu-Natal (Wickström, 2008b). That study found the use of love medicines was about maintaining a balance of power between women and men rather than a subversion of power by women. The study suggests that the use of love medicines, or even the potential to use them, is a way for couples to protect their relationship from the vulnerabilities of misfortune and outside forces. As such love medicines are described as a way of negotiating moral behaviour and gender norms. These findings are in line with those of Eileen Krige who, in the 1950's, challenged the depiction of gender relations in Zulu culture as dichotomous, antagonistic and male dominated (Krige, 1968). I believe that the difference in our findings are in fact not incompatible, and actually reflect multiple perspectives of love medicines in Zulu culture – those of well-established couples in Wickström's study and those of women who perceive themselves at risk of HIV in my own study. The differences in our findings highlight that rather than dismissing love medicines in order to distinguishing them from microbicides, we need to understand more about the role that love medicines play in relationships and how the couples who consider love medicines as a way of negotiating a balance of power, will perceive microbicides. It also illustrates the need to consider the multiple realities of gender dynamics and not reduce them to a single perception of male dominance.

One potential area for an inter-connection between microbicides and love medicines is in relation to *umhlume*. The term *umhlume* appears to be very local to the Umkhanyakude district of KwaZulu-Natal. There are only a few references to *umhlume* in the literature and they refer to it as a traditional Zulu illness, a childhood diarrhoea with perineal rash considered to be caused by a mothers transgression of social taboos or a "projection" in the genital area thought to be caused by sexually transmitted infections (Myer, 2003, Ndawonde, 2006, Kauchali, 2004). The only translated references are in relation to names of specific trees – although these translations are not consistent across sources. Although it is very colloquial, the concept of an ambiguous illness like this, with natural and supernatural causes, is likely to resonate outside of this district. This syncretism of biomedical and traditional beliefs of a single illness is well documented in Africa (Ashforth, 2001). The narratives regarding the treatment of

umhlume are consistent with ideas of both proximate and ultimate causes of ill-health in Zulu ethno-medical understanding (Wickström, 2008b). As such, the symptoms of *umhlume* offer a proximate existential explanation of the illness, while the causes of *umhlume* may still be explained by ultimate (or what Wickström calls 'optimal') underlying causes. As Wickström argues, the "focus on optimal causes does not mean that people deny biomedical accounts of germs and viruses, but that they try to complete a biomedical understanding with more explanatory depth" (n.d;10). As such, women interpreted the microbicide gel as treating the proximate symptoms – regardless of whether they assume an ultimate underlying cause or not. This example illustrates the fluidity between biomedicine and ethno-medicine in a highly medically plural society, even in the context of women's attempts to define the microbicide gel as biomedical and natural.

My final discussion point is to look at how microbicides fit within the broader socio-cultural notions of love and relationships. Over the last few years there has been increasing criticism of the extent to which public health HIV research has ignored issues of love, intimacy and desire when dealing with sexual relationships in Africa (Hunter, 2010, Cole, 2009, Wainaina, 2008). Indeed even in this study we did not attempt to collect data on relationship dynamics per se. However, when given the opportunity to talk about their relationships in open ended discussions, women infused the discussions about sex acts with details of their relationships. The description of love medicines illustrates the desperate measures some women go to in order to elicit intimacy and love. Other studies have highlighted that the growing trend in administering love medicines in the genital area via *ukugcaba* illustrates the insecurity that women feel in relationships and the lengths they will go to in order secure fidelity (Scorgie, 2009, Scorgie, 2010). Although microbicides are distanced from love medicines, it was clear in this analysis that some women perceived that their use of microbicides enhanced the love, intimacy and passion of their relationships. This is in stark contrast to the perception in South Africa of condoms as reducing intimacy by symbolising a lack of trust and creating a physical barrier during sex (MacPhail, 2001, Stadler, 2011). The fact that a HIV prevention option has the potential to transcend what has been called the 'pleasure and danger' binary so inherent in HIV discourse (Sharma, 2001) is cause for optimism. This highlights the need to address issues of love and intimacy in microbicide acceptability research and consider the implications of marketing messages within this broader context of relationships.

One limitation of this analysis is that despite conducting workshops with religious leaders, we never broached the issue of love medicines, or any form of vaginal practices, in these discussions. Scorgie's work in KwaZulu-Natal found that women from the more traditionalist Zionist churches were over 4 times more likely to use *ukugcaba* vaginally for the

administration of traditional medicines (Scorgie, 2010). This raises the possibility that Zionist religious leaders may have held a less antagonistic view towards love medicines than the views expressed in this chapter. However, approximately half of the trial participants described themselves as Zionist and there were no observable differences in the narratives based on religious background. The second omission in this analysis is that not a single *izinyanga* volunteered to participate in the traditional healer FGD. The reasons why only *izangoma* and *abathandazi* volunteered are not clear. The key informant interview with the practitioner who was trained in all three practices did not hint at any particular distinctions in attitudes between the various practitioners in relation to love medicines. Nonetheless, we need to acknowledge that the views of *izinyanga* were not included sufficiently in this analysis.

Another limitation is that I never asked respondents for a direct comparison of microbicides and love medicines, or microbicides and other forms of traditional medicines, both natural and supernatural. However, this can also be interpreted as a strength of the analysis as I did not ask people to consciously compare the two, but rather compared and contrasted the narratives used in relation to the two subject matters independently. This allowed me to look for a sub-conscious transfer of language from one subject to the other. It is this less conscious transfer of meaning from existing products to newly introduced products, such as microbicides, that is likely to have a substantial bearing on how microbicides are ultimately accepted within a community and incorporated into sexual norms.

7.5 Conclusion

In this chapter I have demonstrated that women distance microbicides from love medicines. The fact that women are able to successfully distance microbicides from supernatural love medicines could be beneficial to microbicide roll out in the future. This analysis highlights three key messages. The first is that introductory messages about microbicides need to take account of local contexts of health beliefs and practices. While it may be appropriate in this area of South Africa to introduce microbicides as a way to 'make sex hot' it may not be appropriate to introduce them as a way to 'make your partner love you more'. The second key message is that introductory messages about microbicides need to take account of local contexts of gender dynamics. The discourse surrounding women's subversion of gender norms could potentially affect microbicide acceptability in the longer term. This study could only hypothesise the potential impact, but identifies the need for a more in-depth understanding of this discourse in relation to microbicides. Finally, this chapter highlights the extent to which women discuss microbicides not only within the context of sex or risk, but within the broader context of love and intimacy. It is vital that we as researchers avoid reducing love to sex or sex

to risk. This type of reductionist approach fails to acknowledge the complexities that women experience in relation to HIV prevention. This breadth of understanding about how women position microbicides in relation to other socio-cultural constructs will be vital in ensuring that introductory messages avoid the pitfalls that have been experienced with the roll out of male and female condoms in many communities across South Africa.

8 'What have men got to do with it': discussing microbicides with male partners

Summary

Microbicides are designed to be used by women, with or without the cooperation of their male partners. The evidence to date suggests that women in Africa are both expected to, and prefer to, discuss microbicides with their partners before using them. However, our understanding of the ways in which microbicides are discussed between women and their partners is still limited. In this chapter, I return to the microbicide acceptability literature identified in chapter 2 in order to review evidence regarding communication about microbicides. Using the MDP 301 data, I investigate the characteristics of women who talked to their partners about the microbicide in the trial. In addition I explore socio-cultural norms regarding communication about sex, the expectations regarding communication about microbicides, and the patterns of communication about microbicides that occurred during the trial. This analysis is based on quantitative data collected during the trial as well as qualitative data collected during in-depth interviews and focus-group discussions. The analyses aim to understand the discussions between women and their partners about microbicide use within the context of socio-cultural norms regarding sexual communication between women and men in KwaZulu-Natal.

8.1 Literature review

8.1.1 Discussing microbicides

As described in chapter 2 section 2.3, there are gaps in the evidence regarding our understanding of the communication processes that take place between women and men regarding the use of microbicide gels. During the systematic review of literature on microbicide acceptability, presented in chapter 2, I identified 28 articles out of the 45 articles on microbicide acceptability that reported on the ways in which women do or do not discuss microbicides with their partners. These articles are listed in Table 8-1 which shows that 24 of these papers were identified in stage 1 searches and 4 in stage 2 searches.

Table 8-1: Systematic literature review extraction table: discussing microbicides

No	Ref	Phase	Product	Countries	Discuss Use	Search stage
1	Behets 2008a*1	Pilot	Acidform: gel, diaphragm	Madagascar	X	s1
2	Turner 2009*1	Pilot	Acidform: gel, diaphragm	Madagascar	X	s2
3	Coggins 1998	Pilot	N-9: gel, film, suppository	Côte d'Ivoire, Thailand, USA, Zimbabwe	X	s2
4	Hira 1995	Pilot	N-9: foam, suppository, tablets	Zambia	X	s2
5	Bentley 2004	1	BufferGel	India, Malawi, Thailand, Zimbabwe	X	s1
6	Kilmarx 2008*2	1	Carraguard	Thailand	X	s1
7	Martin 2010*2	1	Carraguard	Thailand	X	s1
8	Ramjee 2007	1	Carraguard	South Africa	X	s1
9	Whitehead 2006*2	1	Carraguard	Thailand	X	s1
10	Whitehead 2011	1	Carraguard	Thailand	X	s1
11	El-Sadr 2006	1	CS	USA	X	s1
12	Malonza 2005	1	CS	India, Nigeria, Uganda	X	s1
13	Rustomjee 1999	1	N-9 film	South Africa	X	s1
14	Joglekar 2006	1	Praneem polyherbal	India	X	s1
15	Joglekar 2007	1	PRO2000	India	X	s1
16	Morrow 2003	1	PRO2000	South Africa, USA	X	s1
17	Carballo-Diéguez 2007	1	Tenofovir	USA	X	s1
18	Hoffman 2010*4	1	Tenofovir	USA	X	s1
19	Rosen 2008*4	1	Tenofovir	USA	X	s1
20	Carballo-Diéguez 2011	1	VivaGel® (SPL7013)	Puerto Rico, USA	X	s1
21	Altini 2010	2	Carraguard	South Africa	X	s1
22	Jones 2009	2	Carraguard	Thailand	X	s1
23	van der Straten, 2008	2	CS: gel, diaphragm	Zimbabwe	X	s1
24	Woodsong 2008	2B	BufferGel, PRO2000	Malawi, Zimbabwe	X	s1
25	Greene 2010	3	CS	Benin, India, Uganda	X	s1
26	Visness 1998	3	N-9 film	Cameroon	X	s2
27	Vandebosch 2004	3	N-9 gel	Benin, Côte d'Ivoire, South Africa, Thailand	X	s1
28	Montgomery 2010b	3	PRO2000	South Africa, Tanzania, Uganda, Zambia	X	s1

**1, 2, 4 identify multiple articles that refer to a single study*

In this section I review the literature on microbicide acceptability and communication about microbicides from trials of candidate microbicides. Firstly I summarise findings relating to the expectations regarding communication about microbicides in the Americas, Asia and Africa. In order to further critique the evidence from Africa, I also draw on literature from hypothetical and surrogate studies presented in chapter 2. Secondly I summarise the proportion of women

who have discussed microbicides with their partners before using them in clinical trials to date. I conclude the review by highlighting gaps in our knowledge regarding communication about microbicides.

8.1.2 Expectations regarding communication about microbicides

The possibility of using a microbicide without a partner's knowledge has often been heralded as the most promising feature of microbicides (Koo, 2005). However, the extent to which women are expected to discuss microbicides with their partners before using them varies substantially between women according to the context of their own sexual relations and perceptions of HIV-risk. The literature suggests that the trend towards or away from a desire to discuss microbicides with partners also differs geographically.

Americas

Of the 28 manuscripts that report on communication about microbicides from clinical trials, 7 include data from the United States of America. Women and men in the America's tend towards prioritizing the need for microbicides that would be 'unnoticeable' during sex (Carballo-Diéguez, 2007, Coggins, 1998, El-Sadr, 2006, Hoffman, 2010, Morrow, 2003, Rosen, 2008, Carballo-Diéguez, 2011). The 'noticeability' of a microbicide has been driven by the product's physical properties and the volume of gel required and clearly impacts on women's ability to use specific microbicides without a partners knowledge. For example, the Invisible Condom was found to be highly acceptable by women mainly because it was imperceptible to the male partner (Trottier, 2007) whereas the acceptability of VivaGel® was limited due its visibility during sex (Carballo-Diéguez, 2011). The trend in the USA has been against the need to discuss microbicides with partners. However the dichotomy between a woman's right to control her own body versus a desire to be open and honest with an intimate partner was evident (Hoffman, 2010).

Asia

Of the 28 manuscripts that report on communication about microbicides from clinical trials, 12 include data from Asia, with 4 including evidence from India, 7 from Thailand and 1 from both. Studies in Asia focused on whether or not it would be feasible to use a microbicide without a partner noticing it. Opinions on this topic were split with 7 studies (2 from India, 4 from Thailand and 1 from both) tending towards use without partner's knowledge not being feasible (Bentley, 2004, Joglekar, 2006, Kilmarx, 2008, Martin, 2010, Coggins, 1998, Jones, 2009, Malonza, 2005) and 5 studies (2 from India, 3 from Thailand) tending towards it being feasible (Greene, 2010, Joglekar, 2007, Vandebosch, 2004, Whitehead, 2006, Whitehead, 2011). There

were no clear divisions on this point between the two countries. Unlike in the United States, there were no references to women's rights as a rational for using microbicides without a partner's knowledge. In a few studies, a motivation to discuss use with stable partners was driven by a desire to avoid accusations of infidelity if the partner noticed the gel during sex (Greene, 2010, Joglekar, 2007, Bentley, 2004, Joglekar, 2006). The ability to have privacy to insert the microbicide before sex emerged as another concern in relation to the feasibility of the discreet use of microbicides, specifically in India (Greene, 2010, Joglekar, 2006). Use without the knowledge of a commercial client was perceived as more feasible than use without the knowledge of an intimate partner (Vandebosch, 2004, Martin, 2010). Interestingly, in one study although only 15% of women thought it would be feasible to use a microbicide without their partner noticing it, 43% of men thought it was feasible as men would not notice (Whitehead, 2006). This highlights disparities throughout the literature between women's and men's views.

Africa

In total, 16 articles reported on communication around microbicides in Africa. Evidence from clinical trials in African countries tends to stress an expectation that women should discuss microbicides with men prior to using them and even suggests that most women would in fact prefer their partners to be aware of their use of microbicides (Bentley, 2004, Coggins, 1998, Turner, 2009, Montgomery, 2010b). In fact one study in Zimbabwe found that less than a quarter of women thought that it would be important to be able to use a microbicide without the partners knowledge (van der Straten, 2008). As described in chapter 2 section 2.2.1, this evidence is supported by hypothetical evaluations in east and southern Africa particularly, where acceptability of microbicides was generally premised on the need for women to discuss microbicides with men prior to use (Veldhuijzen, 2006, Ramjee, 2001, van de Wijgert, 1999, Coggins, 2000b, Bisika, 2009). Similarly, as described in chapter 2 section 2.2.2, in studies conducted with surrogate products in Africa, there were clear expectations that women in long-term relationships would need to discuss the use of a microbicide with their partner prior to use (Salter, 2008, Jones, 2008, Green, 2001, Pool, 2000, Montgomery, 2008). Indeed one of the surrogate studies in Uganda found that even though the ability to use a microbicide without prior discussion emerged as an important feature of the product in focus group discussions, the vast majority of women (87%) did inform their partners about using the products (Pool, 2000). A preference to discuss microbicides prior to use was reported to be driven by the idea that a couple should not have secrets (Woodsong, 2008) and a fear of the ramifications if a male partner discovered his partner using a microbicide without prior discussion (Coggins, 1998). However, as in Asia, there were far lower expectations of the need

for women to discuss microbicides with either casual partners or with commercial clients than with stable or marital partners (Rustomjee, 1999, Vandebosch, 2004, Greene, 2010, Visness, 1998).

Although the above evidence suggests a trend in Africa towards the need to discuss microbicides prior to using them, the evidence from South Africa presents a more nuanced picture. There is still an expectation that ideally a couple should discuss microbicides before using them and there is still a preference to use them with the knowledge of a partner. Indeed in one study almost three-quarters of women thought that it would not be possible to use a microbicide without a partners' knowledge (Altini, 2010). However in 2 out of 6 studies in South Africa, there appears to be more tolerance for the use of microbicides without prior discussion than in other African countries (Ramjee, 2007, Morrow, 2003). For example in a small phase I trial in Durban, although the majority of women and men thought that the decision to use a microbicide should be made by both partners, almost half of the men interviewed found it acceptable for women to use the product without discussing it with their partners (Ramjee, 2007). Again this is supported by evidence presented in chapter 2 section 2.2.1 from hypothetical studies in South Africa, where women's use of a microbicide without the male partner's knowledge was deemed acceptable in some circumstances (Orner, 2006, MacPhail, 2009). Indeed a phase I trial in both South Africa and the USA did not find any distinguishable differences between the countries in attitudes towards using a microbicide without prior discussion (Morrow, 2003).

In South African hypothetical studies, the recognition that male partner involvement may not always be possible or preferable was influenced by a number of factors: 1) a discourse of women's rights and empowerment in South Africa, 2) women's experience of men resisting condoms and injectable contraceptives due to a reduction in male sexual pleasure, 3) an overwhelming distrust of male fidelity, 4) an assumption that the introduction of a HIV-prevention option into an existing relationship is a sign of infidelity, and 5) the risk of men forcing women to have sex without a condom or enacting other violent behaviour (Orner, 2006, MacPhail, 2006). These factors appear specific to South Africa and distinguish the evidence on this topic in South Africa from that in other African countries.

8.1.3 Communicating about the use of microbicides

Although there is considerable literature on how women feel about using microbicides without their partners' knowledge, there is little data regarding how many women actually talk to their partners about microbicides before using them in clinical trials.

Only one study has compared the proportion of women who have discussed microbicides with their partner's in the Americas, Africa and Asia. This study found that more women discussed the microbicide with their partners in Thailand than in Zimbabwe, Côte d'Ivoire or the USA (Table 8-2) (Coggins, 1998). Conversely, another multi-country country, this time with commercial sex workers, found that women in Thailand were less likely to inform both clients and partners about their use of the microbicide than women in South Africa, Côte d'Ivoire, and Benin (Vandebosch, 2004). In other studies, the proportion of women who have discussed microbicides with sex clients ranged from 0% in South Africa to 65% in Madagascar (Rustomjee, 1999, Turner, 2009), and with partners ranged from 22% to 100% both in Thailand (Vandebosch, 2004, Jones, 2009). As Table 8-2 illustrates, there are no obvious patterns within or between countries or population groups.

Table 8-2: Proportion of women who discussed microbicides with their partners/clients

No	Ref	Duration	Proportion of women who discussed microbicides
1	Altini 2010	6–12 months	South Africa=98% partner
2	Coggins 1998	12 weeks	Thailand=86-96% partner Zimbabwe=83% partner Côte d'Ivoire=75% partner USA=73% partner
3	Hira 1995	28 days	Zambia=86% foam; 89% tablets; 94% suppositories (partner)
4	Jones 2009	12 months	Thailand=100% partner
5	Malonza 2005	7 days	India, Nigeria, Uganda = 30% Cellulose Sulphate & 37% K-Y jelly – sexually abstinent (Partners of all sexually active women were informed as part of study)
6	Rustomjee 1999	2 months	South Africa= 0% client & 50% partner
7	Turner 2009	4 weeks	Madagascar=65% client
8	Vandebosch 2004	Up to 2 years	Thailand=22% client & 22% partner South Africa= 23% client & 41% partner Côte d'Ivoire=51% client & 54% partner Benin=54% client & 45% partner
9	van der Straten, 2008	6 months	Zimbabwe Gel=97% partner Diaphragm= 97% partner

To date, there has been no attempt to characterise women who do or do not discuss their use of a microbicide with a partner. One study which compared three different formulations of N-9, found no correlation between women's preferences for formulations and discussing the product with their partners (Coggins, 1998). In addition, the impact of discussing microbicides before using them has rarely been evaluated as a predicator of adherence to gel. One study found that the male partner's approval of the woman using a microbicide was independently

associated with adherence (van der Straten, 2008). However another study found that although communication improved women's adherence to the use of gel with a diaphragm, it did not impact on women's adherence to gel alone (Turner, 2009). Two clinical trials have found that women's own acceptability of microbicides was largely influenced by their *perception* of male acceptability (Greene, 2010) or the anticipated reaction of their partner (Woodsong, 2008). This has been reported more frequently in hypothetical and surrogate studies than in clinical trials (Montgomery, 2008, Tolley, 2006, Salter, 2008, Jones, 2008, Green, 2001, Tanner, 2010).

There is hardly any evidence from microbicide clinical trials regarding patterns of communication over time. One study with a surrogate product in Uganda found that within the first week of the study only 60% of women had talked to their partners about using the vaginal product, but that this increased to almost 80% after 10 weeks in the study (Green, 2001). In a diaphragm and microbicide trial in Zimbabwe, although 97% of women using the gel alone had talked to their partners about the products, 27% of the women explained that their partners did not necessarily know every time they used gel (van der Straten, 2008). Similarly another study among commercial sex workers in Madagascar found that some partners were only aware that the women had used a gel about a quarter of the time it was actually used (Turner, 2009). This evidence highlights that communicating about microbicides is an on-going process that we still understand little about.

8.1.4 Sexual communication and microbicides

In the early days of development, microbicides were often referred to as a 'female-controlled' prevention technology (Braunstein, 2003). However, evidence suggesting that women would require male agreement to use microbicides highlighted that even though microbicides are used by women, women may not necessarily be in control of them in gender-inequitable relationships. Consequently microbicides are now more likely to be referred to as 'female used' than 'female controlled'. Some authors argue that the evidence conclusively demonstrates that women in Africa are expected to, and prefer to, use microbicides only with the full knowledge of their partner (Domanska, 2012).

However, I argue that there are still major gaps in our understanding of communication around microbicide use. Firstly, the evidence suggests that in South Africa attitudes towards women's control over microbicide use may be distinct from other parts of Africa. We therefore need to understand the expectations regarding communicating about microbicides within the context of socio-cultural norms relating to communicating about sex more generally. Secondly, we need more evidence regarding the proportion of women who discuss microbicides with

their partners and which characteristics may predict which women are likely to use microbicides without their partner's knowledge. Similarly we need to understand the impact on gel adherence, of using microbicides without a partner's knowledge. Thirdly, most of the research to date has looked at communication about microbicides from a binary perspective – either women have told their partners or not. However, we know very little about the patterns of communication that take place over time. We need to understand more about the processes involved in communication in order to evaluate the impact that the availability of a female-used microbicide could have on reducing women's reliance on male approval of HIV prevention strategies.

In an attempt to address some of these gaps in the evidence, in this chapter I use quantitative data to estimate the proportion of women who discuss microbicides with their partner prior to use and characterise women who do and do not engage in such discussion. I use qualitative data to explore the broader socio-cultural context of expectations regarding communication about sex and microbicides in KwaZulu-Natal. Finally, I use qualitative data to examine the communication process that takes place between women and their partners using a microbicide gel for up to a year.

8.1.5 Terminology

Before presenting my findings I want to address two terminological issues in relation to this topic. To date the most frequently used term to describe the communication that takes place between couples prior to the use of microbicides is 'disclosure'. This is used in terms of women 'disclosing' to men their intention to use microbicides or their actual use of microbicides. The use of microbicides without prior 'disclosure' is most frequently referred to as 'covert' use. Of all the manuscripts reviewed as part of this literature review, over two-thirds use the word 'covert' to describe the use of microbicide gels by women without the knowledge of their sexual partners.

In this thesis I am avoiding the use of the word disclosure for a number of reasons: Firstly in HIV literature the term 'disclosure' is most commonly associated with the disclosure of someone's HIV status. As such the word has negative connotations relating to a HIV-positive status in some communities. Secondly, the Oxford English dictionary definition of disclose is: "make (secret or new information) known or allow (something hidden) to be seen " (OED, 2012). Although this definition makes clear that disclosure can relate to making 'new information known', its interpretation is heavily influenced by its association with disclosure of something 'secret' or 'hidden'. Thirdly, the word 'disclosure' infers a single act of disclosing information. As demonstrated by the literature on HIV disclosure, communication about HIV or

HIV prevention is often a process not a single act (Eustace, 2010). Similarly, while the initial communication about microbicides is about 'new information', it is my contention that the on-going dialogue, or lack thereof, is equally as important as that initial dialogue and cannot strictly be described as 'disclosure'. In order to avoid these potentially negative associations and over simplifications, throughout this thesis I am purposefully avoiding using the word 'disclose' and instead will discuss the process of communication that takes place around the use of microbicides.

Similarly, I am avoiding the use of the word 'covert' for a number of reasons: the Oxford English dictionary definition of covert is: "not openly acknowledged or displayed*"(OED, 2012).* Although 'covert' can relate to a range of activities the majority of dictionary descriptions draw on militaristic examples, such as: *"*covert operations against the dictatorship" (OED, 2012)*,* "covert military operations; covert funding for the rebels" (Farlex, 2012) or "the government was accused of covert military operations against the regime"(Cambridge, 2012). The use of militaristic vocabulary such as 'fighting HIV' or combatant language such as 'struggle, battle or campaign' in reference to HIV has been discouraged as it has the potential to be stigmatising of people living with HIV (UNESCO, 2006). In relation to microbicides, I believe that the use of the word 'covert' also has the potential to be stigmatising to women who, for whatever reason, decide to use a microbicide without their partner's knowledge. In addition I believe that the idea that microbicides are used either covertly or not, is insufficient to address the nuances that are involved with communicating about the use of microbicides over time. Consequently in this thesis, I am purposefully avoiding using the term 'covert' and instead will discuss the use of microbicides without prior communication with a partner.

8.2 Methods

8.2.1 Quantitative data

The data collection, management, and analysis of the quantitative data have been described in chapters 3 and 4.

Dependent variables

At the week 4 follow-up visit, counsellors administered the long sexual behaviour CRF. On the long sexual behaviour CRF data were collected about each sex act in the last week, or the last 4 weeks if the women had not had sex in the last week. For each sex act, if a woman had used gel she was asked if she had told her partner she was using gel. For the purpose of this analysis, a woman is defined as communicating with her partner about gel use if she informed her partner about using the gel at any single sex act.

The outcome variable for this quantitative analysis is talking to the partner about gel use in the period of reporting by the week 4 visit. Only women who reported gel use in the period of reporting (last week or last 4 weeks) are included in this analysis. I compare the demographic, socio-economic and sexual behaviour characteristics of women who talked with their partners about gel use to women who did not.

Independent demographic, sexual behaviour and socio-economic variables

In the literature, age, educational status and socio-economic status are identified as factors associated with sexual communication (Ndinda, 2007, Sahin-Hodoglugil, 2011). To assess the impact of these factors on communication about gel use, the following variables described in chapter 4 section 4.5 are included in this analysis: age, highest educational level achieved to date, employment status, household access to electricity, water source, main fuel source used for cooking, household size and household ownership of a telephone, radio, television, bicycle, fridge, motorbike and cattle.

Marital status, rural residency, low condom use and low levels of sexual activity have been identified in the literature as potential influencing factors on women's ability to discuss sex with a partner (Ndinda, 2007, Sahin-Hodoglugil, 2011). Consequently, in the absence of marital status, I use the relationship to the head of the household as a proxy for relationship structure, as well as including area of residency, consistency of condom use in the last week or 4 weeks and sexual activity in the last week or 4 weeks in the analysis.

Religion is included in the analysis on the basis that some religions, such as Shembe, are more traditionalist than other religions and this could impact on sexual communication within a relationship. I also included clinic of enrolment in order to control for the differential impact of counselling at the different clinics. In case previous participation in microbicide research influenced communication about gel, I included a variable that identified women who had participated in the previous Africa Centre MDP feasibility or pilot studies.

Quantitative analysis

In STATA, I initially compared the women who did talk to their partners about gel use by the week 4 study visit, to the women who did not talk to their partners about gel use. Univariate associations were assessed using the Pearson Chi2 test. I tested the contribution to the multivariable model of each variable that was significant in univariate analysis at the 0.10 level using likelihood ratio tests (Kirkwood, 2003). I created missing values for previous MDP participation for 3 women and retained these within the multivariable models (not presented).

Multivariate associations were assessed at the 0.05 level, after controlling for potential confounding factors, through multiple logistic regression analyses.

8.2.2 Qualitative data

The collection, management and analysis of the qualitative data have been described in chapters 3 and 4. For this qualitative analysis I use data from the community FGDs and trial IDIs. There were two stages to the qualitative data analysis for this chapter.

Firstly, I analysed the 19 community FGDs thematically coding all text that addressed issues relating to sexual communication. I present findings for each emergent theme in the results. I specifically did not include the participant FGDs in the first part of the analysis as I wanted to assess socio-cultural norms regarding sexual communication without the influence of the trial or the experience of the gel. However, I do subsequently compare the views of the trial participants in the IDIs with the views of the community in the FGDs.

Secondly, I analysed data from interviews with the 79 trial participants who were interviewed around the time of their week 4 visit, as described in chapter 3 section 3.3.2. I coded the IDIs thematically for all text relating to partner involvement in gel use. Among women who had talked to their partners about the gel, I identified the main reasons for discussing the gel with a partner, the ways in which gel was discussed, and, where possible, if they had told their partners about the gel before or after using it. Finally I identified reasons why women had not talked to their partners about the gel and how they were using it without their knowledge. I specifically excluded the male interviews from the second part of the analysis as these males were distinct in that they had all discussed the gel with their partners and, by virtue of their participation in in-depth interviews, were specifically engaged in the trial. On subsequent review of the male IDI text, I concluded that it did not contribute to the findings as it merely confirmed that male partners believed that women should talk to their partners about the gel. The data did not add to the description of how the microbicides were discussed between the couple.

In the results, I firstly present the quantitative data describing the proportion of women who communicated with their partners about gel use and their characteristics. I present findings from the community FGDs regarding socio-cultural norms about sexual communication, and finally the trial IDI findings describing the reasons, processes and timing of discussions about gel.

8.3 Results – quantitative analysis

In this section I investigate the characteristics of women who communicated with their partners about gel use within the first 4 weeks of using gel. In total, 1177 women enrolled in the Africa Centre MDP 301 clinical trial. Eighty five women were dropped from this analysis. Of these, 59 women did not return for the week 4 follow up visit. Of those who did return, 5 women had not had sex in the 4 weeks prior to the visit and 21 had not used gel in the reporting period of the last week or 4 weeks prior to the visit. Consequently data from 1092 women were included in this analysis.

8.3.1 Univariate analysis

By week 4, 60% of women had discussed gel use with their partners. Of the 651 who did discuss gel with their partners, 578 (89%) said their partners always knew they were using it and 73 (11%) said they sometimes knew they were using it. As shown in Table 8-3, Table 8-4 and Table 8-5 the following variables were significantly associated with discussing the gel in univariate analysis at a 10% level: age, head of household, clinic of enrolment, previous participation in MDP studies, water source, household ownership of cattle and condom use. However, head of household (p=0.61), previous participation in MDP studies (p= 0.23) and condom use (p=0.18) did not contribute to the model in likelihood ratio tests and were consequently excluded from the multivariate model.

