PREVALENCE OF SEXUALLY TRANSMITTED DISEASES, HIV/ AIDS AMONG FEMALE SEX WORKERS AND ACCEPTABILITY OF INTRAVAGINAL RING IN MUKURU, NAIROBI, KENYA

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(I84/5018/04)

A THESIS SUBMITTED IN FULLFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF DOCTOR OF PHILOSOPHY (PUBLIC HEALTH) IN THE SCHOOL OF PURE AND APPLIED SCIENCES OF KENYATTA UNIVERSITY

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OCTOBER, 2010
DECLARATION BY THE CANDIDATE

I Sabina Wakasiaka declare that this thesis is my original work and has not been presented for a degree in any other university.

Signature ___________________________ Date 22. Oct. 2010

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DEDICATION

This thesis is dedicated to my late mother Teresa Nyakara, my husband Weston Wakasiaka, our children Vanessa, Frank and Alvin.
ACKNOWLEDGEMENTS

The extensive research work presented in this thesis was achieved through team work that involved committed team players in Kenya and United States of America. My sincere gratitude is bestowed on the late Prof. J. J. Bwayo, formerly of Kenya AIDS Vaccine Initiative, University of Nairobi, who initiated me into the world of research in yesteryears. Secondly, I want to appreciate my supervisors: Dr. John J. Mbithi, Chairman, Department of Medical Laboratory Science, Kenyatta University for his guidance, supervision and encouragement. Prof. Fran Priddy, Department of Medicine, Emory University for her tremendous leadership and provision of project funds. Prof. Omu Anzala of Kenya AIDS Vaccine Initiative, University of Nairobi for management support and supervision. I also thank Prof Ndinya Achola, Kenya AIDS Vaccine Initiative and University of Nairobi for his invaluable advice and encouragement.

Many thanks to the school of Pure and Applied Sciences, Kenyatta University for giving me the opportunity to enroll in the doctoral programme. My appreciation also goes to project staff, for their hard work and commitment to this study. I also wish to record my gratitude to the staff at Mama Alice Nursing Home in Mukuru and the patients who participated in this study. Last but not least, many thanks to my daughter Vanessa, Mr. Samuel Kazungu, Donna Smith and Tina Hong for their tireless efforts in data entry.
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<td>AIDS</td>
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<td>ARV</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>Clade</td>
<td>Subtype of related HIV viruses</td>
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<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
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<td>FSW</td>
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<td>FTA</td>
<td>Rapid Regian Test</td>
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<td>FP</td>
<td>Family Planning</td>
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<td>GUD</td>
<td>Genital Ulcer disease</td>
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<td>HCP</td>
<td>Health Care Provider</td>
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<td>HRT</td>
<td>Hormone Replacement Therapy</td>
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<td>HIV</td>
<td>Human Immuno Deficiency Virus</td>
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<td>HLA</td>
<td>Human Leukocyte Antigen</td>
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<td>IAVI</td>
<td>International Aids Vaccine Initiative</td>
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<td>Abbreviation</td>
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<td>IVR</td>
<td>Intra Vaginal Ring</td>
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<td>KAVI</td>
<td>Kenya AIDS Vaccine Initiative</td>
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<td>KAIS</td>
<td>Kenya AIDS Indicator Survey</td>
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<td>KDHS</td>
<td>Kenya Demographic and Health Survey</td>
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<td>MC</td>
<td>Maternal Child Health</td>
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<td>MVA</td>
<td>Modified Vaccine Ankara</td>
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<td>Medical Research Council</td>
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<td>MOH</td>
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<td>NG</td>
<td>Neisseria Gonorrhoea</td>
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<td>PID</td>
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<td>RTI</td>
<td>Reproductive Tract Infection</td>
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<td>STI</td>
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<td>SPSS</td>
<td>Statistical Package for Social Sciences</td>
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<td>TPHA</td>
<td>Treponema Pallidum Hemaglutination Test</td>
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<td>Joint United Nations Program on HIV/AIDS</td>
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<td>USAID-</td>
<td>United States Aid for International Development</td>
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<td>VCT</td>
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<td>VD</td>
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<tr>
<td>VDRL</td>
<td>Venereal Disease Research Laboratory Test</td>
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<td>WHO</td>
<td>World Health Organization</td>
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DEFINITION OF TERMS

High Risk Group: A group of people in the community with a higher-than-expected risk for developing a particular disease, which may be defined on a measurable parameter such as an inherited genetic defect, physical attribute, lifestyle, habit, socioeconomic and/or educational feature, as well as environment.

Primary Partner: In this study, a primary partner denotes a client of a sex worker who does not necessarily pay for sex; instead he pays in kind and serves as the official boyfriend.

Regular Partner: This is a client of a sex worker who seeks services at a regular interval, although he is well known to the sex worker, he pays for service rendered.

Casual Partner: This is a one time client, the sex worker does not necessarily know him, and he too pays for services rendered.
ABSTRACT

Human Immunodeficiency Syndrome (HIV and AIDS) has escalated into a humanitarian and developmental crisis. Out of 33.2 million people living positive worldwide, majority (22.5 million) live in Sub Saharan Africa (UNAIDS 2008). Gender roles and responsibilities in African communities bring forth inequalities which often reduce the power of women in negotiating for safer sex. In many African communities, women are care givers. They are expected to care for the spouse, children and the extended family. However, when a woman is infected with HIV, she may be divorced, denied access to family inheritance and care. This prospective cohort study recruited one hundred female sex workers in Mukuru informal settlement in the period between October 2005 to May 2008. The aim of this study was to recruit and characterize individuals for future efficacy clinical trials for HIV Vaccines and Microbicides. Part of the clinical site requirements for such trials is that cohorts must have documented high risk behaviour, high STI prevalence and high retention rates. In order to establish baseline Sexually Transmitted Infections (STI) burden in the community, health care providers were interviewed regarding common STI they treat. Health care providers were asked about their views regarding acceptability of an intravaginal ring which may be used to deliver Microbicides when they become available. Data was analyzed using Statistical Package for Social Sciences (SPSS). Results indicate that Female Sex Workers (FSW) in the cohort are at a higher risk of contracting STI. Majority FSW (67%) were young, with a mean age of 28. Literacy levels were low with 45% reporting no formal schooling. On average, FSW had three clients per day with the earliest sex debut being 9 years. Almost half (53%) said they used condoms sometimes with primary partners. At baseline HIV prevalence was 11.3%, this is higher than the national prevalence which stands at (7.4%). Vaginal discharge symptoms and Pelvic inflammatory disease were the most common STI seen. Out of 75 symptomatic patients, 30 (40%) reported having vaginal sex in the same period. Only 4% reported anal sex during the symptomatic period. Diagnosis of Trichomoniasis correlated significantly with income of more than 200 Kenya shillings per week. In multivariate analysis, diagnosis of STI (Chlamydia, gonorrhea, Trichomoniasis or syphilis) was strongly associated with alcohol use (OR=3.35, P=0.002). Intravaginal rings were well accepted by majority of health care providers who asked for more information regarding the rings and Microbicides. Recruitment, characterization and establishment of this cohort provide an opportunity to access Vaccine and Microbicides strategy for HIV prevention especially for women.
CHAPTER ONE
INTRODUCTION

1.1 Background

Acquired Immunodeficiency syndrome (AIDS) has exploded into a global threat and a humanitarian crisis on a scale never seen before. In this regard, developing countries are most affected by this crisis. For instance, Sub-Saharan Africa accounts for 22.5 out of 33.2 million people living positive globally (UNAIDS, 2008).

The Kenya Indicator survey (KAIS, 2007) indicates that 7.1% of Kenyans aged 15-64 were HIV positive; this is equivalent to 1.4 million people. This new data shows an increase in HIV prevalence from 6.3% reported in 2003 to 7.1% in 2008. The proportion of HIV positive women to men is 8.7% to 5.6%, this implies that 3 out of 5 HIV infected Kenyans are female (KAIS, 2007).

The increase in HIV prevalence can be attributed to several factors including; rate of new infections, mortality from the disease and the length of time people are able to survive based on available treatment options. In Kenya, it is also estimated that over 300 new infections occur daily and nearly 300 people die each day from AIDS related complications. Although these figures are lower than 500 new infections reported in previous years, AIDS continue to ravage the country, (NASCOP, 2008).
In addition, global statistics show that half of all new infections occurring worldwide occur in young people between the ages of 15 to 24 years, majority being women. Both HIV and AIDS morbidity and mortality affect the most productive age groups. Over the past 20 years, surveillance reports show half of the 33.2 million people currently living with AIDS became infected at an early age of 15 to 24 years, (UNAIDS, 2008).

Past studies suggest that women typically become infected earlier than men. This may be attributed to traditional and behavioural practices where girls begin having sex at an early age than boys. Social science studies in Nyanza document the myth that sex with young girls' helps older men prevent and or treat STI, HIV and AIDS, (Helen, 2006). This observation explains partly why females from developing countries are 30 times more likely to die from STI, HIV and AIDS than women from developed countries (Glynn et al., 2004; Helen et al., 2001).

Given the modest successes and considerable costs associated with current efforts, it is crucial to look for alternative methods of containing the pandemic. Many scientists believe preventive vaccines provide a potential and cost-effective HIV preventive option, (Wilkinson et al., 2000). Success involving preventive vaccines such as smallpox and vast reductions in the prevalence of diseases such as measles, tetanus and hepatitis B suggest the potential of HIV vaccine technology. It is believed that an effective HIV vaccine will reduce AIDS mortality and morbidity, (Mugyenyi, 2002). Development of an HIV vaccine follows rigorous scientific processes. This begins with identification of a viable laboratory experiment. After this initial experiment, the product is tested in
animals to evaluate safety and immunogenicity. Successful animal studies pave way for phase I clinical trials which involves testing the product in humans.

The science of testing vaccines in humans occurs in three main phases; Phase 1: This follows animal studies; usually the objective in this phase is to establish safety and immunogenicity of the product. To participate in this phase, individuals should be healthy adults, at low risk of HIV and HIV naïve. In most cases, study duration is 18 to 24 months with a sample size of 20 to 50 participants. Phase II follows a successful phase I trial. Study requirements and objective is the same as Phase I except for the sample size which is 200 to 500 participants. A candidate vaccine which does not meet its objective in phase II will not be used for phase III trials (KAVI, 2008).

Therefore a phase III trial occurs only when a phase II trial has been successful. Phase III trials are also referred to as efficacy trials. To participate in this phase, participants must be aged above 18, healthy, HIV negative, at risk of HIV infection and able to keep up with scheduled visits. The main research objective in this phase is efficacy and expanded safety. In order to accelerate the process of vaccine development, cohort developments should be done prior to initiation of efficacy trial (KAVI, 2008). Risk characteristics and cohort retention levels should be documented early to avoid delays when a phase III vaccine or Microbicide becomes available. For this reason, the author embarked on developing the Mukuru cohort presented in this dissertation.
In this study, the term “High risk group” is used to describe individuals who by the nature of their work or sexual behaviour are at a higher risk of HIV infection. Some of the characteristics of high risk individuals include: Multiple sex partners, recurrent STI, inconsistent condom use, oral and anal sex. High risk groups include; female sex workers and their clients, men who have sex with men, intravenous drug users and discordant couples (Beaten et al., 2000). Since intravaginal rings are intended for use among women, only female sex workers were recruited for study.

1.2 Women and Vaccine Research

Women living in situations of poverty, with limited access to societal resources face inequality both within their public and private domains. These vulnerable groups have the least HIV preventive and treatment options available to them. For instance, Women have limited access to female condoms, and often lack the power to negotiate the use of male condoms. The continued spread of HIV amongst marginalized communities has lead to an increasing consensus that a preventive vaccine is essential in the control of the expanding and intensifying global HIV epidemic (Alliance, 2007).

1.3 Conceptual Framework

Mathematical modeling of transmission of sexually transmitted infections and HIV has considerably advanced HIV research by highlighting the importance of certain types of partnerships in epidemic spread. Notably, concurrent partnerships, defined as a sexual partnership in which one or more of the partnership members have other sexual partners, while continuing sexual activity with the original partner. Such partnerships have shown
to play a fundamental role in potentiating the spread of STI and HIV (Bwayo et al., 2001). Risk behaviour such as concurrency and sex without condoms as well as STI/HIV prevalence vary with physical, social, and emotional factors within partnerships. The efficiency of STI/HIV transmission appears to vary across types of concurrent partnerships according to the differing dynamics within them. Previous research on partnership dynamics has improved our understanding of the multidimensional aspects of sexual partnering, but little is understood of how these aspects of sexual partnering interact and increase risks for HIV or how types of partnerships, partnership dynamics, and concurrency work together to affect both the behaviour of condom use and the biological transmission of disease. This study focuses on documenting concurrency including partnerships among sex workers, difference between types of partnerships; modify risks within partnerships and to break the chain of infection through STI diagnosis and treatment. The study also introduces a conceptual framework that reflects how individual and partner characteristics influence partnership dynamics. In turn influence risk behaviour, such as concurrency and non condom use associated risks for STI and HIV.

1.4 Problem Statement

Surveillance reports in Kenya show that the greatest burden of disease lies with women. Most new infections are occurring in women of reproductive age. In addition, women are twice as affected by HIV compared to men of the same age (8.9% versus 4.5%), (KAIS, 2008). The high infection rates among women pose a serious public health problem because of low condom use coupled with poor health seeking behaviour among high risk
populations. This implies that STI clients continue spreading infections either knowingly or unknowingly (Bwayo et al., 2001). Although behaviour modification, condom use and VCT uptake seem to lower HIV prevalence, to this day, there is no preventive vaccine or Microbicides to curb this scourge.

Evidence adduced from Kenya AIDS Vaccine Initiative (KAVI Report, 2004) indicates that Kenyan women are not adequately represented in HIV vaccine trials (Wakasiaka, 2005). This observation highlights gender imbalance in HIV vaccine development processes. The International code of conduct of clinical trials requires trials sites to observe gender balance in evaluating candidate vaccines or Microbicides. A clinical trial that does not observe gender balance will not be allowed to market the product for all populations because drug interactions differ across gender and age.

Kenya Aids Vaccine Initiative enrolled fewer women in earlier vaccine trials. This implied that even the most viable vaccine candidate developed in Kenya will not meet international licensure standards. This study was designed to balance the gender equation and also accelerate volunteer recruitment for efficacy trials at KAVI. In this regard, the first part of this study focused on recruitment and retention of FSW in Mukuru. Part two of this study focused on diagnosis and treatment of STI, Voluntary Counseling Testing (VCT) and Health Promotion Services. Part three of the study focused on acceptability of Intra Vaginal Rings as a device for Microbicide delivery.

1.5 Justification

Evaluation of candidate HIV vaccines is a relatively new concept in Kenya. For this reason, clinical trial sites were not prepared early for efficacy trials. Documentary
evidence at KAVI shows that the ratio of men to women in early studies was 8:1 (Wakasiaka, 2005). When women are excluded from medical research, the results are often alarming because such results cannot be generalized for the target population. Hence the vaccine will not meet requirements for licensure. For example, research drugs which treat the male body as the prototype may have side effects or are simply not applicable to women because women differ from men in both physiologic and anatomic parameters.

Part of the requirements for efficacy trials include; a well characterized cohort, a viable product and a highly trained and qualified staff to conduct such high level evaluations. At KAVI, the main limitation that was there four years ago was lack of a well defined cohort who could participate in either vaccine or Microbicides efficacy trials. In any clinical site, cohort development requires that individuals are recruited at one point in time and followed up for at least two years. During this period, key characteristics are documented to include; HIV status at entry point and at every three months, STI surveillance, mobility patterns, recruitment and retention rates. To achieve these, clinical trial sites need to create community partnerships, develop capacity and have sufficient funding for a long time (IAVI, 2008).

Success of an efficacy trial is based on how fast sites can recruit and retain volunteers over a period of time. In order to extrapolate recruitment and retention rates, cohorts should be developed long before trials begin. Given the high mobility among sex workers, sponsors require documentary evidence demonstrating good retention patterns.
This is because when participants receive a trial product, it is mandatory to follow them for three years to assess adverse events as well as immune responses. Failure to which, no one will ever know how a participant responded. A previous study among Kenyan Female Sex Workers reported that older Sex Workers completed follow up visits compared to younger FSW who were difficult to follow up (median 30 vs. 25 years old; p<0.001) (Bwayo et al., 1992). This study highlights challenges in retaining young sex workers in a clinical trial which lasted for three years. In addressing the low retention rate, the author recruited Female Sex Workers in Mukuru.

1.6 Research Questions

i. What factors predispose Mukuru sex workers to STI, HIV and AIDS?

ii. What Sexual Transmitted Infections are common in Mukuru slum?

iii. How effective is Syndromic approach compared to etiologic STI management among FSW?

iv. What are the perceptions of Health Care Providers regarding IVR as a device for HIV prevention?

1.7 Hypothesis

H1: Female sex workers are at a higher risk of contracting STI, HIV and AIDS

H2: Health Care Providers are likely to accept IVR as a device for HIV prevention.

1.8 Objectives

1.8.1 General Objective

To establish a high risk cohort for a vaccine or Microbicides clinical trials, relevance of Sexually Transmitted Infections, assess efficacy of Syndromic STI management and
document acceptability of Intra Vaginal Rings as a device for delivery of microbicides among Health Care Providers in Mukuru, Nairobi.

1.8.2 Specific Objectives

i. To determine STI and HIV risk factors among FSW in Mukuru.

ii. Determine the prevalence of STI and HIV in Mukuru.

iii. Evaluate the efficacy of Syndromic approach to STI management.

iv. Determine cohort retention during the study period.

v. Describe perceptions of Health Care Providers regarding intravaginal rings.

vi. Describe family planning practices among FSW in Mukuru.

1.9 Significance and Anticipated Outcome

Cohort development is a prerequisite for phase III clinical trials for either vaccine or Microbicides. This study was established to provide a pool of volunteers whose STI/HIV and AIDS prevalence are well characterized. It was also expected that by the end of the study, a comprehensive assessment of risk behaviour, description of retention patterns, family planning practices and VCT uptake could be achieved.

1.10 Limitations

Mukuru Kwa Njenga is a research naïve community. Human Immunodeficiency Virus and AIDS programs are limited to behaviour change communication. Society perceives sex workers negatively; this prevents FSW from participating in activities that target them. The study site is one of the informal settlements in Nairobi. Therefore, findings presented herein may not be representative of sex workers from other parts of the
country. The ethnography study was based on a hypothetical IVR ring and involved only twenty participants. In this view, the reports by Health Care Providers are based on assumptions from a small section of HCPs and may not be generalized for HCPs in Kenya.

1.11 Study Benefits

The study established a phase III cohort with well characterized high risk behaviour, retention rate and STI profiles. The study has therefore met the requirements for future vaccine and Microbicide clinical trials. Through this cohort, the duration and funding required to prepare volunteers for a phase III trial has reduced, hence accelerating the process of vaccine development. Female sex workers were treated for STI reducing associated complications and further infection spread. Community members were able to access VCT and ART services at no cost thereby improving the quality of life for both the infected and affected persons in Mukuru.
CHAPTER TWO

LITERATURE REVIEW

2.1 HIV and AIDS in the World

According to World Health Organization (WHO) and the Joint United Nations Project on HIV and AIDS (UNAIDS), 33.2 million (Range 30.6 – 36.1 million) people were estimated to be living with HIV and AIDS by the end of 2007, of which 22.5 million people were concentrated in some of the world’s poorest countries, located in sub-Saharan Africa (UNAIDS, 2008). This situation underscores the urgent need for an effective HIV preventive method.

Testing of preventive HIV vaccines presents various ethical dilemmas, particularly in Africa. Despite the dangers involved in testing, there are ethical problems in avoiding those dangers. The failure to act, like silence, has moral consequences, (Mugyenyi et al., 2002). Therefore, vaccine research institutions must seek a balance between three ethical principles namely: Respect for human sanctity, beneficence, justice and equitability (Mugyenyi et al., 2002).

2.2 HIV and AIDS in Sub-Saharan Africa

The ever increasing new HIV infections in sub-Saharan Africa imply that the region will continue to be the epicenter of the pandemic for many years to come. Not surprisingly, the impact of the pandemic has created a severe developmental crisis in sub-Saharan Africa. Although the latest report show a reduction of new infections worldwide
(UNAIDS, 2008), women and children continue to bear the burden of disease unabated. It is estimated that 12 million children, who have been orphaned by HIV and AIDS, live in sub-Saharan Africa. Such data suggest that even if exceptionally effective prevention interventions and care programs are implemented immediately, the scale of the current crisis will make the human and socio-economic costs of AIDS significant for many generations to come.

In sub-Saharan countries, both adults and children are becoming infected with the virus at a higher rate than ever before (USAID, 2002). The vast majority of new infections appear to be due to sexual transmission (UNAIDS, 2004). In Africa, 8.6% of adults are HIV positive compared with only 0.6% of American adults (USAID, 2004). The HIV and AIDS burden in sub-Saharan Africa is obviously disproportionate when compared with other regions that have lower prevalence (UNAIDS, 2008). Given the burden of disease and the high rate of infections, the researcher designed this study to facilitate evaluation of candidate vaccines and Microbicide for Africa.

2.3 The HIV Pandemic in Kenya

In the past, National HIV Prevalence in Kenya had decreased from a high of 14% in the mid 1990s to 7.1% in 2007, (KAIS, 2008). This prevalence has put Kenya among the nine African countries most severely affected by the pandemic. It was estimated that at the end of 2007, 1.4 million adults in Kenya were living with HIV and AIDS. The crude death rate in Kenya was higher in 2002 than it was in 1990. Life expectancy dropped
from 60 years in the 1990 to 49 in 2000 (NASCOP, 2003) yet there is no intervention on sight to curtail this scourge.

Studies show that the peak ages for HIV infections in Kenya is 25 to 29 for women and 30 to 34 for men (NASCOP, 2001). KAIS report of 2008 show that HIV among people aged 50 to 60 is about 5% compared to 7.1 % in the general population. This observation clearly shows that older people are equally affected by HIV and AIDS. Girls and young women are particularly vulnerable to infection, females aged 15 to 24 were more than twice as likely to be infected as men of the same age (Glynn et al., 2000). This age difference, between regular male and female partners is often cited as a contributing factor for increased overall prevalence of HIV amongst Kenyan women (Glynn et al., 2000, Helen et al., 2001). The Ministry of Health indicates that high health care costs and lost income from HIV and AIDS is a major burden on the Kenyan economy. Kenya’s gross domestic product was projected to be 14.5% lower than it would have been in the absence of AIDS (NASCOP, 2003).

2.4 HIV Infection in Women

The number of women with HIV infection and AIDS has been increasing steadily worldwide. According to WHO, 15.4 million women were living with HIV and AIDS worldwide. This accounts for a 50 percent of the 42 million adults living with HIV and AIDS (UNAIDS 2008). More than 90 percent of all adolescent and adult HIV infections are due to heterosexual sex and females are particularly vulnerable to heterosexual transmission. This is attributed to substantial mucosal exposure to seminal fluids (Glynn
et al., 2000). This biological fact amplifies the risk of HIV transmission when coupled with the high prevalence of forced, non-consensual sex, sex without condom, and the high-risk sexual behaviors of male partners. Women suffer from the same complications of AIDS that afflict men. Women also suffer additional gender-specific manifestations of HIV disease, such as recurrent vaginal yeast infections and severe pelvic inflammatory disease. Pelvic Inflammatory disease increases risks of cervical cancer (Glynn et al., 2000).

Frequently, women with HIV infection have great difficulty accessing health care. They carry a large burden of the care for children and other family members who may also be HIV-infected. Often, they lack social support and face other challenges that may interfere with their ability to adhere to treatment regimen. Traditionally, men are decision makers by virtue of being household heads and providers. A majority of these women have no economic power. Thus, a woman will stay in a relationship even when she knows her partner is being promiscuous. Since her partner is frequently the sole provider, the woman will remain exposed to the increased risk because of her commitment to support her children (Helen et al., 2002).

2.4.1 Intra Vaginal Rings

Intra Vaginal Rings (IVR) was originally developed to deliver hormonal contraceptives and hormone replacement therapy. Intravaginal Rings are flexible, doughnut shaped; silicone rings approximately 2 centimeters in diameter. They are designed to be inserted into the vagina by the women where they sit near the cervix and release a steady concentration of the drug for up to 12 months (Figure 2.1), (Speroff et al., 2003). They
Woman when necessary. Intra vaginal rings are either reservoir or matrix types. Reservoir IVRs contain the active drug mixed into a silicone core, then encapsulated by a sheath of non-medicated silicone which acts as a rate-controlling membrane while matrix IVRs contain the active drug mixed into silicone without a rate controlling membrane.

Currently, three IVRs are licensed for use in the United States of America and Europe for contraception of hormone replacement therapy (HRT). String (Pharmacia and Upjohn) is a reservoir IVR with a loaded core containing 2ug micronized 17B-estradiol which provides a constant release of 7.5ug/day for 3 months. Femring (Galen Holdings, UK) is a reservoir IVR with a drug loaded core providing continuous release of estradiol lactate at 50ug or 100ug/day for 3 months. Nuvaring (Organon) is also a silicone reservoir IVR for contraception delivering 120ug/day etonogestrel and 15ug ethinyl estradiol/day for 3 weeks (Shattock et al., 2003; Woolfson et al., 2006).

Measures 2.5 cm diameter, and 2cm in thickness

Figure 2.1: Nuvaring (Organon) Intra Vaginal Ring (Source: Pharmacia and Upjohn, United Kingdom)
Intra Vaginal Rings could offer several biologic and acceptability benefits over topical HIV and Microbicides currently in development. Microbicide creams, suppositories or films have been shown to have decreased intravaginal retention over time after application (Brown, 1997). Intra Vaginal Ring would provide steady local and serum levels of the HIV Microbicides. This ensures that both topical and vaginal coverage of the epithelium as well as submucosal lymph tissues, inguinal lymph nodes which are also thought to be targets of HIV infection. With steady state pharmacokinetics, IVR would decrease the risk of dose dependent adverse events such as epithelial toxicity which is a concern with topical products requiring repeated applications (Shattock, 2003).

Long-acting IVR could be inserted every 3-12 months. This regimen, eliminates daily dosing, improved adherence and therefore improves effectiveness (Woolfson, 2006). Vaginal delivery will also avoid first pass metabolism and induction or inhibition of hepatic enzymes possible with oral post exposure prophylaxis strategies (Brown et al., 1997). Equally important, IVR are likely to be a more private form of HIV prevention than topical Microbicides. This is because they are unlikely to cause noticeable changes in vaginal moisture, discharge or sensation during sexual activity (Shattock et al., 2003).

There are two major reasons for conducting ethnographic assessments in Mukuru. Foremost, cultural and sexual practices differ among African countries, so ideally acceptability and feasibility studies provide a better understanding of the potential for intravaginal ring use in Kenya (Wakasiaka et al., 2008). In this study, the Health Care
Providers (HCP) ethnography study was conducted prior to the actual STI study among women in Mukuru to allow for appropriate treatment regimens and culturally acceptable design. Furthermore, Intra Vaginal Rings have not been used in Kenya and there are no studies done so far to assess acceptability of these rings among Health Care Providers.

2.5 Challenges and Opportunities for HIV Vaccine Development

Soon after the identification of HIV as the cause of AIDS, the search for an HIV vaccine began nearly twenty years ago with great optimism. This optimism was based partly on recognition that some individuals were resisting infection even when exposed. Others who were infected (non-progressors) were capable of remaining relatively healthy despite persistent infection. However, progress has not matched the initial hopes despite a large concerted effort (KAVI, 2008). Development of an HIV vaccine has encountered a number of scientific, financial and logistical challenges. Some of the scientific challenges include poor understanding of correlates of protection, genetic diversity of the virus, particularly of isolates from different populations or different geographical regions (IAVI, 2008).

AIDS differs from other vaccine-preventable diseases in that HIV infection may persist, and AIDS may develop, despite a broad range of immune responses from the host. Therefore, the major conceptual problem for HIV vaccine development is the lack of information on immune responses known to correlate with protection against HIV or AIDS. Another potential obstacle for the development of broadly protective HIV vaccines is related to the extensive genetic variability of the virus, which is further
compounded by the high mutation rate in an infected individual (Mertens, 1994). Phylogenetic analysis of the nucleotide sequence of the envelope genes (env) of numerous HIV-1 strains from different parts of the world has resulted in their classification within a “major” or M group and two minor groups, O and N (Mertens et al., 1994). HIV-1 strains belonging to the M group are sub-divided into at least nine pure genetic subtypes or clades (A-D, F-H, J and K). Strains belonging to the same subtype can differ by up to 20% in their envelope sequences, whereas the differences between subtypes can be up to 35% (Cornelissen et al., 1996).

In 2000, it was estimated that most of the new HIV infections in the world, approximately 47% of them, were caused by subtype C virus. This subtype is prevalent in Southern Africa, Ethiopia and India (Cornelissen et al., 1996). Subtype B viruses are prevalent in America and Western Europe, while sub-types A and D are prevalent in Central and Eastern Africa. It is important, to emphasize, however, that HIV is constantly evolving, increasing the genetic distance between strains and generating new inter and intra-sub-type recombinant viruses, (Cornelissen, 1996). The key question is: Is there a need to develop candidate vaccines specific for each HIV subtype or would it be possible to design immunogens capable of inducing broad cross-clade protective immunity? Because of the high variability of the envelope gene, it is generally assumed that vaccine approaches based on envelope will be subtype or even strain-specific (Cornelissen, 1996).
The envelope gene codes for gp120 and gp41 are responsible for the induction of neutralizing antibodies (Katz et al., 1990). Conversely, vaccine approaches aimed at the induction of Cytotoxic T lymphocytes (CTLs) against gag gene products and other relatively conserved HIV-1 proteins, are usually assumed to be more cross-reactive. This offers hope for the development of broadly protective vaccines. Immune responses to CTL epitope, however, are restricted by the HLA makeup of the host, and this may require the design of specific candidate vaccines for use in different populations (Des Jarlais et al., 1987).

2.6 Process of Vaccine Development and Evaluation

Despite the scientific uncertainties described above, a wide range of candidate vaccines and Microbicides have been developed and tested in animal models and in humans. Before a candidate HIV vaccine is administered in humans, tests to assess the safety, toxicity, and immunogenicity of the vaccine are conducted in lower animals and non-human primates, the chimpanzee or baboons. The efficacy of a vaccine or Microbicides can also generally be assessed to a limited degree in these non-human primates. This can be done by vaccinating chimpanzees with HIV vaccines and challenging them experimentally with HIV. Phase I trials provide safety and immunogenicity data and are conducted among small numbers of volunteers (20 to 50) at low risk of HIV infection. Phase II safety and immunogenicity trials are conducted in about 100-200 volunteers including those at high risk of HIV infection (table 2.1). Depending on the results obtained, candidate vaccines may progress to phase III trials. This phase aims at
obtaining definitive information about vaccine efficacy in inducing protection against infection or disease (KAVI, 2008).