Table 8-3: Individual characteristics of women who discussed gel use with their partner compared to women who did not discuss gel use at week 4

	Not Discussed	Discussed	Chi2 P-value
	441 (40%)	651 (60%)	
Age			
Mean (95% CI)	36.15 (35.07-37.22)	34.20 (33.29-35.10)	<0.01
SD	11.49	11.70	
Median (95% CI)	38 (35-39)	34 (31-36)	0.01
IQR	25-46	23-44	
Educational level			
Primary or lower	228 (43%)	307 (57%)	0.14
Secondary or higher	213 (38%)	344 (62%)	
Employment status			
Employed	81 (44%)	103 (56%)	0.27
Unemployed	360 (40%)	548 (60%)	
Head of household			
Partner	208 (44%)	264 (56%)	0.09
Parent/in-law	142 (36%)	249 (64%)	
Self	50 (43%)	66 (57%)	
Other	41 (36%)	72 (64%)	
Area of residency			
Rural	353 (41%)	504 (59%)	0.30
Peri-urban/urban	88 (37%)	147 (63%)	
Religion			
Zionist	202 (40%)	305 (60%)	0.88
Shembe	104 (39%)	161 (61%)	
Christian - mainstream	101 (42%)	137 (58%)	
Other	34 (42%)	48 (58%)	
Clinic of enrolment			
KwaMsane	191 (46%)	228 (54%)	0.02
Mtubatuba	128 (36%)	225 (64%)	
Madwaleni	122 (38%)	198 (62%)	
Previous MDP participation (3 missing)			
No	425 (41%)	615 (59%)	0.09
Yes	14 (29%)	35 (71%)	

Table 8-4: Household characteristics of women who discussed gel use with their partner compared to women who did not discuss gel use at week 4

	Not Discussed	Discussed	Chi2 P-value
	441 (40%)	651 (60%)	
Access to electricity			
No	235 (43%)	315 (57%)	0.11
Yes	206 (38%)	336 (62%)	
Water source			
Inside house/yard	127 (38%)	206 (62%)	0.03
Community source	234 (39%)	365 (61%)	
Free flowing	80 (50%)	80 (50%)	
Fuel for cooking			
Electricity	143 (39%)	221 (34%)	0.86
Gas	39 (44%)	49 (56%)	
Paraffin	57 (41%)	82 (59%)	
Wood	202 (40%)	299 (60%)	
Radio			
No	56 (41%)	82 (59%)	0.96
Yes	385 (40%)	569 (60%)	
Television			
No	259 (42%)	360 (58%)	0.26
Yes	182 (38%)	291 (62%)	
Telephone			
No	54 (45%)	65 (55%)	0.24
Yes	387 (40%)	586 (60%)	
Fridge			
No	222 (42%)	301 (58%)	0.18
Yes	219 (38%)	350 (62%)	
Bicycle			
No	373 (41%)	538 (59%)	0.40
Yes	68 (38%)	113 (62%)	
Cattle			
No	304 (38%)	490 (62%)	0.02
Yes	137 (46%)	161 (54%)	
Household size			
4 people per room or more	106 (44%)	134 (56%)	0.43
3 people per room	136 (38%)	226 (62%)	
2 people per room	165 (40%)	245 (60%)	
1 person per room or less	34 (43%)	46 (57%)	

Table 8-5: Sexual behaviour characteristics of women who discussed gel use with their partner compared to women who did not discuss gel use at week 4

	Not Discussed	Discussed	Chi2 P-value
	441 (40%)	651 (60%)	
Average sex in last week			
Less than once	91 (46%)	106 (54%)	0.14
1 to 3	126 (41%)	179 (59%)	
4 to 6	129 (41%)	187 (59%)	
7 to 9	54 (36%)	96 (64%)	
10+	41 (33%)	83 (67%)	
Condom use in last week/4 weeks			
Always	221 (38%)	360 (62%)	0.09
Never/sometimes	220 (43%)	291 (57%)	
Gel use during trial			
Always	277 (40%)	421 (60%)	0.53
Never/sometimes	164 (42%)	230 (58%)	

There were no statistically significant differences between women who discussed gel use to women who did not discuss gel use in terms of education level, employment status, area of residency, religion, access to electricity, fuel source used for cooking, household ownership of a radio, television, telephone, fridge or bicycle, household size, frequency of sexual activity or gel use.

8.3.2 Multivariate analysis

Table 8-6 presents the output from the final multivariate model. Women who discussed gel use with their partners by the week 4 visit were significantly younger than women who did not discuss gel use with a mean age of 34 compared to 36 years of age. Communication decreased with age. By age group, 64% of 18 to 24 year olds, 62% of 25 to 34 year olds, 58% of 35 to 44 year olds and 54% of women 45 and older had discussed gel use with their partner. Discussion was less likely to occur among women who lived in households that owned cattle.

Table 8-6: Multivariate model comparing women who discussed gel use with their partner to women who did not discuss gel use at week 4

	Adjusted Odds Ratio	Lower CI	Upper CI	P-value
Age (mean)	0.98	0.97	0.99	<0.01
Clinic of enrolment				
KwaMsane	1.00			
Mtubatuba	1.54	1.14	2.07	<0.01
Madwaleni	1.32	0.97	1.80	0.07
Water Source				
Inside house/yard	1.00			
Community source	1.01	0.76	1.36	0.93
Free flowing	0.70	0.48	1.03	0.07
Household ownership of cattle				
No	1.00			
Yes	0.72	0.55	0.95	0.02

Women who enrolled at Mtubatuba clinic were significantly more likely to have discussed gel use with their partner than women who enrolled at KwaMsane clinic. To explore possible reasons for differences in clinic of enrolment, in a subsequent analysis I created a variable to identify clinic specific counsellors. In total 13 staff were responsible for gel adherence counselling in the 3 clinics during this period of observation. In a subsequent model I created a binary variable which compared the 3 main counsellors at KwaMsane clinic to the other 10 staff (not presented). When included in the model, there was no longer a difference between women who discussed gel use with their partners depending on if they enrolled at Mtubatuba (AOR: 1.00 95% CI: 0.64, 1.56) or Madwaleni (AOR: 0.81 95% CI: 0.50, 1.32) compared to KwaMsane. The women counselled by the main 3 counsellors at KwaMsane were significantly less likely to have discussed the gel with their partners than women counselled by any of the other 10 staff members (AOR: 0.56 95% CI: 0.36, 0.88).

In summary, older women, women enrolled at KwaMsane clinic and women who live in households that own cattle were less likely to discuss gel use with their partners after 4 weeks in the trial. However there were few other differences.

I repeated the analysis, this time comparing women who had talked to their partners about the gel at any time in the 52 weeks of follow up. By the end of the trial 84% of the women in this sample had discussed the gel with their partners. In the same multivariate model only water source and cattle ownership were significant, with women who rely on free flowing water (AOR: 0.56 95% CI: 0.34, 0.93) and women who live in households that own cattle (AOR:

0.67 95% CI: 0.47, 0.94) being significantly less likely to have discussed gel with their partners. Overall, demographic and socio-economic characteristics do not sufficiently predict who will or will not discuss gel use with their partner.

8.4 Results – qualitative analysis of community FGDs

In this section I explore socio-cultural norms about sexual communication and expectations relating to communication about microbicide gels from the communities perspective. I also outline specific relationship issues that the community FGDs suggest could exacerbate challenges in discussing microbicides and attitudes towards the use of microbicides without a partner's knowledge.

8.4.1 Sexual communication

All respondents in the community FGDs had a shared understanding of the traditional norms regarding sexual communication. Within this traditional context, women were not supposed to talk about sex, initiate sex, or even refuse to have sex with their partner. Breaching these norms was considered a sign of infidelity on the assumption that the woman must have 'learnt' to talk about or initiate sex from another man, or must be having sex with another man in order to refuse sex with her partner.

It was often stated that men were the ones who proposed marriage to women and paid the bride wealth, and consequently were the ones who should make all other decisions regarding the relationship. In Zulu, bride wealth is called *lobola*. *Lobola* traditionally involves the transfer of cows (usually around 11) from the groom's family to the bride's family. The practice of *lobola* is still common place, although nowadays payments are more likely to be based on the equivalent cash value of the agreed number of cows. On payment of *lobola*, traditionally the new wife moves from her own family homestead to that of her husband's family. In the FGDs, some respondents referred to a man's ability to return a wife to her family and demand the refund of *lobola* if his wife 'misbehaves' which may include breaches of cultural traditions. This man's view illustrates the most extreme version of the socio-cultural role of women and men:

> "In our culture the women don't have a right to tell the man what she thinks…. Males are the ones who pay *lobola* and bring a woman to his house. According to the bible the man is the first God for the woman, it says that the woman would be under the man's rules. That is why women always humble themselves under men. The men are made to rule over women" (Community FGD, 38 year old man)

However, there was a palpable schism in opinion about how these traditional norms informed contemporary sexual communication. Approximately half the respondents believed that these

traditional norms still dominated community expectations. The other half believed that the advent of HIV had changed norms regarding sexual communication. The differences were predominately gendered and generational, with most women and younger men believing that communicational norms in relationships had changed or were changing. However, it was not uncommon for young men to differ in opinion between the domination of old or contemporary norms as this dialogue from a male community FGD demonstrates:

> **Interviewer:** "To your knowledge is it common that men and women involved in a relationship talk about sex?"
>
> **Participant 8:** "It is not common because men are like ***lions*** to their women. You find that a woman cannot talk just anyway to him" (Community FGD, 22 year old man)
>
> **Participant 5:** "I would like to oppose this guy participant 8 that men and women cannot talk about sex. I believe that most people here in the community have learnt about sexually transmitted infections. It cannot happen that people in a relationship don't talk about these things… People who are ***lions*** were there in the olden days, when a man had more power than a woman" (Community FGD, 20 year old man) (emphasis added).

Nonetheless, it was widely acknowledged that the ability of women to discuss, initiate or refuse sex largely depended on the attitudes of the men in the relationship. There was a continuum from women being completely prohibited from talking about sex to women being seen as equal in communication. The social expectation still appeared to revert to the 'traditional' and men who continued to act like the '***lions'*** mentioned in the quote above, were rarely challenged by familial, community or religious structures.

There were risks involved for women who discussed sex. For merely initiating communication about sex, women talked about the risk of abandonment, mistrust, financial marginalisation, verbal conflict or even physical abuse:

> "It is difficult because a man might beat a woman (for talking about sex) even if the discussion was started by him because men are in control" (Community FGD, 31 year old woman).

Conversely this man's explanation illustrates the potential for changing norms regarding sexual communication even within this context of gendered expectations:

"(Women) have a right to take decisions about their life. If we are talking about love, love is equal. It doesn't work that I am the one who proposes to her, what works is that we are in love, all that we are doing must come to an agreement…. It is very important to respect each other. In love we must be equal….. Let us put our powers aside, according to love everyone is allowed to do what he or she wants with his or her life" (Community FGD, 45 year old man).

8.4.2 Communication about microbicides

Although the FGD participants were split about women's ability to initiate discussion about sex, all of them agreed that from a Zulu cultural perspective, women should not use a microbicide before discussing it with their partners. However, there were different expectations about the form that the discussion should take which inferred different expectations regarding the decision making process and the role of the male partner.

The main Zulu words used in this context were *imvume, cela, xoxa*, *tshela* and *azisa*. *Imvume* means 'permission'. This was used within the context of women asking men for permission to use the gel with men being the ultimate decision makers about whether or not women could use gel.

The word *cela* means to 'ask'. However, *cela* or *ukucela* are used to describe the first step in the *lobola* negotiations when the groom's negotiators establish the *isicelo* or 'asking price' for the bride. As such, *cela* can be used purely to 'ask' or within the context of a process of negotiation. In this context it is distinct from *imvume*, inferring a process of negotiation between the couple before the use of gel.

The word *xoxa* refers to talking or telling someone about something, also used when 'telling a story' or 'giving an account' of something. *Tshela* also means to 'tell' or narrate or give an account of something. *Tshela* was the most frequently used term. Again, like *cela*, *xoxa* and *tshela* had an inference of negotiation in the process of seeking agreement.

The final word, a*zisa,* means to inform, although there are two different uses of this word. Some women used *azisa* when describing the range of strategies that they employed to 'inform' men of things in order to convince them to agree. In this way it was similar to the negotiated discussion that was described by the words *cela*, *xoxa* and *tshela*. These words were used within the context of women and men negotiating the use of gel. In some descriptions this was a process of shared decision-making. In other descriptions it was the woman trying to convince the man to allow her to use it. Either way, these descriptions were all premised on the assumption that gel could only be used if the male agreed to its use.

However, a few mainly younger women used either *tshela* or *azisa* in terms of literally telling or informing the partner without any expectation of a negotiation or any requirement for permission or consent, as this quote from a married woman illustrates:

> "I think I must discuss (*ngiphumele obala* – speak out or pronounce) so that he will know that I am using this thing (gel). This is my life not his life, I can tell (*ngingamtshela*) him that there is something that I am using like this and this, I am protecting myself from the diseases because you are not faithful, I do not know the places you go, you cannot trust a person these days. I can tell (*ngimtshele*) him that I am using this thing father (husband) with my life, the life is mine" (Community FGD, 44 year old woman).

In these rarer examples, women were viewed as the ultimate decision makers about whether or not to use gel.

8.4.3 Use of microbicides without a partners knowledge

Although everyone agreed that ideally male partners should know about the gel before it is used, a minority of the respondents thought that women could be justified in using the gel without the male partner's knowledge in some circumstances. One example was if a woman had experience of her partner refusing specific requests previously. In these circumstances some women believed that women should use the gel without telling their partner:

> "You do not do something without asking a person, you know your partner. You firstly ask him that can I use this or can we use this. If you see that he is not allowing it, you just keep quiet and continue using it secretly" (Community FGD, 41 year old woman).

Even a few younger men agreed that in some circumstances, use without a partners' knowledge was justified. Some examples were if a male partner was HIV positive, had other partners, refused to use condoms, or was frequently drunk, thereby unreliable in terms of condom use. The sense in these examples was that if males failed to be what was traditionally considered a good and reliable husband, then his partner had the right to breach traditional norms in response to his failings as a husband or partner.

In these circumstances, the respondents commented that if the woman was caught using the gel secretly, then she would have to tell her partner the truth. However, they all agreed that this could lead to accusations of infidelity and would cause conflict in the relationship.

8.4.4 Relationship issues

Communicating about sex was described as always being difficult or embarrassing. Sexual communication was viewed as more challenging in some relationships than others. The main issue was in marriage. This returns to the issue of *lobola*. If a woman was married, it was perceived that she was more under the control of her husband than in she was unmarried, as this quote demonstrates:

> "If we are not married he must know that he cannot take decisions for me because I am not married to him. He can only take decisions for me if we are married. Whatever you say I must then do it because I am married, but if we are not married we will have to talk and we will have to know that I do not like this" (Community FGD, 31 year old woman).

Similarly, some men thought that it was more difficult to talk about sex with their wives than with a casual partner as this man explains:

> **Interviewer**: "Why don't you talk (about sex) to them (wives)?"
>
> **Participant**: "We see it as *ihlazo* (shameful) to talk to wives, it is better with someone I won`t see most of the time (casual partner)" (Community FGD, older man).

Communication was also deemed to be more difficult depending on the age of the woman, especially if she was a lot younger than her partner, and educational status of the woman, especially if her partner was less educated than her. In both of these circumstances it was assumed that the man may feel threatened if the woman tried to make suggestions about sex and may consequently be firmer in his response.

The overwhelming sentiment from the FGDs, among women and men, young and old, was that in contemporary KwaZulu-Natal, both women and men must break with tradition and talk about sex in response to the HIV epidemic, as this young women explains:

> "There should be no secrets. We must help each other to know each other very well. .. It's not like the olden days. Tell him that there's something I have found and I will be using it to protect ourselves because no-one wants to die, everybody wants to live, no-one wants to be HIV positive. Try to talk, maybe he will end up understanding. Don't be shy to talk and be together in life" (Community FGD, 24 year old woman).

8.5 Results – qualitative analysis of trial IDIs

In this section I explore trial participant's views about sexual communication, as well as the reasons for talking about the gel, strategies used, different decision making roles, and the timing of the discussions. I also examine why and how some women used the gel without discussing it with their partners.

8.5.1 Talking about sex

The vast majority of trial IDI participant's thought that women should not talk about sex, but that this was changing as a result of HIV. In addition there was a tension between different expectations regarding the role of women as both submissive and independent. These contradictory expectations appeared to be informed by traditionalist images of women obeying their husbands, and nationalist images of independent women which exalt women's empowerment and promote women's rights. These tensions were often subtle, but emerged when women talked about needing to ask their partners if they could use the gel, while asserting at the same time that it was their right to use gel.

There were a number of examples where women clearly drew on particular scripts of expected behaviour depending on what they wanted to do – for example if they did want to tell their partner about the gel they may claim that culturally they were supposed to talk about sex; alternatively if they did not want to tell their partners about the gel they may claim that culturally they were not supposed to talk about sex. Women at times used these scripts of expected behaviour interchangeably, assigning different priorities to often competing expectations of behaviour depending on the topic.

8.5.2 Talking about microbicides

More than three quarters of participants believed that women should discuss gel use with their partners before using it. However, this apparently simplistic statement that the gel should be discussed with the partner was not without its contradictions – as this quote illustrates:

> "It is important to tell (*umtshela*) your partner about the things that you do ***but only if you know that your partner will agree with you***" (Trial IDI, 38 year old woman) (emphasis added).

There were numerous examples of women stating that talking about sex, and the gel, with a husband was more difficult than with an unmarried partner, and that talking to partners a lot older was especially difficult, although the issue of educational differences was not raised as a

barrier to sexual communication by the trial participants. However, when referring to the gel many women's reports demonstrated that they felt they had the upper hand in the negotiations given that they were the ones with the information about the trial. On the contrary, a few women explicitly said that this made it more difficult for them, as their partners did not accept being 'told' new information by the woman. An additional issue that emerged in the IDIs was the perception that it would be especially difficult to use the gels without talking to the partner if the couple were living together.

Of the 79 women interviewed at week 4, 56 had talked to their partners about the gel. There were different reasons for talking about the gel, different ways of talking about it, and discussions took place at different times in the process of introducing gel into the relationship.

Reasons for talking about the gel

Women offered two main reasons for discussing the gel with their partners:

The first reason was merely that the couple discussed sex and the women felt that as the gel would be present during sex the men should be aware of it. As stated previously in this thesis, the majority of the women interviewed were in long term stable relationships. Many of the women described these as loving relationships in which they trusted each other and did not have secrets from each other, as stated by this woman:

> "We don't hide things from each other, he also doesn't hide anything from me. We usually discuss things before doing them" (Trial IDI, 22 year old woman).

However, it was noteworthy that some of the women who said they talked about the gel as part of general sexual communication, had not discussed their use of hormonal contraceptives with their partners. The fact that they did not know if the partners would be able to feel the gel appeared to influence their decision to discuss it.

The second reason, which often overlapped with the first reason, was in order to avoid conflict if the partner found out about the gel. Women usually described this as avoiding 'problems' with their partners. The concerns expressed included if the partner noticed the gel during sex, or found the applicators, or heard about the gel and suspected his partner was using it, or if he had penile problems, or even if the gel was found to have safety concerns. Women were also concerned that if their partner felt a difference during sex they may assume they were having sex with someone else. There were also a concerns that if their partners suspected they were inserting something vaginally but did not know what, then they may think that it was some

form of love medicine or other intravaginal insertion – which could lead to misunderstandings or conflict.

Discussing the gel

All of the words listed as forms of sexual communication in the FGDs were used by women in the IDIs. By far the most frequently used term was *tshela* – to tell, narrate or give an account of the gel. In addition to this term, woman sometimes used the word *chaza* meaning to explain. The use of this word is understandable in the IDIs as women were describing how they 'explained' the gel within the context of the clinical trial. *Imvume (permission), cela (ask)* and *azisa* (inform) were used very rarely, and *xoxa (tell)* was only used occasionally when the women described how they introduced the topic of the gel to their partners.

The discussions described by the women can be categorised into 4 main groups: 1) the couple being jointly informed about the gel and deciding together to use it, 2) the women deciding to use the gel, and the partner accepting it when told about it, 3) the male partner's accepting the study or gel but based on the receipt of only partial information from the women and 4) discussions or negotiations between the couple. I discuss each of these 4 categories below.

Jointly informed: In a few cases, the male partner heard about the gel and took information back home to the female partner and they jointly decided to join the study. In a few other cases, couples were together at community events or health clinics when they first heard about the study. They subsequently talked about the gel and jointly decided for the woman to join the study, as in the quote below:

> "He was here at the clinic when the clinic staff made the talk, he asked some questions and he liked it, when we arrived home he said I can join if I want I don't have a problem" (Trial IDI, 34 year old woman).

Told and accepted: In some cases, when first told about the gel, the partners accepted the women's decision to join the study, as in this case:

> "He normally tells me that he doesn't want me to explain because this thing (gel) is mine; he is not part of it. He didn't have a problem, he just said he won't be part of it, it will only be my 'baby'" (Trial IDI, 43 year old woman).

Accepted on partial information: Not surprisingly, almost all women introduced the gel to their partners within the context of the broader benefits of the study in terms of regular HIV counselling and testing, STI testing and treatment, and cervical cancer screening. However, in a

minority of cases women took this to the extreme and told their partners they had joined a research study but did not tell them anything about the gel. Other women told their partners that they were using a vaginal gel, although they did not tell them the true purpose of the gel. Instead the gels were described as preventing other sexually transmitted infections, as treatment for vaginal problems, or even, as in the example below, to prevent cervical cancer:

> "I told my partner that I went to the clinic to do a cancer check-up…. I told him that they said we must use this gel to be protected because it might happen that I have cancer and it won't be right for us to have sex…. I didn't tell my partner what the gel is really for but I did mention that even if you have a virus this gel might protect you but I emphasized the cancer because I didn't want him to stop me from using the gel…. My partner wasn't going to agree, he is a typical Zulu he wasn't going to agree" (Trial IDI, 32 year old woman).

This reference to being a 'typical Zulu' was regularly used to refer to men who hold traditional opinions about gender relations.

Again this woman explained she was using a gel, but gave no other details:

> "I did not tell him that I will use the gel every time. I just told him that I got the gel that I am using, as to how and when it is only me who knows. I don't tell him because I am afraid that if he experiences some problems he will blame them on me because I use the gel" (Trial IDI, 42 year old woman).

It appeared that by providing partial information, women felt that they could claim they had tried to explain the gel if their partners subsequently challenged them about it. The main reason for only providing partial information appeared to be to avoid having to discuss HIV. Many of these attempts to distance the gel from a conversation about HIV were tied up with issues of trust and fidelity. This woman's description of needing protection against 'diseases in the water', reflect the on-going challenges to discussing HIV directly:

> "My partner asked what the gels are for. I told him that … there are diseases that cannot be cured. Some of those diseases are found in water and go up with the veins and we are not safe with that. Even if you are not sleeping around but we as women we are weak against diseases" (Trial IDI, 48 year old woman).

This contrasted to examples from a small portion of women who used the availability of a microbicide gel, as the only potential HIV prevention option available to them, in order to open communication about trust, infidelity and HIV, as this quote illustrates:

> "We don't trust our partners because they stay where they work and we don't know what they are doing, that is why we use the gel…….I tell him that I am using the gel because I don't trust you, even if you say you don't cheat" (Trial IDI, 19 year old woman).

Discussion or negotiation: In the majority of cases, women described how they relayed the information that they had been given about the study and the gel, to their own partners. When these women talked to their partners about the gel for the first time there were extended periods of questions, discussions and negotiations. In some instances women gave the male partners the study information sheet to read before discussing the gel. Interestingly, very few male partners ever visited the clinic to get additional information about the study, thereby relying purely on information from their partners.

The strategies employed by women to discuss the gel with their partners largely depended on the decision-making roles in the relationships. This varied dramatically and appeared to depend on the character of the male partner and the dynamics of the relationship.

In some examples, it was clear that the ultimate decision of whether or not to use the gel rested with the male partner. In these cases woman described how they had to convince, cajole and plead with their partners in order to use the gel:

> "My partner refused at the beginning. I kept on begging him and he allowed me in the end" (Trial IDI, 32 year old woman).

In the vast majority of cases the decision making was based on a process of negotiation with the aim of meeting a joint agreement:

> "We discussed and agreed that we should use the gels. It was easy because we are living together and I decided to inform him that I am using the gels because he will be surprised if he finds out that I am using the gels but he does not know" (Trial IDI, 22 year old woman).

In some cases, the decision making process was on-going and involved continuous dialogue between the couple, as this quote demonstrates:

> "The first time that I heard from my friends about the study, I sat down with him, talked to him about it, and then he allowed me. Even by the time I came back from the clinic, I as well sat down and informed him about what had been said. I also told him about the gel that there is a preventative thing that they have also given us at the

clinic which is in a form of a gel and he asked how it is being used. I then told him. He then said, can I please demonstrate for him how is it being done, I then did as taught, I demonstrated for him" (Trial IDI, 29 year old woman).

There were other cases where men only provided non-verbal cues. For example some women talked about the fact that their male partner walked away during the conversation, in which case the woman would assume he was not particularly happy about the gel but was not going to object to her using it. In other cases, women read men's silence and lack of objection as acceptance of the gel:

"If my partner didn't like the gel he would have had a lot of questions" (Trial IDI, 26 year old woman).

Nonetheless, in these examples the decision still appeared to rest with the male even if his decision making was non-verbal.

Less than a quarter of the women viewed the decision to use the gel as theirs alone. However, some were willing to state this independence of decision making even when faced with culturally loaded questions, as the exchange below shows;

Interviewer: "Does your partner allow (*uyakuvumela*) you to insert gel?"

Participant: "I insert gel on my own, not because my partner allows (*engivumela*) me to insert" (Trial IDI, 40 year old woman).

Timing

The majority of the women who discussed the gel with their partners did so after first learning about the trial at a screening visit, but before enrolling in the trial. However about a fifth of women who discussed gel use with partners did so after enrolling in the trial. In some of these circumstances it appeared that women only wanted to enter into negotiations with their partners after deciding for themselves whether they wanted to join the study and use the gel.

About a sixth of women initially used the gel without discussing it with their partners at all. Interesting, half of them described how they were 'caught' using the gel either by the partner finding the gel applicators or noticing a difference during sex. However, the other half described how, after using the gel, they told their partners about it only when asked. One woman had left gel applicators visible in the bathroom, and when her partner saw them he asked her what they were. Although she said that she had not purposefully intended for him to

find them, it did appear that a few women left study related items in sight as an introduction into a conversation about the gel.

Although the majority of women told their partner's that they were using the gel, few referred to its use every time they had sex. There were three main categories of how gel insertion was managed before sex: 1) the majority of women inserted the gel discretely before sex without telling the partner; 2) a smaller group of women overtly told the partner they were going to insert the gel when passions were roused. These women expressed the partner's willingness to wait for them to insert as an act of support. Only a very few women actually inserted the gel in-front of their partners and only one woman talked about her partner inserting the gel for her; and 3) a small group of women described how their male partners would remind them to insert the gel as a hint for sex, as this quote shows:

> "If he wants sex he just says 'gel, or, we are ticking' (ticking refers to ticking the coital diary), I know that it is time for sex, so he is happy about the diary and he has also found the easy way to ask for sex" (Trial IDI, 34 year old woman).

In this way, women described the gel as encouraging communication about sex, which often opened up opportunities for other discussions, for example about condom use.

Men's Objections

Women were not systematically asked if they would use the gel regardless of their partner's response. However, of the women who discussed the gel with their partners, approximately a tenth spontaneously reported they would not have used the gel if their partners had objected, as these quotes demonstrate:

> "If he didn't allow me to fetch gel (from the study clinic) I wouldn't have come to fetch the gel" (Trial IDI, 48 year old woman).

> "I wouldn't have come back (if he refused). I would have come to deregister myself (from the trial)" (Trial IDI, 48 year old woman).

An equal number spontaneously reported that if their partners had objected to the gel after discussing it with them, then they would have used it anyway, as these quotes demonstrate:

> "He refused in the beginning (the gel). I said that he did not want to use condoms and I would be using the gel even if he would not allow me to use it" (Trial IDI, 28 year old woman).

> "I think that it is good for men to know and if they refuse, a woman has the right to take her own decision about her life" (Trial IDI, 46 year old woman).

A few women did continue to use the gel secretly despite their partner's refusal, such as in this example:

> "My partner did not allow me to use the gel because he said that his employers advised him about HIV/AIDS… so he will not cheat. He said that he did not want me to use the gel if I had sex with him, but I used the gel secretly in the dining room where I used to go to insert the gel and came back to sleep" (Trial IDI, 38 year old woman).

Throughout the IDIs, there was a sense that the whole discussion hinged on the woman being able to guess her partners response sufficiently enough to find the right words and use the right strategy, at the right time. A lot of the expectations were based on how well the woman knew her partner as this woman explained:

> "A person knows her partner and how a male partner reacts if he is told something" (Trial IDI, 28 year old woman).

However, there was a definite sense that women succeeded in negotiating their own use of microbicide gels where they failed in negotiating the males' use of condoms.

8.5.3 Using microbicide gel without prior discussion

After 4 weeks in the trial, 23 women had not discussed their use of microbicide gel with their partner. When talking about using it without their partner's knowledge, women mainly referred to using it secretly (*fihlo*) or hiding it (*fila*) and described how it was only theirs as in the description of '*kuphela ukwazi kwami*', mine alone.

Four main reasons for using the gel without telling the partner emerged from the data:

Firstly, most of the women still thought it was preferable to discuss gel with their partner and hoped to do so some time in the future but had not yet found the right time.

Secondly, some of the women did not think that it was important to discuss the gel with their partners and had no intention of doing so:

> **Interviewer**: "Do you think that women should inform their partners about things they are doing? "

> **Participant**: "No, it is not important… If you are a woman there are things your male partner should know and there are things he is not supposed to know" (Trial IDI, 19 year old woman).

Thirdly, half a dozen women explained that they had not discussed the gel with their partners because they were afraid that their partners would take their use of gel as a sign of mistrust and respond violently towards them. Women talked about their partners being aggressive, or of being afraid or scared of their partners:

> "He doesn't know about the gel and I don't want him to know because he is jealous and if he finds out he will beat me. I can't just talk, I'm afraid of him" (Trial IDI, 21 year old woman).

The risk of physical violence was a real threat for some women. As previously reported (in chapter 6), one woman, who had agreement from her partner to use the gel, was subsequently forced to stop using the gel due to her partner physically assaulting her after hearing rumours in a bar that women were using the gel to hide infidelity.

Fourthly, some women did not want to risk talking to their partners about the gel as they assumed that they would object to the gel. This young woman's quote illustrates that by not living in her partner's house (not being married or cohabitating) she felt she had more ability to decide about the gel:

> "I think he will have a problem, maybe say I should stop the gel so I thought it is better to continue and hide it from him. He cannot control me because it is my home" (Trial IDI, 29 year old woman).

Some women had experienced prior objections when they had talked to partners about male condoms, female condoms or even the use of a placebo gel in the early microbicide pilot study.

> "I remember the other day when I took female condoms and put it in the place where I hide my things and I do not know how he found them and then he asked me what are those things and I informed him that it was female condoms and then he asked that why should I take them and I explained that I should protect myself because he refuse to use condoms. He took the condoms and threw them in the toilet" (Trial IDI, 26 year old woman).

Some of these examples with the gel, mirrored women's experiences of using contraceptives without their partners knowledge, for example:

Interviewer: "Does your partner know that you use contraception?"

Participant: "I told him before but he complained and I decided to keep it a secret from him now" (Trial IDI, 36 year old woman).

Most of the women who were still using gel without their partners knowledge at this point were concerned in case their partners found out about the gel before they had chance to discuss it. However, a few had decided that it was a risk they were willing to take, as this woman explains:

Participant: "I tried to tell him last year (pilot study) but he refused. Because it helps me and I like it I continued…… We as women should not be discouraged by that and stop from participating in things that will help us in future. We should stand up for ourselves so that we can take care of ourselves"

Interviewer: "What will you do if he finds out?"

Participant: "I will tell him that I told you and you did not listen" (Trial IDI, 39 year old woman).