### Table 2.1: Summary of Clinical Trial Phases and Their End Points (KAVI Updates, 2005)

<table>
<thead>
<tr>
<th>Phases</th>
<th>Sample size</th>
<th>Inclusion/Exclusion criteria</th>
<th>Endpoints</th>
<th>Duration (Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>20-50</td>
<td>Healthy, HIV-negative, at lower risk for HIV-infection, dose, regimen</td>
<td>Safety, Preliminary Immunogenicity</td>
<td>18-24</td>
</tr>
<tr>
<td>II</td>
<td>100-200</td>
<td>(Healthy), HIV-negative, at lower to higher risk, dose, regimen</td>
<td>Safety, Immunogenicity</td>
<td>18-24</td>
</tr>
<tr>
<td>III</td>
<td>5000-10,000</td>
<td>HIV-uninfected, at risk (FSW, discordant couples, general population)</td>
<td>Expanded safety, Efficacy, Correlates of protection</td>
<td>36-60</td>
</tr>
</tbody>
</table>

#### 2.7 HIV Vaccine Clinical Trials in Kenya

The first Phase I HIV vaccine clinical trial to take place in Africa started at KAVI in the year 2001 as a joint collaboration between University of Nairobi (KAVI), Medical Research Council- UK (MRC), and International Aids Vaccine Initiative (IAVI). Since then several candidate vaccine trials have been tested with good safety profiles. However immune responses among the volunteers in these studies were poor hence the products
have not moved to efficacy trials. This essentially means that many more candidate vaccines or Microbicides have to be tested to identify those that are promising and can therefore move to phase III. In the meantime, trials site has embarked on basic science research as well as developing cohorts for possible vaccine and or Microbicides efficacy trials.

2.8 Preparation of a Cohort for Phase III HIV Vaccine Trial

Phase III trials are large scale tests involving those considered to be at high risk of HIV infection to test the success of the vaccine in either preventing infection, or in preventing the progression of HIV infection. Because of the nature of these large scale trials, high risk individuals need to be characterized early to help narrow the preparatory phase for efficacy trials. To do this, multisite cohorts need to be developed prior to the advent of phase III trials (Nelson et al., 1994).

A Cohort is defined as a group of people with known characteristics at baseline; they are well characterized and often followed up for a long period. Usually, these cohorts are large studies ranging from 2 to 10,000 volunteers, often multi-centered with a long follow up period lasting 3 to 5 years (Nelson et al., 1994). Volunteers in these cohorts have to be HIV negative but are at a high risk of infection, they include: Commercial sex workers and their clients, discordant couples (HIV negative partner), intravenous drug abusers, and Homosexual and Bisexual individuals. The end points of Phase III studies is expanded safety data, efficacy which measures the rate of HIV Prevention of infection,
prevention of chronic infection or Transient infection, occurrence of other infection but AIDS is prevented or delayed, (Nelson et al., 1994).

2.9 Requirements for Conducting Phase III Vaccine Trial

An informed community is the key to the success of any clinical trial. Communities should be involved early during study design, implementation and distribution of results. This creates community ownership of the process thereby increasing product acceptability. The study populations must be stable, large, well defined with sufficiently high incidence rates. Research teams are expected to provide Supplemental health care, facilitate access to medical care where treatment of inter-current illness is provided (Mantel et al., 2005). Sound scientific principles require that before any phase III trials are conducted, a candidate vaccine with promising Phase II results must be availability and that funding for these studies should be stable and long term (KAVI Reports, 2008).

Cohort development occurs in the midst of multiple challenges. KAVI-Kangemi cohort reports show a high prevalence of co-morbid chronic illnesses, high HIV prevalence with limited access to ARVs, multitude of other social problems such as poverty, crime, drug abuse, alcoholism, stigmatization of sex work and unemployment (KAVI Reports, 2008). Because literacy levels are low, Information dissemination is a big challenge given the technical nature of trial information. The Concept of voluntarism is also new, compounded by high poverty levels. In an attempt to expand the scope of well defined cohorts in Nairobi, KAVI identified Mukuru as a research naïve community with diverse high risk groups whose characteristics have never been documented. Because of the risk
implications and complications of STI, the study focused on the management of STI among FSW.

2.10 Sexually Transmitted Infections

2.10.1 The burden of Sexually Transmitted Infections

Sexually transmitted diseases are of major public health importance as they predominantly affect young adults, carry stigma and facilitate transmission of HIV infection. Sexually Transmitted Infections pose complications which constitute a great socio-economic burden. Complications resulting from failure to diagnose and treat infections include pelvic inflammatory disease (PID), infertility, ectopic pregnancy, chronic pelvic pain, cervical cancer and urethral stricture (Hanson et al., 1996). The impact on fetuses and newborns can be devastating, as manifested by miscarriages, stillbirths, neonatal deaths, mental retardation, neonatal conjunctivitis and pneumonia. In 1993, the World Bank reported that STI excluding HIV are the second most important cause of healthy life lost in women after maternal mortality and morbidity. In spite of this burden, STI have been accorded low priority in many developing countries. Most countries lack an effective STI control programme (Adler et al., 1996).

Fortunately, interest in STI has been boosted by evidence from recent studies confirming that control of STI could contribute considerably to reducing the incidence of HIV (Grosskurth et al., 1995; Day and Ward 1997). The main aims of STI control are to interrupt their transmission, development and consequences. Primary prevention measures include detecting and curing disease by providing adequate diagnostic and
treatment facilities. Syndromic case management is one approach for the secondary prevention of STI (Grosskurth et al., 1995).

In Kenya, Reproductive Tract Infections (RTIs) and sexually transmitted infections (STI) are a major public health problem. In early 1990s the Ministry of Health (MOH) in conjunction with National STI and Aids Control Program (NASCOP) developed guidelines and policies governing STI management in Kenya. These guidelines adopt the Syndromic approach to diagnosis and treatment of STI as outlined in the 1991 World Health Organization (WHO) convention. This dissertation discusses STI management among FSW as a secondary measure in prevention and control of STI, HIV and AIDS.

2.10.2 Syndromic STI Management

A syndrome is set of signs and symptoms that characterize a clinical condition. Extending this definition, Syndromic management implies an approach in which clinical algorithms such as decision trees for commonly presenting signs and symptoms (such as urethral discharge or genital ulcer) are used in case management. The symptoms selected are reasonably consistent and easy to recognize. The algorithm provides treatment for the commonest biological causes of the syndrome. For example, for genital ulcer disease (GUD), treatment is provided concomitantly for the two commonest causes, chancroid and syphilis in the absence of laboratory support and in recognition of the limitations of clinical diagnosis. Examples of STI treated syndromically include vaginal discharge, male urethral discharge, lower abdominal pain, scrotal swelling and ophthalmia neonatorum. Education and counseling for prevention of future infections, condom
promotion, compliance promotion and partner management are integral components of patient management (WHO, 1991).

Traditionally, diagnosis of a presumed STI was based on either clinical diagnosis which is after inaccurate and incomplete examination or laboratory diagnosis which is often complex, expensive and may delay treatment. Because of these difficulties in diagnosis and treatment of STI, WHO introduced and promoted the Syndromic management guidelines in 1991 (Van, 1996). The Syndromic approach is based on the identification of a syndrome that is a group of symptoms, easily recognized signs associated with a number of well defined etiologies. This approach does not require identification of the underlying specific pathogen instead treatment is based on the presenting group of signs and symptoms, referred to as syndromes.

Like many African countries, Kenya adopted a Syndromic approach because it offered enormous advantages especially in rural settings where laboratory access is very limited. Furthermore, the new approach can be learned and applied by primary healthcare providers and it allows treatment of symptomatic patients in one clinic visit. A major disadvantage of the Syndromic treatment regime is over reliance on reported prevalence and etiologic agents of STI which vary widely by geographical area and population. This may lead to over treatment of individual patients, increase in costly drug wastage, side effects and inadequate care of asymptomatic patients. For example, over time there has been a drop in chancroid and syphilis and an increase in genital herpes which is attributed
to improved diagnostic of herpes simplex virus (HSV) by the HIV control programs (NASCOP, 1996).

2.10.3 Rationale for Choosing Syndromic Management

The signs and symptoms of the various STI are not specific making accurate clinical diagnosis difficult. About 70% of single infections of genital ulcer disease are correctly diagnosed clinically (Dangor et al., 1990). Nairobi study reports 40% of chancroid and 24% of syphilis infections were correctly diagnosed clinically (Bwayo et al., 1994). Laboratory-confirmed etiological diagnosis is the usual approach used in the management of many diseases and is therefore considered ‘scientific’ by many practitioners. Use of microscopy, cultures and serology is expensive and could lead to delays in diagnosis. Many patients with STI were reported to have mixed infections. The limitations of clinical diagnosis without laboratory diagnosis have led to development of the Syndromic approach to STI management.

2.10.4 Efficacy of Syndromic STI Management

Mwanza Intervention studies provide the most convincing evidence in support of the efficacy of Syndromic case management. The study reports 30–50% reduction in the prevalence of active syphilis and symptomatic male urethral discharge (Mayaud et al., 1997; Grosskurth et al., 1995). In Abidjan, Syndromic case management achieved cure rates of 91% (La Ruche et al., 1995) and 96–98% in Mwanza (Mwijarabi and Mayaud 1997). Studies from Zambia and Côte d’Ivoire report cure rates of 87–97% for vaginal
discharge, 92 - 97% for male urethral discharge, 82–100% for female GUD and 69–100% for male GUD (La Ruche et al., 1995). Differences in cure rates reflect factors such as definition of cure, choice of drugs, compliance with treatment and antibacterial resistance.

The sensitivity of approaches to diagnosis and management of genital ulcer have been documented in Rwanda. The approaches were a concomitant algorithm in which patients with genital ulcers were treated for both chancroid and syphilis without laboratory tests, a hierarchical algorithm in which the choice of treatment was based on the results of laboratory test for syphilis and a clinical approach in which treatment was indicated on clinical diagnosis alone without laboratory tests. The proportion of correctly managed chancroid and or syphilis cases by these approaches was 99%, 82.1% and 38.3%, respectively. The authors concluded that in situations where no laboratory support is available and where chancroid and/or syphilis are the major causes of genital ulcers, a simple Syndromic approach should be used for case management (Hanson et al., 1996).

2.10.5 Advantages of Syndromic Management

Syndromic approach provides a useful mechanism for STI services to be integrated into the primary health care (PHC) system. High STI prevalence rates, lack of specialized staff and limited laboratory services in many developing countries warrant the use of approach. As treatment is provided at the first visit, the Syndromic approach avoids the pattern in the categorical approach in which patients have to visit the clinic, then go to a separate laboratory, return to the clinic for diagnosis, prescription, and then go to a pharmacy to buy drugs (Ryan and Hormes, 1995). Immediate treatment could prevent the
development of complications or further infection transmission while waiting for laboratory results. Patients unwilling or unable to return for follow-up visits are not required to do so. Those who are infected but might be denied treatment based on false-negative test results (especially where laboratory facilities are of marginal quality) are assured of treatment with this approach. Money is saved on laboratory tests which could be used to improve drug availability. In Mwanza, a follow-up of non-returning patients at their homes revealed that about 70% were clinically cured; recurrences being due to untreated partners (Mwijarabi and Mayaud1997).

The use of Syndromic case management standardizes Sexually Transmitted Infection (STI) care, thus replacing a plethora of regimens which may be ineffective. Patients receive the same treatment for a given condition in local health facilities, thus boosting their confidence in health services. Sexually Transmitted Infections (STI) data collection and analysis is simplified, thereby facilitating surveillance and planning. Standardizing treatment may also delay the development of antimicrobial resistance of STI bacteria (Bakari et al., 2000).

In Côte d'Ivoire, the cost of effective STI treatment with the Syndromic approach (US$ 5.60) is less than a fifth of the cost with the laboratory-based approach. While Syndromic management may lead to overtreatment of patients with single infections, the cost per patient cured may be two to three times less than clinical diagnosis and three to four times less than etiologic diagnosis (Islam et al., 1994). Management of STI by Syndromic method achieves high cure rates and is cost-effective (Mayaud et al., 1997).
Syndromic approach is generic and can easily be adapted to local conditions. In Sultanate of Oman, where latent syphilis has been targeted and where male doctors are prohibited from performing vaginal examinations, STI case management includes mandatory syphilis testing and the use of an algorithm for vaginal discharge that excludes vaginal examinations (Venkataram et al., 1997).

2.10.6 Disadvantages Syndromic Management

Syndromic management of STI is the preferred approach in resource-poor countries. However, a number of limitations hinder its wide acceptability, such as overtreatment of patients. However, the limitations of the other approaches mean that some patients with atypical clinical features, false negative results or with mixed infections will be inadequately managed. Such patients may have to return for further investigation, suffer prolonged morbidity and then treated at further cost.

The Syndromic approach for vaginal discharge is a poor predictive of the presence of cervical Chlamydia or gonococcal infection. Using three different algorithms for vaginal discharge in women presenting at a STI clinic, Ronsmans (1996) reported positive predictive values of 25–35% for diagnosing trichomoniasis and 42–43% for gonococcal or chlamydial cervicitis. The algorithm had a sensitivity of 9% for detecting chlamydial infection in a low-risk population of Turkish women (Ronsmans et al., 1996) and a sensitivity of 43% among pregnant women for Chlamydial or gonococcal cervicitis in Tanzania (Mayaud et al., 1995). The introduction of risk assessment such as having more than one partner, new partner in the last 3 months and those below 21 years was an attempt to improve the sensitivity and specificity of the algorithm. The strategy has not
been very successful owing to country dynamics and lack of monitoring and evaluation mechanisms. In one study, being unmarried or having more than two sexual partners in the past 5 years or the presence of vaginal or cervical discharge on examination had a sensitivity of 76%, a specificity of 42% and a positive predictive value of 5% for gonorrhoea (Gertig et al., 1997). Generally, the use of different algorithms, different study populations and diverse prevalence’s of syndromes limit comparison between studies.

As the Syndromic approach is based on self-reported symptoms, it does not detect or treat patients with asymptomatic infections. Detection of asymptomatic infections remains one of the thorny problems in STI control. In rural Tanzania, with a gonorrheal prevalence of 2.2% among males aged 15–44 years, only 15% of infected males were symptomatic (Grosskurth et al., 1996). Similarly, only 16% of pregnant women with gonococcal or chlamydial infection in rural Tanzania complained of a vaginal discharge (Mayaud et al., 1995).

The approach has not been easily acceptable by doctors who regard it as unscientific inferior medicine and feel threatened by any restriction on their freedom to prescribe. This is partly due to the emphasis placed by medical school training on microbiological diagnosis in the treatment of infections. The approach has been challenged by dermatovenereologists who cite among other reasons, the lack of specificity of signs and symptoms of GUD and the presence of mixed infections (Kumar et al., 1995). Yet, these are very reasons that justify the Syndromic approach.
Another disadvantage is that no single algorithm is appropriate for every setting. In Papua New Guinea, where chancroid is rare and most ulcers are caused by Calymmatobacterium donovani (Richens, 1985), treatment should be directed at the latter rather than at both chancroid and syphilis, as practiced in East Africa. Algorithms need to be evaluated for validity, feasibility, cost and acceptability to facilitate their effective use. In view of changing antimicrobial susceptibility patterns and continuing research, algorithms will need to be regularly updated. It is important that the simplistic nature of the algorithm is not misunderstood to imply automatic clinical response. The approach should not negate the need for referral and full clinical investigation when required.

Other problems with Syndromic case management relate to its implementation. Funds are often not available in resource-poor countries for initial and refresher training of doctors and primary health care workers. Often, training in Syndromic management excludes clinicians in the private sector, pharmacists and other health care providers. There may be psychological and logistic barriers to changing reporting systems to reflect the STI syndromes.

In some countries, antibiotics for STI treatment are tied to the level of health care or cadre of prescriber. In such situations, decentralizing the Syndromic approach demands a revision of such policies. Such policy revision has recently been effected in Ghana, albeit at the risk of potential development of antimicrobial resistance since drugs such as ciprofloxacin for enteric fever or other conditions are unchecked.
2.10.7 How Does Syndromic Approach Work

Introduction of risk assessment to improve the algorithm for vaginal discharge has not been successful. There is urgent need for simple, rapid, cheap tests for screening gonococcal and chlamydial infections in health facilities lacking laboratory support. Algorithms that are highly sensitive will permit the treatment of the more patients in the interest of public health and avert the potential sequelae of cervical infection. Training has been shown to improve STI case management. It should emphasize appropriate referral in all cases.