Using the gel without the knowledge of a stable partner was not viewed as the ideal, but importantly was viewed as possible in some circumstances and was achieved by the majority of women who did not discuss the gel with their partners. Although only a few women in the IDIs had secondary casual partners, in the main they had not talked to their casual partners about the gel. There was no suggestion in the qualitative data that women who did not use condoms were more likely to use the gel without their partner's knowledge.

8.6 Discussion

In this chapter, I set out to explore the process of communication that takes place between couples regarding microbicides in KwaZulu-Natal. Using quantitative data I estimated the proportion of women who talked to their partners about using the microbicide and compared those who did talk to their partner with those who did not. Using qualitative data I examined community perceptions regarding sexual communication, discussing microbicides, using microbicides without a partner's knowledge, and the impact of relationship dynamics on communication. Finally, I explored how women in the trial communicated with the partner's about the microbicide gel.

By drawing on both the quantitative and qualitative data, I found that expectations of communication about microbicides are informed by traditional gender norms as well as

modern ideas of women's rights. Women clearly prefer to use microbicides with their partner's knowledge and the balance of decision-making responsibility within a relationship appears to determine the way in which microbicides are discussed. The main strength of these analyses is that the qualitative findings allow the quantitative findings to be interpreted within the socio-cultural context of sexual communication in a rural part of KwaZulu-Natal.

8.6.1 Cultural norms relating to sexual communication

The qualitative data clearly demonstrated that women and men have a shared understanding that traditionally women were not supposed to talk about sex. This description of the traditional perspective of sexual communication is supported by previous ethnographic evidence from KwaZulu-Natal (Berglund, 1976). However, it was also clear that these traditional norms were being replaced by modern ideas that allowed women to talk about sex. This is consistent with findings from the formative microbicide feasibility study in this area (Ndinda, 2007) as well as evidence from other parts of KwaZulu-Natal (Susser, 2009, Hunter, 2010). These types of tensions between traditional and modern norms regarding gender and sexuality have been documented previously in many parts of sub-Saharan Africa (Cole, 2009).

The qualitative data suggests that the changing perspectives are in response to two issues: first, the magnitude of the HIV epidemic and second the national discourse of women's rights and gender equality. This is not surprising given that the South African Constitution of 1996 contains the Bill of Rights which hinges South African politics on the principles of human rights. The response to the HIV epidemic has been framed within this context of 'rights', in terms of the right to confidentiality in testing, the right to choose ABC prevention, and the right to antiretroviral treatment (Susser, 2009). It is evident from the FGDs and IDIs that the national political rhetoric of human rights and women's rights is influencing gendered traditional norms regarding sexual communication in this rural part of South Africa. The fact that over half of the community members in the FGDs believed that women could and should initiate discussions about sex provides a good platform for the introduction of microbicides.

8.6.2 Discussing microbicides

It was resoundingly clear from the focus group discussions that community members thought women should talk to their partner's about microbicides before using them. The majority of trial participants agreed that it was preferable for male partner's to know about the women's use of microbicides. These findings were supported by the quantitative data which showed that the majority of women discussed microbicides with their partners. At the week 4 interview, 60% of women said they had discussed using the microbicide with their partner, by the end of the trial (week 52) this had risen to 84%. The qualitative IDI data suggest that,

except in a minority of cases, women who used the gel without their partner's knowledge did so because they thought their partner would not agree to their use of microbicides. Based on this qualitative finding, it appears reasonable to conclude from the quantitative data that the women who had not discussed the gel with their partners after 4 weeks of using it were women who felt least able to negotiate its use with their partners.

Older women were less likely to discuss microbicides with their partners than younger women. This may be explained by ideas that were expressed in the qualitative data; firstly that traditional views regarding women not being able to talk about sex still prevail and secondly that discussing sex is more difficult between married couples. It is possible that older women's ability to discuss microbicides was limited by these factors more than younger women, although yet again my inability to control for marital status in the quantitative analysis is a limitation. Although there is no comparable evidence from microbicide trials, a study in South Africa and Zimbabwe found that older women were less likely to discuss the use of a diaphragm with their partners than younger women (Sahin-Hodoglugil, 2011). This finding highlights that older women may be less able to discuss microbicides with their partners and therefore the ability to use a microbicide without a partner's knowledge may be more important to older women than to younger women.

In the quantitative data, women who lived in households that relied on free flowing water and owned cattle were less likely to discuss microbicides with their partners. The significance of water source diminished in the multivariate model at week 4 but remained at week 52. As described in chapter 4 section 4.5.1, these variables were included in this analysis as socio-economic determinants. However, in addition to indicating household wealth, these variables may also indicate traditional status. Cattle are the most important symbol of status in Zulu culture, and as illustrated in the qualitative data, are the basis of marital arrangements. While the use of free flowing water is usually an indicator of lower socio-economic status, in this area it also suggests that the household is particularly remote (Muhwava, 2007). On the basis of the discussions about traditional versus modern views about communication, I suggest that cattle ownership and the use of free flowing water, in this analysis, are signs of more traditional households in which it is more difficult for women to talk about microbicides.

It is of particular note that discussing the gel prior to use does not appear to be associated with the consistency of microbicide use in this analysis. This is counter to the assumption that using the gel without a partners knowledge may hinder adherence, and therefore this should be monitored in future trials (Montgomery, 2008, Montgomery, 2011). Also of note is that using the gel without a partner's knowledge was not associated with lower condom use, as

was found in the diaphragm trial (Sahin-Hodoglugil, 2009). The difference in findings may be explained by the fact that in this quantitative analysis I measured the consistency of condom use in the last week or 4 weeks, whereas in the diaphragm trial they measured 'ever use' of condoms. By measuring condom use as 'ever used' the prevalence was extremely high (98%) and not representative of consistent use. As such, my finding runs counter to the assumption that microbicide use without a partner's knowledge could be of particular use to women who are unable to use condoms. However, it also suggests that women are able to discuss microbicides with their partners, regardless of their ability to negotiate condom use. This is an important advantage for women in stable relationships.

The qualitative findings also suggest that it would be more difficult for women to use microbicides without a partner's knowledge if they were living together. There were no differences in the proportion of women who discussed microbicides with their partners based on their relationship to the head of the household, although I was not able to control for cohabitation with a partner in the quantitative analysis. Not cohabitating has been shown to be associated with using a diaphragm without a partner's knowledge (Sahin-Hodoglugil, 2009). The qualitative data also raised the possibility that age and educational differences between couples may affect women's ability to discuss microbicides, but without demographic details of the male partner's I was not able to test these hypotheses. These variables should be considered when measuring communication about microbicides in the future.

The main limitation of this study is that discussions about enrolling in the clinical trial and using a microbicide gel are merged into one conversation. It was impossible to separate these conversations as for women they were one in the same. The reasons for discussing microbicides when they are known to prevent HIV acquisition and are available in the public health sector are likely to be slightly different to the reasons for discussing microbicides in the context of a clinical trial. Nonetheless, these findings provide important insight into some of the challenges that women face when discussing microbicides.

8.6.3 Not discussing microbicides

As shown in Table 8-2, only 9 microbicide trials have reported the proportion of women who have discussed microbicides with their partner's. Many of the previous studies have been conducted with commercial sex workers, most have very short follow up periods, and some were conducted in the 1990's possibly making their findings less relevant now. Consequently it is difficult to compare the level of communication that took place in this trial with other studies. The level of communication in the MDP trial after 4 weeks in the study (60%) is lower than the level reported in other trials with short follow up periods with women not involved in

commercial sex work in other African countries (75-94%) (Hira, 1995, Coggins, 1998). Similarly the level of communication in the MDP trial after 52 weeks in the study (84%) is lower than the level reported in the Carraguard trial with a similar follow up period with women not involved with sex work in South Africa (98%) (Altini, 2010). While acknowledging the limitations of comparing the data, the proportion of women who discussed microbicides with their partners in the MDP trial is lower than what has been observed previously among women not involved with sex work.

When interpreting these findings there are two issues to consider. Firstly, the qualitative and quantitative data both suggest that women in the MDP trial who used the gel without their partner's knowledge were the ones who felt least able to discuss microbicides with their partners. This is likely to explain the lower level of communication that was reported in this MDP analysis compared to the Carraguard trial (Altini, 2010). The Carraguard trial was conducted in the urban South African areas of Gugulethu and Ga-Rankuwa, were women may have felt less constrained by the prevailing traditional gender ideas described in this rural area of Umkhanyakude. In this context we could speculate that rural women in the MDP trial were less able to talk about microbicides with their partners than urban women in the Carraguard trial.

Secondly, the qualitative data, especially from the IDIs with trial participants, suggest that within the context of changing socio-cultural expectations regarding sexual communication, women's right to protect themselves from HIV is viewed as justification to use microbicides without the partner's knowledge. A diaphragm trial found that only 1% of women in Zimbabwe used the diaphragm without their partner's knowledge compared to 15% and 19% in Durban and Johannesburg respectively. The authors found that "women in South Africa seemed to emphasize individual rights and personal agency to justify covert use as compared to women from Zimbabwe, who made a stronger case about negative consequences if caught" (Sahin-Hodoglugil, 2009;1552). This evidence is consistent with relatively high levels of use without partner's knowledge in other trials in South Africa (Rustomjee, 1999, Vandebosch, 2004) and a notable difference in attitudes to women's use without a partner's knowledge in South Africa than other parts of Africa (MacPhail, 2009, Orner, 2006). In this context we could speculate that South African women in the MDP trial felt more justified to use microbicides without their partner's knowledge than women in other African countries.

When measuring the proportion of women who use microbicides without their partner's knowledge it is important to consider exactly what we are measuring in order to interpret what the level of communication between couple's means for a women's ability to use

microbicides. This ability to consider what we are measuring is the main strength of this analysis in that the qualitative data enable me to interpret the quantitative data within the socio-cultural context of the area. The MDP findings suggest that some women feel unable to talk to their partners about microbicides and yet at the same time feel justified and able to use microbicides without their knowledge. Certainly the qualitative data demonstrate that there is considerable tolerance for women's use of microbicides without a partner's knowledge in this area. These findings are consistent with other evidence in South Africa which has also highlighted the influence of the women's rights discourse on communication about microbicides (Ramjee, 2007, Morrow, 2003, Orner, 2006, MacPhail, 2009).

Even in this context of changing socio-cultural norms, the qualitative data demonstrated that the implications of male partner's finding out about women's use of microbicides could be considerable. It is evident from these findings that male partner's opposition to microbicides and the risks involved with using microbicides without a partner's knowledge will remain a barrier to microbicide access for some women. However, it is important to note that the quantitative data demonstrated that 16% of women were able to use a microbicide for up to a year without their partner's knowledge.

8.6.4 Female used or female controlled?

As stated at the beginning of this chapter, microbicides were initially perceived as a 'female-controlled' HIV prevention option. More recently the extent to which women really can have *control* over microbicides has been questioned given that many woman are perceived to lack decision making power in relationships (Woodsong, 2008). Similarly, the importance of microbicides being 'female-controlled' has been questioned given the evidence suggesting that women in Africa are both expected to, and prefer to, discuss microbicides with partners prior to use (Domanska, 2012). However, I believe that the importance of microbicides being 'female-controlled' has been over simplified by a focus on whether women ever talk to their partners about microbicides or not. The findings from this evaluation highlight that communicating about microbicides is far more complex and nuanced than simply whether or not a woman talks to her partner about them. Below I highlight 3 key findings which demonstrate the complexity of communicating about microbicides.

Firstly, both the quantitative and qualitative data consistently show that discussions about microbicides often take place after women have started using them. The fact that some women only discuss microbicides with partners after using them has been shown before in a surrogate study and a diaphragm trial, although it is rarely been measured in microbicide trials (Green, 2001, van der Straten, 2010b). Clearly the majority of women ultimately discuss

microbicides with their partners; however microbicides are the first HIV prevention option that women can try themselves before needing to discuss them.

Secondly, the quantitative and qualitative data both demonstrate that although the majority of women discuss microbicides with their partners, they do not necessarily inform their partners they are using the gel every time they have sex. This has been reported previously in one microbicide and one diaphragm trial (van der Straten, 2008, Sahin-Hodoglugil, 2009). This finding demonstrates that it is wholly insufficient to assess women's 'control' over microbicides in terms of whether or not they have *ever* discussed microbicides with their partners. In this study, the fact that women 'use' the microbicide clearly shifts the balance of 'control' in their favour. This is similar to evidence from a surrogate study in Uganda which found that "even though, use of these products in practice often involved negotiation with male partners, the fact that use was contingent on women's action was empowering and increased somewhat their ability to control their sexual health" (Green, 2001;585).

Thirdly, the qualitative IDI data suggest that the ways in which women discuss microbicides depends on the decision making roles within the relationship. Over half of the women described the decision to use the gel as a joint one, to varying degrees. Only in a minority of cases were men considered the ultimate decision makers. This analysis highlights that many women perceived themselves as having a joint decision making role in their relationships and as such viewed themselves as having substantial control over the use of microbicides.

These three key findings illustrate that in this part of KwaZulu-Natal, the availability of a female-used microbicide clearly increases women's control of HIV prevention. To a large extent the distinction between female-used versus female-controlled is probably purely academic and possibly only of relevance within the context of western feminist debates (Montgomery, 2010a). However, while it is important to recognise the barriers that gender inequality present for women in terms of microbicide use, it is equally important not to reinforce those barriers by assuming that women don't make decisions about their sexual health or diminishing the decisions women make on the basis that they are made jointly. For many women, female-used may actually be the same as female-controlled, and we need to be careful not to exaggerate the difference between these two terms.

8.6.5 Power dynamics

My findings reinforce the importance of power dynamics in relationships in terms of communication about microbicides. Power dynamics were particularly illustrated in the differences in communication between older versus younger women and women from more versus less traditional households. Similarly the most important factor influencing if, when and

how women discuss microbicides with their partner appears to be the distribution of decision-making responsibilities in the relationship. The importance of power dynamics for HIV prevention (Jewkes, 2008, Jewkes, 2010a, Pettifor, 2004a) and microbicide acceptability is well recognised (Woodsong, 2008, Mantell, 2006a, MacPhail, 2009), although rarely measured in microbicide trials. In order to better understand the association between microbicide use and power dynamics, we need to start measuring relationship control and decision-making equity between couples in microbicide trials. A 'Sexual Relationship Power Scale' has been adapted for South African and validated in a number of studies relating to HIV prevention (Jewkes, 2002, Jewkes, 2010b). By using the Sexual Relationship Power Scale in microbicide trials we would be able to better interpret what the level of communication between couple's means for a women's ability to use microbicides.

8.6.6 Supporting women to discuss microbicides

The quantitative data showed that the proportion of women who discussed microbicides with their partners differed between the clinics. Although the counselling scripts were supposed to be standardised, this difference appears to be related to specific counsellors. This has not been measured previously in microbicide or diaphragm trials. This finding suggests that the counselling process is likely to influence women's ability to discuss microbicides with their partners.

The qualitative data showed that women were creative in their approaches to discussing microbicides, providing as much or as little information as they felt was warranted depending on their knowledge of their partners character. The use of partial information was also reported by women negotiating the use of diaphragms (Sahin-Hodoglugil, 2009). Woodsong concluded an evaluation of gender roles in Zimbabwe and Malawi by stating that "Although woman–initiated use is an important goal in development of microbicides, the need for men's cooperation or agreement must be addressed in strategies for future product introduction" (2008;171). At the same time I suggest that in the process of addressing men's cooperation, we need to be careful not to undermine women's ability to be creative in how they discuss microbicides with their partners.

8.7 Conclusion

Women in this socio-cultural context would clearly prefer to use microbicides with their partner's knowledge. Changing attitudes to gender relations appears to support most women being able to talk about microbicides although traditional ideas of women's roles still prevent some women from being able to negotiate their use. However, this analysis demonstrates that women in the main are very successful at negotiating their use and/or feel justified in using

microbicides without a partner's knowledge when necessary. Although researchers have shifted from talking about female-controlled to female-used HIV prevention options, for the women in this study the fact that microbicides are used by women clearly increases many women's ability to control their use. Microbicide introductory programmes will rely on clear and consistent counselling messages. In terms of sexual communication, these counselling messages should be tailored to women's specific circumstances and should avoid undermining the control that microbicides do offer to many women. These findings demonstrate that in KwaZulu-Natal the socio-cultural norms relating to sexual communication are amenable to the introduction of microbicides. The findings also present yet another example of the important contribution that microbicides can make in terms of offering women HIV prevention options that they can both use and control.

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9 Discussion

Summary

In this final chapter I summarise the findings in response to my overall research question and consider the significance of these findings in relation to existing evidence. I discuss the implications of my findings for both future research and service delivery. In addition I consider the extent to which this evidence calls for a repositioning of 'sexual pleasure' within sexual health programmes and reconsideration of how we deal with gender equality issues in HIV prevention. Finally I discuss some of the limitations of my findings.

9.1 Compatibility of microbicides and socio-cultural norms

I set out to explore whether microbicides are compatible with socio-cultural norms regarding sexuality and sexual health in rural KwaZulu-Natal, South Africa. In chapter 1 I outlined the urgent need for HIV prevention options that women can use to protect themselves from HIV acquisition even in the presence of gender-based social drivers of the epidemic. In chapter 2 I laid out the long history of microbicide research and summarised what we know to date about microbicide acceptability. To date, acceptability research has focused on women's willingness to use microbicides, satisfaction with product characteristics, and the acceptability of product use. I depart from this linear perspective of microbicide acceptability by exploring a series of socio-cultural practices relating to female sexuality and sexual health, and compare these to the use of microbicides. As such I assess the extent to which the use of vaginal microbicide gels is compatible with socio-cultural norms relating to intravaginal cleansing, intravaginal insertion, love medicines and sexual communication.

As described in chapters 3 and 4, in order to address the research question I applied a mixed qualitative and quantitative methods approach. This approach allowed me to look at microbicide acceptability from a cultural perspective. It also favoured the emic perspective, thereby prioritising women's experiences of the gel over women's responses to predefined questions about acceptability. Using both qualitative and quantitative data enabled me to both characterise and situate the findings within the socio-cultural context.

In chapters 5 to 8 I presented evidence relating to each topic of interest. Overall the answer to my question is that microbicides are compatible with socio-cultural norms relating to intravaginal insertion and sexual communication, but may be less compatible with norms relating to intravaginal cleansing and love medicines. In chapter 5 I found that although the majority of women did not intravaginally cleanse, post-coital intravaginal cleansing practices among a substantial minority of women could undermine the roll out of microbicides if we fail

to change cleansing practices. In chapter 6 I found that the desired effects of using intravaginal insertions to enhance sexual pleasure are compatible with the experiences of using microbicide gels and that local knowledge, language and understanding of using products vaginally may actually facilitate the introduction of microbicide gels. In chapter 7 I found that microbicides are incompatible with love medicines, but that this could be advantageous for the introduction of microbicides as women were successfully able to distance love medicines from microbicides. This may be important not only in terms of separating microbicides from the supernatural, but also potentially separating microbicides from women's actions that are stigmatised as subversive of gender norms. Finally in chapter 8 I found that in KwaZulu-Natal the contemporary socio-cultural norms relating to sexual communication in the context of the HIV epidemic are compatible to the introduction of microbicides.

Overall the findings highlight that microbicides are more compatible with some socio-cultural norms than with others; incompatibility with love medicines could be seen as a positive finding. The research illustrates the ways in which women incorporate microbicides into their broader sexual lives and underscores the important contribution that microbicides can make in terms of offering women HIV prevention options that they can use and, in many cases, control.

9.2 New findings

Although concerns have been raised about the effects of vaginal practices on microbicide *efficacy, safety* and *acceptability*, the main focus has been the acceptability of microbicides in relation to preferences for 'dry' sex. As such a number of trials have measured acceptability "in communities where 'dry sex' was believed to be common" (Altini, 2010;564). Conversely, the concerns regarding post-coital intravaginal cleansing have generally focused on its impact on product efficacy more so than acceptability. As shown in chapter 5, only one microbicide effectiveness trial has ever reported on post-coital intravaginal cleansing in relation to microbicide use (Halpern, 2008). As such, intravaginal practices to enhance sexual pleasure have been considered a more substantial threat to microbicide acceptability than intravaginal practices for vaginal hygiene. However, my findings suggest the opposite is true in KwaZulu-Natal, that microbicides are less compatible with vaginal hygiene practices than practices to enhance sexual pleasure.

In terms of safety, there have been calls for further research into the potential for *substances* inserted into the vagina to chemically interact with microbicides and cause harmful by-products. The '*substances'* include those used intravaginally as love medicines. However, love medicines have never been considered distinct from intravaginal insertions in terms of microbicide acceptability. Similarly, the WHO GSVP study did not recommend a distinct

classification for love medicines and did not distinguish between natural and supernatural motives for the practice, instead defining them all as ways to 'keep partner's committed' (Hull, 2011). Conversely my findings suggest that women in KwaZulu-Natal did distinguish between supernatural love medicines and other natural forms of enhancing sexual pleasure. This was an important distinction. While it is a positive finding that microbicides are **compatible** with intravaginal practices to enhance sexual pleasure, it is also a positive finding that microbicides are **incompatible** with the concept of love medicines.

In relation to discussing microbicides, my findings support the dominant view that the majority of women in Africa prefer to discuss microbicides with their partners prior to use and that the potential to use microbicides without a partner's knowledge is less important than originally thought. However, my findings depart from the dominant view in terms of assuming that women's desire to discuss microbicides with their partners diminishes women's 'control' over microbicides. The evidence highlights the importance of microbicides being 'woman-used' in terms of when women discuss microbicides with their partners, how they explain their use and when they choose to use them. As such, microbicides are compatible with contemporary socio-cultural norms regarding sexual communication, while also being compatible with the new social discourse of women's rights in South Africa.

Overall, my findings offer new insights into microbicide acceptability by comparing microbicides with socio-cultural norms of sexuality and sexual health. I provide new evidence about the compatibility of vaginal practices and microbicides. My research demonstrates that intravaginal cleansing is of greater concern than intravaginal insertion in KwaZulu-Natal. However, although the incompatibility of microbicides with intravaginal cleansing practices raises concerns, the incompatibility of microbicides with love medicines could be advantageous for the introduction of microbicides. The evidence supports the assumption that women prefer to discuss microbicides with their partners, yet highlights that this does not diminish the importance of microbicides being 'woman-controlled'. As such, my findings contribute to our understanding of the interaction between socio-cultural perspectives and microbicides and in doing so, challenge many conventional attitudes regarding microbicide acceptability.

9.3 Implications for research

My findings have a number of implications for future research which include lessons for data collection, considerations for assessing factors that influence adherence, the need for additional pharmacokinetic research, and a call for more research around gel use during menses.

9.3.1 Data collection

My findings highlight the need to reconsider how we measure intravaginal practices and sexual communication in microbicide clinical trials.

In KwaZulu-Natal, it is clear from this evidence that microbicides are more compatible with some intravaginal practices than others. Although this is likely to differ in other cultural contexts, it draws attention to the need to accurately and consistently measure different types of intravaginal practices. Since starting my PhD, the WHO GSVP study has provided a clear classification of vaginal practices. However, my findings also highlight a distinction between intravaginal insertions to enhance sexual pleasure versus being used as love medicines, in terms of their association with microbicides. The difference between the natural and supernatural use of intravaginal insertions is clearly relevant for microbicide acceptability and should be differentiated in the WHO list of motives for, and intended effects of, specific intravaginal practices. I suggest that all future microbicide trials use this adapted WHO classification. This would provide a better understanding of the role of intravaginal cleansing, intravaginal insertion and love medicines for women's sexuality and sexual health in various settings. It would also enable comparisons across cultures of the compatibility of microbicides with various intravaginal practices.

Despite concern that post-coital intravaginal cleansing could diminish the efficacy of microbicide gels, microbicide trials have been inconsistent in how they have measured intravaginal cleansing. Trials have defined intravaginal cleansing in different ways, have not systematically documented the products used for intravaginal cleansing, have not consistently measured cleansing within one hour after sex, and have rarely reported on intravaginal cleansing during follow-up. My findings reveal moderately high rates of post-coital intravaginal cleansing during microbicide use which emphasises the need for the systematic collection of data on intravaginal cleansing practices in all future microbicide trials. Diaphragm trials, with or without gels, have evaluated intravaginal cleansing practices more rigorously than microbicide trials (Sahin-Hodoglugil, 2011, van der Straten, 2010b). As such microbicide trials should adapt data collection tools used in diaphragm trials and other vaginal practices studies (Francis, 2012) in order to capture accurate data on intravaginal cleansing, distinguish between external and internal cleansing, categorise the products or items used and measure the timing of intravaginal cleansing in relation to sex and gel use. Using consistent categorises would not only enable comparisons across social and cultural settings, but also across various gel products and between gels, rings and diaphragms.

My findings highlight the nuances and complexities for women in stable relationships in terms of discussing microbicides with their partners. I suggest that we need to move beyond merely thinking about communication in dichotomised terms of 'disclosure' or 'covert' use. Again the diaphragm trials provide some useful tools in the ways that they have measured 'disclosure' as a continuum – from the male partner always, mostly, occasionally, rarely or never knowing about the women's use of the diaphragm (Sahin-Hodoglugil, 2009). However, I also think we need to reconsider what we really need to understand about microbicide gel use and sexual communication. We need to document the *reasons* women use microbicides with or without their partner's knowledge in order to know if this represents women's power or lack thereof in terms of sexual decision making. It would also help to know more about men's responses to women's introduction of microbicides, women's subsequent use of them, or men's discovery that women were using microbicides without their knowledge.

Ultimately I hope that my findings, in combination with the WHO GSVP study evidence, highlight the nuances involved in intravaginal practices and put an end to the over simplification of these practices so that they are no longer measured in terms of preferences for 'dry sex'. I also hope that my findings illustrate the complex nature of discussing microbicides thereby signalling a move away from using overly simplified notions of 'disclosure' and 'covert use' to measure the multiple processes involved in communicating about microbicides.

9.3.2 Adherence

Acceptability is a central tenet of microbicide research because of its impact on adherence, which in turn is critical for effectiveness. There are two key issues relating to adherence that emerged from my findings that require additional research in the future. The first is the need to further explore the link between adherence and post-coital intravaginal cleansing. My findings, in combination with evidence from the diaphragm trials, suggests that we need to be able to distinguish between a) specific microbicides increasing the risk of women intravaginally cleansing versus b) women who intravaginally cleanse being less likely to use microbicides consistently.

The second issue is the need to further explore the link between adherence and a partner's knowledge of the gel. With improved measurements of how women discuss microbicides with their partners, it would be easier to assess the associations with adherence and compare the impact of discussing microbicides on gel adherence across settings. This issue is particularly pertinent in the context of the FACTS 001 trial that requires women to insert a gel after as well

as before sex and in terms of contrasting the impact between peri-coital gel use and slow release vaginal rings.

9.3.3 Pharmacokinetics

A lack of consistent evidence regarding the causal associations between intravaginal practices and HIV acquisition has prevented the delivery of clear and concise messages about the HIV risks of intravaginal practices. We need to avoid being hamstrung by inconclusive evidence in terms of microbicides and vaginal practices. All microbicide effectiveness trials to date have advised women against intravaginally cleansing after sex. However, our understanding of the effect of intravaginal cleansing on microbicide efficacy is limited. My findings demonstrate that, for some women, post-coital intravaginal cleansing is a deeply entrenched practice with socio-cultural meaning. As stated in a report on the 'elimination of traditional practices affecting the health of women and the girl child', we have to be careful not to demonize cultural norms in the process of protecting the health of women (Warzazi, 1999). Hence we need to understand the impact of the various post-coital intravaginal cleansing practices on microbicide pharmacokinetics before 'demonizing' the usual vaginal hygiene routines of some women.

9.3.4 Sex during menstruation

Although I did not specifically investigate socio-cultural norms regarding sex during menstruation, they emerged while exploring intravaginal cleansing practices. Evidence from other studies has demonstrated that intravaginal cleansing is often linked to menses. A few microbicide safety trials have reported lower adherence to gels applied daily or every other day during menstruation (Altini, 2010, HPTN059, 2008). One phase I trial among couples in Thailand found that only a quarter of women reported using gel for sex during menstruation (Whitehead, 2006). However, none of the microbicide effectiveness trials to date have reported on gel use in relation to sex during menstruation. My findings highlight the need to understand the associations between sex during menstruation, gel use and intravaginal cleansing. At the same time, they demonstrate that despite cultural taboos, sex is practiced during menstruation thereby also emphasising the need to understand more about gel use generally in terms of sex during menstruation and the impact of menstruation on microbicide efficacy.

9.4 Implications for service delivery

If the FACTS 001 trial confirms the CAPRISA 004 results, microbicides may be available in South Africa within the next few years, at least on a restricted basis. Therefore in addition to having implications for future research, my findings also have implications for health policy and

service delivery. These include implications for marketing, point of access and counselling strategies, as well as public health messages about intravaginal practices.

9.4.1 Marketing

To date evidence on the best ways to create demand for microbicides and market microbicides is limited. A few hypothetical and one surrogate study have considered who microbicides should be marketed to (Coggins, 2000b, van de Wijgert, 1999, Montgomery, 2008). One researcher has investigated South African women's preferred marketing and distribution strategies extensively as part of her PhD, although evidence has only been presented as conference papers to date (Terris-Prestholt, 2009, Terris-Prestholt, 2008b, Terris-Prestholt, 2008a). My findings contribute to the debate regarding marketing strategies in a number of ways. In line with previous analysis of MDP data, they demonstrate that women attach benefits to microbicides in terms of both vaginal hygiene and sexual stimulation (Montgomery, 2010b). The ability to negotiate microbicides on the basis of these benefits, and not just as a HIV prevention option, was clearly an advantage for some women. My findings also suggest that in KwaZulu-Natal, while it may well be acceptable to market microbicides as enhancing sexual pleasure, it will not be advisable to market them as a way to enhance love in case of evoking concerns about love medicines. Similarly, marketing microbicides as a female-used or even controlled option may be preferable in contemporary South Africa, but marketing it specifically as a 'secret' product that can be used 'covertly' is probably not. I believe that my research, in the context of what else we know about women's use of microbicides, supports the need for a marketing strategy that can demonstrate the utility of microbicides for different women and for different purposes, and ideally avoid microbicides being tagged as only about HIV and risk reduction.

9.4.2 Point of access

Given that the first vaginal microbicides are likely to be ARV-based, they will probably need to be delivered by health care professionals. CAPRISA are currently evaluating the impact of accessing microbicides at family health clinics on adherence and ultimately HIV acquisition in KwaZulu-Natal (CAPRISA008, 2012). In South Africa traditional health practitioners have often served as health care providers in conjunction with health care professionals. The most notable and successful example is of traditional health practitioners providing treatment for tuberculosis through directly observed therapy programmes (Ntshanga, 2009). It is evident from my findings that women, and men, in Umkhanyakude use both biomedical and traditional health care. Traditional health care practitioners are held in high esteem and are important and prominent in the community. Traditional health practitioners may eventually be able to assist in providing access to microbicides. However, given my findings regarding the

incompatibility of love medicines and microbicides and the central role that traditional health practitioners play in the provision of love medicines, their role in microbicide delivery would need careful consideration.

9.4.3 Counselling

When available in South Africa, microbicides are likely to be incorporated into the existing HIV prevention counselling package along with information about abstinence, being faithful, condom use and male circumcision (Gafos, 2012). The counselling package will be essential to ensure microbicides are used correctly and consistently, and used to enhance instead of replace existing risk reduction strategies. The evidence presented in this thesis provides a number of lessons for future counselling packages.

My findings support evidence from other trials that vaginal practices are amenable to change with effective messaging and counselling. Given the moderately high prevalence of post-coital intravaginal cleansing in the trial, the counselling provided on this practice was clearly insufficient. Although there were hardly any reports of women using intravaginal insertions during the trial, it is not possible to know if women who usually intravaginally insert simply did not volunteer for the trial. Counselling models to reduce the prevalence of vaginal douching have been tested in the USA (Grimley, 2005). However, the socio-cultural meanings of intravaginal cleansing and insertion are likely to differ in Africa and therefore it is essential that counselling models are developed, tested or validated in South Africa in order to support microbicide roll out. In addition, the evidence presented in chapter 8 suggests that counselling models should ideally assist women in identifying the best ways to open dialogue with their partners about microbicides and consider the implications of using microbicides without his knowledge.

9.4.4 Public health messages about intravaginal practices and HIV

Although my research focused on intravaginal practices in relation to microbicide acceptability, it was clear from the findings in chapters 5 and 6 that there was a lack of knowledge about the risks of intravaginal practices in relation to HIV acquisition. A number of authors continue to call for additional research into the causal association between intravaginal practices and HIV infection (Hilber, 2007). However, in the meantime the lack of information about the risks of intravaginal practices is unhelpful for women trying to mitigate their risk of HIV acquisition. Although we are not yet able to definitively identify practices that do increase the risk of infection, we at least need clear messages about good vaginal hygiene. Low et al suggest that intravaginal cleansing with water alone could be recommended as a safer option as this was not associated with HIV acquisition in the meta-analysis (2011). I would argue that most

evidence, including my own, is not precise on how water is used internally without the use of a douch bag, fingers, cloth or other products. Consequently it may be simpler to explain that the 'healthiest' option is to allow the vagina to clean itself naturally and thereby recommend that women cleanse only externally after sex. This message would be consistent with microbicide use while at the same time it would avoid demonising cultural norms without substantial evidence.

9.5 Repositioning sexual pleasure

In addition to thinking about the implications for research and service delivery, we also need to consider what my findings tell us more broadly about addressing women's sexual pleasure within the context of HIV prevention. My findings support those of the GSVP study in highlighting that sexuality is central to women's perception and management of their sexual health (Hilber, 2012). Issues relating to sexuality emerged throughout the thesis in terms of vaginal hygiene, sexual arousal, foreplay, female orgasm, mutual gratification, love, intimacy, passion, mutual respect, and sexual communication. My findings, especially in chapter 6, poignantly illustrate women's expectations of sexual pleasure. Although this evidence is not unique (Koster, 2008, Bagnol, 2008, Scorgie, 2011), it is in contrast to the dominant views on sexuality in Africa which focuses almost exclusively on male sexual pleasure.

Sexual pleasure is recognised as a key component of sexual health (WHO, 2006, WASH, 2008), yet HIV prevention discourses are dominated by sex-negative, fear-, risk- and disease-based approaches. Sex is motivated by different reasons, for different people, at different times and can include "intimacy, procreation, money, power, coercion, relief of tension, escapism and boredom" (Philpott, 2006b;2028). However the main motivator, for at least one person in the coupling, is usually the pursuit of pleasure. There is an increasing demand for a more holistic approach to women's sexuality in order to explore the linkages between sexual pleasure and sexual health (Hilber, 2010b, Boyce, 2007, Hull, 2008, Coleman, 2008, Parker, 2009, Philpott, 2006b, Philpott, 2006a). Philpott et al argue that "safer sex and sex education can be promoted in a positive way by considering the role of pleasure and desire in sexual behaviour" (2006b;3). There are a number of examples demonstrating that sex-positive, pleasure-focused, eroticised safer sex marketing can increase safer sex practices, including condom uptake (Knerr, 2008).

Social constructs of sexual pleasure and eroticism are obviously culturally specific (Philpott, 2006b, Richters, 2009). My findings demonstrate that microbicides are clearly compatible with cultural constructs of sexual pleasure in Umkhanyakude. I believe that the most important lesson from my research is the potential to apply sex-positive, pleasure- intimacy- and safety-

focused messages to microbicides. The very fact that microbicides can reduce pain during sex for many women and improve sexual pleasure for many women and men is likely to be a key determinant in women deciding between the use of oral PrEP or vaginal microbicides if this choice becomes a reality in the future.

9.6 Reconsidering gender (in)equality

In chapter 1 I highlighted some of the many challenges that women face as a result of gender inequality in South Africa. The need for microbicides hinges on the need for HIV prevention options that women can use (or control), on the premise that they cannot always insist on condom use. Certainly a separate analysis of the Africa Centre MDP 301 qualitative data illustrated that the biggest barrier to condom use for women was male opposition (Mzimela, 2010). My findings concur with previous evidence, that gender inequalities will influence women's willingness and ability to use microbicides – for example, as presented in chapter 8, with some women being unwilling or unable to use microbicides without their partner's approval.

To date, most of the microbicide acceptability literature relating to women's power or agency has focused on relationship dynamics, sex communication (mainly 'disclosure'), and risk management (Severy, 2005, Koo, 2005, Woodsong, 2008). My findings support the importance of all of these factors. However, my findings also hint at another dimension to women's power that attracts less attention in microbicide literature, and that is women's power more generally over their bodies. My evidence suggests that women in KwaZulu-Natal are likely to add microbicides to the array of vaginal practices that they use to manage their sexuality and sexual health. The meta-analysis, described in chapter 5 section 5.1.3, found that "vaginal practices are continuously being reinvented in time and place; …are used to negotiate social, economic and relationship challenges in women's lives; … (and that) modern renditions of local practices appear to remain important sources of power for women" (Hilber, 2012;30). As such, women are likely to position microbicides in a way that maximises the beneficial effects, while minimising the negative effects – as demonstrated in chapters 6 and 7 where they describe microbicides in terms of intravaginal insertions that enhance sexual pleasure, while distancing them from love medicines which could be considered subversive of gender norms.

It is important to continue to highlight the gender inequalities that limit women's ability to mitigate the risk of HIV infection. However, it is also important not to prioritise discourses of HIV prevention that reinforce gender inequalities and reify women as disempowered and vulnerable. Based on research in South Africa, Gacoin has argued that HIV prevention discourses validate, instead of challenge, social constructions of masculine privilege (2010). By

arguing that microbicides can only be 'used' by women, not 'controlled' by them, I think we are at risk of prioritising male decision making over female decision making. Although, as I say in chapter 8, this may be an academic distinction with little meaning for the women using microbicides – our focus on this distinction as researchers could well influence how microbicides are introduced and positioned in the market. Gacoin argues that "within discourse, the ability for resistance to gendered inequalities, and agency for HIV prevention, lies in the ways that norms can change" (2010;440). My evidence suggests that microbicides offer the opportunity to resist inequalities and include women's agency in HIV prevention discourse – thereby creating a discourse around microbicides more in terms of gender equality than gender inequality. This finding is important for both microbicides and oral PrEP in the future, and I would argue, could be used to re-invent the notion of female condoms in South Africa alongside microbicide delivery programmes.

9.7 Limitations

In addition to the topic specific limitations I have detailed in each of the empirical chapters, there are a number of limitations in terms of the relevance of my findings.

Throughout the literature from hypothetical, surrogate and candidate studies, perceptions of microbicide acceptability have differed in South Africa compared to other African countries. Many of these differences have illustrated the peculiarities of gender dynamics in South Africa. Indeed the influence of the contemporary national 'rights based' discourse on gender norms was clearly evident in chapter 8. As such, the findings from this thesis are unlikely to be relevant outside South Africa. Nonetheless, these analyses highlight the need to look at vaginal practices and communication about microbicides in a more nuanced manner in all settings.

Although a substantial part of the microbicide literature is based on evidence from South Africa, the vast majority is based on research in peri-urban or urban settlements. MDP 301, HPTN035 and CAPRISA 004 were the only effectiveness trials to include rural South African sites, at the Africa Centre, Hlabisa and Vulindlele respectively. The approach that I adopted in this thesis, assessing the compatibility of microbicides to socio-cultural norms, may well be less relevant in more urbanised areas. In urban settlements in Gauteng, cultural norms have been described as a rural phenomenon, something that is 'abandoned' in the process of urbanisation or 'suspended' in an urban environment (Saethre, 2009). Certainly the WHO survey reported differences in vaginal practices between rural and urban women in KwaZulu-Natal (Scorgie, 2011). Similarly in the MDP 301 trial, differences were reported between the rural and urban South African sites in relation to sexual expectations (Montgomery, 2010b). As

such, the extent to which microbicides are compatible with socio-cultural norms may apply in rural rather than urban settings in South Africa.

Finally, in this thesis I have investigated the compatibility of microbicides with socio-cultural norms regarding sexuality and sexual health. However, I have not considered how the compatibility (or otherwise) of microbicides with some socio-cultural norms impacts specifically on gel use and long term adherence. Nonetheless, I have been able to offer insights into socio-cultural norms that need to be considered in terms of their influence on acceptability and adherence in the future.

9.8 Conclusion

After a quarter of a century of research, vaginal microbicides may be available as an additional HIV prevention option in the foreseeable future. We have learnt a great deal about microbicide acceptability by measuring women's willingness to use microbicides, satisfaction with product characteristics, and use of candidate microbicides. As we look forward to microbicide roll out programmes, we need to consider other less tangible socio-cultural factors that could influence acceptability.

In this thesis I have shown that microbicides are compatible with socio-cultural norms relating to intravaginal insertion and sexual communication, but may be less compatible with norms relating to intravaginal cleansing and love medicines. In terms of planning for the introduction of microbicides, incompatibility with love medicines could be beneficial, while incompatibility with intravaginal cleansing raises a number of challenges. Nonetheless, I have illustrated that with effective marketing, distribution, counselling, and public health messaging we can overcome the challenges presented by intravaginal cleansing norms among a minority of women.

My findings may only reflect the compatibility of microbicides with socio-cultural norms in rural South Africa. However, the findings highlight lessons for future research in terms of the need for more accurate collection of data on vaginal practices and sex communication, further understanding of the impact of intravaginal cleansing and sex communication on product adherence, confirmation of the impact of post-coital cleansing on microbicide efficacy, and a better understanding of gel use and sex during menstruation. Hopefully this evidence will ensure that the nuances and complexities of intravaginal practices and sexual communication will be considered in terms of microbicide acceptability in the future. In addition, I hope this evidence encourages researchers, policy makers and advocates to adopt language that promotes microbicides in terms of sex-positive and gender-equality discourses.

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Microbicides, sexuality and sexual health in KwaZulu-Natal, South Africa

Volume 2: Appendices

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Appendix A: Ethics Approval

UNIVERSITY OF
KWAZULU-NATAL

14 December 2005

Professor M L Newell
Director : Africa Centre for Health and Population
P O Box 198
MTUBATUBA
3935
Fax : (035 550 7565)

Dear Professor Newell

PROTCOL : (MPD 301 – version 1.2) An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection. Marie-Louise Newell, Africa Centre. Ref.: T111/05

Thank you for your responses dated 27 November 2005 to queries raised on 24 November 2005.

The Biomedical Research Ethics Committee considered the abovementioned application and the protocol was approved at its meeting held on 07 June 2005 pending appropriate responses to queries. These conditions have now been met, the study is given full ethics approval and may begin as at today's date: 14 December 2005.

This approval is valid for one year from 14 December 2005. To ensure continuous approval, an application for recertification should be submitted a couple of months before the expiry date. In addition, when consent is a requirement, the consent process will need to be repeated annually.

May I take this opportunity to wish you everything of the best with your study. Please send the Biomedical Research Ethics Committee a copy of your report once completed.

Yours sincerely

PROFESSOR A DHAI
Chair: Biomedical Research Ethics Committee

Nelson R Mandela School of Medicine, Faculty of Health Sciences,
Head: Bioethics, Medical Law and Research Ethics

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Founding Campuses: Edgewood Howard College Medical School Pietermaritzburg Westville

Appendix B: MCC Approval

GW 12/40

MEDISYNEBEHEERRAAD

Republiek van Suid-Afrika

MEDICINES CONTROL COUNCIL

Republic of South Africa

DIE REGISTRATEUR VAN MEDISYNE
DEPARTEMENT VAN GESONDHEID
PRIVAATSAK X828
PRETORIA
0001

Telefoon: (012) 312-0000
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THE REGISTRAR OF MEDICINES
DEPARTMENT OF HEALTH
PRIVATE BAG X828
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Navrae • Inquiries: MISS NOLUNTU QODI

Verwysing • Reference: N2/19/8/2 (1629)

Datum * Date 10 March 2006

FAX AND MAIL TO

M Gafos

Africa Centre for Health & Population Studie
P O Box 198
Mtubatuba
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3935

Tel: 0123120276
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Dear Gafos,

PROTOCOL: **MDP 301**

PRODUCTS: **0.5% PRO 2000/5 (P) AND 2% PRO 2000/5 GEL (P)**

TITLE: **AN INTERNATIONAL, MULTI-CENTRE, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF 0.5% AND 2% PRO 2000/5 GELS FOR THE PREVENTION OF VAGINALLY ACQUIRED HIV INFECTION.**

RE : APPROVAL OF NEW PI- AFRICA CENTRE

We acknowledge receipt of your letter dated 01 November 2005 with the following documentation pertaining to the above-captioned trial.

Amendment Date:
Amendment Number:
Amendment Version:
Received Date: 2005/11/01

Prof ML Newell is approved for participation as the new Principal Investigator at the Africa Centre for Health and Population Studies.

Yours faithfully,

MISS NOLUNTU QODI

FOR AND ON BEHALF OF THE REGISTRAR OF MEDICINES MCC TRIAL REFERENCE NO: 20040968

Appendix C: Participant information sheets (PIS)

Female Participant Information Sheet
February 2008

Microbicides Development Programme (MDP) Trial 301
An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection
MDP 301 (2.0) February 2008

You have been given an explanation of the trial, but we would like you to read this, or ask a friend to read it to you, so that you fully understand what is involved before you agree to take part in this research. If you decide you want to take part, it is important for you to understand why the research is being done and what it will involve. Agreeing to be screened, does not mean that you have to take part in the trial. If you do enrol in the trial, you will be free to stop using the gel or to stop attending at any time. Please ask if there is anything that is not clear or if you would like more information.

Why is this trial being done?

Throughout the world the most common way in which the Human Immunodeficiency Virus (HIV) is spread is through sexual contact between men and women. Although **condoms are a very effective form of prevention**, women do not always use them out of choose or because it is not always possible for a woman to get her partner to agree to use them. Therefore there is an urgent need for other methods of protection that can be used by women. For this reason, we are studying the safety and effectiveness of a gel that is a microbicide. The gel contains an experimental ingredient called PRO 2000/5. We are testing a gel that has 0.5% PRO2000/5 in it. **This gel may prevent HIV infection** if put in the vagina using an applicator before sexual intercourse.

However, **WE DON'T KNOW FOR SURE IF 0.5% PRO2000/5 DOES OR DOES NOT WORK** and that is **WHY** the trial is being done.

What do we know about PRO 2000/5?

Nearly 300 women in Europe, the United States, South Africa, Uganda and India have used PRO 2000/5 for short periods up to a maximum of twice daily for 28 days to see if it was safe. Some of these women used strengths higher than the one being tested in this trial. In these studies women were examined weekly or fortnightly. The gels were safe and caused few side effects. Some women complained of mild itching or other discomfort whilst using the gel, although this was not definitely related to the gel as these can be common symptoms for some women even when not using a vaginal gel. Some women using the gel more than twice a day noticed more discharge than usual. Other symptoms that may be linked to using the gels include light bleeding from the vagina (spotting).

We do not know if 0.5% PRO2000/5 is safe to use in pregnancy and it is important that women stop using gel if they are pregnant. We would like to continue to see you while you are pregnant, and if you are still being followed you can restart gel after your pregnancy if you want to. We do not know if you will be prevented from getting pregnant during the sex act when you use the gel. There is no reason to think the gel will affect your chance of becoming pregnant later. You should use a reliable method of contraception every time you have sex.

What have we learnt about PRO2000/5 since we started the trial?

We were also studying 2% PRO2000/5 from October 2005 to February 2008. Every 4 to 6 months a committee of experts that are independent of the trial review the information on safety and effectiveness. They met on 8th February 2008 and advised that 0.5% PRO2000/5 gel should continue to be tested and compared to the placebo gel. They also advised that 2% gel should not continue as there was very little chance of showing that 2% gel would prevent HIV. Because of this we are now only studying 0.5% PRO2000/5 gel against the placebo gel for the rest of the trial to find out whether 0.5% PRO2000/5 gel could reduce the risk of HIV infection.

What does the MDP 301 trial involve?

The trial is taking place in several sites in Africa shown in the map. Your site is the Africa Centre for Health and Population Studies

PRO 2000/5 0.5% gel is being studied at each site. A second gel which has been specially matched is a dummy gel known as a 'placebo'. This dummy gel does not contain any ingredients that prevent HIV and therefore it does NOT reduce the risk of HIV infection. Both the 0.5% PRO2000/5 and placebo gels will be packaged in the same applicator and cartons and will look identical so neither you nor the study staff can tell the difference. Chance will determine whether you receive the 0.5% PRO2000/5 gel or the dummy gel. You will receive the same type of gel throughout the trial. **NO-ONE KNOWS WHICH GEL THEY ARE ON,** including the study staff. This is the best and only way to test the PRO2000/5 gel to see if it prevents HIV infection.

What will happen to me if I agree to be screened?

After you have had all your questions answered and feel you understand what you will have to do, you will be asked to sign, or put your thumbprint on a consent form. If you cannot read then we recommend that you have a witness present for the discussion and to see your thumbprint. You are not obliged to have someone present. You will then be given a number which is unique to you, and which will help us to ensure that all your test results and answers to our questions remain private. There will be some screening tests, so the whole visit will take about one and a half hours. The tests will be:

- A blood test for HIV and syphilis, after you have received private counselling, to help you decide whether or not you wish to have the HIV test
- A urine test for pregnancy
- General questions including health questions
- Sensitive questions about your partners and your sexual practices.

Not all women will be able to take part in the study and if this is the case for you, the research staff will explain why. If you can take part, and you want to, we will ask you to go away, and to think carefully about the trial. You will be asked to come back again to enrol in the study within 1- 6 weeks.

What will happen to me if I agree to enrol in the trial?

You will be asked to sign or put your thumbprint on another consent form (with a witness, if you cannot read and write), and after this there will be:

- Some more general and sensitive questions
- A general examination of your body, an examination of your genital area and collection of genital specimens using a speculum
- Blood will be collected to store until the end of the study and urine will be collected to test if you are pregnant

If you are eligible, you will be invited to join and providing you are still willing you will be given another number which is unique to you and which determines by chance the gel that you use throughout the trial. We strongly recommend that you use condoms as well because we know that condoms protect against HIV and other sexually transmitted infections, as well as pregnancy, if used properly every time you have sexual intercourse. An applicator will be used to insert the gel and the staff will explain to you how it should be used. This should be done within one hour before sex, so the gel can be inserted immediately before sex or up to 60 minutes before sex. Once the gel has been inserted you should not wash inside your vagina, or put anything else in your vagina, for at least one hour after sex. If you do take part in the study and are given some of the gel you must only use it yourself and not share it with anyone else, even if they are also in the study.

We want you to keep the empty applicators and bring them back to the clinic, as well as unused gel, each time you collect new supplies and at your final visit. This will help you and the staff to work out how much gel you have used and how much more you need. This information will be very important to the result of the trial and so we want you to try to be as accurate as possible.

You will be asked to come to the clinic every 4 weeks for pregnancy tests, to answer some questions and to collect more gel and condoms. At approximately every third visit (every 12-16 weeks), the visit will take longer as there will be more questions about your health and sexual behaviour, as well as a genital examination, swabs and blood tests. One of these tests will be an HIV test, and the staff will explain how you can receive the result. Once the blood has been tested some of it will be kept frozen in the laboratory. This is because the test may have to be repeated and also because new and better tests may become available in the future. This blood will not be given to anyone except appropriate staff involved in medical research, and this trial.

If you become pregnant, you will have to stop using the gel, but we would like you to continue to attend every 12 weeks. Once your pregnancy has ended you can start using gel again after an examination to make sure it is safe to do so.

Most women will be followed for 52 weeks (approximately 12 months).

We might also ask you to keep a diary and take part in a longer recorded interview with another member of the study team during the study. We may also ask you to participant in a focus group discussion with between 6 to 8 other study participants to talk about your views of the gel. You will be asked to give your written consent before any of these procedures.

You will be asked if we can contact your partner to ask him some questions about the gel. We will not contact your partner if you do not want us to. We will ask for your written permission before we contact your partner.

If you do not want to participate in the coital diaries, interviews, focus group discussions or do not want us to contact your partner, this will not affect your participation in the trial.

You will receive compensation for any costs involved with coming to the clinic and this will be: R150 per scheduled clinical visit, in the form of vouchers redeemable at Mtubatuba Boxer store.

What if something new is learned about the gel whilst I am in the trial?
You will be told of any new information learned during the course of the trial that might cause you to change your mind about staying in it.

Do I have to take part?
No. It is up to you to decide, when you feel ready, whether you would like to take part. Once you enrol you are free to stop using the gel and continue attending the clinic, or to stop attending the clinic if you wish to. This will not affect any care you receive now or in the future.

Can I stop taking part?
Yes, you can decide to stop taking part whenever you choose. This would mean that you do not need to explain why you want to stop taking part to anyone, just that you want to stop.

What are the risks and benefits?
The risks are:

- Taking blood and having genital examinations may be uncomfortable
- The questions might be embarrassing
- It is possible that the gel will not protect you against HIV. If you believe that it will, you may put yourself at risk. Condoms will protect you from HIV if used properly.
- You may experience genital, or other problems that you think are related to the gel. Though vaginal gels containing PRO2000/5 were considered to be safe in previous studies, less than 300 women have used the gel so far and none for longer than 4 weeks.

You should contact the research staff immediately if you have a genital or other problem that you think is related to the gel.

Contact name: Mitzy Gafos, Project Leader Contact number: 072 798 3158
Hlengiwe Ndlovu, Clinic Coordinator Contact number: 072 268 2875

Physical address: Africa Centre for Health and Population Studies, R618 en route to Hlabisa, Somkhele. Contact number: 035 5507500

If you feel that you have suffered harm as a result of taking part in the study then you should discuss this with the staff at the clinic. If you would like to speak to someone outside the research team you should contact:
Contact name: Mduduzi Mahlinza, Community Liaison Office Contact number: 035 550 7500

If you feel that you have suffered harm because of the study or would like to know more about your rights as a research participant, contact the Research Ethics Committee at (031) 260 4495.

The benefits are:

- You will receive a general health check and examination
- You will receive treatment for vaginal and sexually transmitted infections free of charge
- Staff will refer you to a government health clinic if they find other conditions that need treatment
- You will receive free condoms and advice to help you to use them with your partners

Can I be withdrawn from the study even if I want to continue?
Yes. The staff can end your participation in the study without your consent if they feel it is in your best interest. Your participation will also be ended if the study is stopped by the authorities responsible for running the trial.

Will the information from the trial be confidential?
Yes. Your contact details will only be available to certain staff involved with the study. Staff that monitor the study have to check the consent forms, and they will see your names when this is being done. All the other information that is collected for the trial will not be identified by your name, only by your trial number, including the tests sent to the laboratory.

What will happen to the results?
After the study has been completed the results will be analysed. This can take between 3-6 months, and after this you will be told the results of the study. You will also be told which product you received. The results of the study will be written up and submitted for review by a medical journal. They may also be presented at scientific conferences. If the products are shown to work, then we will try to get a license so that they can become widely available.

This trial is conducted in accordance with international guidelines for Good Clinical Practice in Clinical Trials and with the approval of:

The University of KwaZulu-Natal, Biomedical Research Ethics Committee.
Contact numbers: Telephone: 031-2604769/2601074; email: wassenaar@ukzn.ac.za
Date: 14th December 2005, ref. number: T111/05

SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001
Contact details: fax: (012) 312 3105; e-mail: labusa@health.goc.za.

Date: 10th March 2006, ref. number: N2/19/8/2 (1629)

If you have questions about this study you should discuss them with a member of the study team (contact details as provided under 'What are the risks and benefits?' on this form), or the ethics committee (contact details provided above). If they have not provided you with answers to your satisfaction, you should write to the South African Medicines Control Council (MCC) at:

The Registrar, SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001 Fax: (012) 312 3105 Email: labusa@health.goc.za

Thank-you for taking the time to read this!

Information Sheet for Social Science Female Participants
February 2008

Microbicides Development Programme (MDP) Trial 301
An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection

MDP 301 (2.0) February 2008

You have been given an explanation of the social science component of the trial, but we would like you to read this, or ask a friend to read it to you, so that you fully understand what is involved. If you decide you want to take part, it is important for you to understand why this component is being done and what it will involve. Agreeing to participate in the trial does not mean that you have to take part in the social science component. If you decide to do the social science component, you will be free to stop at any time. Please ask if there is anything that is not clear or if you would like more information.

Why is the social science component of the trial being done?

We are studying the safety and effectiveness of microbicide gels in preventing vaginally acquired HIV infection. In order for us to develop a microbicide that will best fit women's needs, it is important for us to hear from participants about their experiences with the gel. We would like to find out what women like most about the gel, what they like least, how easy it is to use, and what they would suggest to make it better. To learn this information, we are asking a subset of study participants to provide a more detailed description of their sexual activity and gel use.

Why am I being asked to participate?

In order to get a general view from women enrolled in the clinical trial, we are asking every 8th women who enrolls to participate in the social science component of the study. You can still be part of the trial even if you do not want to be part of the social science component.

What will happen to me if I agree to take part in the social science component?

After you have had all your questions answered and feel you understand what you will have to do, you will be asked to sign, or put your thumbprint on a consent form. If you cannot read then we recommend that you have a witness present for the discussion and to see your thumbprint.

In addition to the questionnaires about sexual behavior that you will fill out at every visit, you will also be asked to participate in the following at different times during the trial:

- Completion of a coital diary to indicate when and with whom you had sex, and whether gel and/or a condom was used

A member of the study staff will give you a blank coital diary at the appropriate visit, and show you how to complete the diary. We will ask you to fill in the coital diary as soon after having sex as possible so as you do not forget anything. You will be asked to complete the diary every time you have sex and to record the type of partner (regular or casual), type of sex (vaginal or anal), condom use (whether you used a condom or not), gel use (whether you used the gel or not), other products used, and if you had sex during menstruation. We will ask you to fill in the coital diary for 4 weeks, and return the completed diary at your next clinic visit.

- A longer recorded interview with a member of the social science study team that includes sensitive questions about your partners, your sexual practices, and gel and condom use

This interview will include questions about the people you have had sex with recently, the type of sex that you had, and whether you used gel and condoms during sex. In addition, the

interviewer will ask you about your experiences using the gel, and ask for feedback about how the gel could be improved.

We will also ask for your permission to contact your male partner to invite him to an interview, but **WE WILL NOT CONTACT HIM WITHOUT YOUR WRITTEN CONSENT.** If you agree to us contacting him, we will invite him to an interview but no information that you give to us will be discussed with him. Even if you do not want to be interviewed we would still like to interview your partner if you are happy for us to speak to him. If you want more information about this ask a study team member for the Male Information Sheet.

Do I have to take part in the social science component?
No. It is up to you to decide whether you would like to take part. You will continue to participate in the trial regardless of your decision about the social science component, and this will not affect any care you receive now or in the future. If you take part we would like you to participate in completing coital diaries and participate in interviews.

Can I stop taking part?
Yes, you can decide to stop taking part whenever you choose. This would mean that you do not need to explain why you want to stop taking part to anyone, just that you want to stop.

What are the risks and benefits?
The risks are:
- The questions might be embarrassing or uncomfortable
- Your partner might ask you questions about the coital diary

If the clinic team can not answer your questions to your satisfaction you can contact a member of the social science team at the Africa Centre:
Mitzy Gafos, Project Leader Contact number: 072 798 3158
Misiwe Mzimela, Social Science Coordinator Contact Number: 035 550 7500

Physical address: Africa Centre for Health and Population Studies, R618 en route to Hlabisa, Somkhele Contact Number: 035 550 7500

If you feel that you have suffered harm as a result of taking part in any part of the study then you should discuss this with the staff at the clinic. If you would like to speak to someone outside the research team you should contact:
Contact name: Mduduzi Mahlinza, Community Liaison Office Contact number: 035 550 7500

If you feel that you have suffered harm because of the study or would like to know more about your rights as a research participant, contact the Research Ethics Committee at (031) 260 4495.

The benefits are:
- You will have an opportunity to tell the study team in detail about your experiences using the microbicide gel
- Your comments will help us develop a microbicide gel that will best serve women's needs

Will the information from the interviews and coital diary be confidential?
Yes. The interview transcripts and coital diaries will not be identified by your name, only by your trial number.

Information Sheet for Social Science Female Participants
February 2008

This trial is conducted in accordance with international guidelines for Good Clinical Practice in Clinical Trials and with the approval of:

The University of KwaZulu-Natal, Biomedical Research Ethics Committee.
Contact numbers: Telephone: 031-2604769/2601074; email: wassenaar@ukzn.ac.za
Date:14th December 2005, ref. number: T111/05,

SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001
Contact details: fax: (012) 312 3105; e-mail: labusa@health.goc.za.

Date: 10th March 2006, ref. number: N2/19/8/2 (1629)

If you have questions about this study you should discuss them with a member of the study team (contact details as provided under 'What are the risks and benefits?' on this form), or the ethics committee (contact details provided above). If they have not provided you with answers to your satisfaction, you should write to the South African Medicines Control Council (MCC) at:

The Registrar, SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001 Fax: (012) 312 3105 Email: labusa@health.goc.za

Thank-you for taking the time to read this!

Male Information Sheet
February 2008

Microbicides Development Programme (MDP) Trial 301
An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection

MDP 301 (2.0) February 2008

You have been given an explanation of the trial, but we would like you to read this, or ask a friend to read it to you, so that you fully understand what is involved before you agree to take part in this research. Please ask if there is anything that is not clear or if you would like more information.

Why is this trial being done?
This trial is being done to test a new gel called PRO2000/5 0.5% microbicide. **This gel may prevent HIV infection** if put in the vagina using an applicator before sexual intercourse.

However, **WE DON'T KNOW FOR SURE IF IT DOES OR DOES NOT WORK** and that is **WHY** the trial is being done. We know that condoms, when used properly, do protect against HIV, sexually transmitted infections and pregnancy. So it is important that you and your partner try to use condoms to protect yourselves.

What do we know about PRO 2000/5?
Nearly 300 women in Europe, the United States, South Africa, Uganda and India have used PRO 2000/5 for short periods up to a maximum of twice daily for 28 days to see if it was safe. Some of these women used strengths higher than the one being tested in this trial. In these studies women were examined weekly or fortnightly. The gels were found to be safe. Some women complained of mild itching or other discomfort whilst using the gel, although this was not definitely related to the gel as these can be common symptoms for some women even when not using a vaginal gel. Some women using gel twice a day noticed more discharge than usual. Other symptoms that may be linked to using the gels include light bleeding from the vagina (spotting).

We do not know if the PRO2000/5 0.5% gel is safe to use in pregnancy and it is important that women stop using gel if they are pregnant, although they can start using the gel again when they are no longer pregnant if they want to. We do not know if pregnancy will be prevented during sex acts when gel is used. There is no reason to think the gel will affect the chance of women becoming pregnant later.

What will happen to the women who are taking part?

Women who participate will be asked to sign a consent form and will undergo some tests for pregnancy and sexually transmitted infections. They will be given general and genital examinations and will be asked some questions about their sexual behaviour. If they are able and willing to take part in the study they will be given some gel to insert before each time they have sex. They will be asked to come back to the clinic on a regular basis and study team members may contact them at other times to see how they are getting on using the gel. We strongly recommend that couples use condoms as well because we know that condoms protect against HIV and other sexually transmitted infections, as well as pregnancy, if used correctly every time they have sexual intercourse.