Owing to the large prevalence of asymptomatic infection, improving partner notification and management is essential. The use of tests such as polymerase chain reaction and ligase chain reaction as gold standards to assess the Syndromic management of genital infections in women in resource-poor settings has been reported (Ryan 1995). Clinicians should refrain from medicalizing STI syndromes, as a holistic and intersectoral approach may sometimes be required for total care. Implementation support in the form of political stability, high staff morale, adequate remuneration, effective drug distribution systems and regular supervision are necessary to make Syndromic treatment work (WHO, 1996).

2.10.8 Role of Monitoring and Evaluation in Syndromic Management

Regular monitoring should make Syndromic management more effective. It should cover variables related to management (number of training sessions, availability of drugs), health workers (number of trained health workers), patients (patient satisfaction) and germs (susceptibility patterns). Monitoring antimicrobial resistance for gonococci could
be done on a selected sample of patients once a year. The evaluation of the algorithms could be undertaken regularly and assess cost-effectiveness of the approach in areas of gonococcal resistance where more expensive second or third-line drugs are given. Overall, the Syndromic approach is a simple, attractive and effective approach for STI management particularly in resource-poor countries where laboratory facilities are unavailable. On balance, the advantages of the approach seem to outweigh its disadvantages. The approach is both rational and scientific. However, the decision to adopt the approach should be country specific considering the variations in STI epidemiology, operational issues, cost and available drugs.

2.10.9 Changing Patterns of STI post Syndromic Management

Epidemiological studies suggest that the presence of genital ulcers and urethral and vaginal discharge increase risk of HIV transmission. For this reason, treatment and monitoring of STI syndromes are an important component of HIV prevention efforts in Kenya. The NASCOP sentinel surveillance report show a decline in the proportion of genital ulcer diseases (GUD) from 1996 to 2000 (p<0.0001). A similar decline in the proportion of urethral discharge in males occurred during the 1996 to 2000 (p<0.0001). Similar trends were also observed for vaginal discharge in females.

The decline in the proportion of genital ulcer disease, urethral and vaginal discharge syndromes from 1996 to 2000 may have been due to the wide-spread application of STI Syndromic management starting at full-scale in 1996. In Nakuru, studies reported increased STI prevalence in 2001; this coincided with termination of funding for free STI
drugs (Maggwa et al., 1999). It is with this background that NASCOP recommends use of Syndromic management and free STI drugs in all public clinics.

2.11. Classical STI Syndromes

2.11.1 Genital Ulcer Disease (GUD)

A genital ulcer is a loss of continuity of the skin of the genitalia. The ulcer may present with or without pain. It may be associated with inguinal lymph node enlargement also referred to as bubo. Genital Ulcer Disease increases HIV transmission as seen in studies that report an increase of herpes culture positive among HIV positive individuals in Rwanda. The most common etiologic agents of (GUD) are Herpes simplex Type 1 (HSV-1), HSV-2, Treponema pallidum which causes syphilis and Heamophilus ducreyi which causes chancroid (Ronsmans, 1996). In many developing countries, the leading causes of GUD are infections with Heamophilus ducreyi, followed by Treponema pallidum and HSV infections. These pathogens can occur singly or in combination (Coutinho et al., 1996). Genital Ulcer Disease presents in various forms. The classic lesion of primary syphilis, the chancre is a single, painless, indurate ulcer with a clean base. The herpetic lesion is characterized by multiple painless lesions which may be recurrent. However there is significant variability in morphologic presentation making clinical interpretation unreliable when used without confirmatory laboratory test (Kapiga et al., 1998; Gertig et al., 1997).

Different laboratory tests can be used to discriminate between the causative agents of GUD; each test differs with respect to sensitivity, specificity, and turnaround time.
Culture provides direct evidence for infection and is the “Gold standard” for HSV detection. However, it may take up to one week to get definitive negative results. Positive results can be obtained within two days. The differentiation into HSV-1 or HSV-2 is possible by using monoclonal antibodies. Direct detection of HSV antigen by immunoassay also enables a fast diagnosis; however, the sensitivity of immunoassay is considerably lower than that of culture (Hanson et al., 1996). *Haemophilus ducreyi* is a Fastidious microorganism that is detected by a rather problematic culture technique (Hawkes et al., 1992). Nevertheless, culture is the Gold standard for *Haemophilus ducreyi* in vitro culturing of *Treponema pallidum* (TP) is not possible at all.

*Treponema pallidum* is detected by dark-field microscopic examination, but this is a specialized test and it is not routinely performed. Serology provides a suitable and accepted method for the diagnosis of syphilis. The most commonly used tests are *Treponema pallidum* specific serological test, like a *Treponema Pallidum* Hemaglutination Assay (TPHA) and Fluorescence Test (FTA) in combination with a rapid regian (RPR) which is not *Treponema pallidum* specific (Hanson et al., 1996). A positive RPR is considered indicative of an active infection. In the past decade amplification techniques such as PCR, have been developed to detect many different infectious agents, including HSV-1, HSV-2, *Treponema pallidum* and *Haemophilus ducreyi* PCR can be performed for each agent separately or, more efficiently, by a multiplex assay.
The advantages of PCR are the direct detection of the pathogen itself, the high sensitivity, and the potentially short turnaround time (Kumar et al., 1995). A disadvantage is that it should be performed with great care to prevent carryover contamination (Bwayo et al., 2001). In this study, diagnosis and treatment of GUDs was done using RPR and NASCOP guidelines as outlined in Figure 2.2.

Fig. 2.2: Treatment Algorithm for Vaginal Discharge as Recommended by Ministry of Health (NASCOP, 1996).

When a patient presents with History of vaginal discharge; Examine for discharge and abdominal pain

No abdominal pain

Provide Vaginitis Treatment and 4Cs

If No improvement after 7 days

Abdominal Pain is present

Use flow chart for lower abdominal pain

Refer for Gynaecological

Cervicitis Treatment
Norfloxan 800mg stat and Doxycycline 100mg BD x 7 days

Vaginitis Treatment
Clotrimazole Pessaries Intravaginal daily for 6 days and Metronidazole 400mg TDS x 5 days.

If Pregnant Refer
2.11.3 Vaginal Discharge in Female

Vaginal discharge is a common presenting symptom seen by doctors in many services (primary care, gynecology, family planning, and departments of genitourinary medicine). Vaginal discharge may be physiological or pathological. Although abnormal vaginal discharge often prompts women to seek screening for sexually transmitted infections (STI), vaginal discharge is poorly predictive of the presence of an STI.

2.11.4 Etiology of Physiological Discharge

Normal vaginal flora (lactobacilli) colonizes the vaginal epithelium and may have a role in defence against infection. They maintain the normal vaginal pH between 3.8 and 4.4. The quality and quantity of vaginal discharge may alter in the same woman in cycles and over time; each woman has her own sense of normality and what is acceptable or excessive for her. Figure 2.2 illustrates the recommended diagnosis and treatment algorithm for vaginal discharge.

2.11.5 Pelvic Inflammatory Disease

Pelvic inflammatory disease (PID) is an ascending infection of the female upper genital tract (the female structures above the cervix. Pelvic inflammatory disease is the most common and serious complication of sexually transmitted diseases, aside from AIDS, among women. The signs and symptoms of PID include fever, foul-smelling vaginal discharge extreme pain, including pain during intercourse, and vaginal bleeding. Pelvic Inflammatory can scar the fallopian tubes, ovaries, and related structures and lead to
ectopic pregnancies, infertility, chronic pelvic pain, and other serious consequences (Grosskurth et al., 1995). The infectious microorganisms in PID migrate upward from the urethra and cervix into the upper genital tract. Many different organisms can cause PID, but most cases are associated with gonorrhea and chlamydial infections, two very common STI. The gonococcus (Neisseria gonorrhoea), which causes gonorrhea, probably travels up into the fallopian tubes, where it causes sloughing (casting off) of some cells and invades others.

It multiplies within and beneath these cells. The infection then spreads to other organs, resulting in more inflammation and scarring. The presence of a cervical mucus plug normally helps prevent the spread of microorganisms to the upper genital tract, but it is less effective during ovulation and menses. The gonococcus may gain access more easily during menses, if menstrual blood flows backward from the uterus into the fallopian tubes, carrying the organisms with it. This may explain why symptoms of PID caused by gonorrhea often begin immediately after menstruation as opposed to any other time during the menstrual cycle. Women with STI are at greater risk of developing PID. A prior episode of PID increases the risk because the body's defenses are often damaged during the initial bout of upper genital tract infection. Sexually active teenagers are more likely to develop PID than are older women. The more sexual partners a woman has, the greater is her risk of developing PID. Women who douche once or twice a month may also be more likely to have PID (Helen et al., 2000). Douching may push the microorganisms up into the upper genital tract and it may also ease the discharge, masking the infection, so the woman delays seeking health care. The diagnosis of PID can be difficult to make. If symptoms such as lower abdominal pain are present, a
physical exam may be done to determine its location, check for abnormal vaginal or cervical discharge and for evidence of cervical chlamydial infection or gonorrhea. Other tests, such as a sonogram, endometrial biopsy, or laparoscopy may be used to distinguish between PID and other serious problems that may mimic PID. Because cultures of specimens from the upper genital tract are difficult to obtain and because multiple organisms may be responsible for an episode of PID, the treatment is to prescribe at least two antibiotics that are effective against a wide range of infectious agents. The symptoms may go away before the infection is cured therefore it is important for the patient to complete their treatment regimen (NASCOP, 1996). Figures 2.2 and 2.3 below illustrate the preferred STI treatment algorithms as recommended by the Ministry of Health in Kenya. (NASCOP, 1996).
Fig. 2.3: Treatment Algorithm for Lower Abdominal Pain in Women; as Recommended by Ministry of Health. (NASCOP, 1996).

HISTORY OF ABDOMINAL PAIN

Abdominal mass, abdominal tenderness?

- No tenderness on abdominal examination

- Refer for surgical or gynecological assessment

Do abdominal and bimanual examination

Abdominal tenderness or tenderness

- Symptomatic treatment or vaginitis treatment if there is vaginal discharge

- PID treatment

- If no improvement after 3-7 days

- Start flow chart again after repeating abdominal examination

If no improvement after 3-7 days

Investigate

Surgical or gynecological causes are determined by rebound tenderness and/or guarding; last menstrual period overdue; recent abortion or delivery; menorrhagia or metrorrhagia

Pelvic Inflammatory Disease Treatment.
Norfloxacin 800mg start and Doxycycline 100mg BD x 7 days and Metronidazole 400mg BD x 10 days

The 4Cs that form part of treatment guidelines are; (Counseling, Compliance, Contact tracing for partner and Condom use are treatment components emphasized at every clinic visit).
CHAPTER THREE
MATERIALS AND METHODS

3.1 Study Site

The study was conducted in Mukuru; a slum area located southeast of Nairobi, Embakasi Division of Nairobi Province and is about 8 kilometers from Nairobi City centre. The area comprises of three locations namely: Mukuru Kwa Njenga, Mukuru Kwa Reuben, and Kware. Mukuru Kwa Njenga is the largest neighborhood. Mukuru population is estimated at 365,000 consisting of 98,000 males and 267,000 females as documented in 1999 by World Vision (World Vision Reports, 1999). The area is overpopulated with average income far below the poverty line, unemployment and school dropout rates are common.

Rationale for choosing Mukuru is based on the fact that there are many bars running 24 hours seven days a week. Female bar attendants who double up as commercial sex workers have an average of 5 clients per week compared to 3 clients per day for women practicing prostitution in brothel like homes. The prevalence of HIV and AIDS in the area which was 7.6% (KDHS, 2003). There are no government health care facilities and community support programmes in the community. Records from local private clinics show that about 30-50 cases of STI are seen per month. Besides, this is a research naïve, low social-economic and high-risk population ideal for HIV intervention studies. In this Study, One hundred FSW was enrolled for study in a period of three years from October 2005 to May 2008.
3.2 Study Population

3.2.1 Sex Workers Cohort

There were two study populations namely Female Sex Workers and Health Care Providers. World Health Organization (WHO) defines adults as women and men aged 18 and above. This study included individuals aged 18 to 50 years; this age range covers people in their most sexually active years. Study participants were drawn from existing high risk group’s of Commercial Sex Workers. High risk individual refers to a person or groups of people who report recurrent history of STI, multiple sex partners and does not use protective device such as male or female condoms. In this study, the term “High risk group” is used to describe individuals who by the nature of their work or sexual behaviour are at a higher risk of HIV infection. The researcher conducted group specific vaccine literacy seminars, VCT promotion and health promotion sessions. Although all participants were invited to join the study; only interested participants were referred by the community Mobilizer to the study nurse-counselor at the dispensary. The counselor then assessed eligibility as outlined below; willing and consenting participants were enrolled for study using a standard questionnaire (Appendices III and IV). The same tool was completed at the last scheduled visit.

3.2.2 Health Care Providers

First, ethnography study included twenty health providers (community health workers, nurses, medical officers) practicing at Mukuru. They were invited to participate in face-to-face interviews. Two interviewers were trained, after which they conducted in-depth
Interviews using a structured questionnaire. The following data was collected using interview guide (Appendix VI); level of education, type of provider, years in practice, type of population served, opinions about common STI in and around Mukuru, feasibility of condoms and topical Microbicides as HIV prevention methods in their population and opinions about the feasibility of intravaginal ring use by FSW in their catchment area. Explored further was barriers to IVR use among sex workers and feasibility of distributing the rings.

3.3 Study Design

This was a prospective cohort study conducted over a three year period. The study was designed in two ways; first an ethnography study was initiated to assess acceptability of IVR as a method of delivering Microbicides and also document common STI that HCPs encountered in their routine practice. The second part of the study was to characterize STI among sex workers in Mukuru, assess their risk taking behaviour.

3.3.1 Participant Recruitment

3.3.2 Sex Workers Recruitment Strategies

Before community empowerment process was initiated, a baseline survey was conducted, the villages were identified and zones mapped. A VCT site was also set up at Alice Nursing Home, Mukuru. Twenty peer educators were trained after the baseline survey and at 12 months, KAVI peer manual was used for this training. In preparation for the focus groups, a series of community meetings with local administrators and village elders both to provide them with background information about microbicide research and
development, and to attain community support for the study were held. Simultaneously, field workers mapped Mukuru and identified key points for recruitment, such as bars and brothels, within which contact with FSW and their male clients was established. Willing 'at risk' participants were invited to attend presentations at the study site to learn more about the study and participate in HIV testing and counseling. Eligible women were HIV negative, age 18-50, residents of the Mukuru slum area, and reported exchanging sex for money, or vice versa for at least 3 times in the past month. Those who tested HIV positive during the screening process were counseled and provided support to receive further evaluation and management at the site. Individuals who tested HIV negative were invited to attend one-on-one information sessions at the study site, a local Mukuru community health clinic. Written, informed consent was obtained from qualifying participants who were then booked for enrollment, the procedures outlined below were strictly followed.

3.4 Study Procedures

3.4.1 Visit 1: Informed Consent and Enrollment Visit

At the enrollment visit, the study nurse obtained a written informed consent from women after ensuring that they qualified as per the inclusion criteria:

Inclusion Criteria:

i. Exchanged sex for money at least 3 times in the past month.

ii. Aged 18 to 50 years on the day of interview

iii. HIV-1 negative

iv. Not pregnant

v. Willing to comply with the requirements of the study protocol.
vi. In the opinion of the principal investigator or designee has understood the information provided.

Exclusion criteria

i. Does not exchange sex for money.

ii. Under age 18 and more than 51 years on the day of interview.

iii. HIV Positive

iv. Pregnant

v. Unwilling to comply with the requirements of the study protocol.

vi. In the opinion of the principal investigator or designee has not understood the information provided.

The Female Sex Workers received a directed physical exam and speculum pelvic exam. Samples of endocervical secretions were collected to test for gonorrhea and Chlamydia. Vaginal secretions were collected to test for Candida, trichomonas, and bacterial vaginosis (Appendix VII, SOP3). Where genital discharge or genital ulcers were present, Syndromic STI treatment was provided based on Kenyan National STI Syndromic treatment guidelines. Women who received treatment were asked to return in 2 weeks to review lab results, and receive further STI or vaginitis treatment, if required. The Female Sex Workers also completed a baseline behavioural and risk assessment. Females able to bear children were given family planning counseling and if desired, provided referral to the adjacent family planning clinic. The FSW were required to come to the clinic every four months for scheduled protocol visits.
3.4.2 Visit 2

Behavioural and risk assessment, Medical history, Screening and treatment for STI using Kenyan National STI Syndromic treatment guidelines (NASCOP, 1996) were done. Where genital discharge or genital ulcers were present, women were given treatment based on Kenyan National STI Syndromic treatment guidelines (NASCOP, 1996). Women who received treatment were asked to return in 2 weeks to review laboratory results, and receive further STI or vaginitis treatment, if required. During this visit, HIV risk reduction counseling, free condoms and family planning options and referral were provided.

3.4.3 Visit 3

Behavioural and risk assessment, Medical history, Screening and treatment for STI using Kenyan National STI Syndromic treatment guidelines (NASCOP, 1996). If genital discharge or genital ulcers are present, women were given treatment based on Kenyan National STI Syndromic treatment guidelines. Women who received treatment were asked to return in 2 weeks to review lab results, and receive further STI or vaginitis treatment, if required. HIV test and counseling, HIV risk reduction counseling; free male and female condoms, Family planning counseling and referral.

3.4.4 Visit 4

Behavioural and risk assessment, Medical history, directed physical exam and speculum pelvic exam were done. Samples of endocervical secretions were collected to test for gonorrhea, and Chlamydia. Vaginal secretions were collected to test for Candida,
trichomonas, and bacterial vaginosis. Where genital discharge or genital ulcers are present, Syndromic STI treatment was provided based on Kenyan National STI Syndromic treatment guidelines. Women who received treatment were asked to return in 2 weeks to review lab results, and receive further STI or vaginitis treatment, if required. HIV tests and counseling, HIV risk reduction counseling; free male and female condoms, Family planning counseling and referral. This was the final visit.

3.4.5 STI and Vaginitis Laboratory Evaluations at Visits 1 and 4

All samples were collected and transported to Kenya AIDS Vaccine Initiative for analysis. Appendix VX was used in sample collection. Wet preps samples for trichomonas, Candida and Bacterial Vaginosis were done. Endocervical swab specimen from each FSW was placed in PCR buffer and tested using Gonorrhea and Chlamydia PCR (Amplicor, Roche Diagnostic Systems) according to manufacturer’s instructions. For bacterial Vaginosis and Trichomonas Vaginalis, a smear was put on a glass slide and fixed for Gram stain preparation. Gram stains were assessed at a magnification of x1000 under oil immersion for Nugents scoring. The gram stain was also assessed for Candidiasis. Specimens for identification of Trichomonas Vaginalis were inoculated directly into an InPouch TV test (Biomed Diagnostics) for culture. The pouches were incubated at 37°C. Direct microscopic examination of the plastic pouch was performed at 24 hours, and if the results were negative, evaluation was repeated at 48 hours on day 5.
3.5 Health Care Providers

Twenty of the most commonly visited Health facilities were identified for study; one HCP was randomly sampled from each facility. Following Community sensitization, Health Care Providers were informed about the study. They were invited for a half-day presentation that focused on STI and HIV available preventive technologies, ongoing clinical trials with specific reference to the IVR study. To be eligible for study, HCP were required to have a practice within Mukuru, possess a minimum of a diploma certificate from a recognized institution such as Kenya Medical Training, Nairobi or its constituent colleges. Four famous herbalists were included for study because they were mentioned previously in focus group discussions that involved FSW and their clients in the area.

3.5.1 In-depth Interviews

Qualifying HCPs were invited for one on one in-depth interviews; a review of informed consent document was done prior to signing the consent form (Appendix VI). Respondents were informed that Microbicides are being developed to protect against exposure to HIV, that the intravaginal rings have been approved for family planning and are being considered as a way to deliver Microbicides, but are not yet available for this purpose. Participants were asked about the burden of disease in their community. After which they were shown a sample of a hypothetical IVR and asked about first impressions regarding size, ring use among commercial sex workers, safety concerns and duration of IVR use and mode of distribution.

3.6 Determination of Sample Size

The sample size for this study was determined using the formula shown below, (Fisher et al., 1991). 

\[ n = \frac{pq^2}{d^2} \]
\[ n = \text{Minimum sample size required}, \]
\[ p = \text{Proportion of the target population estimated to have a particular problem,} \]
\[ q = 1 - p, \quad d = \text{Degree of accuracy desired.} \]

In this study,
\[ P = 4\% \]
\[ q = 1 - p = 0.5 \]
\[ d = 0.01 \]
\[ 4 \times (0.5 \times 0.5) = 100 \]
\[ (0.01)^2 \]

Sample size required = 100

### 3.7 Ethical Considerations

Prior to data collection, the study was approved by Kenyatta National Hospital/University of Nairobi Ethics and Research committee. Study participation was voluntary; willing participants were required to give written consent (Appendix II) that contained study information. Outcome of the study was shared with the study population through community based forums and in publications. The Kenyatta National Hospital/University of Nairobi Ethics and Research Board as well as Emory University reviewed and approved this study before it was executed.

### 3.8 Data Collection Tools

A structured questionnaire (Appendix III and IV) were used to collect information on respondent’s demographic data, history of high risk behaviour, condom use and VCT uptake. A structured questionnaire was used to collect information on behaviour modification during follow up visits (Appendix V) was used to confirm eligibility based
on medical history and physical examination. Data was collected over a two year period; during this time periodic reports and presentations were made.

3.9 Data Management

Data collected was edited, Epi-Info version 6.03 was used for data entry; Statistical Package for Social Sciences (SPSS) for Windows version 11.5 used for data analysis. In SPSS, the Chi-square test of hypothesized proportions was used to establish relationships and a 95% significance level was desired. The Crosstabs procedure was used to test for associations between variables. Qualitative data was coded and analyzed using NVIVO7.
CHAPTER FOUR

RESULTS

4.1 Cohort Demographic Characteristics

Section 4 presents results of the one hundred enrolled volunteers. The youngest sex worker was 18 years while the oldest was 50 Years old. Majority 72 (72%) were young, aged between 18 – 30 years; 31-40 were 18 (18%) while those aged above 40 years were 10 (10%). The mean age was 28 with a standard deviation of 8.252. Only 5 (5%) of the respondents had completed secondary education while more than half had primary education 50 (50.6%) and 45 (45%) had no formal education at all (See Table 4.1). Only 1 (1.1%) reported having completed middle college. Christianity was cited by the highest number of respondents 88 (88%), only 3 (3%) reported Islam as their faith, while the rest 9 (9%) did not identify themselves with any religion.

Notable, none of the respondent was married, majority were separated 51 (51%) single 39 (39%), divorced 4 (4%) and widowed 6 (6%). Majority of the respondents 92 (92%) reported sex work as their main occupation while 8 (8%) were casual workers. Among those who reported casual work as their occupation, bar attendant and changaa (local brew) beer brewer were mentioned most. The respondents mean income per day from all sources was 209 Kenya shillings, with median earnings of 200 shillings and minimum of 50 and maximum of 1,500. Table 4.1 below presents the social demographic characteristics.
Table 4.1: Cohort Social Characteristics

<table>
<thead>
<tr>
<th>Demographic Characteristic</th>
<th>Number (N=100)</th>
<th>Percentage (%)</th>
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<tr>
<td><strong>Education</strong></td>
<td></td>
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<tr>
<td>None</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>Primary</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Secondary</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Middle level college</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Christianity</td>
<td>88</td>
<td>88</td>
</tr>
<tr>
<td>Muslim</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single never married</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td>Separated</td>
<td>51</td>
<td>51</td>
</tr>
<tr>
<td>Divorced</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Widowed</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female Sex Worker</td>
<td>92</td>
<td>92</td>
</tr>
<tr>
<td>Casual worker</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 20</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>21-30</td>
<td>53</td>
<td>53</td>
</tr>
<tr>
<td>31-40</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>41-50</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

4.2 Social Responsibilities

4.2.1 Past Pregnancies and Social Life

Apart from the respondents’ demographic characteristics, they were also required to provide information regarding their social life focusing mainly on their immediate family, particularly the number of pregnancies they had and the dependants living with them in the same household. Ninety six respondents (96%) had children. The number of past
pregnancies ranged from 1 to 13 while the number of other people living in the same household was from 0 to 6 (table 4.2).

Table 4.2: Past Pregnancies and other People Living in the Household

<table>
<thead>
<tr>
<th>Social Responsibility Number (N=100)</th>
<th>Number</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Past Pregnancies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>1-4</td>
<td>77</td>
<td>77</td>
</tr>
<tr>
<td>5-8</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>9 and above</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>People living in the house hold</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>1-2</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>3-4</td>
<td>36</td>
<td>36</td>
</tr>
<tr>
<td>5-6</td>
<td>8</td>
<td>8</td>
</tr>
</tbody>
</table>

4.3 Prevalence of HIV and AIDS among Female Sex Workers in Mukuru

To be eligible for the study, respondents were required to have a negative HIV test at the enrollment visit as is described in the methods section (3.4.1). For this reason, all registered FSW were tested at baseline before study participation. Over a twelve month period, a total of 740 FSW were tested for HIV, 84 (11.3%) tested HIV positive, 656 (88.6%) had a negative HIV test in 2006. To obtain the monthly HIV prevalence rate, the number of HIV positive tests was divided by the total number of tests done; in this case the total was 740. The first three months of the year 2006 (January, February and March)
recorded the highest number of VCT client inflow at the study site. Notably, the last three months of the year recorded low client inflow as presented in table 4.3 below.

Table 4.3: HIV Prevalence at Baseline, 2006

<table>
<thead>
<tr>
<th>Period</th>
<th>No of HIV Positive</th>
<th>% of HIV Positive</th>
<th>No of HIV Negative Result</th>
<th>% of HIV Negative Result</th>
<th>Total Tested monthly</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>13</td>
<td>1.8</td>
<td>76</td>
<td>10.2</td>
<td>89</td>
</tr>
<tr>
<td>February</td>
<td>4</td>
<td>0.5</td>
<td>65</td>
<td>8.8</td>
<td>69</td>
</tr>
<tr>
<td>March</td>
<td>11</td>
<td>1.5</td>
<td>95</td>
<td>12.8</td>
<td>106</td>
</tr>
<tr>
<td>April</td>
<td>3</td>
<td>0.4</td>
<td>45</td>
<td>6</td>
<td>48</td>
</tr>
<tr>
<td>May</td>
<td>8</td>
<td>1</td>
<td>55</td>
<td>7.4</td>
<td>63</td>
</tr>
<tr>
<td>June</td>
<td>6</td>
<td>0.8</td>
<td>80</td>
<td>10.8</td>
<td>86</td>
</tr>
<tr>
<td>July</td>
<td>11</td>
<td>1.5</td>
<td>65</td>
<td>8.8</td>
<td>76</td>
</tr>
<tr>
<td>August</td>
<td>7</td>
<td>0.9</td>
<td>55</td>
<td>7.5</td>
<td>62</td>
</tr>
<tr>
<td>Sept</td>
<td>4</td>
<td>0.5</td>
<td>42</td>
<td>5.6</td>
<td>48</td>
</tr>
<tr>
<td>Oct</td>
<td>6</td>
<td>0.8</td>
<td>37</td>
<td>5</td>
<td>41</td>
</tr>
<tr>
<td>November</td>
<td>5</td>
<td>0.7</td>
<td>15</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>December</td>
<td>6</td>
<td>0.8</td>
<td>26</td>
<td>3.5</td>
<td>32</td>
</tr>
<tr>
<td>Total</td>
<td>84</td>
<td>11.3</td>
<td>656</td>
<td>88.6</td>
<td>740</td>
</tr>
</tbody>
</table>
4.4 Reasons for Ineligibility and Knowledge of Partner’s HIV Status

Out of the 656 FSW who tested HIV negative, 114 FSW were screened for this study on a first come first serve basis. The rest of the sex workers were rolled over to other KAVI cohort studies at Kangemi and KNH clinic sites. Among the 114 who were screened for this study, 14 were ineligible for study. Reasons for ineligibility included: Pregnancy 10/114 (8.8%), relocation 3/114 (2.6%) and 1 (0.9%) was married. The remaining 100 were eligible and were therefore enrolled into this study.

Out of the 100 FSW who were enrolled, majority 94 (94%) reported that they never knew the HIV status of their clients despite the fact that they themselves had HIV negative results. The main reason for not asking about client’s HIV status was fear of losing a client and that the client might spread falsehoods about her status, hence she will lose her clientele. Only one FSW (1%) said that they always inquired about their client’s status as shown in the table 4.4 below.

Table 4.4: Knowledge of Partner’s HIV Status

<table>
<thead>
<tr>
<th>How often do you know the HIV status of the people you engage in sexual contact with:</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>94</td>
<td>94</td>
</tr>
<tr>
<td>Sometimes (about 50% of the time)</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Always (100% of the time)</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Rarely (about 20% of the time)</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
4.5 Risk Factors for STI among Female Sex Workers in Mukuru

4.5.1 Age at First Sexual Intercourse

Among the respondents, the earliest reported age of first sexual intercourse was 9 years, while the highest age was 23 years. The mean age at first sexual intercourse was 16 years. Most respondents 70% had their first sexual debut at below 18 years which is the required age where one is considered an adult in Kenya. Female sex workers who reported having an early sexual debut (below 18 years) were more likely to be paid more than 50 shillings for vaginal sex compared to those who had a later debut, with a likelihood ratio of 59.3.

Furthermore, FSW who had an early debut reported more anal sex practices compared to the group that had a late debut (p =0.7): both groups were paid more for anal sex compared to vaginal sex. Female Sex Workers receiving two hundred shillings for every anal sex act. In general, younger FSW were likely to participate in anal sex than the older FSW, (table 4.5)
Table 4.5: Age at First Sexual Debut by Sex Type and Payment Made

<table>
<thead>
<tr>
<th>Age at first sexual intercourse</th>
<th>Vaginal Sex Number (%)</th>
<th>Oral Sex Number (%)</th>
<th>Anal sex Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9-17 years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ksh. 20 and below</td>
<td>4 (4)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ksh. 50</td>
<td>27 (27)</td>
<td>3 (3)</td>
<td>0</td>
</tr>
<tr>
<td>100-150</td>
<td>33 (33)</td>
<td>8 (8)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>200 or more</td>
<td>5 (5)</td>
<td>8 (8)</td>
<td>14 (14)</td>
</tr>
<tr>
<td><strong>18-21 years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ksh. 20 and below</td>
<td>2 (2)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ksh. 50</td>
<td>4 (4)</td>
<td>1 (1)</td>
<td>0</td>
</tr>
<tr>
<td>100-150</td>
<td>16 (16)</td>
<td>3 (3)</td>
<td>0</td>
</tr>
<tr>
<td>Ksh. 200 or more</td>
<td>4 (4)</td>
<td>1 (1)</td>
<td>6 (6)</td>
</tr>
<tr>
<td><strong>Above age 22</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ksh. 20 and below</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ksh. 50</td>
<td>1 (1)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>100-150</td>
<td>2 (2)</td>
<td>1 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Ksh. 200 or more</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td><strong>Total 94</strong></td>
<td></td>
<td><strong>Total 24</strong></td>
<td><strong>Total 22</strong></td>
</tr>
</tbody>
</table>
4.5.2 Amount Paid for Sex without a Condom

Respondents were asked about sex without condom and amount they were paid. Most FSW said that they are paid Ksh 50 for sex without condom, while sex with male condom fetched as low as K.sh 5.