What will happen to me if I agree to take part?
You will be asked to take part in an in-depth interview. After you have had all your questions answered and feel you understand what you will have to do, you will be asked to sign, or put your thumbprint on a consent form. A study team member will ask you some questions about how you felt about your partner using the gel and if you felt it made a difference to your sexual pleasure. They will ask you if you mind if the discussion is recorded. The interview will be

casual and you will be encouraged to talk freely about anything you feel is related to your partner using the gel.

You will receive compensation for any costs involved with participating in the focus group discussion and this will be R80 in the form of vouchers redeemable at Mtubatuba Boxer store.

What are the risks and benefits?

We do not think there are any risks involved in you taking part in this study. However, if you do feel that you have suffered harm as a result of taking part in the study then you should discuss this with:

Contact name: Mitzy Gafos, Project Leader Contact number: 072 798 3158
Misiwe Mzimela, Social Science Coordinator
Contact Number: 035 550 7500

Physical address: Africa Centre for Health and Population Studies, R618 en route to Hlabisa, Somkhele Contact number: 035 550 7500

If you feel that you have suffered harm as a result of taking part in the study then you should discuss this with the staff at the clinic. If you would like to speak to someone outside the research team you should contact:

Contact name: Mduduzi Mahlinza, Community Liaison Office Contact number: 035 550 7500

If you feel that you have suffered harm because of the study or would like to know more about your rights as a research participant, contact the Research Ethics Committee at (031) 260 4495.

- You will receive free condoms and advice to help you to use them with your partners
- You will have an opportunity to tell the study team in detail about your experiences using the microbicide gel

Do I have to take part?

No. Your participation is completely voluntary. If you choose not to take part it will not affect any care you receive now or in the future.

Will the information that is collected be confidential?

Yes. Your contact details will only be available to the staff involved in the study. The information you provide will not be available to your partner.

What will happen to the results of the study?

All the information will be closely looked at, at the end of the study. You will be told the result, which may also be published in medical journals and presented at meetings.

This study is conducted in accordance with international guidelines for Good Clinical Practice in Clinical Trials and with the approval of:

The University of KwaZulu-Natal, Biomedical Research Ethics Committee.
Contact numbers: Telephone: 031-2604769/2601074; email: wassenaar@ukzn.ac.za
Date:14th December 2005, ref. number: T111/05,

SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001
Contact details: fax: (012) 312 3105; e-mail: labusa@health.goc.za.

Date: 10th March 2006, ref. number: N2/19/8/2 (1629)

If you have questions about this study you should discuss them with a member of the study team (contact details as provided under 'What are the risks and benefits?' on this form), or the ethics committee (contact details provided above). If they have not provided you with answers to your satisfaction, you should write to the South African Medicines Control Council (MCC) at:

The Registrar, SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001 Fax: (012) 312 3105 Email: labusa@health.goc.za

Thank-you for taking the time to read this!

Information Sheet for Female Participants
Focus Group Discussion
February 2008

Microbicides Development Programme (MDP) Trial 301
An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection
MDP 301 (2.0) February 2008

You have been given an explanation of the trial and the focus group discussion, but we would like you to read this, or ask a friend to read it to you, so that you fully understand what is involved. If you decide you want to take part, it is important for you to understand why we are conducting focus group discussions and what it will involve. If you decide to participate in the focus group, you will be free to stop at any time. Please ask if there is anything that is not clear or if you would like more information.

Why are focus group discussions being done?
In addition to asking you about your own experiences of using of the gel when you come to the clinics, we would like to find out more about women's views about the gel, condom use, male partners involvement in decision making about the use of gel and condoms, sexual practice, and the trial procedures. This is important so as we can ensure that the study and gel is acceptable and to help us develop a microbicide that can be used in this community. To learn this information, we are asking some women who are participating in the trial to discuss microbicides with our study staff in a group setting.

What will happen to me if I agree to take part in the focus group discussion?
After you have had all your questions answered and feel you understand what you will have to do, you will be asked to sign, or put your thumbprint on a consent form. If you cannot read then we recommend that you have a witness present for the discussion and to see your thumbprint.
The team member leading the discussion will ask you if you mind if the discussion is recorded. The focus group will be casual and you will be encouraged to talk freely about your knowledge and opinions of microbicides. We will ask you and 6 to 8 other women about your views of microbicides and the trial.

You will receive compensation for any costs involved with participating in the focus group discussion and this will be R80 in the form of vouchers redeemable at Mtubatuba Boxer store.

Do I have to take part in the focus group discussion?
No. Your participation is completely voluntary. If you choose not to take part it will not affect your participation in the trial or any care you receive now or in the future.

Can I stop taking part?
Yes, you can decide to stop taking part whenever you choose. This would mean that you do not need to explain why you want to stop taking part to anyone, just that you want to stop.

What are the risks and benefits?
We do not think there are any risks involved in you taking part in this focus group discussion. However, if you do feel that you have suffered harm as a result of taking part in the focus group discussion then you should discuss this with:
Mitzy Gafos, Project Leader Contact number: 072 798 3158
Misiwe Mzimela, Social Science Coordinator Contact Number: 035 550 7500

Physical address: Africa Centre for Health and Population Studies, R618 en route to Hlabisa, Somkhele Contact Number: 035 550 7500

Information Sheet for Female Participants
Focus Group Discussion
February 2008

If you feel that you have suffered harm as a result of taking part in the focus group discussion then you should discuss this with the staff at the clinic. If you would like to speak to someone outside the research team you should contact:
Contact name: Mduduzi Mahlinza, Community Liaison Office Contact number: 035 550 7500

If you feel that you have suffered harm because of the focus group discussion or would like to know more about your rights as a research participant, contact the Research Ethics Committee at (031) 260 4495.

The benefits are:

- You will have an opportunity to tell the study team in detail about your thoughts and opinions of microbicides
- Your comments will help us develop a microbicide gel that will best serve the needs of the community

Will the information from the focus group discussions be confidential?

Yes. Your contact details will only be available to the staff involved in the study and during the discussion you will be identified by a number not your name. Although the research team will treat all information confidentially, other participants may not be as strict about confidentiality even though they will be encouraged to do so. Participants are advised to be cautious about disclosing very personal information.

What will happen to the results of the study?

All the information will be closely looked at, at the end of the study. You will be told the result, which may also be published in medical journals and presented at meetings.

This trial is conducted in accordance with international guidelines for Good Clinical Practice in Clinical Trials and with the approval of:

The University of KwaZulu-Natal, Biomedical Research Ethics Committee.
Contact numbers: Telephone: 031-2604769/2601074; email: wassenaar@ukzn.ac.za
Date: 14th December 2005, ref. number: T111/05

SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001
Contact details: fax: (012) 312 3105; e-mail: labusa@health.goc.za.

Date: 10th March 2006, ref. number: N2/19/8/2 (1629)

If you have questions about this study you should discuss them with a member of the study team (contact details as provided under 'What are the risks and benefits?' on this form), or the ethics committee (contact details provided above). If they have not provided you with answers to your satisfaction, you should write to the South African Medicines Control Council (MCC) at:

The Registrar, SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001 Fax: (012) 312 3105 Email: labusa@health.goc.za

Thank-you for taking the time to read this!

Information Sheet for Community Focus Group Discussion February 2008

Microbicides Development Programme (MDP) Trial 301
An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection
MDP 301 (2.0) February 2008

You have been given an explanation of the trial and the focus group discussion, but we would like you to read this, or ask a friend to read it to you, so that you fully understand what is involved. If you decide you want to take part, it is important for you to understand why we are conducting community focus group discussions and what it will involve. If you decide to participate in the focus group, you will be free to stop at any time. Please ask if there is anything that is not clear or if you would like more information.

Why are focus group discussions being done?
We are conducting a microbicide clinical trial in this area, and we want to know what people in the community are hearing about the study. In order for us to develop a microbicide that can be used in this community, it is important for us to hear from the community about their awareness and opinions of microbicides. We would like to find out what people know about microbicide gels, how they feel about using microbicides, what they like and dislike about the idea of microbicides, and what they would suggest to improve microbicides. To learn this information, we are asking members of the community to discuss microbicides with our study staff in a group setting.

What will happen to me if I agree to take part in the focus group discussion?
After you have had all your questions answered and feel you understand what you will have to do, you will be asked to sign, or put your thumbprint on a consent form. If you cannot read then we recommend that you have a witness present for the discussion and to see your thumbprint.
The team member leading the discussion will ask you if you mind if the discussion is recorded. The focus group will be casual and you will be encouraged to talk freely about your knowledge and opinions of microbicides. We will show you and 6 to 8 other community members like you the gel and the applicator that the women in the trial have been using. We will ask you to discuss the gel and applicator with the other people in the group, and to think of certain situations where the gel might be used.

You will receive compensation for any costs involved with participating in the focus group discussion and this will be R80 in the form of vouchers redeemable at Mtubatuba Boxer store.

Do I have to take part in the focus group discussion?
No. Your participation is completely voluntary. If you choose not to take part it will not affect any care you receive now or in the future.

Can I stop taking part?
Yes, you can decide to stop taking part whenever you choose. This would mean that you do not need to explain why you want to stop taking part to anyone, just that you want to stop.

What are the risks and benefits?
We do not think there are any risks involved in you taking part in this focus group discussion. However, if you do feel that you have suffered harm as a result of taking part in the focus group discussion then you should discuss this with:

Mitzy Gafos, Project Leader	Contact number: 072 798 3158
Misiwe Mzimela, Social Science Coordinator	Contact Number: 035 550 7500

Information Sheet for Community Focus Group Discussion
February 2008

Physical address: Africa Centre for Health and Population Studies, R618 en route to Hlabisa, Somkhele Contact Number: 035 550 7500

If you feel that you have suffered harm as a result of taking part in the focus group discussion then you should discuss this with the staff at the clinic. If you would like to speak to someone outside the research team you should contact:
Contact name: Mduduzi Mahlinza, Community Liaison Office Contact number: 035 550 7500

If you feel that you have suffered harm because of the focus group discussion or would like to know more about your rights as a research participant, contact the Research Ethics Committee at (031) 260 4495.

The benefits are:

- You will have an opportunity to tell the study team in detail about your thoughts and opinions of microbicides
- Your comments will help us develop a microbicide gel that will best serve the needs of the community

Will the information from the focus group discussions be confidential?

Yes. Your contact details will only be available to the staff involved in the study and during the discussion you will be identified by a number not your name. Although the research team will treat all information confidentially, other participants may not be as strict about confidentiality even though they will be encouraged to do so. Participants are advised to be cautious about disclosing very personal information.

What will happen to the results of the study?

All the information will be closely looked at, at the end of the study. You will be told the result, which may also be published in medical journals and presented at meetings.

This trial is conducted in accordance with international guidelines for Good Clinical Practice in Clinical Trials and with the approval of:

The University of KwaZulu-Natal, Biomedical Research Ethics Committee.
Contact numbers: Telephone: 031-2604769/2601074; email: wassenaar@ukzn.ac.za
Date: 14th December 2005, ref. number: T111/05

SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001
Contact details: fax: (012) 312 3105; e-mail: labusa@health.goc.za.

Date: 10th March 2006, ref. number: N2/19/8/2 (1629)

If you have questions about this study you should discuss them with a member of the study team (contact details as provided under 'What are the risks and benefits?' on this form), or the ethics committee (contact details provided above). If they have not provided you with answers to your satisfaction, you should write to the South African Medicines Control Council (MCC) at:

Information Sheet for Community Focus Group Discussion
February 2008

The Registrar, SA Medicines Control Council, Department of Health, Private Bag X828, PRETORIA 0001 Fax: (012) 312 3105 Email: labusa@health.goc.za

Thank-you for taking the time to read this!

Appendix D: Informed consent forms (IC)

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit: ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)

Screening number:	Initials:	Year of Birth:
☐☐☐☐☐☐☐	☐☐☐	☐☐☐☐

Microbicides Development Programme Trial 301 (MDP 301)
Protocol version (2.0)
Female Informed Consent Part 1A

PLEASE CIRCLE THE CORRECT ANSWERS

Print your name and surname:_____

Which member of the study staff have you spoken to about this study:_____
(please print his or her name and surname)

1	Has the MDP 301 trial been explained to you and have you been given a Female Information sheet dated February 2008?	YES	NO
2	Have you had an opportunity to ask questions and discuss this study?	YES	NO
3	Have you received satisfactory answers to all of your questions?	YES	NO
4	Do you understand that we do not know if the PRO2000 0.5% gel prevents HIV and that we know the placebo gel does not prevent HIV?	YES	NO
5	Do you understand that the correct and consistent use of condoms will prevent HIV?	YES	NO
6	Do you agree to appropriate members of trial staff and the authorities responsible for licensing the gels having access to your medical records?	YES	NO
7	Do you understand that agreeing to be screened does not mean you have to join the trial?	YES	NO
8	Do you agree to be screened for this study?	YES	NO

If 'NO' to any of the above the volunteer is ineligible for the study

Signature	Print name	Date

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit: ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)

Screening number:	Initials:	Year of Birth:
☐☐☐☐☐☐☐	☐☐☐	☐☐☐☐

Signature/Thumbprint of volunteer

Signature or thumb-print		Date of signature	
Print name and surname			

Signature of witness (if volunteer illiterate) to state: "I witnessed the information and consent process and confirm that the above named participant consented of free will"

Signature		Date of signature	
Print name and surname			

Tick box if participant is illiterate and refuses to have witness present: ☐

Time of Signature or thumb print (24 hour clock): ☐☐:☐☐

Signature of study staff taking consent

Signature		Date of signature	
Print name and surname			

Signature	Print name	Date

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit: ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)

Screening number:	Initials:	Year of Birth:
☐☐☐☐☐☐☐	☐☐☐	☐☐☐☐

Microbicides Development Programme Trial 301 (MDP 301)
Protocol version (2.0)
Female Informed Consent Part 1B

PLEASE CIRCLE THE CORRECT ANSWERS

1	Have you signed part 1A of the informed consent form?	YES	NO
2	Have you been given pre test HIV counselling?	YES	NO
3	Do you agree to your blood being taken, for HIV testing now and stored for possible testing in the future?	YES	NO

If 'NO' to any of the above the volunteer is ineligible for the study

Signature/Thumbprint of volunteer

Signature or thumb-print		Date of signature	
Print name and surname			

Signature of witness (if volunteer illiterate) to state: "I witnessed the information and consent process and confirm that the above named participant consented of free will"

Signature		Date of signature	
Print name and surname			

Tick box if participant is illiterate and refuses to have witness present: ☐

Time of Signature or thumb print (24 hour clock): ☐☐:☐☐

Signature of study staff taking consent

Signature		Date of signature	
Print name and surname			

Signature	Print name	Date

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit: ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)		
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Year of Birth: ☐☐☐☐	Trial number: ☐☐☐☐☐☐

Microbicides Development Programme Trial 301 (MDP 301)
Protocol version (2.0)
Female Informed Consent Part 2

PLEASE CIRCLE THE CORRECT ANSWER

Print your name and surname:_____

1	Have you received enough information about the study?	YES	NO
2	Have you received your HIV test result?	YES	NO
3	Do you understand that we do not know if the PRO2000 0.5% gel prevents HIV and that you may receive a placebo gel that will definitely not prevent HIV?	YES	NO
4	Do you agree to use condoms and gel as much as possible when having sexual intercourse during this study?	YES	NO
5	Do you understand that you will have to stop using gel if you become pregnant?	YES	NO
6	Do you understand that you must report any new symptoms to the study team, even if you think they are not related to the gel?	YES	NO
7	Do you understand that you should give accurate answers to the questions you are asked by the study team and return used and unused applicators to them as requested?	YES	NO
8	Do you understand that you are free to withdraw from the study: - at any time - without having to give a reason for withdrawing - and without affecting future medical care?	YES	NO
9	Do you agree to take part in this study?	YES	NO

Signature	Print name	Date

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit: ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)

Screening number:	Initials:	Year of Birth:	Trial number:
☐☐☐☐☐☐☐	☐☐☐	☐☐☐☐	☐☐☐☐☐☐

If 'NO' to any of the above the volunteer is ineligible for the study

Signature/Thumbprint of volunteer

Signature or thumb-print		Date of signature	
Print name and surname			

Signature of witness (if volunteer illiterate) to state: "I witnessed the information and consent process and confirm that the above named participant consented of free will"

Signature		Date of signature	
Print name and surname			

Time of Signature or thumb print (24 hour clock): ☐☐:☐☐

Signature of study staff taking consent

Signature		Date of signature	
Print name and surname			

Signature	Print name	Date

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit (dd/mm/yyyy) □□/□□/□□□□

Screening number:	Initials:	Year of Birth:	Trial number:
□□□□□□□	□□□	□□□□	□□□□□□

Microbicides Development Programme Trial 301 (MDP 301)
Protocol version (2.0)
Informed Consent Female Social Science

PLEASE CIRCLE THE CORRECT ANSWER

1	Has the Social Science component of the MDP 301 trial been explained to you and have you been given an Information Sheet for Social Science Female Participants dated February 2008?	YES	NO
2	Have you received enough information about the social science component?	YES	NO
3	Do you agree to participating in the social science component of the trial by completing a coital diary and participating in in-depth interviews at different times during the trial?	YES	NO

If 'NO' to any of the above the volunteer is ineligible for the social science component but this will not affect her participation in the trial

Signature/Thumbprint of volunteer

Signature or thumb-print		Date of signature	
Print name and surname			

Signature of witness (if volunteer illiterate) to state: "I witnessed the information and consent process and confirm that the above named participant consented of free will"

Signature		Date of signature	
Print name and surname			

Tick box if participant is illiterate and refuses to have witness present: ☐

Signature of study staff taking consent

Signature		Date of signature	
Print name			

Signature	Print name	Date

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐

Trial number:	Initials:	Year of Birth:
☐☐☐☐☐☐☐	☐☐☐	☐☐☐☐

Microbicides Development Programme Trial 301 (MDP 301)
Protocol version (2.0)
Informed Consent Male IDI

PLEASE CIRCLE THE CORRECT ANSWER

1	Has the MDP 301 trial been explained to you and have you been given a Male Participant Information sheet dated February 2008?	YES	NO
2	Have you received enough information about the trial?	YES	NO
3	Do you agree to being interviewed about your experiences with your partner participating in this study?	YES	NO

If 'NO' to any of the above the volunteer is ineligible for the study

Signature/Thumbprint of volunteer

Signature or thumb-print		Date of signature	
Print name and surname			

Signature of witness (if volunteer illiterate) to state: "I witnessed the information and consent process and confirm that the above named participant consented of free will"

Signature		Date of signature	
Print name and surname			

Tick box if participant is illiterate and refuses to have witness present: ☐

Signature of study staff taking consent

Signature		Date of signature	
Print name			

Signature	Print name	Date

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit (dd/mm/yyyy) □□/□□/□□□□

Screening number:	Initials:	Year of Birth:	Trial number:
□□□□□□□	□□□	□□□□	□□□□□□

Microbicides Development Programme Trial 301 (MDP 301)
Protocol version (2.0)
Informed Consent Female Participant FGD

PLEASE CIRCLE THE CORRECT ANSWER

1	Has the MDP 301 trial been explained to you and have you been given a Female Participant Focus Group Discussion Information sheet dated February 2008?	YES	NO
2	Have you received enough information about the trial?	YES	NO
3	Do you agree to participate in a focus group discussion about your experiences and knowledge of microbicides?	YES	NO

If 'NO' to any of the above the volunteer is ineligible for the FGD

Signature/Thumbprint of volunteer

Signature or thumb-print		Date of signature	
Print name and surname			

Signature of witness (if volunteer illiterate) to state: "I witnessed the information and consent process and confirm that the above named participant consented of free will"

Signature		Date of signature	
Print name and surname			

Tick box if participant is illiterate and refuses to have witness present: ☐

Signature of study staff taking consent

Signature		Date of signature	
Print name			

Signature	Print name	Date

Site name: AFRICA CENTRE – SOUTH AFRICA	Date of visit: ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)

Study number: ☐☐☐☐☐	Initials: ☐☐☐	Year of Birth: ☐☐☐☐

Microbicides Development Programme Trial 301 (MDP 301)
Protocol version (2.0)
Community Focus Group Discussion Informed Consent

PLEASE CIRCLE THE CORRECT ANSWER

1	Has the MDP 301 trial been explained to you and have you been given an MDP 301 Information sheet on Community Focus Group Discussions dated February 2008?	YES	NO
2	Have you received enough information about the trial?	YES	NO
3	Do you agree to participate in a focus group discussion about your views and knowledge of microbicides?	YES	NO

If 'NO' to any of the above the volunteer is ineligible for the focus group

Signature/Thumbprint of volunteer

Signature or thumb-print		Date of signature	
Print name and surname			

Signature of witness (if volunteer illiterate) to state: "I witnessed the information and consent process and confirm that the above named participant consented of free will"

Signature		Date of signature	
Print name and surname			

Tick box if participant is illiterate and refuses to have witness present: ☐

Signature of study staff taking consent

Signature		Date of signature	
Print name and surname			

Signature	Print name	Date

Appendix E: In-depth interview guides

MDP 301 IN-DEPTH INTERVIEW GUIDE FOR WOMEN version 5 **16 October 2005**

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

INSTRUCTIONS

1. This interview is linked to the CRF and the CD and is intended to find out about sexual behaviour, gel and condom use, opinions about the trial and acceptability of its procedures, understanding of consent, etc. But it is also intended to check the accuracy of responses to these topics in the CRF and the CD.
2. If the respondent had sex during the week before her clinic visit (i.e. the period covered by question 6 on the long CRF), discuss the topics below in relation to that week. If she did not have sex in that week, then ask her about the four weeks before her clinic visit (i.e. the period covered by question 7 on the long CRF). You will have to adjust some of the questions depending on whether the participant had a partner in the last week or the last four weeks (i.e. whether she filled in Q6 or Q7 on the sexual behaviour CRF).
3. **MAKE SURE THAT THE PERIOD YOU DISCUSS WITH THE PARTICIPANT MATCHES THE PERIOD COVERED ON THE LAST CRF**.
4. Explain that you want to discuss some of the topics already covered in the CRF, but that you want to discuss them more informally and in greater detail.
5. There are two levels of questions:

   # **Research questions: the questions that we as MDP researchers want to get answers to.**

   Interview questions: the questions that you as interviewer could ask respondents in order to get answers to the research questions.
6. *Instructions/suggestions to interviewer are in italics.*
7. The interview schedule is divided into three columns.
   - **The left-hand column** contains the research questions, interview questions and instructions. The interview questions are suggestions for getting answers to the research questions. Because the interview is open and in-depth, much of this will be improvised and depend on how the interview actually goes in practice.
   - **The middle column** is for questions for which there is likely to be a yes/no answer, or similar simple answer.
   - **The right-hand column** is for summarising the answers. These should be summaries of the research question, **NOT** of the individual interview questions. These summaries should be more than just yes/no, but not longer than a few sentences of bullet points. They do not need to be detailed, as we have the details on the tape. The summaries and yes/no answers can be filled during the interview, or immediately after.
8. The interview should be tape-recorded if the participant agrees.

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

INTRODUCTION

Here you need to establish exactly when the respondent's last clinic visit was and make sure that she is aware that this interview is about the week before that clinic visit (or the four weeks before, if she didn't have sex in that week).

When did the participant last have sex?	**In the last week** ☐	**In the last 4 weeks** ☐	**More than 4 weeks ago** ☐

GEL ACCEPTABILITY

1. Is the gel generally acceptable? *→Get the respondent to talk about her experience with the gel. You should cover the following points:* • **What do you think of the gel? Do you like it? Why/why not? What do you like/not like about it? Were there any problems using the gel? If so, tell me about them.** • **Was it easy or difficult to insert? Was it convenient or inconvenient to use? Why?** • **Where do you store the gel?** • **Have you notice any symptoms (e.g. discharge, irritation) that you associate with the gel? Tell me about them.** • **Does using the gel have any effect on your sexual enjoyment. If so, what kind of effect? Does this relate to dry/wet sex?** • **Do you think the gel affected your partner(s)' enjoyment of sex; and if so how?**	**Yes** ☐ **No** ☐ **Unclear** ☐	MAIN REASONS

Site _____ Interviewer _____ Date: □□/□□/□□□□ Screening number: □□□□□□□ Trial number: □□□□□□

GEL AND CONDOM USE

2. How many times did she have sex during the last week (four weeks)? How many times did she use the gel and condoms during this period? And what were her reasons for this behaviour? *→Get the respondent to talk about sex, gel and condom use in the last week (four weeks). Make sure she remembers the definition of "sex act" that was used in the CRF.* • **How often did you have sex in the last week/four weeks before the last clinic visit?** • **Did you use gel in the week/four weeks before the last clinic visit?** • **If so how often? If not why not?** • **Did you use a condom in the week/four weeks before the last clinic visit?** • **If so how often? If not why not?** • **How frequently did you use both condom and gel together?** • **How often did you have sex without using either condom or gel?** • **If you didn't always use the gel, why not?** • **When exactly did you insert the gel (how long before sex)?**	No. of sex acts □□* No. of times BOTH gel & condom used □□* No. of times ONLY gel used □□ No. of times ONLY condom used □□ No. of times NOTHING used □□ **NB If these numbers are not the same, then you should note reasons in the column on the right*	MAIN REASONS FOR NOT USING GEL MAIN REASONS FOR NOT USING CONDOM HOW LONG BEFORE SEX DID SHE INSERT THE GEL?

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

3. Was reporting of gel and condom use consistent between CRF, CD and IDI? →*Compare what she has just told you with what she answered on the CRF and in the coital diary. If there are any discrepancies, explore the reasons for these.*	Consistent ☐ Some inconsistency ☐ Major inconsistency ☐	TYPE OF INCONSISTENCY MAIN REASONS FOR INCONSISTENCY

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

PARTNERS

4. How many partners and what kind of partners did she have sex with during the last week (four weeks)? *→ Explain that you need some more details about partners and frequency of sex in order to understand gel use.* • **Are you in a long-term stable relationship?** • **Did you have other partners during the week/four weeks before the last clinic visit? If so, how many different partners?** • **How often did you have sex with each of these partners in the week/four weeks before the last clinic visit?** • **On which of these occasions did you use gel/condom?**	No. of partners ☐	SUMMARY
5. Was reporting of numbers and types of partners consistent between CRF, CD and IDI? *→Compare what she has just told you with what she answered in section 2 above, on the CRF, and in the CD. If there are any discrepancies, explore the reasons.*	Consistent ☐ Some inconsistency ☐ Major inconsistency ☐	TYPE OF INCONSISTENCY MAIN REASONS FOR INCONSISTENCY

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

6. What is the nature and extent of partner involvement?	**Partner involved?**	SUMMARY
• **What do you think about women involving their partners in decisions about using such products? Is this good or bad?** • **Do you and your partner(s) discuss things relating to sex, such as whether to use a condom? If not, why not? If so, tell me how that works.** • **Have you told your partner(s) that you are using the gel? Why/why not?** → *If she had more than one partner and only told some of them, find out who she did and did not tell, and explore the reasons.* → *If she didn't tell them, did they find out? Try and find out what she told them.* • **How did your partner(s) respond when you told him?** • **How supportive was he/were they?** • **Does he influence whether/how the gel and condoms are used?** • **Does your partner(s) know that you have been keeping a coital diary? Why/why not? If only some partners, why those?**	**Yes** ☐ **No** ☐	

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

VAGINAL PRACTICES

7. What post-sex vaginal washing practices did she engage in during the week/4 weeks before her last clinic visit? → *You could introduce this by discussing hygiene practices relating to sex in the community generally. Then focus on the respondent herself and try and find out whether she washes inside her vagina after sex. Probe for details about frequency and when exactly she does this.* • **What sort of vaginal hygiene practices are common in this community?** • **Do you wash inside your vagina after sex? How long after?** • **If so, when, what do you use, why do you do it?** →*Compare what she tells you with what she answered on the CRF and entered in the CD. If there are any discrepancies, explore the reasons.*	**Practices?** **Yes** ☐ **No** ☐	KINDS OF PRACTICES
8. Has she inserted anything into her vagina (excluding water/fingers/tampon) during the week/4 weeks before her last clinic visit? • **Do you ever insert anything (excluding water/fingers/tampon) into your vagina? If so, what/when/why?** • **Did you do this in the week (four weeks) before the last clinic visit? If so, what/when/why?**	**Yes** ☐ **No** ☐	SUMMARY

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

SEXUAL PRACTICES

9. Did she have sex while menstruating during the last 4 weeks? • **Is it common to have sex during menstruation?** • **Do you do this?** • **If so, did you do this in the last 4 weeks?** → *Compare what she has just told you with what she answered on the CRF and in the coital diaries. If there are any discrepancies, explore the reasons.*	**Yes** ☐ **No** ☐	SUMMARY
10. Did she have anal sex during the last 4 weeks, and if so, did she use a condom? → *Tell the respondent that some people practise anal sex.* • **Do you think that anal sex occurs in this community?** • **Do you ever practise anal sex?** • **If so, did you do so in the four weeks before your last clinic visit?** • **If so, did you use a condom?** → *Compare this to the coital diary. Probe about any inconsistencies.*	**Anal sex** **Yes** ☐ **No** ☐ **Condom** **Yes** ☐ **No** ☐	SUMMARY

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

DIARY ACCEPTABILITY

11. Are the coital diaries acceptable and feasible? • **What did you think of the CDs?** • **Was it easy/difficult to keep? If difficult, why?** • **Did your partner(s) know you were keeping it?** • **If yes, what was their response? If no, why not?** → *If some knew and some didn't, explore.* • **How accurate do you think the diary data is?**	**Yes** ☐ **No** ☐	SUMMARY

CONSENT AND INFORMATION PROCEDURE

NB These questions will be asked in detail in the first interview. In subsequent interviews they will be adjusted.