4.5.3 Vaginal Douche Practices

This objective aimed at establishing respondent’s practices that may impeach on the efficacy of vaginal Microbicides and predispose them to STI infections. All the women reported that they wash or douche their genitalia, and most, 88 (88%), douche after every sexual act. Water and soap was most commonly used for douching. The FSW said that they douche to keep themselves clean and to prevent odors and infections. They reported douching using all sorts of chemical and liquids that included water and detergent 75 (75%), lemon 15 (15%), others (Dettol, salt, tea leaves and coca cola) 61 (61%) as shown in table 4.6.

Table 4.6. Douche Practices

<table>
<thead>
<tr>
<th>Douching Practices;</th>
<th>N=100</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>How often do you wash or douche your genitalia?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After every sex act</td>
<td>88</td>
<td>88</td>
</tr>
<tr>
<td>Once a day</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What do you use to wash or douche your genitalia?</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Water and detergent/soap</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>Lemon</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Others, Herbs, Dettol, Omo, Salt, lemon and coca cola.</td>
<td>61</td>
<td>61</td>
</tr>
</tbody>
</table>
4.5.4 Douching and Use of Lubricants during Symptomatic Period

Most Female Sex Workers with a clinical diagnosis of Genital Ulcer Disease (GUD), Pelvic Inflammatory Disease (PID), vaginal discharge or Urinary tract infection reported douching as a common practice. Table 4.7 below shows that all sex workers were douching at some point either before or after every sex act. Out of 100 FSW in the study 75 (75%) reported douching during the symptomatic period. An additional question regarding use of lubricants was posed to these 75 sex workers. The probability of a Mukuru sex worker using a lubricant was 0.3 with 23 (30.7%) reported having used various types of lubricants.

4.5.4 Douching and Use of Lubricants during Symptomatic Period

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Table 4.7: Douching During Symptomatic Period and Use of Lubricants

<table>
<thead>
<tr>
<th>Douching Practices during symptomatic period N=75</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you wash or douche your genitalia?</td>
<td>48 (64%)</td>
<td>27 (36%)</td>
<td>75 (100%)</td>
</tr>
<tr>
<td>Do you use lubricants during symptomatic period?</td>
<td>23 (30.7)</td>
<td>52 (69%)</td>
<td>75 (100%)</td>
</tr>
</tbody>
</table>

4.5.5 Family Planning Practices and Health Seeking Behaviour

Thirty two (32%) said that they were not using any contraceptive method at enrollment, while 38 (38%) mentioned that they used injectables more often than the pills, 13 (13%). Notably, 31 (31%) of the FSW did not have regular periods. As shown in table 4.8, the average number of pregnancies per women was 2.86, and about 95% reported least 1 pregnancy. Asked where they go for treatment when they have an STI, majority 62 (62%) mentioned the clinic, followed by pharmacy 20 (20%), traditional healer 18 (18%).
Table 4.8: Reproductive Health Characteristics

<table>
<thead>
<tr>
<th>N=100</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
</table>

Where do you go for treatment when you have STI?

<table>
<thead>
<tr>
<th>Method</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional healer</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Clinic</td>
<td>62</td>
<td>62</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

Method of family planning being used

<table>
<thead>
<tr>
<th>Method</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Pills</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>IUD</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Tubal Ligation</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Male condoms</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Female condoms</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Injection</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>Norplant</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

4.6 Risk Characteristics

4.6.1 Primary Partners

Two thirds 40 (66%) of the women had a primary sexual partner, out of these 39 (97.5%) engaged in vaginal sex, 5 (12.5%) had anal sex with their primary partners most of the times. Of the FSW who had vaginal sex with primary partners, more than half 21 (53.8%) never used condoms during vaginal sex and 10 (25.6%) always used a condom during vaginal sex. For those who engaged in anal sex, most 3 (60%) did not use condoms.
4.6.2 Regular Partners

Ninety seven (97%) of FSW had at least one regular partner. On average, women had 6.41 regular partners per week. Most women 97 (97%) reported vaginal sex with regular partners, 34 (34%) reported anal sex, and twenty four percent reported oral sex with regular partners. Female Sex workers who reported vaginal sex with regular partners, 34.3% said they always used condoms during vaginal sex. Similarly, of women who had anal sex, 12 (34.5%) always used condoms during anal sex. Women did not report using condoms with oral sex as often. Of the women engaging in oral sex, 5 (20.8) always use condoms for oral sex.

4.6.3 Casual Partners

Ninety four (94%) of the women reported having at least 1 casual partner. All of the women had at least one regular or one casual partner. Women reported having an average of 5.03 casual partners per week. Most women reported having vaginal sex with casual partners (93%). A smaller percentage of women reported anal and oral sex with casual partners than with regular partners. Condom use was higher with casual partners than regular partners; more than 50% always used condoms with casual partners for vaginal or anal sex, but always using condoms with oral sex was also lower with casual partners (see table 4.9 below).
Table 4.9: Sexual Orientations

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N=100</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of sexual partner (N=100)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>Regular</td>
<td>97</td>
<td>97</td>
</tr>
<tr>
<td>Casual</td>
<td>94</td>
<td>94</td>
</tr>
<tr>
<td><strong>Sexual orientation with primary partner (n=40)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>39</td>
<td>97.5</td>
</tr>
<tr>
<td>Anal</td>
<td>5</td>
<td>12.5</td>
</tr>
<tr>
<td>Oral</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td><strong>Sexual orientation with regular partner (n=97)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>95</td>
<td>97.9</td>
</tr>
<tr>
<td>Anal</td>
<td>34</td>
<td>34</td>
</tr>
<tr>
<td>Oral</td>
<td>24</td>
<td>24.7</td>
</tr>
<tr>
<td><strong>Sexual orientation with casual partner (n=94)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>93</td>
<td>93.9</td>
</tr>
<tr>
<td>Anal</td>
<td>23</td>
<td>23.5</td>
</tr>
<tr>
<td>Oral</td>
<td>16</td>
<td>17</td>
</tr>
</tbody>
</table>

4.6.4 Sex Practice with Primary Partner during Symptomatic Period

Of the 75 symptomatic FSW 30 (40%) reported having vaginal sex always even when a diagnosis of sexually transmitted infection was made, p value of 0.1. Under the anal sex category, only 3 (4%) said that they sometimes had anal sex when they have an STI. At least two out of seventy five FSW reported oral sex during symptomatic period. There was a significant difference between those who practiced vaginal sex p=0.01 and those who practiced anal sex P, 0.00 during symptomatic period. A diagnosis was made based on both history and pelvic examination. Notably, majority 15 (50%) of the FSW said that they never used condoms for vaginal sex even though they had an STI, see table 4.10 below.
Table 4.10: Sex Practice with Primary Partner during Symptomatic Period

<table>
<thead>
<tr>
<th>Sex Type with primary Partner</th>
<th>Always %</th>
<th>Sometimes %</th>
<th>Never %</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=75</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>30(40)</td>
<td>3(4)</td>
<td>1(1)</td>
</tr>
<tr>
<td>Anal</td>
<td>1(1.3)</td>
<td>3(1.3)</td>
<td>29(38.6)</td>
</tr>
<tr>
<td>Oral</td>
<td>2(2.6)</td>
<td>1(2.9)</td>
<td>31(91.1)</td>
</tr>
</tbody>
</table>

Condom use n=10

<table>
<thead>
<tr>
<th>Sex Type</th>
<th>Symptomatic (Minimum, Ksh)</th>
<th>Asymptomatic (Maximum, Ksh)</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal</td>
<td>30</td>
<td>300</td>
<td>200</td>
</tr>
<tr>
<td>Anal</td>
<td>70</td>
<td>350</td>
<td>210</td>
</tr>
<tr>
<td>Oral</td>
<td>50</td>
<td>500</td>
<td>300</td>
</tr>
</tbody>
</table>

4.7 Amount Paid for Sex during Symptomatic and Asymptomatic Period

Below, table 4.11 shows that these sex workers continued to conduct their sex trade even during symptomatic period. Compared to Vaginal sex, Anal and Oral sex still fetched a higher price of Ksh 70 and 50 respectively table (4.11). In addition, majority (59%) reported always having vaginal sex during the symptomatic period. Only 6% reported always having (Table 4.12)
Table 4.12: Sex Type during Symptomatic Period

<table>
<thead>
<tr>
<th>Sex Type</th>
<th>Always</th>
<th>Sometimes</th>
<th>Never</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal (n=41)</td>
<td>20 (49%)</td>
<td>3(7%)</td>
<td>1(3%)</td>
<td>0.2</td>
</tr>
<tr>
<td>Anal (n=34)</td>
<td>1(3%)</td>
<td>3(9%)</td>
<td>20(59%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Oral (n=28)</td>
<td>2(7%)</td>
<td>0%</td>
<td>22(78%)</td>
<td>0.1</td>
</tr>
</tbody>
</table>

4.8 Alcohol and Drug Use

A little more than half of the women reported drinking alcohol. Of those women who do drink, about half drink daily and another half drink occasionally. About 50% have 3 to 5 drinks at one time, and about 40% have 6 drinks at one time. The women drink mostly beer or changaa. Three fourths of the women said that they do not use drugs. Eighteen percent reported using Bhang. One third of the women who use drugs or alcohol reported being under the influence of drugs/alcohol about fifty percent of the time during sex. Almost 20% of those who use drugs or alcohol are always under the influence of the drug or alcohol during sexual intercourse.

Other risk practices included having sex while under the influence of alcohol, 57 (57%). Of these, 11 (11%) said they would always have sex while under the influence of alcohol. Other factors include but are not limited to age at first sexual intercourse, number of sex partners, sexual orientation and drugs use. Thus, respondents were to indicate the age at which they had their first sexual encounter, the number of sexual partners, use of
protection during sexual intercourse and the type of sex they engaged in as presented in table 4.13.

Table 4.13: Alcohol Consumption and Drug Use

<table>
<thead>
<tr>
<th>Do you drink Alcohol? (n= 71)</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>41</td>
<td>57.75</td>
</tr>
<tr>
<td>No</td>
<td>30</td>
<td>42.25</td>
</tr>
</tbody>
</table>

How often do you drink alcohol? (n= 41)

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Often (Daily)</td>
<td>19</td>
<td>46.34</td>
</tr>
<tr>
<td>Occasionally (once a week)</td>
<td>21</td>
<td>51.22</td>
</tr>
<tr>
<td>Rarely (once a month)</td>
<td>1</td>
<td>2.44</td>
</tr>
</tbody>
</table>

How much alcohol do you consume at one time? (n=41)

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 2 drinks</td>
<td>5</td>
<td>12.20</td>
</tr>
<tr>
<td>2 – 5 drinks</td>
<td>20</td>
<td>48.78</td>
</tr>
<tr>
<td>6 drinks</td>
<td>16</td>
<td>39.02</td>
</tr>
</tbody>
</table>

What type of drug do you use? (n = 100)

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>72</td>
<td>72</td>
</tr>
<tr>
<td>Bhang</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Cocaine</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Miraa</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Others- Cigarette</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

(Multiple responses were allowed)

4.9 Condom Use

Most women 81(81%) prefer male condoms while 72 (72%) used them most often. About a third of the women have not seen a female condom. Twenty eight percent reported that they had actually used a female condom. Women thought female condoms were good
because they could be used covertly and were reusable. Most women said that they liked male condoms because they prevent STI/HIV and pregnancies as shown in table 4.14 below.

**Table 4.14: Condom Preferences and Usage**

<table>
<thead>
<tr>
<th>Type of Condom</th>
<th>Male</th>
<th>Female</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which type of condom do you and your partner prefer?</td>
<td>81 (81%)</td>
<td>10 (10%)</td>
<td>9 (9%)</td>
</tr>
<tr>
<td>Which type of condom do you use most often?</td>
<td>72 (72%)</td>
<td>19 (19%)</td>
<td>9 (9%)</td>
</tr>
</tbody>
</table>

**4.10 Cost of Male and Female Condoms**

The women disliked female condoms because they were more costly than male condoms and were not easily available. The average cost of a female condom was Ksh. 85 while mean cost of male condom cost Ksh. 11.80. This implies that male condoms were cheaper by Ksh. 73.20 compared to female condom; however, sex workers felt that male condoms tear or burst easily and that usage was controlled by the client. Table 4.15 below shows cost of condoms.
Table 4.15: Cost of Condoms

<table>
<thead>
<tr>
<th>Cost of Condoms</th>
<th>N</th>
<th>Mean</th>
<th>Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>A packet of male condoms</td>
<td>82</td>
<td>11.80</td>
<td>10.00</td>
</tr>
<tr>
<td>A packet of female condoms</td>
<td>14</td>
<td>85</td>
<td>70</td>
</tr>
</tbody>
</table>

4.11 Facilities Where Condoms were obtained

Asked about the source of male condoms, most sex workers mentioned shops 56 (78.9%) followed by clinics 36 (50.7%). Only 4 (5%) of the clients were said to bring their own condoms, (Table 4.16 )

Table 4.16: Where Clients Get Their Male Condoms

<table>
<thead>
<tr>
<th>Facility Where Condoms are Obtained</th>
<th>N=71</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic</td>
<td>36</td>
<td>51</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>19</td>
<td>27</td>
</tr>
<tr>
<td>Public places</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Shops</td>
<td>56</td>
<td>79</td>
</tr>
<tr>
<td>Clients bring condoms with them</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>
### Table 4.17: Clinical Diagnosis compared Lab Tests

<table>
<thead>
<tr>
<th>Syndrome</th>
<th>Number Negative</th>
<th>Number positive</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genital Ulcer Disease</td>
<td>RPR -ve</td>
<td>RPR +ve</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>94</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>1</td>
<td>99</td>
</tr>
<tr>
<td>Vaginal discharge</td>
<td>Trichomonas -ve</td>
<td>Trichomonas +ve</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>76</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11</td>
<td>5</td>
<td>87</td>
</tr>
<tr>
<td>Vaginal discharge</td>
<td>BV -ve</td>
<td>BV +ve</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>49</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>PID</td>
<td>GC or Chlamydia -ve</td>
<td>GC or Chlamydia +ve</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>70</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13</td>
<td>4</td>
<td>84</td>
</tr>
</tbody>
</table>

*p=0.000*

### 4.15 Effectiveness of Drugs Used

Respondents were treated at first contact using the Kenyan version of Syndromic management guidelines as spelt out by the Ministry of Health MOH. Follow up visits reviewed laboratory results and treatment was changed accordingly. Most of the STI cases were treated and resolved as demonstrated in table 4.18 below. Notably, some respondents presented with multiple STI, some had initial treatment changed based on laboratory results or non-compliance with treatment regimen.
Table 4.18: Diagnosis and Treatment Regimens provided

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>No of patients</th>
<th>Treatment</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Vaginosis</td>
<td>22</td>
<td>Azithromycin, Metronidazole</td>
<td>Resolved</td>
</tr>
<tr>
<td>Candidiasis</td>
<td>14</td>
<td>Clotrimazole</td>
<td>Resolved</td>
</tr>
<tr>
<td>Cervicitis</td>
<td>8</td>
<td>Norfloxacin, Doxycycline</td>
<td>Resolved</td>
</tr>
<tr>
<td>Genital Ulcer</td>
<td>5</td>
<td>Erythromycin, Benzathine penicillin</td>
<td>Resolved</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>16</td>
<td>4 Norfloxacin, Azithromycin, Secnidazole</td>
<td>Resolved</td>
</tr>
<tr>
<td>Pelvic Inflammatory</td>
<td>30</td>
<td>Norfloxacin, Doxycycline, Metronidazole,</td>
<td>Resolved</td>
</tr>
<tr>
<td>disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal Discharge</td>
<td>47</td>
<td>Clotrimazole, Pessaries, Metronidazole</td>
<td>Resolved</td>
</tr>
</tbody>
</table>
4.16 Volunteer Follow up and Retention Status

Out of the 114 volunteers who were screened, 100 were enrolled and followed up over a 12 month period. Retention was 92% at 6 month period and 87% at 12 months of follow-up. One Volunteer died after her visit 2, the cause of death was a fire that occurred in the neighborhood. Seasonal migration back to rural home towns accounted for the majority of loss to follow-up as shown in table 4.19.

Table 4.19: Volunteer Follow up and Retention

<table>
<thead>
<tr>
<th>Visit</th>
<th>No. of Volunteers</th>
<th>No. who Missed Visits (%)</th>
<th>No. who made Visits (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1 (Month 0)</td>
<td>100</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Visit 2 (Month 3)</td>
<td>100</td>
<td>3</td>
<td>97</td>
</tr>
<tr>
<td>Visit 3 (Month 6)</td>
<td>97</td>
<td>0</td>
<td>97</td>
</tr>
<tr>
<td>Visit 4 (Month 9)</td>
<td>97</td>
<td>8</td>
<td>89</td>
</tr>
<tr>
<td>Visit 5 (Month 12)</td>
<td>89</td>
<td>2</td>
<td>87</td>
</tr>
</tbody>
</table>

4.17 Health Care Providers Survey

Twenty HCPs were interviewed, 90% (18) were males and 10% (2) females. Most mid level health professions were represented as follows: Nurses 25% (5), Pharmacists 10% (2), Laboratory Technologists 15% (3), Clinical Officers 20% (4), Public Health Officers 10% (2), and Herbalists 20% (4), (see below table 4.20). Regarding facility type, Majority Health Care Providers 80% (16/20) of nurses, Clinical officers, pharmacy technicians, laboratory technicians and herbalists worked in private clinics only 20%(4/20) of nurses and Public health technicians worked in government/public clinics.
Table 4.20: HCP Characteristics

<table>
<thead>
<tr>
<th>Profession</th>
<th>Gender</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>Male</td>
<td>5</td>
</tr>
<tr>
<td>Laboratory Technologist</td>
<td>Male</td>
<td>3</td>
</tr>
<tr>
<td>Public Health Officer</td>
<td>Male</td>
<td>2</td>
</tr>
<tr>
<td>Clinical Officer</td>
<td>Male</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>1</td>
</tr>
<tr>
<td>Pharmacy Technologist</td>
<td>Male</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>1</td>
</tr>
<tr>
<td>Herbalist</td>
<td>Male</td>
<td>4</td>
</tr>
</tbody>
</table>

4.17.1 Perceptions about Ring Size

When asked about views regarding the size of the ring, almost all participants 80% (16/20) reported that the Ring size was big and thick. They felt that the user will be uncomfortable once the ring is in situ. To address these concerns HCP suggested that the rings should be reduced in size and made more flexible.

4.17.2 Duration of Ring Use

Almost half 35% (7/20) of HCP mentioned 1-3 months as the preferred duration of ring use. It was suggested that the Rings should be used only once just like condoms. However, some said that six months of continuous ring use is appropriate while others felt that the ring can be used up to one year, 10% (2/20) respectively.
4.17.3 Intra Vaginal Ring Use among Commercial Sex Workers

Respondents were asked what they thought a woman’s paying partner would think about a FSW using an Intra vaginal ring. Many HCPs felt that a Microbicides intravaginal ring would be the preferred method of HIV prevention, for commercial sex workers. Mostly, they liked the fact that IVR is female-controlled, can be used covertly, slow drug release and would be less messy than Microbicides creams or gels. Few 10% (2/20) respondents reported that some clients may think that FSW using the Ring are HIV positive; such women will be rejected in the community. It was suggested that prior to actual IVR promotion and deliver, community education and sensitization need to be done. This will help destigmatizing IVR users. Safety of the FSW will not be jeopardized because most of their clients were said to be married men who will not want to infect their wives, as such more men will frequent such a woman and she can negotiate a higher fee.

4.17.4 Ring Distribution

Every respondent was given a chance to suggest how best an IVR would be distributed when they become available. Almost half of providers felt that IVR should be distributed through public and private health care facilities at no cost. Mainstreaming IVR use in existing MCH services was envisaged as ideal way to distribute the rings. A few respondents 25% (5/20) said that the rings could easily be distributed through pharmacies, shops and in social amenities such as bars and restaurants.
4.17.5 Ring use compared to Condoms, Gels and Creams

Asked to compare the four available options, 50% (10/20) of respondents reported that IVR are the best because they are discrete, female controlled, and that they do not require other procedures before use. IVR were preferred than creams as they were said to be stable in all temperatures and are not messy during sex. 35% (7/20) reported preference for the gel and cream, reason being that the vagina always has secretions thus the male partners can not notice when creams and gels are applied. Condoms were least liked mainly because they are male controlled, reduces sexual satisfaction and possibilities of the partner rupturing or tearing it up is high.

4.17.6 Safety Concerns

Out of twenty respondents, only eight voiced questions about potential side-effects and discomforts of IVR, particularly with long-term use. Insertion procedures were seen as a way of introducing infection just like coils do. Only 10% (2/20) HCPs raised concerns about how specific religious beliefs and cultural practices prevalent in their communities might affect uptake of IVR.
CHAPTER FIVE
DISCUSSION

5.1 STI and HIV Risk Characteristics among Female Sex Workers in Mukuru.

In this study among Female Sex Workers in Mukuru, we found that out of 100 FSW, 65(65%) of sex workers had an STI, they engaged in both vaginal and non vaginal sex with minimal condom use. The first year of study focused on VCT service provision, STI/HIV/AIDS education and behaviour modification interventions such as condom promotion. The second year of study focused on documentation of risk behaviour and screening for sexually transmitted infections. Essentially, part one of this discussions will cover general characteristics of the target population and part two covers Characterization of STI and acceptability of IVR among Health care providers.

Table 4.1 in section 4.1 shows that education level among Mukuru based sex workers was low. For this reason, specific and targeted information was consistently given to the cohort over a two year period. The assumption was that consistent behaviour modification information could positively influence condom use and improve health seeking behaviour. On the contrary, inconsistent condom use was observed throughout the study period as described herein in section 4.10 of the results. None of the sex workers reported using condoms always despite the fact that they had reported sex with five different partners per day as shown in (Table 4.3). Data in table 4.7 shows that these women continued having sex without a condom even during symptomatic period. This finding concurs with previous studies in Meru where non vaginal sex was prevalent (Beaten et al., 2000). Ordinarily, the inflamed mucosal lining of the vagina becomes
more permeable to pathogenic and non pathogenic organisms, a state that has been shown to amplify the risk of HIV transmission (Glynn et al., 2000). This observation also shows that there is a disconnect between knowledge and behaviour change. Some studies attribute this disconnect to lack of women empowerment, culture and fear of partner rejection (Helen et al, 2002).

Majority 96 (96%) of FSW had children and only 22 (22%) reported use of a family planning method. Chances of unwanted pregnancy are high in this cohort considering that these FSW had multiple sex partners with minimal condom and family planning use; this is in agreement with (Gertig et al., 1997). Inadequate family planning uptake impeaches on any vaccine or microbicide clinical trial because participants are required to prevent pregnancy during the study period for simple reasons that no one knows what effects medicines can have on unborn child. Because of this requirement many women fail to enroll in studies creating a gender imbalance in clinical research as documented by Wakasiaka in 2005.

In the African contest, it is common place to talk of HIV and AIDS as strictly heterosexual in nature. Contrary to this belief, Female Sex Workers in Mukuru reported other types of sex apart from vaginal, (34) 34% reported anal, (24) 24.7% reported oral sex with regular clients. Notably, majority non vaginal sex acts were conducted without a condom because sex workers assumed that they cannot get infected through anal or oral sex (Table 4.5). Non vaginal sex was commonly reported among regular clients who may likely be HIV positive and want to just pass it around. The less highlighted invisible
presence of homosexuality and other non vaginal routes of sex have far reaching implications in HIV and AIDS prevention (Martins et al., 1994). The assumption here is that a sex worker cannot get STI/HIV when they practice oral and anal sex. This misconception gives them false protection hence condoms are kept at bay. This peculiar occurrence demands for a HIV preventive technology such as Microbicides or Vaccines that FSW can use to protect themselves and their clients from STI/HIV infections.

Further evidence adduced from this study indicate that sex work in Mukuru slum is fueled by glaring poverty and unemployment given that 92 (92%) of sex workers had no other source of income as shown in table 2. Majority (51%) of the sex workers in this study were single or separated. Social responsibility of child rearing was clearly bestowed upon them, the mean number of children born and living with the mother was three. This burden puts sex workers at risk as many reported receiving as little as Ksh. 20 or even food in exchange for sex. Sex without a condom fetches Ksh. 50 which is more than double the Ksh. 20 paid for sex with a condom (Table 4.5). Female Sex Workers often opt for the former because they are not sure when the next paying client will come along. As providing shelter and food for their children is a priority over HIV risk (O’Connor et al., 1996).

In order to supplement daily income, some FSW workers introduce their children and relatives to the trade at an early age (Helen et al., 2002; Martin, 1994). Studies propose that introducing Income generating activities in such cohorts can prevent young people from joining the sex trade (Helen et al., 2002). As part of economic empowerment, a
revolving fund was available for the FSW at Mukuru, however; only two elderly sex workers utilized the fund to set up small scale business in the village.

Most FSW were young, youngest being 18 years with a reported sexual debut at age 9 (Table 2). Sixty-two 62/450, (13.7%) FSW tested HIV positive at baseline as described in section 4.3 of the results. It was observed that these sex workers are at a higher risk of acquiring HIV/AIDS given that HIV prevalence in the general population was 6% at the time (NASCOP, 2006). Previous studies in various countries show similar HIV prevalence among female sex workers (Bwayo et al., 1992). The implications of these findings are that; today, HIV continues to spread among FSW in the same magnitude as it occurred ten years ago. It is with this knowledge that societies perceive FSW as reservoirs for STI/HIV/AIDS. Stigma and discrimination against sex work notwithstanding, high HIV prevalence among sex workers has a direct public health implication because majority of clients of sex workers are married men who tend to mediate the transmission between sex workers and married women (Martin et al., 1994).

With this background, urgent HIV preventive options such as vaccines or Microbicides are needed especially for women in Africa where 60% of new infections occur in women (UNAIDS 2008).

Majority, 95 (95%) of the 100 FSW never bothered to ask about the HIV status of their clients despite the fact that they knew about their negative HIV status during the study period. Similar studies among brothel based FSW in Nyanza indicate that sex workers never asked clients about their HIV status and that HIV status was not a basis to negotiate
pay yet clients often decline condom use (Helen et al., 2002). These findings are not unique to Mukuru and Nyanza, in 1995, a cohort study in Thailand reported that sex workers never enquired about HIV status of their clients despite a government policy that requires monthly medical reports for all sex workers (Kunawararaka et al., 1995).

5.2 Common Sexually Transmitted Infections and Efficacy of Treatment Regimen

Female sex workers in Mukuru have no access to health care services in the community. Lack of health care provision for high risk groups is not unique to Mukuru; studies show that in many parts of Africa there is lack of effective STI control program specific for high risk populations (Adler et al., 1996). STI prevalence in this cohort was high as expected owing to risk behaviour.

Almost all the FSW who enrolled for study had one or more STI at some point during the study period. This was double the prevalence of STI among FSW reported in Majengo where the cohort had been followed up for a long period (Bwayo et al., 2001). Other published observations from a number of countries report increased rates of STI in FSW compared with the general population (Martin et al., 1994). However, vaginal discharges accounted for most of the difference in STI prevalence and were the commonest single STI symptom. The significant variations that arise from frequent vaginal douching practices reported by women in this cohort are acknowledged. The seroprevalence of HIV in the FSW was 13.7% and was considerably higher than the seroprevalence in non-FSW. High HIV prevalence rate among at risk cohorts were reported in Thailand (Nelson et al., 1994) and in Mombasa (Jackson et al., 1995).
Table 4.18 shows that most vaginal discharges were due to Bacterial Vaginosis (47\%) 47%. The high incidence of vaginal discharge in this cohort may be attributed to douching practices by most FSW in this cohort. In a previous documentation (Wakasiaka et al., 2008) demonstrated that most FSW were douching after every sexual encounter. Products such as Omo, Coca-Cola, Jik and Lemon were used for douching. Unknown to these women, such products corrode the mucosal lining of the vagina causing changes in the environment and subsequently kills the normal flora of the vagina. This makes the vagina more receptive to both pathogenic and non-pathogenic organisms. It’s these pathogenic processes that bring forth vaginal discharges. Other studies report 55% STI rates among FSW with gonorrhea (Costello et al., 1994).

Out of one hundred FSW who were tested for syphilis, only five had a positive RPR test. Out of the five positive tests, only one patient presented with a genital ulcer disease. This has multiple explanations, first Genital Ulcer Diseases have long incubation periods, and it takes time before clinical signs can be observed. Secondly, having four positive tests in the absence of a visible ulcer is an indication that laboratory test is the best diagnostic method for syphilis and other ulcerative diseases (Kunawararaka et al., 1995). However, in many developing countries laboratory testing for STI is limited owing to poor health infrastructure development especially in rural areas (WHO, 2003). It’s for this reason that Kenya adopted the WHO policy which provides treatment guidelines currently used in the prevention and treatment of STI in Kenya (NASCOP, 2006).

In other related studies, GUD has been shown to be an important marker for HIV infection (Kunawararaka et al., 1995). In the Mukuru study, none of the patients who
tested HIV positive had a positive RPR test or a feasible ulcer. The high prevalence of STI in this cohort and the inconsistent condom use compounded by the absence of effective prevention strategies demonstrates how sex workers continue to serve as a bridge population for further infections, (Hawkes et al., 1992). In Nyanza, Helen in 2002 documents similar finding in which majority of clients of sex workers are married men who decline condom use, thereby spreading STI from FSW to their wives and other regular partners. These observations call for urgent preventive and treatment programs specific for FSW and their clients must be put in place.

Pelvic inflammatory disease is commonly caused by Chlamydia trachomatis. Women at greater risk for PID include those at risk for sexually transmitted infections (STI) and those with a prior episode of PID. The FSW in this study were young, age 9 being the earliest debut. Pelvic Inflammatory Disease presents other complications such as infertility, septicemia, and ectopic pregnancy (Kumar et al., 1995). In this study, 13 (13%) FSW were diagnosed with PID on pelvic examination. On laboratory testing, the same patients tested positive for GC and CL with a specificity of 84.3. This means that Syndromic approach to STI management is an effective tool in PID diagnosis, this is probably because the patient presents with a classical picture as described in figure III of the NASCOP algorithms’. From a public health perspective, screening high risk women for GC and CL could have an added advantage in the prevention and control of PID and other STI. This observation notwithstanding, there is little information from clinical studies about screening women for cervical chlamydial infection which can eventually

Other studies in developing countries (La Ruche *et al.*, 1995) show that data on STI and related complications are limited; this implies that the burden of these diseases among sex workers is substantially underestimated (Schwandt *et al.*, 2006). Some of the rationale behind this underreporting could be the fact that STI are often asymptomatic, technically difficult and expensive to diagnose especially in resource poor settings. As a response to this situation WHO developed the Syndromic guidelines to help standardize diagnosis and treatment of STI in developing nations. Like many other countries in the region, Kenya adopted these guidelines as a unified approach to STI management.