→*Here you should explore how much the respondent has retained from the informed consent process, in particular the three critical points that were emphasised during screening:*		

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12. Does she know that the gel may not prevent the transmission of HIV, STDs, and that it may not prevent pregnancy? • **Why are you participating in this study?** → *Here you should probe to find out whether the reimbursement is a motive for participation.* • **What do you think about the gel? What do you think the gel is for? Why is it being tested?** • **Do you think it protects you in any way against HIV or other diseases?** • **If so, how/to what extent?** • **Do you think you can become pregnant while using the gel?** → *If she knows that the gel may not protect against HIV and pregnancy:* • **How do you know that the gel may not protect against HIV and pregnancy?**	**Yes** ☐ **No** ☐	SUMMARY
13. Does she know that that the correct and consistent use of condoms protects against HIV and STDs? • **What sort of things can you do to prevent yourself getting infected with HIV?** • **Do you think that condoms protect against HIV?**	**Yes** ☐ **No** ☐	SUMMARY

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14. Has she been using condoms more or less frequently compared to before she was using gel? • When you think about the period before you started using the gel, would you say that you used condoms more or less than you do now? • What are the reasons for this?	**More** ☐ **Less** ☐ **Same** ☐	REASONS

15. Does she know that she will have to stop using gel if she becomes pregnant? • **At the beginning, what did they tell you would be the reasons for not being able to continue using the gel?** • **What do you think will happen if you become pregnant during the trial?** • **Do you think you can continue using the gel if you become pregnant?**	**Yes** ☐ **No** ☐	SUMMARY

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

ACCEPTABILITY OF PROCEDURES

16. How acceptable are the trial procedures generally? • **Do you have any problems with the gel?** • **Have you experienced any side effects that you associate with the gel?** • **Do you have a problem with clinical procedures (HIV test, medical exams)?** • **Is the study too demanding in terms of time?** • **Are there family demands, work/employer demands, partner demands? Tell me about them.** • **Is it difficult keeping appointments (time and day of the week, accessibility from home/ work, travel difficulties, change in location of accommodation or work)? If so, tell me about it.** • **Do you have problems with the way the data are collected? If so what are these?** • **How accurately do you think you were able to answer the gel, condom and sexual behaviour questions in the CRF?** • **Have you experienced any discrimination because of participating in this study? If so, how?** • **What sort of things would cause you to drop out of this study?**	Generally acceptable ☐ Partly acceptable ☐ Not acceptable ☐	SUMMARY

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ Trial number: ☐☐☐☐☐☐

RISK PERCEPTION

17. Does she feel at risk of HIV infection? *→ Probe to find out whether she feels at risk of HIV infection and, if so, why she feels at risk.* • **Do you feel at risk of getting HIV/AIDS?** • **If so why?**	**Yes** ☐ **No** ☐ **Don't know** ☐	MAIN REASONS

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REASONS FOR DROP-OUT/DEFAULT (for participants who drop-out/default)

18. Why did she drop out/default from the study? *→Explain to the respondent that, while she had the right to withdraw from the study at any time, we are interested in finding out her reasons, so that we can learn from them and improve procedures.* • **Why did you drop out of the study?** *→Explore her reasons.* *→The questions under 1 and 15 are also relevant here.*		MAIN REASONS

IMPORTANT. Here you need to confirm partner involvement. If the woman had agreed to her partner being interviewed, you must now ask her:

- **whether she still agrees**
- **whether she has asked her partner, and if so, whether he agreed**
- **if she still agrees but has not yet asked him, whether she can do so.**

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INSTRUCTIONS

1. **THIS INTERVIEW IS TO BE CONDUCTED WITH MALE PARTNERS OF WOMEN WHO HAVE AGREED TO THIS AND WHO HAVE OBTAINED AGREEMENT FROM THESE PARTNERS.**
2. **IT IS LINKED TO THE WOMAN'S IDI, CRF AND CD, SO BEFORE DOING THIS INTERVIEW YOU MUST MAKE SURE THAT THE WOMAN HAS INFORMED HER PARTNER THAT SHE HAS BEEN KEEPING A CD AND THAT THE INTERVIEWER WILL ALREADY HAVE KNOWLEDGE ABOUT THEIR SEXUAL BEHAVIOUR, CONDOM USE, ETC.**
3. **YOU MUST ALSO MAKE SURE THAT YOU DO NOT REVEAL ANY INFORMATION THAT THE WOMAN MAY NOT WANT HER PARTNER TO KNOW ABOUT (E.G. REGARDING EXTRAMARITAL PARTNERS). IF IN DOUBT, CHECK THIS WITH THE WOMAN BEFORE INTERVIEWING HER PARTNER.**
4. If they had sex during the week before her clinic visit (i.e. the period covered by question 6 on the long CRF), discuss the topics below in relation to that week. If they did not have sex in that week, then ask him about the four weeks before her clinic visit (i.e. the period covered by question 7 on the long CRF). You will have to adjust some of the questions depending on whether they sex in the last week or the last four weeks (i.e. whether she filled in Q6 or Q7 on the sexual behaviour CRF).
5. **MAKE SURE THAT THE PERIOD YOU DISCUSS WITH THE PARTICIPANT MATCHES THE PERIOD COVERED ON HIS PARTNER'S LAST CRF.**
6. Explain that you want to discuss some of the topics already discussed with his partner, but that you want his views as well.
7. There are two levels of questions:

   # **Research questions: the questions that we as MDP researchers want to get answers to.**

   Interview questions: the questions that you as interviewer could ask respondents in order to get answers to the research questions.
8. *Instructions/suggestions to interviewer are in italics.*
9. The interview schedule is divided into three columns.
   - **The left-hand column** contains the research questions, interview questions and instructions. The interview questions are suggestions for getting answers to the research questions. Because the interview is open and in-depth, much of this will be improvised and depend on how the interview actually goes in practice.
   - **The middle column** is for questions for which there is likely to be a yes/no answer, or similar simple answer.
   - **The right-hand column** is for summarising the answers. These should be summaries of the research question, **NOT** of the individual interview questions. These summaries should be more than just yes/no, but not longer than a few sentences of bullet points. They do not need to be detailed, as we have the details on the tape. The summaries and yes/no answers can be filled during the interview, or immediately after.
10. The interview should be tape-recorded if the participant agrees.

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GEL ACCEPTABILITY

1. Is the gel generally acceptable to him? *→Get the respondent to talk about his experience with the gel. You should cover the following points:* • **What do you think of the gel? Do you like it? Why/why not? What do you like/not like about it? Have you experienced any problems using the gel? If so, which?** • **Have you noticed any symptoms (e.g. irritation) that you associate with the gel? If so, tell me about them.** • **Does using the gel have any effect on your sexual enjoyment? If so, what kind of effect? Does this relate to dry/wet sex?** • **Have you told anyone about your partner participating in the study (friends, relatives); and if so, what was their reaction?** • **What was your reaction when you first heard about the study and the gel? How did you respond to your partner when she told you?**	Yes ☐ No ☐	MAIN REASONS
2. Was the gel acceptable to his partner? *→ Get the respondent to tell you about how he thinks his partner experienced the gel. You should cover the following points:* • **What does your partner think of the gel? Does she like it? Why/why not? What does she like/not like about it? Has she had any problems using the gel? If so, tell me about them.** • **Do you think she has had any symptoms (e.g. irritation) that she associated with the gel? Tell me about them.** • **Do you think the gel affects your partner's enjoyment of sex; and if so how? Does this relate to dry/wet sex?**	Yes ☐ No ☐	

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐ ID:☐☐

GEL AND CONDOM USE

3. How frequently and consistently did his partner use the gel and condoms during the week/four weeks before her last clinic visit? And what were her reasons for this behaviour? *→Get the respondent to talk about sex, gel and condom use in the last week.* • **How often did you have sex with your partner in the week/4 weeks before her last clinic visit?** • **Did your partner use gel when you had sex together?** • **If so how often? If not, why not?** • **Did you use a condom in the last week/four weeks before the last clinic visit?** • **If so how often? If not, why not?** • **How frequently did you use both condom and gel together?** • **How often did you have sex without using either condom or gel?** • **If she didn't always use the gel, why not?** • **How accurately do you think you were able to answer these questions?**	No. of sex acts ☐☐* No. of times BOTH gel & condom used ☐☐* No. of times ONLY gel used ☐☐ No. of times ONLY condom used ☐☐ No. of times NOTHING used ☐☐ **NB If these numbers are not the same, then you should note reasons in the column on the right*	MAIN REASONS FOR NOT USING GEL MAIN REASONS FOR NOT USING CONDOM

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐☐ ID:☐☐

4. Was reporting of gel and condom use consistent between what he told you and what his partner reported? *→Compare what he has just told you with what his partner answered. If there are any discrepancies, explore the reasons for these.*	Generally consistent ☐ Some inconsistency ☐ Major inconsistency ☐	TYPE OF INCONSISTENCY MAIN REASONS FOR INCONSISTENCY

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐☐ ID: ☐☐

PARTNER INVOLVEMENT

5. What was the nature and extent of his involvement? • **What do you think about women involving their partners in decisions about using such products? Is this good or bad? Do you think that men should always be involved? To what extent?** • **Do you and your partner discuss things relating to sex, such as whether to use a condom? If not, why not? If so, tell me how that works.** • **When did your partner tell you that she was using the gel?** • **How did you respond when she told you?** • **Did you support her or did you disagree?** • **Do you influence whether/how the gel and condoms are used?**	**Involved?** **Yes** ☐ **No** ☐	SUMMARY

Site _____ Interviewer _____ Date: ☐☐/☐☐/☐☐☐☐ Screening number: ☐☐☐☐☐☐☐☐ ID: ☐☐

SEXUAL PRACTICES

6. Did they have sex while his partner was menstruating during the 4 weeks prior to her last clinic visit? • **Is it common to have sex during menstruation?** • **Do you do this?** • **If so, did you do this in the last week/four weeks before the last clinic visit?**	**Yes** ☐ **No** ☐	SUMMARY
7. Did they have anal sex during the 4 weeks prior to her last clinic visit, and if so, did they use a condom? → *Tell the respondent that some people practise anal sex.* • **Do you think that it occurs in this community?** • **Do you ever practise anal sex? If so, have you done so during the four weeks before your partner's last clinic visit?** → *Compare this to the data from the partner and probe about any inconsistencies.*	**Anal sex** **Yes** ☐ **No** ☐ **Condom** **Yes** ☐ **No** ☐	SUMMARY

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DIARY ACCEPTABILITY

8. Are the coital diaries acceptable and feasible? • **What do you think of your partner keeping a CD? Is this acceptable? If not, why not? (Probe to find out whether he finds this threatening)** • **What did you think when you first heard that your partner was keeping/going to keep a CD? How did you respond?** • **Do you think your partner entered all sex acts, and details of gel and condom use in the CD? How accurate do you think the diary data is?** • **If she did not enter everything, or did not enter accurately, why not?**	**Yes** ☐ **No** ☐	SUMMARY

CONSENT AND INFORMATION PROCEDURE

→Here you should explore how much the respondent passed on to her partner about the informed consent process, in particular:		

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9. Does he/his partner know that the gel may not prevent HIV/STD transmission or pregnancy? • **Why did your partner agree to participate in this study?** • **What do you think the gel is for? Why is it being tested?** • **Do you think it protects your partner or yourself in any way against HIV or other diseases?** • **If so, how/to what extent?** • **Do you think your partner can become pregnant while using the gel?** *→ If he knows that the gel may not protect against HIV and pregnancy:* • **How did you find out that the gel may not protect against HIV and pregnancy?**	**Yes** ☐ **No** ☐	
10. Does he/his partner know that that the correct and consistent use of condoms protects against HIV & STDs? • **What sort of things can you do to prevent yourself getting infected with HIV?** • **Do you think that condoms protect against HIV?**	**Yes** ☐ **No** ☐	SUMMARY

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11. Have they been using condoms more or less frequently compared to before they used gel? • When you think about the period before you started using the gel, would you say that you used condoms more or less than you do now? • What are the reasons for this?	**More** ☐ **Less** ☐ **Same** ☐	REASONS

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INSTRUCTIONS

1. This FGD covers the same topics as the IDI. It is intended to collect more general information on these topics from a wider group of trial participants who are not being interviewed.
2. Explain that you want to discuss some of the topics already covered individually in the CRF, but that you want to discuss them more informally and get the views of women more generally.
3. The FGD should be tape-recorded if the participants agree.
4. There are two levels of questions:

   # Research questions: the questions that we as MDP researchers want to get answers to.

   Interview questions: the questions that you as interviewer could ask respondents in order to get answers the research questions.

5. *Instructions/suggestions to interviewer are in italics.*
6. The FGD guide is divided into three columns.
   - **The left-hand column** contains the research questions, FGD questions and instructions. The FGD questions are suggestions for getting the discussion going. Much will depend on how the discussion develops, and the facilitator will have to ensure that at the end the research questions have been answered.
   - **The middle column** is for questions for which there is likely to be consensus and a clear response from the group.
   - **The right-hand column** is for summarising the themes. These should be summaries of the general issues raised in connection with the research question, **NOT** responses of individual women in response to particular points or questions. These summaries should be more than just yes/no, but not longer than a few sentences of bullet points. They do not need to be detailed, as we have the details on the tape. The summaries and yes/no answers can be filled during the FGD by the assistant.

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GEL ACCEPTABILITY

1. Was the gel generally acceptable? *→Get the participants discuss their experiences with the gel. You should cover the following points:* • **What do they think of the gel? What do they like and what don't they like? Reasons? What sort of problems have arisen from using the gel (e.g. symptoms, inconvenience of use, problems with partners)?** • **Does using the gel affect on sexual enjoyment. If so, how?** • **What do male partners think about the gel?** • **Where do they store the gel? What problems have they encountered relating to storage?**	**Yes** ☐ **No** ☐	MAIN REASONS FOR AND AGAINST

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: ☐☐/☐☐/☐☐☐☐ No. ☐☐

GEL AND CONDOM USE

2. How frequently do they use gel and condoms when having sex. What are the reasons? *→Get the participants to discuss the use of gel and condoms, focusing on:* • **Do they always use both gel and condom? If not get them to discuss the reasons.** • **What role do partners play in this?**	Generally use both ☐ Generally use only gel ☐ generally use only condom ☐ Generally use neither ☐	MAIN REASONS FOR USING GEL MAIN REASONS FOR **NOT** USING GEL MAIN REASONS FOR USING CONDOM MAIN REASONS FOR **NOT** USING CONDOM

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: ☐☐/☐☐/☐☐☐☐ No. ☐☐

PARTNERS

3. What is the nature and extent of partner involvement? • **What do they think about women involving their partners in decisions about using such products? Is this good or bad?** • **Do they discuss things relating to sex, such as whether to use a condom with their partners? Explore reasons.** • **Have they told their partners that they are participating in the trial/using the gel? Explore reasons.** • **How did their partners respond? How supportive have they been?** • **To what extent do partners influence whether/how the gel and condoms were used? What do they think about this influence?** • **Have they told their partners that they are keeping a coital diary? Explore the reasons. How have partners responded to this?**	Partners generally supportive? Yes ☐ No ☐	SUMMARY

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VAGINAL PRACTICES

4. What kind of post-sex vaginal washing practices do they engage in? → *You could introduce this by getting the participants to discuss hygiene practices relating to sex in the community generally. Then get them to focus on their own practices such as washing inside the vagina after sex. Probe for details about frequency and when exactly they do this.*	**Are practices common?** **Yes** ☐ **No** ☐	KINDS OF PRACTICES
5. Do they insert anything into the vagina (excluding water/fingers/tampon)? → *You could introduce this by getting the participants to discuss whether the insertion of herbs, etc. is common in their community. Then get them to focus on their own practices such as inserting herbs, etc. in relation to dry/wet sex, etc.*	**Do they generally insert things?** **Yes** ☐ **No**	SUMMARY

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: □□/□□/□□□□ No. □□

	□	

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SEXUAL PRACTICES

6. Do they sometimes have sex while menstruating? How common is this? → *Find out whether it is common for women to have sex during menstruation in this community. Probe to find out whether they do this, and if so try to get some idea of frequency. If it is not common, what are the reasons?* → *The probing will have to be adjusted to what is locally considered acceptable.*	**Common among FGD participants** **Yes** ☐ **No** ☐	SUMMARY
7. Do they ever have anal sex? → *Find out whether anal sex is common in this community. Probe to find out whether they ever do this, and if so try to get some idea of frequency. If it occurs, why?* → *The probing will have to be adjusted to what is locally considered acceptable.*	**Does occur among FGD participants** **Yes** ☐ **No**	SUMMARY

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	□	

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CONSENT AND INFORMATION PROCEDURE

8. How much have they retained from the informed consent process, in particular the three critical points that were emphasised during screening: *→ You will need to probe this by asking them open questions*		
9. Do they know that the gel may not prevent HIV transmission or pregnancy? • **Why are they participating in the trial?** *→ Here you should also probe to find out whether the reimbursement is a motive for participation.* • **What do they think about the gel? What do they think the gel is for? Why is it being tested?** • **Do they think it protects against HIV or other diseases? How /to what extent?** • **Do they think the gel also prevents pregnancy?**	**All** ☐ **Some** ☐ **None** ☐	SUMMARY
10. Do they know that that the correct and consistent use of condoms protects against HIV? • **What sort of things do they think they can do to prevent themselves getting infected with HIV?**	**All** ☐ **Some** ☐ **None**	SUMMARY

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• **Do they think that condoms protect against HIV?**	☐	

11. Did they know that participation in the study would involve answering sensitive questions about sexual activity, having an HIV test, and being told her HIV test result? • **At the beginning, what were they told about what they would have to do in the study?** • **Did the HIV test come as a surprise?** • **Were they surprised when they were asked about sexual partners and condom use?**	**All** ☐ **Some** ☐ **None** ☐	SUMMARY

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: ☐☐/☐☐/☐☐☐☐ No. ☐☐

ACCEPTABILITY OF PROCEDURES

12. How acceptable are the trial procedures generally? • **Do they have any problems with the gel?** • **Have they experienced any side effects that they associate with the gel?** • **What do they think of the clinical procedures (HIV test, medical exams)?** • **Is the study too demanding in terms of time?** • **Are there family demands, work/employer demands, partner demands?** • **Is it difficult keeping appointments (time and day of the week, accessibility from home/ work, travel difficulties, change in location of accommodation or work)? If so, probe.** • **What do they think about the way the data are collected?** • **How accurately do they think they were able to answer the gel, condom and sexual behaviour questions in the CRF?** • **Have they experienced any discrimination because of participating in this study? If so, how?** • **What do they like and dislike about this study?**	Generally acceptable ☐ Partly acceptable ☐ Not acceptable ☐	<u>SUMMARY</u>

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INSTRUCTIONS

1. This FGD is intended to collect more general information about the trial from community members who are not participating in the trial.
2. Explain that you want to get their opinion on a study that is being carried out in their community.
3. The FGD should be tape-recorded if the participants agree.
4. There are two levels of questions:

   # **Research questions: the questions that we as MDP researchers want to get answers to.**

   Interview questions: the questions that you as interviewer could ask respondents in order to get answers to the research questions.
5. *Instructions/suggestions to interviewer are in italics.*
6. The FGD guide is divided into three columns.
   - **The left-hand column** contains the research questions, FGD questions and instructions. Much will depend on how the discussion develops, and the facilitator will have to ensure that at the end the research questions have been answered.
   - **The middle column** is for questions for which there is likely to be consensus and a clear response from the group.
   - **The right-hand column** is for summarising the themes. These should be summaries of the general issues raised in connection with the research question and the bullet-point questions in the left-hand column, **NOT** responses of individual participants in response to particular points or questions. These summaries should be more than just yes/no, but not longer than a few sentences of bullet points. They do not need to be detailed, as we have the details on the tape. The summaries and yes/no answers can be filled during the FGD by the assistant.

7. This guide can be used for community FGDs with both men and women

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: ☐☐/☐☐/☐☐☐☐ M/W No. ☐☐

MDP TRIAL

1. Have they heard about the MDP trial? If so what have they heard? What do they think about the trial? Are they generally positive or negative about it? *→Ask the participants whether they have heard of MDP? Get them to tell you what they have heard, and to discuss their experiences and opinions relating to MDP. In particular probe about rumours that may be circulating in the community about the trial.* *→ If they do not know about important aspects of the trial or the product, you may have to inform them and then probe for their opinions. How you do this will depend on the level of knowledge and the direction the discussion takes, and will have to be improvised to a large extent.* • **How much to they know about the trial (i.e. as a research project)? Why is this research being conducted in their community? What do they think about research being carried out in their community? Is this good or bad? For what reasons?**	Most heard of trial ☐ Some heard of trial ☐ No one heard of trial ☐	<u>SUMMARY</u>

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: □□/□□/□□□□ M/W No. □□

• **Have they heard complaints or rumours about the study? If so, probe. Are there any other rumours relating to research or health issues? If so, probe.** • **Why do they think some women are participating in this trial and others are not?** • **Are they generally positive or negative about the trial?**	Generally positive □ Generally neutral □ Generally negative □ Mixed views □	

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THE GEL

What do they think of the gel? • **What do they think of the gel? How much do they know about it? What do they think it is for?** • **Do they think the gel protects against HIV? Explore the reasons for the response.** • **Do they think it prevents pregnancy?** • **Do they think that women should keep its use secret, or should they tell their partners? What are the reasons?** • **Do they see HIV/AIDS as a problem in their community? Do they think a product like this will help to reduce HIV in their community? If not, how can HIV be reduced?** • **Probe to find out their views on condoms. Do they protect against HIV? If not, why not?**	Generally positive ☐ Generally neutral ☐ Generally negative ☐ Mixed views ☐	

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: □□/□□/□□□□ M/W No. □□

PARTNER INVOLVEMENT

2. What are participants' views on women involving their partners in decisions relating to sexual matters? • **What do they think about women involving their partners in decisions about sexual issues generally and using such products in particular? Is this good or bad?** • **Do they discuss things relating to sex, such as whether to use a condom with their partners? Explore reasons. Is this good or bad?** • **To what extent do partners influence whether/how condoms are used? What do they think about this influence.**	Involvement good □ Involvement bad □ Mixed views □	SUMMARY

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: □□/□□/□□□□ M/W No. □□

VAGINAL PRACTICES

3. Are post-sex vaginal washing practices common in this community? What kind of practices are there? → *You could introduce the topic by explaining that this is important in relation to testing the gel. You may need to give some more explanation about the trial here. You could start by getting them to discuss general hygiene practices in the community. Then get them to focus on practices relating to sex. Probe for details about frequency and when exactly they do this.*	**Are practices common?** **Yes** □ **No** □	SUMMARY
4. How common is it for women to insert anything into the vagina (excluding water/fingers/tampon)? → *You could introduce this by getting the participants to discuss whether the insertion of herbs, etc. is common in their community (e.g. in relation to dry/wet sex, etc.).*	**Do they generally insert things?** **Yes** □ **No** □	SUMMARY

Site _____ Facilitator _____ Note taker: _____ Venue: _____ Date: □□/□□/□□□□ M/W No. □□

SEXUAL PRACTICES

5. How common is sex during menstruation in this community? → *Find out whether it is common for women to have sex during menstruation in this community. Probe to get some idea of frequency. If it is not common, what are the reasons?* → *The probing will have to be adjusted to what is locally considered acceptable.*	**Common** □ **Uncommon** □ **Doesn't happen** □	SUMMARY
6. How common is anal sex in this community? → *Find out whether anal sex occurs, and if so whether it is common in this community. Probe to find out how common. Do certain kinds of people engage in anal sex? Probe to find out which kinds of people.* → *The probing will have to be adjusted to what is locally considered acceptable.*	**Common** □ **Uncommon** □ **Doesn't happen** □	SUMMARY

Appendix F: Case report forms (CRFs)

Site Name: Africa Centre - South Africa		Date of visit: (DD/MM/YYYY)
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

Interviewer: read the questions to the volunteers verbatim and allocate the correct answer from the selection, unless it is indicated that you read out each answer to the volunteer as well. Boxed type is instructions to the interviewer. Type in italics is to be read to the volunteer.

Section 1: Personal details

1 Usuku lokuzalwa
Date of birth ☐☐/☐☐/☐☐☐☐
DD/MM/YYYY

Noma iminyaka (uma usuku lokuzalwa lungaziwa)
Or age (if DOB not known) ☐☐

2 Yiluphi ulimi olukhulumayo ekhaya?
What language do you speak at home? _____

3 Ukhonza kuliphi isonto/Iyiphi inkonzo ongaphansi kwayo?
What religion do you belong to?

- UngumKristu (oyiProtestani) Christian (protestant) ☐
- UngumKristu (oyiKhatholika) Christian (catholic) ☐
- UyiSeventh day Adventist Seventh day adventist ☐
- UyiMuslim Muslim ☐
- UyiSayoni Zionist ☐
- KoFakazi bakaJehova Jehovah's witness ☐
- Okunye Other ☐
- UngumKristu (ongachaziwe) Christian (unspecified) ☐
- Inkolo yesintu Traditional African ☐
- UngumKristu ozelwe kabusha Born again Christian ☐
- UyiHindu Hindu ☐
- KwaShembe Shembe ☐
- Akukho None ☐
- Chaza (Specify)_____ _____

Signature	Print Name	Date

Site Name: Africa Centre - South Africa		Date of visit: (DD/MM/YYYY)
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Section 2: Education and sources of income

"Manje ngizokubuza imibuzo ethize emayelana nezinga lemfundo yakho nokuthi imali engena emndenini wakho itholakala kanjani. Lolulwazi aluyukusetshenziselwa okunye ngaphandle kokuba lube nomthelela ekucubunguleni imiphumela yalolucwaningo. Sifuna ukubona ukuthi abantu abayingxenye yalolucwaningo kulelizwe bayafana yini nabangenele lolucwaningo kwamanye amazwe."

"I am now going to ask you some questions about your level of education and what sources of income there are coming into your household. This information will not be used for any other reason than to contribute to the results of the study. We want to see if people taking part in the study in this country are similar to people taking part in other countries."

4 Yiliphi izinga eliphezulu lemfundo owalithola?
What is the highest level of education you gained?

- Alikho (None) ☐
- Ngaya esikoleni kodwa angiqedanga izinga eliphansi (Went to school but did not complete primary) ☐
- Ngaqeda izinga eliphansi (Completed primary) ☐
- Angiqedanga eSekhondari (Incomplete secondary) ☐
- Ngaqeda eSekhondari (Completed secondary) ☐
- Angiqedanga esikhungweni semfundo ephakeme (Incomplete tertiary) ☐
- Ngaqeda imfundo ephakeme (Completed tertiary) ☐
- Angithandi ukuphendula (Refused to answer) ☐
- Angiqedanga esikhungweni semfundo ephakeme kodwa ngafundela umsebenzi (Incomplete secondary but some vocational training) ☐

5a Ungasichaza kanjani isimo sakho somsebenzi?
How would you define your employment status?

- Ngiqashwe ngokugcwele (Employed full time) ☐ →Q. 5c
- Ngibambe itoho (Employed part time) ☐ →Q. 5c
- Ngingumfundi (Student/scholar) ☐
- Ngisafuna umsebenzi (Work seeker) ☐
- Angivumi ukuphendula (Declined to answer) ☐
- Angiqashiwe (Unemployed) ☐
- Ngihlala ekhaya (Housewife) ☐
- Sengampesha (Retired) ☐
- Okunye (Other) ☐ Chaza (Specify)_____

5b Ngonyaka odlule, ukhona umsebenzi owawuwenza?
During the past year did you do any kind of work?

- Yebo (Yes) ☐
- Cha (No) ☐ →Q. 6

Signature	Print Name	Date

Site Name: Africa Centre - South Africa		Date of visit: (DD/MM/YYYY)
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5c Chaza kafishane ngomsebenzi okuyiwona owenzayo noma owawuwenza.
Describe briefly the main type of work or job that you do/did.
Interviewer tick the answer most relevant to the description – make sure to only tick other if the participant's work does not fit into any of the categories.

Umsebenzi ongafundelwa wamandla Unskilled manual	☐	Ukudayisa/ukwenzela abanye umsebenzi othile Sales/services	☐
Ukulima izitshalo Crop farming	☐	Umsebenzi wasekhaya/endlini Household/domestic	☐
Ukudoba Fishing	☐	Ukufuya Livestock rearing	☐
		Ukukhiqiza izinto Manufacturing	☐
Okunye Other	☐	Chaza (Specify)_____ _____	

5d Ikuphi kulokhu okulandelayo okuwuchaza kangcono umsebenzi wakho?
Which of the following best describes your employment?

Ngihola njalo Regular paid	☐	Ngiyazisebenza Self-employed	☐
Ngiyitoho Casual labourer	☐	Ngihola ngesitokwe Paid per piece	☐
Angiholi nhlobo Unpaid	☐	Okunye Other	☐
		Chaza (Specify)_____ _____	

5e Wenzeka/wawenzeka kuphi lomsebenz? [beka uphawu kukho konke okuyikho]
Where did/does this work take place? [tick all that apply]

Ekhaya Family's dwelling	☐	Emzini womqashi Employer's house	☐
Emgwaqweni On the street	☐	Esitolo/emakethe/endlwaneni yokuthengisela Shop/market/kiosk	☐
Efemini Industry/factory	☐	Emahlathini/epulazini/ engadini Plantation/farm/garden	☐
Kwezokwakha/ezimayini/ enkwalini Construction/mine/quarrying sites	☐	Okunye Other	☐
		Chaza (Specify)_____ _____	

Signature	Print Name	Date

Site Name: Africa Centre - South Africa		Date of visit: (DD/MM/YYYY)
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Section 3: Housing and household

"Manje sengizokubuza imibuzo ethile mayelana nomndeni wakho. Uma sikhuluma ngomndeni sisho izindlu uqobo lwazo, nabantu bonke abayingxenye yalomuzi, kubala wena nabo bonke abahlala kuwo (abomndeni nezihlobo). Kungaba yindlu eyodwa noma izindlu eziningi kodwa kungezomndeni owodwa, noma ngabe lezizindlu zingasondelene. Umndeni wakhiwe iqembu labantu, imvamisa abayizihlobo, abahlanganyelayo ekucazeleni abanakho futhi bavame nokudla ndawonye".

"I am now going to ask you some questions relating to your household. By household we mean the physical and social unit in which you live (either by yourself or with family and relatives). This could be a house or a compound consisting of different buildings that belong together, even though they may not be very close together. A household consists of a group of people, usually relatives, who share resources and regularly share meals."

6 Ubani ongathi uyinhloko yomndeni?
Who would you say is the head of your household?

- Yimina (Self) ☐ →Q. 8
- Uphathina (Partner) ☐
- Ingane yakwethu (Sibling) ☐ →Q. 7a
- Ingane (Child) ☐
- Umakoti/umkhwenyana (Daughter/Son in law) ☐ →Q. 7a
- Umzali (Parent) ☐
- Umamezala/ubabezala (Mother/Father in law) ☐ →Q. 7a
- Ezinye izihlobo (Other relative) ☐
- Umshana (wesilisa/wesi fazane) (Niece/Nephew) ☐ →Q. 7a
- Omunye (Other) ☐ Chaza (Specify)_____ _____ →Q. 7a

We would like to ask you some questions about the head of the household you have just identified.

7a Ungasichaza kanjani isimo somsebenzi wenhloko yomndeni?
How would you define the head of household's employment status?

- Uqashwe ngokugcwele (Employed full time) ☐ →Q. 7c
- Uyitoho (Employed part time) ☐ →Q. 7c
- Umfundi (Student/scholar) ☐
- Ufuna umsebenzi (Work seeker) ☐
- Uyenqaba ukuphendula (Declined to answer) ☐
- Akaqashiwe (Unemployed) ☐
- Owesifazane ongasebenzi (Housewife) ☐
- Usewampesha (Retired) ☐
- Angazi (Don't know) ☐
- Okunye (Other) ☐ Chaza (Specify)_____ _____ _____

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7b Onyakeni odlule ngabe inhloko yekhaya ukhona yini umsebenzi eke yawenza?
During the past year did the head of household do any kind of work?

Yebo (Yes) ☐
Cha (No) ☐ →Q. 8
Angazi (Don't know) ☐ →Q. 8

7c Chaza kafishane okuyiwona msebenzi obalulekile inhloko yekhaya evame ukuwenza noma eyake yawenza.
Describe briefly the main type of work or job the head of household does/did.
Interviewer tick the answer most relevant to the description – make sure to only tick ' other' if the work does not fit into any of the categories

Umsebenzi ongafundelwa wamandla (Unskilled manual) ☐
Ukulima izitshalo (Crop farming) ☐
Ukudoba (Fishing) ☐
Angazi (Don't know) ☐
Okunye (Other) ☐ Chaza (Specify)_____

Ukudayisa/ukwenzela abanye umsebenzi othile (Sales/services) ☐
Umsebenzi wasekhaya/endlini (Household/domestic) ☐
Ukufuya (Livestock rearing) ☐
Ukukhiqiza izinto (Manufacturing) ☐

7d Ikuphi kulokhu okulandelayo okuwuchaza kangcono umsebenzi owenziwa inhloko yalomuzi?
Which of the following best describes the head of household's employment?

Ukukhokhelwa ngazozonke izikhathi (Regular paid) ☐
Itoho (Casual labourer) ☐
Akakhokhelwa (Unpaid) ☐
Okunye (Other) ☐ Chaza (Specify)_____

Uyazisebenza (Self-employed) ☐
Ukhokhelwa ngesitokwe (Paid per piece) ☐
Angazi (Don't know) ☐

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7e Ikuphi lapho wawuwenzela khona noma lapho osebenzela khona? [beka uphawu kukho konke okuyikhona]
Where did/does this work take place? [tick all that apply]

- Endlini yasekhaya (Family's dwelling) ☐
- Emgwaqweni (On the street) ☐
- Embonini/efemini (Industry/factory) ☐
- Ezindaweni zezinkontileka/emayini/ Enkwalini (Construction/mine/quarrying sites) ☐
- Okunye (Other) ☐
- Emzini womqashi (Employer's house) ☐
- Esitolo/emakethe/endaweni encane yokudayisela (Shop/market/kiosk) ☐
- Ehlathini lokutshalwa/ epulazini/engadini (Plantation/farm/garden) ☐
- Angazi (Don't know) ☐
- Chaza (Specify)_____ _____

8 Zingaki izindlu emzini wakho ezisetshenziselwa ukulala?
How many rooms in your household are used for sleeping?

Yisho inombolo yazo (List number) ☐☐

Noma ubeke uphawu lapha uma ungafuni ukuphendula (or tick if declined to answer) ☐

9 Bangaki abantu abalala emzini wakho?
How many people usually sleep in your household?

Isho inombolo yabo (List number) ☐☐

Noma ubeke uphawu lapha uma ungafuni ukuphendula (or tick if declined to answer) ☐

10 Uhlobo luni lomuzi ohlala kulo?
What type of housing do you stay in?

- Indlu osayikhokhela ibhondi (Bonded house) ☐
- Efulethini osalikhokhela ibhondi (Bonded flat) ☐
- Ekamelweni elingaphakathi noma elingaphandle kwendlu (Room inside/outside house) ☐
- Okunye (Other) ☐
- Endlini yomkhandlu wedolobha (Council house) ☐
- Endlini okhokha kuyo irenti (Rented house) ☐
- Efulethini okhokha kulo irenti (Rented flat) ☐
- Emjondolo (Informal dwelling) ☐
- Chaza (Specify)_____ _____

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10a Izindonga zendlu yakho zakhiwe ngani?
What are your walls made of?

- ☐ Ngezitini zikasimende — Cement brick
- ☐ Ngothayela — Iron sheets
- ☐ Ngamapulangwe — Wood
- ☐ Amatshe nosimende — Stones and cement
- ☐ Okunye — Other
- ☐ Ngamasoyi — Mud brick
- ☐ Ngowatela nokuphahlekwa/ngezintingo — Wattle and daub/mud and sticks
- ☐ Notshani — Grass
- ☐ Ngama-prefab — Prefabricated
- ☐ Amatshe nodaka — Stones and mud

Chaza (Specify)_____
_____

10b Lwakhiwe ngani uphahla lwakho?
What is your roof made of?

- ☐ Ukhethe — Zinc/Iron sheets
- ☐ Ngama-tiles — Tiles
- ☐ Ngo-asbestos — Asbestos
- ☐ Okunye — Other
- ☐ Utshani/umhlanga/amakhasi kabanana /ngoqwalo — Grass/reeds/banana leaves/bamboo

Chaza (Specify)_____
_____

10c Lakhiwe ngani iphansi?
What is your floor made of?

- ☐ Amapulangwe angenziwe lutho — Bare wood planks
- ☐ Parquet/ipulangwe elipholishwayo — Parquet/polished wood/wood tiles
- ☐ Umata oyivinyl/imicwana yeasphalt — Vinyl/asphalt strips
- ☐ U- carpet — Carpet
- ☐ Umhlabathi/udaka/isihlabathi/ ubulongwe — Earth/mud/sand/dung
- ☐ Usemende/ukhonkolo/isitini — Cement/concrete/brick
- ☐ Amatiles ayiceramic/iterrazo — Ceramic tiles/terrazo
- ☐ Okunye — Other

Chaza (Specify)_____
_____

11 Ikuphi lapho nivamise ukuthola khona amanzi okuphuza emndenini njengamanje?
What is currently the most often used source of drinking water in your household? _____

11a Ikuphi enikusebenzisa kakhulu ukwenza umlilo wokupheka?
What is the main fuel you use for cooking? _____

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12 Ubani ongumnikazi wendlu/wekhaya lapho uhlala khona?
Who owns the house/place that you live in?

- ☐ Uphathina — Partner
- ☐ Imina — Self
- ☐ Umnikazi ndawo ozimele — Private landlord
- ☐ Owakwethu — Sibling
- ☐ Umzali/abasemzini — Parent/parent-in-law
- ☐ Uhulumeni/umkhandlu — Government/council
- ☐ Esinye isihlobo — Other relative
- ☐ Uyenqaba ukuphendula — Declined to answer
- ☐ Inkampani — Company
- ☐ Okunye — Other: Chaza (Specify)_____

13 Umndeni wakho unakho yini lokhu okulandelayo: {beka uphawu olulodwa kulokho nalokho okuyimpendulo okusohlwini}
Does your household have: [tick one answer for each item]

Ugesi — Electricity	Yebo — Yes	☐	Cha — No	☐
Umsakazo — A radio	Yebo — Yes	☐	Cha — No	☐
Umabonakude — A television	Yebo — Yes	☐	Cha — No	☐
Ucingo — A telephone	Yebo — Yes	☐	Cha — No	☐
Isiqandisi/ifiliji — A refrigerator	Yebo — Yes	☐	Cha — No	☐
I-personal computer — A personal computer	Yebo — Yes	☐	Cha — No	☐
Umshini wokuwasha — A washing machine	Yebo — Yes	☐	Cha — No	☐

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14 Ukhona yini oyilungu lomndeni wakho onalokhu: [beka uphawu olulodwa kuleyo naleyo mpendulo] Does any member of you household own: [tick one answer for each item]

Ibhayisikili A bicycle	Yebo Yes	☐	Cha No	☐
Isithuthuthu /noma isikuta A motorcycle or motor scooter	Yebo Yes	☐	Cha No	☐
Imoto A car	Yebo Yes	☐	Cha No	☐
Imbongolo noma ihashi A donkey or horse	Yebo Yes	☐	Cha No	☐
Izimvu noma izinkomo Sheep or cattle	Yebo Yes	☐	Cha No	☐

Section 4- Access to resources

15 Kulezizinyanga eziyi-12 ezedlule, ngabe wena nanoma iliphi ilungu lomndeni wakho nike nanikezwa yini incwajana ngudokotela yokuyothenga umuthi awunqumileyo kodwa anangakwazi ukuwuthola ngoba ningakwazanga ukuwukhokhela?
In the last 12 months, have you or any member of your household been prescribed medicine that you didn't obtain because you couldn't pay for it?

Yebo Yes	☐
Cha No	☐
Uyenqaba ukuphendula Declined to answer	☐

16 Imali oyingenisayo emndenini ingakanani uma uyiqhathanisa naleyo umyeni/uphathina wakho ayingenisayo?
How does the amount of money you bring into the household compare with what your husband/partner contributes?

N/A	☐
Ngingenisa imali enkulu kunaye I bring in more than him	☐
Ungenisa enkulu kuneyami He brings in more than me	☐
Singenisa imali ecishe ilingane We bring in about the same	☐

Interviewer code: ☐☐☐

Comments_____

_____

Signature	Print Name	Date

Site Name: AFRICA CENTRE – SOUTH AFRICA		Nate of Visit (DD /MM / YYYY): ☐☐/☐☐/☐☐☐☐
Screening Number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	

Interviewer: read the questions to the volunteer verbatim and allocate the correct answer from the selection, unless it is indicated that you read out each answer to the volunteer as well. Boxed type is the instructions to the interviewer. Type in italics is to be read to the volunteer.

Sicela uphendule lemibuzo ngokucophelela ngoba izimpendulo zayo zibaluleke kakhulu emiphumeleni yalolucwaningo. Khumbula ukuthi ulwazi osinikeza lona luzogcinwa luyimfihlo futhi luyosetshenziselwa kuphela izinjongo eziqondene nalolucwaningo.

Please try to answer these questions accurately as the answers to them are very important to the outcome of the study. Remember that the information you give us is confidential and will only be used for the purposes of this study.

Section 1: Family planning

1 Njengamanje zikhona yini izindlela zokuhlela umndeni ozisebenzisayo?
Are you currently using any method of family planning?

Yebo Yes ☐ → Q. 1a
Cha No ☐ → Q. 1b

1a Uma kunguyebo,yiziphi kulezizindlela ezilandelayo ozisebenzisayo?
If yes, which of the following methods are you using?
[Tick all that apply]

Pills	☐	Foam/jelly/spermicide	☐ → Q. 2
Diaphragm	☐	Injectable Nur-Isterate	☐ → Q. 2
Injectable Depo-Provera	☐	Injectable other (specify below if possible)	☐ → Q. 2
IUCD	☐	Norplant implant	☐ → Q. 2
Condom (male or female)	☐	Traditional vaginal	☐ → Q. 2
Traditional oral	☐	Traditional other (specify below if possible)	☐ → Q. 2
Sterilisation	☐		→ Q. 2
Other	☐	Specify_____	

1b Uma kungu cha, kungani ingekho indlela oyisebenzisayo yokuhlela umndeni?
If no, why are you not using any method of family planning?

Uyancelisa Breastfeeding ☐

Signature:	Print Name:	Date:

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Ufuna ukukhulelwa ☐
Wanting to become pregnant

Usukhulile awusayi esikhathini ☐
Menopause

Okunye ☐
Other

Awusayi ocansini ☐
Not sexually active

Sewavala inzalo (wena noma uphathina wakho) ☐
Sterilised (participant or partner)

Chaza _____
Specify

2 Zingaki izinsuku esezedlulile kusukela osukwini lwakho lokuqala lokuya esikhathini kulokhu kuya kwakho esikhathini okwedlule? ☐☐
How many days ago was the first day of your last menstrual period?
[List number, 99 if more than 3 months or 00 if menstruating now]

2a Lokhukuya kwakho esikhathini kwakungesikhathi owawusilindele yini? ☐ Yebo Yes ☐ Cha No
Was this period when you expected it to be?

Section 2: Sexual activity and condom use

Interviewer: please spend sometime ensuring that the volunteer understands what is termed by a sex act: one sex act is "penetrative vaginal sex that may or may not end up with ejaculation."

Also- don't forget to probe for EXACT NUMBERS.

"Manje sengizokubuza mayelana nokwenza kwakho ucansi nokusebenzisa kwakho amakhondomu. Sicela uphendule ngokweqiniso ngoba izimpendulo zakho zibaluleke kakhulu emiphumeleni yalolucwaningo."

"I am now going to ask you about your sexual activity and condom use. Please answer accurately as the responses are very important to the study results."

3 Njengamanje unaye yini uphathina wesilisa oya naye ocansini? ☐ Yebo Yes ☐ Cha No → Q. 5
Do you currently have a male sexual partner?

Ensure that the volunteer understands what we mean by each category of partner.
1*) Long-term stable partners* include some/most of the following characteristics: official marriage, traditional marriage, bride price paid, man known and accepted by woman's family, have children together, live together, long-term relationship, man provides regular financial/material support, may be cohabiting or non-cohabiting.
2) *Other partners)* includes all partners who do not fit into the first category above.

Signature:	Print Name:	Date:

Site Name: AFRICA CENTRE – SOUTH AFRICA		Nate of Visit (DD /MM / YYYY): ☐☐/☐☐/☐☐☐☐
Screening Number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	

4 Luhloboluni lukaphathina onaye njengamanje?
What type of partner do you currently have?
[Tick all that apply]

- ☐ Osekuqhutshekwe isikhathi eside nizwana naye noma nabo (1 noma ngaphezulu)
  Long-term stable partner (1 or more)
- ☐ Ezinye izinhlobo zomaqondana(1 noma ngaphezulu)
  Long-term stable partner (1 or more)

5 Zingaki izinsuku ezedlulile ugcinile ukuya ocansini?
How many days ago did you last have sex?

- ☐ 1 (lokhu kumbandakanya izolo, yilobusuku bayizolo, nanamhlanje)
  1 (includes yesterday, last night and today)
- ☐ 2 (kuthangi)
  2 (the day before yesterday)
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ 1-4 amasonto
  1-4 weeks
- ☐ ngaphezu kwamasonto awu 4
  more than 4 weeks

6 Uyisebenzisile yini ikhondomu ngesikhathi ogcine ngaso ukwenza ucansi?
Did you use a condom the last time you had sex?

- ☐ Yebo
  Yes
- ☐ Cha
  No

7 Wawuneminyaka emingaki mhla uya ocansini okokuqala ngqa?
How old were you the first time you had sexual intercourse?

- ☐ Ngaphansi kweninyaka ewu 15
  Less than 15 years
- ☐ 15 iminyaka kuya ku 19 weminyaka
  15 to 19 years
- ☐ Iminyaka ewu 20 noma ngaphezulu
  20 years or older
- ☐ angikaze ngiye ocansini
  never had sexual intercourse
- ☐ Uyenqaba ukuphendula
  Declined to answer

Section 3: Pregnancy test

Signature:	Print Name:	Date:

Site Name: AFRICA CENTRE – SOUTH AFRICA		Nate of Visit (DD /MM / YYYY): □□/□□/□□□□
Screening Number: □□□□□□□	Initials: □□□	

8 Has urine sample been collected for pregnancy test?

Yes □

No □

8a Why not?

Not indicated in protocol schedule □

Not clinically indicated □

Not possible to obtain urine specimen □

Other □

(specify_____)

Interviewer code □□□

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

Interviewer: read the questions to the volunteers verbatim and allocate the correct answer from the selection, unless it is indicated that you read out each answer to the volunteer as well. Boxed type is instructions to the interviewer as well. Type in italics is to be read to the volunteer.

Sicela uzame ukuphendula lemibuzo ngokucophelela ngoba izimpendulo zayo zibaluleke kakhulu emiphumeleni yalolucwaningo. Khumbula ukuthi ulwazi osinikeza lona luzogcinwa luyimfihlo futhi luyosetshenziswa kuphela ngezinjongo eziqondene nalolucwaningo.

Please try to answer these questions accurately as the answers to them are very important to the outcome of the study. Remember that the information you give us is confidential and will only be used for the purposes of this study.

Section 1: Family planning

1 Njengamanje ikhona yini indlela yokuhlela umndeni oyisebenzisayo?
Are you currently using any method of family planning?

Yebo (Yes) ☐ → Q. 1a
Cha (No) ☐ → Q. 1b

1a Uma kungu yebo, yiziphi kulezizindlela ezilandelayo ozisebenzisayo?
If yes, which of the following methods are you using?
[Tick all that apply]

Pills	☐	Foam/jelly/spermicide	☐ → Q. 2
Diaphragm	☐	Injectable Nur-Isterate	☐ → Q. 2
Injectable Depo-Provera	☐	Injectable other (specify below if possible)	☐ → Q. 2
IUCD	☐	Norplant implant	☐ → Q. 2
Condom (male or female)	☐	Traditional vaginal	☐ → Q. 2
Traditional oral	☐	Traditional other (specify below if possible)	☐ → Q. 2
Sterilisation	☐		→ Q. 2
Other	☐	Specify_____ _____	

1b Uma kungu cha, kungani ingekho indlela oyisebenzisayo yokuhlela umndeni?
If no, why are you not using any method of family planning?

Uyancelisa (Breastfeeding) ☐

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

Ukufuna ukukhulelwa ☐
Wanting to become pregnant

Ukukhula angisayi esikhathini ☐
Menopause

Okunye ☐

Angisayi ocansini ☐
Not sexually active

Sengavala inzalo (wena noma umaqondana wakho) ☐
Sterilised (participant or partner)

Chaza_____
Specify

2 Zingaki izinsuku esezedlule emveni kosuku lwakho lokuqala lokuya esikhathini kulokhu kuya kwakho esikhathini okwedlule? ☐☐
How many days ago was the first day of your last menstrual period?
[List number, 99 if more than 3 months or 00 if menstruating now]

2a Lokhukuya kwakho esikhathini kwakungesikhathi owawusilindele yini? Yebo ☐
Was this period when you expected it to be? Yes

Cha ☐
No

Section 2: Sexual activity and condom use

Interviewer: please spend some time ensuring that the volunteer understands what is termed by a sex act: one sex act is "penetrative vaginal sex that may or may not end with ejaculation"

Also – don't forget to probe for EXACT NUMBERS

"Manje sengizokubuza mayelana nokwenza kwakho ucansi nokusebenzisa kwakho amakhondomu. Sicela uphendule ngokweqiniso ngoba izimpendulo zakho zibaluleke kakhulu emiphumeleni yalolucwaningo."

"I am now going to ask you about your sexual activity and condom use. Please answer accurately as the responses are very important to the study results."

3 Zingaki izinsuku ezedlulile wagcina ukwenza ucansi?
How many days ago did you last have sex?

1 (lokhu kuxuba izolo, yilobusuku bayizolo, nanamhlanje) ☐
1 (includes yesterday, last night and today)

2 (kuthangi) ☐
2 (the day before yesterday)

→ Q. 4

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

3 ☐	4 ☐	→ Q. 4
5 ☐	6 ☐	→ Q. 4
7 ☐		→ Q. 4
	1-4 amasonto 1-4 weeks ☐	→ Q. 7
	Ngaphezu kwamasonto awu 4 More than 4 weeks ☐	→ Q. 9

4	Zingaki izikhathi owenze ngazo ucansi esontweni eledlulile? How many times have you had sex in the last week?	[list number of time or 77 if unsure]	☐☐
5	Bangaki abantu abehlukene owenze nabo ucansi kulelisonto eledlulile? How many different people have you had sex with in the last week?	[list number or 77 if unsure]	☐☐

Ensure that the volunteer understands what we mean by each category of partner.
1*) Long-term stable partners* include some/most of the following characteristics: official marriage, traditional marriage, bride price paid, man known and accepted by woman's family, have children together, live together, long-term relationship, man provides regular financial/material support, may be cohabiting or non-cohabiting.

2) *Other partners)* includes all partners who do not fit into the first category above.

5a	Bangaki kulabophathina ababe: How many of these partners were:	Ophathina abaziwayo osekuqhutshwe isikhathi eside nabo Long term stable partners	☐☐
		Enye inhlobo yophathina Other types of partner	☐☐

Interviewer: check that the total of answers given in question 5a is the same as the answer given in question 5 and rectify if necessary.

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

Interviewer: only fill this table in with participants who HAVE had sex in the last 1 week.

6. "Manje ngizokubuza imibuzo enemininingwane eminingi mayelana nokusebenzisa kwakho ikhondomu ngazozonke izikhathi oye ngazo ocansini kulelisonto eledlulile."

"Now I am going to ask you some more detailed questions about your condom use each time you had sex in the last week."

Interviewer: each question (row) refers to a particular sex act. Go through all columns for the individual sex act before moving on to the next row. Write the number corresponding to the answer code for each column in the box in each cell. Remind the participant about the definition of a 'sex act' and allow enough time for the participant to carefully consider each answer.

Ukuya ocansini **Sex acts**	**Uphathina** **Partner**	**Ikhondomu** **Condom**
Ukwenziwa kocansi kulelisonto eledlulile Sex acts in the last week	Uhloboluni lukaphathina obuwenza nalo lolucansi? What **type** of partner was this act with?	Uyisebenzisile yini ikhondomu kulolucansi? Did you use a condom during this sex act?
Ama Code Codes	1=uphathina eseniqhube naye isikhathi eside 1=long-term stable relationship 2= enye inhlobo kaphathina 2=other type of partner, 8=angikhumbuli 8=don't remember	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember
1 ucansi olwenze ekugcineni last sex act	☐	☐
2 ucansi olungaphambi kwalolo sex act before that	☐	☐
3 ucansi olungaphambi kwalolo sex act before that	☐	☐
4 njalonjalo. etc.	☐	☐
5	☐	☐
6	☐	☐
7	☐	☐
8	☐	☐
9	☐	☐
10	☐	☐

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

Interviewer: only fill this table in with participants who have NOT have sex in the last 1 week but who HAVE had sex in the last 4 weeks. You should only fill in one table for each respondent: either 6 or 7

7. "Manje ngizokubuza imibuzo eneminingwane eminingi mayelana nokusebenzisa kwakho ikhondomu ngaleso naleso sikhathi uya ocansini kulamasonto okugcina amane (4) edlule. Sicela uphendule imibuzo ngalokho nalokho kuya kwakho ocansini."

"Now I am going to ask you some more detailed questions about your condom use each time you had sex in the last 4 weeks. Please answer the questions for each time you had sex."

Interviewer: each question (row) refers to a particular sex act. Go through all columns for the individual sex act before moving on to the next row. Write the number corresponding to the answer code for each column in the box in each cell. Remind the participant about the definition of a 'sex act' and allow enough time for the participant to carefully consider each answer.

Ukuya ocansini **Sex acts**	**Uphathina** **Partner**	**Ikhondomu** **Condom**
Ukwenziwa kocansi kulamasonto okugcina awu- 4 Sex acts in the last 4 weeks	Uhloboluni lukaphathina obuwenza nalo lolucansi? What **type** of partner was this act with?	Uyisebenzisile yini ikhondomu kulolucansi? Did you use a condom during this sex act?
Ama codes Codes	1= uphathina eseniqhube naye isikhathi eside 1=long-term sexual relationship, 2= enye inhlobo kaphathina 2= other type of partner, 8=angikhumbuli 8=don't remember	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember
1 ucansi olwenze ekugcineni last sex act	☐	☐
2 ucansi olungaphambi kwalolo sex act before that	☐	☐
3 ucansi olungaphambi kwalolo sex act before that	☐	☐
4 njalonjalo etc.	☐	☐
5	☐	☐
6	☐	☐
7	☐	☐
8	☐	☐
9	☐	☐

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

10	☐	☐

8 Kulamasonto amane (4) okugcina edlule uke walwenza yini ucansi kanti usesikhathini?
In the last 4 weeks have you had sex whilst you were menstruating?

Yebo Yes ☐

Cha No ☐

Section 3: Other products and practices

"Abanye besifazane bafaka izinto ezithile ezithweni zabo zangasese ngenxa yezizathu eziningi, njengesokuhlanza ingaphakathi lesitho sabo sangasese, noma ukusomisa, noma ukusimatisa ngaphambi kocansi. Imibuzo elandelayo imayelana nalokhu."

"Some women insert products into their vaginas for a variety of reasons, such as cleaning inside the vagina, or drying or lubricating the vagina before sex. The next questions are about this".

9 Kulelisonto eledlule kukhona yini oke wakushutheka esithweni sakho sangasese ngaphandle kwesigcobisi salolucwaningo (lokhu kungabali amanzi noma iminwe)?
In the last week have you inserted anything (excluding water/fingers) into your vagina?

Yebo Yes ☐

Cha No ☐ → Q. 10

9a Kungani ushutheke lokhu okunye?
Why did you insert this other thing?
[Tick all that apply]

Ukuhlanza isitho sami sangasese
To clean the vagina ☐

Ukomisa isitho sami sangasese
To dry the vagina ☐

Okunye
Other ☐

Ukumatisa isitho sami sangasese
To lubricate the vagina ☐

Chaza
Specify
_____
_____

9b Uma kungu yebo, ukwenze kangaki lokhu?
If yes, how many times did you do this?

Ngaphezu kokukodwa ngosuku
If yes, how many times did you do this? ☐

Ayi nsukuzonke kodwa kungaphezulu kokukodwa esontweni
Less than once per day but more than once in the week ☐

Kanye ngosuku
Once per day ☐

Kanye ngesonto
Once in the week ☐

Angikhumbuli
Don't remember ☐

9c Kungasiphi isikhathi sosuku lapho uvamise ukukwenza lokhu? [Beka uphawu kulokho okuyikho]
What time of day did you normally do this? [tick all that apply]

Ekuseni
Morning ☐

Ntambama
Afternoon ☐

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

		Ebusuku Evening	☐		
9d	Kunin,uma uqhathanisa nesikhathi sokwenza ucansi lapho uvamise ukwenza khona lokhu? [**Beka uphawu kukho konke okuyikho**] When in relation to sex did you normally do this? [tick all that apply]	Emveni kocansi After sex	☐	Ngaphambi kocansi Before sex	☐
				Ngesinye nje isikhathi Some other time	☐
9e	**PROBE FOR MULTIPLE ANSWERS** Wafaka ini? What did you insert?	Isihlanzi/isibuli magciwane Disinfectant	☐	U-cream Creams	☐
		Uvaselina Vaseline	☐	Indwangu eyomile Dry cloth	☐
		Amakhambi Herbs	☐	Indwangu emanzi Wet cloth	☐
		Okunye Other	☐	Ulamula Lemon	
				Chaza: Specify: ---------- ---------- ----------	

"Abanye besifazane benza ucansi embotsheni yangemuva. Lemibuzo elandelayo iphathelene nalomkhuba."

"Some women have anal sex. The next question refers to this practice".
Interviewer: spend some time making sure the participant understands what anal sex is: "penetrative anal sex that may or may not end with ejaculation."

Interviewer: spend some time making sure the participant understands what anal sex is: "penetrative anal sex that may or may not end with ejaculation".

10	Uke walwenza yini ucansi embotsheni yendle kulamasonto awu 4 edlule? Have you had anal sex in the last 4 weeks?	Yebo Yes	☐	
		Cha No	☐	→ Q. 11
10a	Wayisebenzisa yini ikhondomu? Did you use a condom?	Njalo nje Always	☐	Isikhathi esiningi Most of the time ☐
		Kwesinye iskhathi	☐	Angikaze ngiyisebenzise ☐

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

Sometimes Never

Section 4: Pregnancy test

11	Has urine sample been collected for pregnancy test?	Yebo Yes	☐
		Cha No	☐
11a	Why not? [volunteer must not be enrolled until a negative urine pregnancy test has been obtained]	Not possible to obtain urine specimen	☐
		Other (specify_____)	☐

Interviewer code ☐☐☐

Comments

_____
_____
_____
_____
_____
_____

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

ISONTO 4 ☐, 24 ☐, 40 ☐, 52 ☐ final visit procedure ☐

Interviewer: read the questions to the volunteers verbatim and allocate the correct answer from the selection, unless it is indicated that you read out each answer to the volunteer as well. Boxed type is instructions to the interviewer. Type in italics is to be read to the volunteer.

"Sicela uzame ukuphendula lemibuzo ngokucophelela ngoba izimpendulo zayo zibaluleke kakhulu emiphumeleni yalolucwaningo. Khumbula ukuthi ulwazi osinikeza lona luzogcinwa luyimfihlo futhi luyosetshenziswa kuphela ngezinjongo eziqondene nalolucwaningo."

"Please try to answer these questions accurately as the answers to them are very important to the outcome of the study. Remember that the information you give us is confidential and will only be used for the purposes of this study."

Section 1: Family planning

1 Njengamanje zikhona yini izindlela zokuhlela umndeni ozisebenzisayo?
Are you currently using any method of family planning?

Yebo Yes ☐ → Q. 1a
Cha No ☐ → Q. 1b

1a Uma kunguyebo, iziphi izindlela ozisebenzisayo?
If yes, which methods are you using?
[tick all that apply]

Pills	☐	Natural/rhythm	☐ → Q. 2
Diaphragm	☐	Foam/jelly/spermicide	☐ → Q. 2
Injectable Depo-Provera	☐	Injectable Nur-Isterate	☐ → Q. 2
IUCD	☐	Injectable other (specify below if possible)	☐ → Q. 2
Condon (male or female)	☐	Norplant implant	☐ → Q. 2
Traditional oral	☐	Traditional vaginal	☐ → Q. 2
Sterilisation	☐	Traditional other(specify below if possible)	→ Q. 2
Other	☐	Specify_____ _____	☐ → Q. 2

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

1b Uma kuwu cha, kungani ingekho indlela oyisebenzisayo yokuhlela umndeni?
If no, why are you not using any method of family planning?

- Uyancelisa / Breastfeeding ☐
- Ukufuna ukukhulelwa / Wanting to become pregnant ☐
- Angisayi ocansini / Not sexually active ☐
- Ukukhula angisayi esikhathini / Menopause ☐
- Sengavala inzalo (noma uphathina wakho) / Sterilised (partner) ☐
- Okunye / Other ☐ Chaza / Specify_____

2 Zingaki izinsuku esezedlule kusukela osukwini lwakho lokuqala lokuya esikhathini kulokhukuya kwakho esikhathini okwedlule? ☐☐
How many days ago was the first day of your last menstrual period?
[List number, 99 if more than 3 months or 00 if menstruating now]

2a Lokhu kuya kwakho esikhathini kwakungesikhathi owawusilindele yini?
Was this period when you expected it to be?

- Yebo / Yes ☐
- Cha / No ☐

Section 2: Sexual activity and condom use

Interviewer: please spend some time ensuring that the volunteer understands what is termed by a sex act: one sex act is "penetrative vaginal sex that may or may not end with ejaculation"

Also – don't forget to probe for EXACT NUMBERS

"Manje ngizokubuza mayelana nokuya kwakho ocansini, ukusebenzisa isigcobisi, kanye nokusebenzisa ikhondomu. Sicela uphendule ngokucophelela ngoba izimpendulo zakho zibaluleke kakhulu emiphumeleni yaloluchwaningo."

"I am now going to ask you about your sexual activity, gel and condom use. Please answer accurately as the responses are very important to the study results."

3 Zingaki izinsuku ezedlule wagcina ukwenza ucansi?
How many days ago did you last have sex?

- 1 (lokhu kumbandakanya izolo, ubusuku bayizolo nanamhlanje) / (includes yesterday, last night and today) ☐
- 2 (kuthangi) / (the day before yesterday) ☐ → Q. 4

Signature:	Print Name:	Date:

Site name: Africa centre – South Africa		Date of visit: DD/MM / YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	☐☐/☐☐/☐☐☐☐

3	☐	4	☐	→ Q. 4
5	☐	6	☐	→ Q. 4
7	☐			→ Q. 4
		1-4 amasonto 1-4 weeks	☐	→ Q. 7
		Ngaphezu kwamasonto awu 4 More than 4 weeks	☐	→ Q. 9

4	Ulwenze kangaki ucansi kulelisonto eledlule? How many times have you had sex in the last week?	[List number of times or 77 if unsure]	☐☐
5	Bangaki abantu abehlukene owenze nabo ucansi kulelisonto eledlule? How many different people have you had sex with in the last week?	[List number or 77 if unsure]	☐☐

Ensure that the volunteer understands what we mean by each category of partner.
1*) Long-term stable partners* include some/most of the following characteristics: official marriage, traditional marriage, bride price paid, man known and accepted by woman's family, have children together, live together, long-term relationship, man provides regular financial/material support, may be cohabiting or non-cohabiting.
2) *Other partners)* includes all partners who do not fit into the first category above.

5a	Bangaki kulabophathina ababe: How many of these partners were:	Ngabobudlelwane obuqinile besikhathi eside. Long-term stable partners	☐☐
		Abangezinye izinhlobo zophathina Other types of partner	☐☐

Interviewer: check that the total of answers given in question 5a is the same as the answer given in question 5 and rectify if necessary.

Signature:	Print Name:	Date:

Site name: AFRICA CENTRE –SOUTH AFRICA		Date of visit: (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Trial number: ☐☐☐☐☐☐

Interviewer: only fill this table in with participants who HAVE had sex in the last 1 week.

6. ***"Manje sengizokubuza imibuzo enemininingwane eminingi mayelana nokusebenzisa kwakho ikhondomu nesigcobisi ngazo zonke izikhathi oye ngazo ocansini esontweni eledlule."***

"Now I am going to ask you some more detailed questions about your condom and gel use each time you had sex in the last week."

Interviewer: each question (row) refers to a particular sex act. Go through all columns for the individual sex act before moving on to the next row. Write the number corresponding to the answer code for each column in the box in each cell. Remind the participant about the definitions of a 'sex act' and or the two types of sexual partner, allow enough time for the participant to carefully consider each answer.
Please note that it is important to record the precise order of the sex acts, as this has to be compared with the coital diaries. In order to help you get the order right, there are two columns on the left of the table. In the first you can note the days or dates on which the participant had sex, to help both you and the respondent to keep track of the sequence. These days/dates do not have to be filled in; they are for your convenience and will not be entered as data. The second column is to keep track of the sequence of sex acts. You will need this if you have already filled in a number of sex acts and the respondent then remembers a previous sex at.
NB Do not forget to probe about gel timing.

Usuku/ Idate Day/ date	**Uhlu** order	**Izenzo zocansi** sex acts	**Uphathina** Partner	**Ikhondomu** Condom	**Isigcobisi** Gel	**Izikhathi zokufakwa kwesigcobisi** Gel timing	**Ukugezwa kwesitho sakho sangasese** Vaginal Cleaning	**Izikhathi zokugezwa kwaso** Washing timing	**Ukwaziswa kukaphathina** Partner informed
	Uhlu lokwenziwa kocansi Order of sex acts	Ukwenziwa kocansi kulelisonto eledlule Sex acts in the last week	Uhloboluni lukaphathina obuwenza nalo lolucansi? What **type** of partner was this act with?	Uyisebenzisile yini ikhondomu kulolucansi? Did you use a condom during this sex act?	Usisebenzisile yini isigcobisi ngaphambi kwalolucansi? Did you use gel before this sex act?	Uma usisebenzisile isigcobisi, kube isikhathi esingakanani esiphelile usishuthekile ngaphambi kocansi? If you used the gel how long before sex did you insert it?	Uligezile yini ingaphakathi lesitho sakho sangasese emveni kokwenza ucansi? **(Lokhu kumbandakanya nokusebenzisa indwangu eyomile)** Did you clean inside your vagina after sex? **(This**	Uma usigezile, lokhu kwenzeke isikhathi esingakanani emveni kocansi? If you cleaned, how long after sex was this?	Uma usebenzise isigcobisi, wamtshela yini uphathina wakho ngalokhu? If you used the gel, did you tell your partner about it?

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							includes using a dry cloth)		
		amaCode Codes	1=uphathina owaziwayo eseniqhubeke naye isikhathi eside 1=long-term stable relationship 2=enye inhlobo kaphathina 2=other type of partner 8=angikhumbuli 8=don't remember	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember	1=ngaphansi kwe hora elilodwa (1) 1=less than 1 hour 2= ihora eli1 kuya kwama 3 2= 1 to 3 hours 3= ngaphezu kwama hora ama 3 3= more than 3 hours 8=angikhumbuli 8=don't remember 9=angisisebenzisanga 9=didn't use it	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember	1=ngaphansi kwehora elilodwa (1) 1=less than 1 hour 2= ihora eli1 kuya kwama 2 2= 1 to 2 hours 3= ngaphezu kwamahora ama 2 3= more than 2 hours 8=angikhumbuli 8=don't remember 9=angisigezanga 9=didn't clean	1=yebo 1=yes 2=cha 2=no 8=angi Khumbuli 8=don't remember 9=angisisebenzisanga 9=didn't use it
		1 ucansi olwenze kugcina 1 last sex act	☐	☐	☐	☐	☐	☐	☐
		2 ucansi olungaphambi kwalolo 2 sex act before that	☐	☐	☐	☐	☐	☐	☐
		3 ucansi olungaphambi kwalolo 3 sex act before that	☐	☐	☐	☐	☐	☐	☐

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		4 njalonjalo 4 etc.	☐	☐	☐	☐	☐	☐	☐	☐
		5	☐	☐	☐	☐	☐	☐	☐	☐
		6	☐	☐	☐	☐	☐	☐	☐	☐
		7	☐	☐	☐	☐	☐	☐	☐	☐
		8	☐	☐	☐	☐	☐	☐	☐	☐
		9	☐	☐	☐	☐	☐	☐	☐	☐
		10	☐	☐	☐	☐	☐	☐	☐	☐

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Site name: AFRICA CENTRE –SOUTH AFRICA		Date of visit: (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐
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Interviewer: only fill this table in with participants who have NOT had sex in the last 1 week, but who HAVE had sex in the last FOUR WEEKS. You should only fill in one table for each respondent: either 6 or 7.

7. *"Manje sengizokubuza imibuzo eneminingwane eminingi mayelana nokusebenzisa kwakho ikhondomu nesigcobisi ngazo zonke izikhathi oye ngazo ocansini kulamasonto amane edlule."*

"Now I am going to ask you some more detailed questions about your condom and gel use each time you had sex in the last four weeks."

Interviewer: each question (row) refers to a particular sex act. Go through all columns for the individual sex act before moving on to the next row. Write the number corresponding to the answer code for each column in the box in each cell. Remind the participant about the definitions of a 'sex act' and or the two types of sexual partner, allow enough time for the participant to carefully consider each answer.

Please note that it is important to record the precise order of the sex acts, as this has to be compared with the coital diaries. In order to help you get the order right, there are two columns on the left of the table. In the first you can note the days or dates on which the participant had sex, to help both you and the respondent to keep track of the sequence. These days/dates do not have to be filled in; they are for your convenience and will not be entered as data. The second column is to keep track of the sequence of sex acts. You will need this if you have already filled in a number of sex acts and the respondent then remembers a previous sex at.

NB Do not forget to probe about gel timing.

Usuku/ idate Day/ Date	**Uhlu** Order	**Izenzo zocansi** Sex acts	**Uphathina** Partner	**Ikhondomu** Condom	**Isigcobisi** Gel	**Izikhathi zokufakwa kwesigcobisi** Gel timing	**Ukugezwa kwesitho sakho sangasese** Vaginal Cleaning	**Izikhathi zokugezwa kwaso** Washing timing	**Ukwaziswa kukaphathina** Partner informed
	Uhlu lokwenzi wa kocansi Order of sex acts	Ukwenziwa kocansi emasontwen i amane adlule. Sex acts in the last 4 weeks	Uhloboluni lukaphathina obuwenza nalo lolucansi? What **type** of partner was this act with?	Uyisebenzisile yini ikhondomu kulolucansi? Did you use a condom during this sex act?	Usisebenzisile yini isigcobisi ngaphambi kwalolucansi? Did you use gel before this sex act?	Uma usisebenzisile isigcobisi, kube isikhathi esingakanani esiphelile usishuthekile ngaphambi kocansi? If you used the gel how long before sex did you insert it?	Uligezile yini ingaphakathi lesitho sakho sangasese emveni kokwenza ucansi? **(Lokhu kumbandakanya nokusebenzisa**	Uma usigezile, lokhu kwenzeke isikhathi esingakanani emveni kocansi? If you cleaned, how long after sex was this?	Uma usisebenzisile isigcobisi, wamtshela yini uphathina wakho ngalokhu? If you used the gel, did you tell your partner about it?

Signature:	Print Name:	Date:

Site name: AFRICA CENTRE –SOUTH AFRICA		Date of visit: (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Trial number: ☐☐☐☐☐☐

							indwangu eyomile) Did you clean inside your vagina after sex? **(This includes using a dry cloth)**		
		amaCode Codes	1=uphathina owaziwayo eseniqhube isikhathi eside naye kwezocansi 1=long-term stable relationship 2=enye inhlobo kaphathina 2=other type of partner 8=angikhumbuli 8=don't remember	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember	1=ngaphansi kwehora elilodwa (1) 1=less than 1 hour 2= ihora eli 1 kuya kwama 3 2= 1 to 3 hours 3= ngaphezu kwamahora ama 3 3= more than 3 hours 8=angikhumbuli 8=don't remember 9=angisisebenzisanga 9=didn't use it	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember	1=ngaphansi kwehora elilodwa (1) 1=less than 1 hour 2= ihora eli 1 kuya kwama 2 2= 1 to 2 hours 3= ngaphezu kwamahora ama 2 3= more than 2 hours 8=angikhumbuli 8=don't remember 9=angisigezanga 9=didn't clean	1=yebo 1=yes 2=cha 2=no 8=angikhumbuli 8=don't remember 9= angisisebenz-isanga 9=didn't use it
		1 ucansi olwenze kugcina 1 last sex act	☐	☐	☐	☐	☐	☐	☐
		2 ucansi olungapha mbi kwalolo 2 sex act before that	☐	☐	☐	☐	☐	☐	☐
		3 ucansi olungapham bi kwalolo 3 sex act before that	☐	☐	☐	☐	☐	☐	☐

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Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Trial number: ☐☐☐☐☐☐

		4 njalonjalo 4 etc.	☐	☐	☐	☐	☐	☐	☐
		5	☐	☐	☐	☐	☐	☐	☐
		6	☐	☐	☐	☐	☐	☐	☐
		7	☐	☐	☐	☐	☐	☐	☐
		8	☐	☐	☐	☐	☐	☐	☐
		9	☐	☐	☐	☐	☐	☐	☐
		10	☐	☐	☐	☐	☐	☐	☐

Signature:	Print Name:	Date:

Site name: AFRICA CENTRE –SOUTH AFRICA		Date of visit: (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐
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8 Uma ungasisebenzisanga isigcobisi ngaso sonke isikhathi wenza ucansi, kungani? (tick each that applies)
If you didn't use the gel every time you had sex, why not? (tick each that applies)

- Ngakuthola kulukhuni ukusishutheka isigcobisi ngokokwakheka komzimba wami — Found it physically difficult to apply the gel ☐
- Ngangingasiphethe isigcobisi — Didn't have the gel with me ☐
- Angisithandanga isigcobisi — Didn't like the gel ☐
- Angilitholanga ithuba lokusishutheka isigcobisi — No opportunity to insert the gel ☐
- Okunye — Other ☐ Chaza: Specify:_____
- Ukunqaba kukaphathina — Partner opposition ☐
- Ngaphelelwa isigcobisi — Ran out of gel ☐
- Angisithandanga isishutheki — Didn't like the applicator ☐

9 Emasontweni amane edlule, uke wasishutheka yini isigcobisi kodwa wangabe usaqhubeka wenza ucansi? ☐
In the last 4 weeks, did you ever insert the gel and then not proceed to having sex?

Yebo — Yes ☐
Cha — No ☐ → Q. 10

9a Kungezikhathi ezingaki kwenzeka lokhu? List number of times or 77 if not sure ☐☐
How many times did this happen?

10 Emasontweni amane edlule uke walwenza yini ucansi usesikhathini? ☐
In the last 4 weeks have you had sex whilst you were menstruating?

Yebo — Yes ☐
Cha — No ☐ → Q. 11

10a Uma kungu yebo, usisebenzise kangaki isigcobisi kulesisikhathi (kulezizikhathi)? ☐
If yes, how often did you use the gel at this (these) times?

- Njalo — Always ☐
- Isikhathi esiningi — Most of the time ☐
- Kwesinye isikhathi — Sometimes ☐
- Angikaze — Never ☐

Section 3: Other products and practices

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Site name: AFRICA CENTRE –SOUTH AFRICA		Date of visit: (DD/MM/YYYY) ☐☐/☐☐/☐☐☐☐
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"Abanye besifazane bafaka izinto ezithile ezithweni zabo zangasese ngenxa yezizathu eziningi, njengokuhlanza ingaphakathi lesitho sabo sangasese, noma ukusomisa, noma ukusimatisa ngaphambi kocansi. Imibuzo elandelayo imayelana nalokhu".

"Some women insert products into their vaginas for a variety of reasons, such as cleaning inside the vagina, or drying or lubricating the vagina before sex. The next questions are about this".

11 Kulelisonto eledlule kukhona yini oke wakushutheka esithweni sakho sangasese ngaphandle kwesigcobisi salolucwaningo (lokhu kungabali amanzi/iminwe/itampon)?
In the last week have you inserted anything other than the study gel (excluding water/fingers/tampon) into your vagina?
Yebo Yes ☐
Cha No ☐ → Q. 12

11a **PROBE FOR MULTIPLE ANSWERS**
Kungani ukushuthekile lokhu okunye?
Why did you insert this other thing?
Ukuhlanza isitho sami sangasese To clean the vagina ☐
Ukumatisa isitho sami sangasese To lubricate the vagina ☐
Ukomisa isitho sami sangasese To dry the vagina ☐
Chaza Specify_____ ☐
Okunye Other ☐

11b Ukwenza kangaki lokhu?
How many times did you do this?
Ngaphezulu kokukodwa ngosuku More than once per day ☐
Kanye ngosuku Once per day ☐
Ayi nsukuzonke kodwa kungaphezulu kokukodwa ngesonto Less than once per day but more than once in the week ☐
Kanye ngesonto Once in the week ☐
Angikhumbuli Don't remember ☐

11c **PROBE FOR MULTIPLE ANSWERS**
Uvamise ukukwenza ngasiphi isikhathi osukwini lokhu?
What time of day did you normally do this?
Ekuseni Morning ☐
Ntambama Afternoon ☐
Ebusuku Evening ☐

11d **PROBE FOR MULTIPLE ANSWERS**
Kunini uma uqhathanisa nesikhathi sokwenza kwakho ucansi lapho uvamise khona ukwenza lokhu?
When in relation to sex did you normally do this?
Ngemuva kocansi After sex ☐
Ngaphambi kocansi Before sex ☐
Ngesinye nje isikhathi Some other time ☐

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11e **PROBE FOR MULTIPLE ANSWERS**
Wafaka ini?
What did you insert?

- Isihlanzi/isibulala magciwane (Disinfectant) ☐
- Uvaselina (Vaseline) ☐
- Amakhambi (Herbs) ☐
- Okunye (Other) ☐
- U-cream ☐
- Indwangu eyomile (Dry cloth) ☐
- Indwangu emanzi (Wet cloth) ☐
- Ulamula (Lemon) ☐

Chaza:
Specify:_____
_____

Interviewer: spend some time making sure the participant understands what annual sex is: "ukungena kowesilisa embotsheni yangemuva yendle okungenza agcine echithile noma engachithanga 'ejaculation'."
"penetrative anal sex that may or may not end with ejaculation".

12 ***"Abanye besifazane benza ucansi embotsheni yangemuva. Lemibuzo elandelayo iphathelene nalomkhuba."***
"Some women have anal sex. The next question refers to this practice".
Uke walwenza yini ucansi lwasembotsheni yendle kulamasonto amane edlule?
Have you had anal sex in the last 4 weeks?

- Yebo (Yes) ☐
- Cha (No) ☐ → Q. 13

12a Wayisebenzisa yini ikhondomu?
Did you use a condom?

- Njalo (Always) ☐
- Kwesinye isikhathi (Sometimes) ☐
- Isikhathi esiningi (Most of the time) ☐
- Angikaze (Never) ☐

Section 4: Acceptability

"Manje sengifuna ukukubuza imibuzwana emayelana nokuthi kulula kangakanani ukusisebenzisa isigcobisi noma ubenezinkinga yini ekusisebenziseni."

"I now want to ask you some questions about how easy the gel is to use and if you had any problems using it."

Interviewer: explain that question 13 is about ease of inserting the gel into the vagina and question 14 is about things in the immediate environment that facilitate or hinder gel use such as having children/partner around, lighting, access to water etc.

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13	Ukushutheka isigcobisi kwakulula noma kwakunzima? Was the insertion of the gel easy or difficult?	Kwakulula kakhulu Very easy ☐	Kwakulula Easy ☐	→ Q. 14
		Kwakunzima Difficult ☐	Kwakunzima kakhulu Very difficult ☐	
13a	Uma kwakunzima/kunzima kakhulu, kwakwenziwa yini? If difficult/very difficult, why?			
14	Bewukwazi kahle ukusebenzisa isigcobisi ngaphandle kukuvinjelwa yilitho noma kube nezimo ezikuvimbelayo ukushutheka isigcobisi? Was it convenient or inconvenient to use the gel?		Azibanga bikho izimo ezingivimbayo Convenient ☐	→ Q. 15
			Zibe khona izimo eziphazamisile Inconvenient ☐	
14a	Uma ungalitholanga ithuba elifanele, kwakungani? If inconvenient, why?			
15	Ukusebenzisa kwakho isigcobisi kwenze ucansi lube mnandi kakhulu noma lube mnandi kancane? Did using the gel make sex more or less enjoyable?		Kakhulu More ☐	
			Kancane Less ☐	
			Lwazifanela nje Same ☐	→ Q. 16
15a	**PROBE FOR MULTIPLE ANSWERS** Uma kukakhulu noma kukancane, kungani? If more or less, why?		Senza ngibe manzi kakhulu messy ☐	
			Siyabanda cold ☐	
			Siyashisa hot ☐	
			Siyaluma itchy ☐	
			Kwanda ukushelela Increased lubrication ☐	

Signature:	Print Name:	Date:

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Kuba nokulinda ngaphambi kokuba kwenzeke ucansi
Had to wait before having sex ☐

Okunye (chaza)
Other (specify) _____ ☐

Section 5: Pregnancy test and clinical symptoms

16 Has urine sample been collected for pregnancy test? Yes ☐ → Q. 17

No ☐

16a If not, why not? [note it is a protocol requirement that a negative urine pregnancy test is taken at this time point]

Not possible to obtain urine specimen ☐

Other (specify)_____ ☐

If not at week 52, complete interviewer code and end interview here; if week 52, complete question 17 below as well.

Section 6: End of trial questions (17-17b) to be asked at week 52 follow up only

17 Ube nophathina abangaphezulu yini koyedwa ngalesisikhathi kuqhubeka lolucwaningo?
Did you have more than one sexual partner during the course of the trial?

Yebo
Yes ☐ →Q. 17a

Cha
No ☐ → END

17a Ukusebenzisa kwakho isigcobisi kwakuya ngokuthi unamuphi uphathina yini?
Did your use of gel vary according to which sexual partner you were with?

Yebo
Yes ☐

Cha
No ☐

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17b Kwakuhluke kanjani?
How did it vary?

Wawusisebenzisa kakhulu isigcobisi nophathina owejwayelekile kunabanye ☐
Used gel more with regular partner than others

Wawusisebenzisa kancane isigcobisi nophathina owejwayelekile kunoma unabanye ☐
Used gel less with regular partner than with others

Okunye (chaza) ☐
Other (specify) _____

Interviewer code ☐☐☐

Signature:	Print Name:	Date:

Appendix G: Systematic literature review criteria

Systematic literature review: Microbicide acceptability

The aim of this systematic literature review was to identify all published articles on the acceptability of microbicides.

Selection criteria

The selection criteria were manuscripts that reported on the acceptability of vaginal microbicides designed to prevent HIV acquisition in women. Microbicides designed for the exclusive prevention of other diseases were excluded. Papers on both female and male acceptability of vaginal microbicides were included. Studies on rectal microbicides were excluded. No age or geographical restrictions were applied to the search. Only papers that presented primary findings and were published in peer-reviewed journals were included. Review articles, commentaries, and conference abstracts were excluded. Abstracts for the first International Microbicide conference in 2000 were published as a supplement to the Journal of AIDS (AIDS; supplement 1, volume 15, February 2001) but were not peer-reviewed for publication and therefore were excluded from the systematic review. Only English language articles were included. Studies were separated depending on whether they presented evidence on hypothetical acceptability of microbicides, acceptability of surrogate products, or acceptability of candidate microbicides.

Search Strategies

Systematic searches were conducted in three search engines, PubMed, Web of Knowledge and POPLINE, which include citations from both clinical and social science journals. The search was conducted in the third week of November 2011 and includes all articles published to that date. I set up alerts on the search engines for subsequent articles meeting the main criteria and reviewed these for relevance even after completing the systematic review.

In PubMed and POPLINE I used key word searches. In Web of Knowledge I used a topic search. The key words and topics in both searches were: 'microbicide' AND 'hiv' AND 'vaginal' AND 'accept*'. A wild card search (*) was used for the word 'accept' to include the following words in the search: 'accept', 'acceptable', 'acceptability', 'acceptably', 'acceptance', or 'accepting'.

Selection of Articles

I initially reviewed the title, and if necessary the abstract, of all manuscripts identified in the search. Papers that obviously did not fit the inclusion criteria were rejected. If it was not clear from the abstract whether the manuscript met the criteria, the full text was reviewed. A primary reason was assigned for the rejection of each article. The full text was reviewed for all studies that potentially met the inclusion criteria. Studies that did not meet the selection criteria were excluded and designated a primary reason for rejection. Studies that did meet the selection criteria during this review were categorised as stage 1 searches (s1). I created separate lists for hypothetical, surrogate and candidate microbicide acceptability studies.

In addition, citations within articles were reviewed and used to identify further articles for potential inclusion. Reviews of microbicide research were also searched for other relevant articles. Articles that had not been identified in the stage 1 search, but met the search criteria, were added to the list of articles on acceptability as stage 2 searches (s2).

After developing a full list of articles that met the inclusion criteria, I extracted data from all manuscripts relating to studies of candidate microbicides assessed during sexual activity. I did not develop a data extract table for hypothetical studies, surrogate studies, or candidate microbicide studies which assessed products in the absence of sex. The following data is included in the data extraction table: clinical phase of study (pilot, phase I, II, IIb, III), name of product, countries where study was conducted, number of women and/or men included in the

study, duration that women were asked to use the product, study dosing schedule, data collection methods, and key acceptability criteria collected.

Search findings

PubMed

In PubMed a search for 'microbicide' AND 'hiv' AND 'vaginal' AND 'accept*' yielded 91 articles. On review 41 articles were excluded and 50 were included: 13 hypothetical, 9 surrogate, and 28 candidate microbicides (table Ga-1).

Web of Knowledge

In Web of Knowledge a search for 'microbicide' AND 'hiv' AND 'vaginal' AND 'accept*' yielded 186 articles. This search found 89 of the 91 articles identified in PubMed including 13 hypothetical, 9 surrogate, and 26 (of the 28) candidate microbicide acceptability papers, plus all 41 of the excluded articles. Of the remaining 97, 67 additional articles were excluded and 30 included: 10 hypothetical, 5 surrogate, and 15 candidate microbicides (table Ga-1).

POPLINE

In POPLINE a search for 'microbicide' AND 'hiv' AND 'vaginal' AND 'accept*' yielded 71 articles. Of these, 22 had been excluded and 32 included (11 hypothetical, 4 surrogate, 17 candidate microbicides) during the previous searches. An additional 17 articles were identified and reviewed. Only 1 of the articles had been peer reviewed and this was a commentary piece. Consequently no additional articles were identified in the POPLINE search.

Table Ga-1: Number of articles included and excluded during the systematic literature review

	PUBMED	**Web of Knowledge***	**POPLINE***
Identified	91	97	17
Excluded	41	67	17
Review, comment, conference	18	10	17
Preclinical	6	8	
Rectal	2	1	
Safety/effective/adhere only	2	16	
Non-HIV outcome	2	6	
Trial/methods	6	10	
Diaphragm	2	5	
Applicator	1	5	
Language	1		
Phd	1		
Duplicates		6	
Included	50	30	0
Hypothetical	13	10	
Surrogate	9	5	
Candidate	28	15	

**Excluding articles identified in PubMed*

Search results

In total 80 papers were identified in the stage 1 search in PubMed and Web of Knowledge: 23 hypothetical, 14 surrogate, and 43 candidate microbicides.

In stage 2 of the literature review, I checked all references in the 80 papers identified in the stage 1 literature search. I also checked all references in key articles which have reviewed microbicide research (Ramjee, 2010, Poynten et al., 2009, Omar, 2011, Elias, 2001, Mantell,

2005, Severy, 2005). On the basis of this secondary review of the literature, I included an additional 28 articles: 4 hypothetical, 9 surrogate and 15 candidate microbicides.

In total 108 articles were reviewed as part of the systematic literature review of microbicide acceptability.

ELIAS, C., COGGINS, C. 2001. Acceptability research on female-controlled barrier methods to prevent heterosexual transmission of HIV: Where have we been? Where are we going? *Journal of women's health & gender-based medicine,* 10**,** 163-73.

MANTELL, J. E., MYER, L., CARBALLO-DIÉGUEZ, A., STEIN, Z., RAMJEE, G., MORAR, N. S., HARRISON, P. F. 2005. Microbicide acceptability research: current approaches and future directions. *Soc Sci Med,* 60**,** 319-30.

OMAR, R., BERGERON, MG. 2011. The future of microbicides. *International journal of infectious diseases (IJID): official publication of the International Society for Infectious Diseases,* 15**,** e656-60.

POYNTEN, I. M., MILLWOOD, I. Y., FALSTER, M. O., LAW, M. G., ANDRESEN, D. N., VAN DAMME, L. & KALDOR, J. M. 2009. The safety of candidate vaginal microbicides since nonoxynol-9: a systematic review of published studies. *AIDS,* 23**,** 1245-54.

RAMJEE, G., KAMALI, A., MCCORMACK, S. 2010. The last decade of microbicide clinical trials in Africa: from hypothesis to facts. *AIDS,* 24 Suppl 4**,** S40-9.

SEVERY, L. J., TOLLEY, E., WOODSONG, C., GUEST, G. 2005. A framework for examining the sustained acceptability of microbicides. *AIDS Behav,* 9**,** 121-31.

Systematic literature review: Vaginal practices in Africa

The aim of this systematic literature review was to identify all published articles on intravaginal cleansing and intravaginal insertion practices in Africa. However, until the recent World Health Organization (WHO) Multi-Country Study on Gender, Sexuality and Vaginal Practices (GSVP Study), the distinctions between intravaginal practices and other vaginal practices were not well defined and therefore it was necessary to search for literature relating to all vaginal practices.

Selection criteria

The selection criteria were manuscripts that reported on any type of vaginal practice in Africa. Geographical restrictions were applied at the point of search so as articles exclusively relating to vaginal practices outside of Africa were excluded. However, multi-country studies that included any African country were included. Papers that presented primary findings were prioritised, however meta-analyses of secondary data and systematically conducted reviews of the literature were also included. Only papers published in peer-reviewed journals were included. Commentaries and conference abstracts were excluded. Only English language articles were included. Articles that related to HIV prevention studies and reported on other vaginal practices were included. Papers that exclusively reported on the use of microbicides, diaphragms, or female condoms as vaginal practices were excluded. Articles were not excluded on the basis of their inclusion in the previous search of microbicide acceptability literature (as described in appendix G_a).

Search Strategies

Systematic searches were conducted in three search engines, PubMed, Web of Knowledge and POPLINE. The search was conducted in the first week of January 2012 and includes all articles published to that date. I set up alerts on the search engines for subsequent articles meeting the main criteria and reviewed these for relevance even after completing the systematic review. Two articles were identified after the systematic review and these are distinguished in the text.

In PubMed and POPLINE I used key word searches for words relating to 'vaginal practices'. I found that using a key word search to apply the geographic restrictions was too narrow and therefore applied an all field search for the word 'Africa'. In Web of Knowledge I used a topic search throughout.

A search for 'vaginal practices' did not identify the breath of literature that is available on this topic. Consequently I conducted a series of searches in each search engine in order to cover the various terms used in relation to this topic area.

I initially conducted 4 main searches in each engine:

1. 'vaginal practices' AND 'Africa'
2. 'vaginal' AND ('insert*' OR 'clean*' OR 'douch*') AND 'Africa'
3. 'dry sex' AND 'Africa'
4. 'vagina' AND 'herb*' AND 'Africa'

During the review it became apparent that some articles referred to 'washing' instead of cleaning, cleansing or douching. Consequently, I conducted a fifth search as follows:

5. 'vaginal' AND wash* AND 'Africa'

A wild card search (*) was used for the following words:

- 'insert' to include: 'inserting, 'insertion', 'insertions', 'inserted'
- 'clean' to include: 'cleaning', 'cleansing', 'cleanse', 'cleansers', 'cleansed'

- ‘douch’ to include: ‘douche’, ‘douches’, ‘douching, ‘douchers’, ‘douched’
- ‘herb’ to include: ‘herbs’, ‘herbal’
- ‘wash to include: ‘washes, ‘washing’, ‘washed’

Selection of Articles
I initially reviewed the title, and if necessary the abstract, of all manuscripts identified in the search. Articles that obviously did not fit the inclusion criteria were rejected. If it was not clear from the abstract whether the article met the criteria, the full text was reviewed. A primary reason was assigned for the rejection of each article. The full text was reviewed for all articles that potentially met the inclusion criteria. Articles that on further review did not meet the selection criteria were excluded and designated a primary reason for rejection.

I developed a full list of all articles that met the inclusion criteria and in a data extraction table indicated the country or countries where the study took place, whether the study reported on intravaginal cleansing, intravaginal insertion and/or love potions. I also noted if the article reported on an association between a vaginal practice and HIV, BV or another STI, as well as the prevalence of use of intravaginal cleansing and intravaginal insertion when reported.

Search findings
PubMed

In PubMed the 5 separate searches yielded a total of 229 articles:

- a search for ‘vaginal’ AND (‘insert*’ OR ‘clean*’ OR ‘douch*’) AND Africa yielded 142 articles,
- a search for ‘vaginal practices’ AND ‘Africa’ yielded 14 articles,
- a search for ‘dry sex’ AND ‘Africa’ yielded 23 articles,
- a search for ‘vagina’ AND ‘herb*’ AND ‘Africa’ yielded 10 articles,
- a search for ‘vagina’ AND ‘wash*’ AND ‘Africa’ yielded 40 articles.

In total 33 were duplicates across the different searches and therefore 196 references were reviewed.

On review, 66 articles were included. However, 130 articles were excluded for the following reasons:

- 31 comments/editorials/reviews/not peer reviewed
- 23 medical
- 18 FP
- 32 pregnancy or new born
- 5 other
- 12 microbicide
- 1 phd
- 5 hiv/sti
- 2 language
- 1 not Africa

Web of Knowledge

In Web of Knowledge the 5 separate searches yielded a total of 221 articles:

- a search for ‘vaginal’ AND (‘insert*’ OR ‘clean*’ OR ‘douch*’) AND Africa yielded 123 articles,

- a search for ‘vaginal practices’ AND ‘Africa’ yielded 19 articles,
- a search for ‘dry sex’ AND ‘Africa’ yielded 45 articles,
- a search for ‘vagina’ AND ‘herb*’ AND ‘Africa’ yielded 16 articles
- a search for ‘vagina’ AND ‘wash*’ AND ‘Africa’ yielded 18 articles.

In total 63 were duplicates across the different searches and therefore 158 references were reviewed. This search found 51 of the 66 articles identified as meeting the criteria in PubMed, plus 75 of the excluded articles. An additional 19 newly identified articles were excluded for the following reasons:

- 11 comments/editorials/reviews/not peer reviewed
- 1 pregnancy
- 2 other
- 2 microbicide
- 1 language
- 2 not Africa

In total 13 new articles were identified as meeting the inclusion criteria in the Web of Knowledge search.

POPLINE

In POPLINE the 5 separate searches yielded a total of 109 articles:

- a search for (vaginal & (insert*/clean*/douch*) & Africa) yielded 67 articles,
- a search for ‘vaginal practices’ & Africa’ yielded 11 articles,
- a search for ‘dry sex’ & Africa yielded 18 articles,
- a search for vagina & herb* & Africa yielded 5 articles
- a search for ‘vagina’ AND ‘wash*’ AND ‘Africa’ yielded 8 articles.

In total 25 were duplicates across the different searches and therefore 84 references were reviewed. This search found 40 of the 79 articles identified as meeting the criteria in PubMed and Web of Knowledge, plus 18 of the excluded articles. An additional 23 newly identified articles were excluded for the following reasons:

- 5 comments/editorials/reviews/not peer reviewed
- 5 medical
- 6 FP
- 1 pregnancy
- 1 other
- 5 microbicide

In total 3 new articles were identified as meeting the inclusion criteria in the POPLINE search.

Search results

In total 82 papers were identified as meeting the selection criteria and were included in the literature review.