This study utilized the Kenyan Version of the algorithms’ (NASCOP, 2006) in the management of STI patients who enrolled for study. Section 4.16 described the efficacy of the treatment regimen; most patients reported symptom resolution after completing prescribed treatment (Table 4.19). Owing to the alcoholic habits of some FSW, two out of thirty had their GC treatment changed to Secnidazole because they could not keep up with the seven day dosage with Metronidazole as shown in table 20. In this regard, there is need for the NASCOP, 1996 algorithms’ to be revised to include drugs with shorter treatment period to take care of individuals who cannot comply with weeklong doses.
5.3 Retention of Female Sex Workers Enrolled for Study

One of the major challenges in cohort development is participant retention in any clinical trial. High risk individuals tend to change residences often making study compliance difficult. In this study, follow up rate at month six was 97% and 87% at month twelve as presented in Table 4.20. Post election violence that necessitated migration to rural homes accounted for most missed visits. Overall, 87% retention at the end of the study is highly desired for future efficacy trials at KAVI. This high level of retention may be attributed to consistent and unified approach to community engagement that was implemented in Mukuru for four consecutive years. Other KAVI studies document high retention rate for same reasons (Wakasiaka, 2005), other studies document low retention in clinical trials (Mugyenyi et al., 2002, Macqueen et al., 2000, Mugusi et al., 2002).

5.4 Perceptions of Health Care Providers Regarding Intravaginal Rings.

This part of the study presents the first documentation of IVR acceptability among Health Care Providers in Nairobi. The outcomes indicate that IVR were highly desirable device for microbicide delivery by an intravaginal ring especially among FSW in a resource constrained environment. These results highlight the importance of addressing HCP attitudes and concerns towards IVR long before they become available in the market. Their ability to mainstream IVR in the existing community outreach programs will invaluably break barriers that may arise when IVR are introduced (Gita et al., 2007). These programmes include mainstreaming Microbicide information in HIV programming, among women groups and in the nongovernmental Organizations. Failure
to which IVR will be available yet potential consumers may shun them as evidenced in the advent of introducing female condom in the market (Bwayo et al., 2001).

The most outstanding reason for positive IVR perceptions in this study were that the ring is female controlled and has covert characteristic. Largely, HCPs expressed the view that the rings were an answer to the dominant male condom where women have diminished power to negotiate its use. In a previous document, (Wakasiaka et al., 2008) reports a dislike for male condom among male clients; reason being that condoms reduce sexual satisfaction thereby clients opt for unprotected sex. Early in year 2000, social scientists in Nyanza documented similar findings in a rural sex worker cohort (Helen et al., 2002). Both studies signify the need for attitude change before preventive technologies can be introduced in the Kenyan market.

HCPs expressed the view that the rings were an answer to the dominant male condom where women have diminished power to negotiate its use. Similar findings were also reported in a study where women reported their inability to negotiate condom use either because of economic benefits or fear of rejection (Helen et al., 2002). Positive responses to female controlled prevention methods such as the female condom or microbides among health care providers have been cited in other studies in Africa (Gita et al., 2007). This study concluded that HCPs in Nairobi are receptive to new methods of HIV prevention.
CHAPTER SIX
CONCLUSION

i. Prevalence of STI among Female Sex Workers in Mukuru was high at 65%. Most sex workers continued having unprotected sex with multiple partners during symptomatic period, only 34.3% reported condom use in the same period.

ii. Unprotected anal sex was common among young FSW. These factors predispose FSW in this cohort to STI, HIV and AIDS.

iii. Female sex workers in Mukuru were likely to present with vaginal discharge. Vaginal discharge (39%) and pelvic Inflammatory (13%) were the commonest presenting symptoms.

iv. Patients who completed treatment regimens had no symptoms on follow up visit. This shows that Syndromic management is an effective strategy in the management of STI.

v. Community involvement enhances volunteer retention. Majority (87%) of Volunteers kept their month twelve visits.

vi. Mukuru female sex workers were at high risk of HIV infection as evidenced by multiple sex partners, low condom use and non vaginal sex such as anal and oral sex.
vii. Health Care Providers are likely to support IVR as a device for microbicide delivery mainly because the rings have covert characteristics and are female controlled.

6.1 Recommendations

i. Targeted STI and HIV literacy programs should focus on Female Sex Workers and their clients.

ii. Syndromic STI management should be revised to include drugs with shorter regimes suitable for high risk populations.

iii. Clinical Study teams comprising doctors, nurses and community mobilizers need to engage target communities in all study processes in order to enhance volunteer retention.

iv. Larger HCP studies need to be conducted to include public and private Health Care practitioners.

6.2 Suggestion for Future Work

Findings from this study present various grey areas for future research. Foremost, a study should be done to assess wider effectiveness of routine STI screening among female sex workers and their clients. Secondly, drug resistance studies specific to STI treatment regimen should be done to provide a guide for NASCOP algorithm revisions. In this study, 65% of the FSW said that they do not have regular periods, a comparative study need to be done to establish the cause and also document STI complications that these women may present with. There is urgent need for a policy document outlining
development, marketing and access of new devices in the Kenyan market. Lastly but not least, health care providers must be involved in a meaningful way in all steps of research that benefits Kenyans, this includes capacity building in research. To do this, a broader study should be done to establish HCP research training needs and develop appropriate programs that will meet these needs.
REFERENCES


**United States International Development Fund.** Progress reports (2008), 465:33-35


APPENDIX I: MAP OF MUKURU: PROVIDED BY NAIROBI CITY COUNCIL
Appendix II: Informed Consent Form

Title: Characterization of an HIV At-Risk Female Cohort in Kenya

Principal Investigator: Prof. JJ Bwayo, PhD, MD

Co investigator: Sabina Wakasiaka, MPH

Sponsor’s Name: US Centers for Disease Control Foundation

Introduction: You are being asked to be part of a research study. The study will be carried out by the Kenya AIDS Vaccine Initiative (KAVI) of the University of Nairobi and Emory University School of Medicine, Atlanta, GA, US. Please take your time deciding whether to join the study. Carefully consider the following information and ask the study counselor any questions you may have.

You will be told the purpose of the study, possible risks and benefits to you, and what would be expected of you. If you agree to be in the study, you will be asked to sign or put a thumbprint on this consent form, and will be given a copy to keep. It is important that you know the following: Your taking part is entirely voluntary, You may decide not to take part in the study without affecting your opportunity to be in other studies or programs, You may decide to withdraw from the study at any time without this decision affecting your opportunity to be in other studies or programs.

1. Why is this study being done?

This study seeks to find out information about HIV (the virus that causes HIV), other sexually transmitted infections and sexual behaviour among women in Mukuru, Kenya. It will measure the rate of HIV infections, the rate of other sexually transmitted infections, how commonly male and female condoms are used, and other sexual behaviours. This study will see how well syndromic treatment for sexually transmitted
infections works to decrease the rate of these infections among women in Mukuru, Kenya. It will also see how well we can follow-up with women in Mukuru during a study over many months. This information will help prepare for a possible research study of microbicides to prevent HIV in the future. You are being asked to be in this study because you are a member of a single-mothers group in Mukuru or you have reported trading sex for money, goods or services recently.

2. If you join the study, are there any risks?

You may feel embarrassed, worried or anxious when answering questions from the study staff about your own sexual behaviours or when being tested for HIV or other STI. You may feel embarrassed, worried or anxious when speaking with the study staff about HIV, condoms, and sexual behaviour in general and during the medical exam.

You will be told in a timely manner about significant new information that might affect your decision to stay in the study.

3. What benefit can you expect?

This study will benefit you by letting you know if you are infected with an STI or vaginitis, and providing treatment for STI and vaginitis. You will also receive free condoms, as well as free counseling to reduce your risk of getting HIV. While the facts we obtain from study might not help you directly, by participating, you will help us learn more about the risk of HIV and STI in this community. We hope that this information will help us develop better methods to prevent HIV in the future.

4. Will you be paid to be in the study?
Yes, you will be given Ksh 500 for your time at each study visit.

5. You may refuse to be in the study.

Your participation is completely voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled.

I have read this consent form and was told about the study. I have been able to have my questions answered.

__________________________________________  __________
Print Volunteer's Name  Time

__________________________________________  __________
Signature or Mark of Volunteer  Date
Appendix III: Social Demographic Data Form

Section I: Social Demographic Data

Q 1.0
Client ID: ____________________________ Date: ______/_____/________
                                                dd/mm/yyyy

How old are you? ______ Years Gender 1. Male
                                                                 2. Female

Where do you live?

________________________________________

Landmark (Please describe)________________________

Q1.1 How would you describe your ethnic background?
1. Kikuyu
2. Kamba
3. Kisii
4. Meru
5. Luo
6. Other
If other please specify__________________________

Q1.2 How would you describe your marital status?
1. Single-never married
2. Married
3. Separated
4. Divorced
5. Widowed
6. Other
If other please specify__________________________

Q1.3 What is the last level of education you completed?
1. None
2. Primary
3. Secondary
4. College
5. Other
If other please specify__________________________
Q1.4 How would you describe your current work situation?
1. Unemployed
2. Housewife
3. CSW
4. Casual worker
5. Other
   If other please specify ____________________________

Q1.5 How would you describe your religious affiliation?
1. Catholic
2. Protestant
3. Seventh Day Adventist
4. Muslim
5. Other
   If other please specify ____________________________

Q1.6 The following questions are about your social network.

1.7.1 Who pays the rent for the house where you live? ____________
1.7.2 Do you live alone in the house?
   1. Yes
   2. No

If the answer is No, Who do you live with (Please list all that applies)

1.7.3 Do you have children under age 18 living with you?
   1. Yes
   2. No
If YES, Number _____ Sons _____ Ages _____
   Daughters _____ Ages ____________________________

Q1.7 Do you smoke?
1. Yes
2. No
If Yes, how many cigarettes do you smoke in a day _____ Week _____

Q1.8 Do you take alcohol?
1. Yes
2. No
If Yes, how many litres do you drink in a day ______ Week______
Q1.9 Do you take drugs that stimulate the body to feel high?
   1. Yes
   2. No
If Yes, how many times do you take these drugs in a day___ week___
Please list all the drugs that you take________________________

Section II: Risk Characteristics
Q2.1 Have you ever had sex where your partner puts his penis in your anus?
   1. Yes
   2. No
If No, go to 2.3
If Yes, do you remember bleeding?
   1. Yes
   2. No
Q2.2 When you have anal sex how often is a condom used?
   1. Always
   2. Sometimes
   3. Rarely
   4. Never
   5. Not applicable
Q2.3 When you have vaginal sex how often is a condom used?
   1. Always
   2. Sometimes
   3. Rarely
   4. Never
   5. Not applicable
Q2.4 How would you describe the last person you had sex with?
   1. Regular partner(Boyfriend, Husband)
   2. Casual partner
   3. Other
   If other please specify_________________________________________
Q2.5 The last time you had sex, did you use a condom?
   1. Yes
   2. No
If answer is No, please explain why not?
Appendix IV: Baseline Demographic and Medical History Questionnaire

Volunteer ID: _________ Date: _____ / _____ / ________

dd/mmm/yyyy

Section 1. Sociodemographics

1.1 How old are you? ______ years

1.2 Where do you live? (tick one)
- Njenga village
- Kware village
- Kimondo
- Vietnam
- Majengo
- Other, please specify ____________________________

Landmark (Please describe) __________________________

1.3 What is the last level of education you completed? (tick one)
- None
- Primary
- Secondary
- College
- Other, please specify ____________________________

1.4 How would you describe your primary ethnic background? (tick one) [Instruct counselor to wait for a response from the subject before reading this list]
- Kikuyu
- Kamba
- Kisii
- Meru
- Luo
- Luhya
- Other, please specify ____________________________

1.5 How would you describe your primary religious affiliation? (tick one)
- Catholic
- Protestant
- Seventh Day Adventist
- Muslim
- Other, please specify ____________________________
1.6 How would you describe your current marital status? (tick one)
- Single-never married
- Married
- Separated
- Divorced
- Widowed
- Other, please specify ________________________________

1.7 If you are currently married, is your marriage polygamist: (tick one)
- Yes
- No

1.8 How would you describe your primary work situation? (tick one) [Instruct counselor to Wait for a response from the subject before reading this list]
- Unemployed
- Housewife
- CSW
- Casual worker
- Other, please specify ________________________________

1.9 What is your total income from all sources:
_____ Per Day
_____ Per Week

1.10 How many people living in your household depend on you for income? _____

Please identify your relationship to every person living in your household and list age, gender, and relationship (son or daughter, other relative, friend or sexual partner):

1.11.1 Relationship: ___________________________ Age: ___________ Gender: ___________
1.11.2 Relationship: ___________________________ Age: ___________ Gender: ___________
1.11.4 Relationship: ___________________________ Age: ___________ Gender: ___________
1.11.5 Relationship: ___________________________ Age: ___________ Gender: ___________
1.11.6 Relationship: ___________________________ Age: ___________ Gender: ___________
1.11.7 Relationship: ___________________________ Age: ___________ Gender: ___________

1.12 Are you currently taking any medications?
- Yes
1.13 If yes, list all medications:


1.14 Are you currently being treated for an STI or vaginitis?

☐ Yes
☐ No

1.15 When you have STI symptoms, where would you go for treatment?

☐ Traditional healer/herbal medicine
☐ Clinic
☐ Pharmacist
☐ Other, please specify

1.16 On average, how many days after your symptoms start do you go for treatment? 
_____ days

1.17 Are you currently pregnant or planning pregnancy in the next six months?

☐ Yes
☐ No

1.18 What was the date of your last pregnancy? (insert D.O.B. or end of pregnancy)

( dd/mmm/yyyy )

1.19 Do you have regular periods?

☐ Yes
☐ No

1.20 When did your last period start? ______ / _____ / _____ (insert date )

( dd/mmm/yyyy )

1.22 What methods of family planning are you currently using? (tick all that apply) [Interviewer: please wait for subjects to volunteer a method.]:

☐ None
☐ Pills
☐ Intra uterine device ( IUCD)
☐ Tubal ligation
☐ Male condom, most of the time (>50%)
Female condom, most of the time (>50%)
Injection
Other, please specify

1.23 How many pregnancies have you had? (insert number)

1.24 What was your age at first intercourse?
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Don't know</th>
</tr>
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<tr>
<td>2.1</td>
<td>Heart problems</td>
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<tr>
<td>2.2</td>
<td>Blood pressure problems</td>
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<td>2.3</td>
<td>Circulation problems</td>
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<td>2.4</td>
<td>Liver problems or disease (hepatitis)</td>
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<tr>
<td>2.5</td>
<td>Diabetes</td>
<td></td>
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<tr>
<td>2.6</td>
<td>Stomach/bowel problems</td>
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<tr>
<td>2.7</td>
<td>Bladder/urinary problems (kidney problems)</td>
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<td>2.8</td>
<td>Blood in stool</td>
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<tr>
<td>2.9</td>
<td>Diarrhea for more than three days</td>
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<td></td>
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<td>2.10</td>
<td>GYN problems</td>
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<td>2.11</td>
<td>Muscle/bone problems/arthritis</td>
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<td>2.12</td>
<td>Skin problems</td>
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<td>2.13</td>
<td>Sores in mouth/tongue</td>
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<td>2.14</td>
<td>Blood disorders or bruising problems</td>
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<td>2.15</td>
<td>Previous blood/blood product transfusion</td>
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<tr>
<td>2.16</td>
<td>Thyroid disease</td>
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<tr>
<td>2.17</td>
<td>Tuberculosis</td>
<td></td>
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<tr>
<td>2.18</td>
<td>Asthma/difficulty breathing</td>
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<tr>
<td>2.19</td>
<td>Anemia</td>
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<tr>
<td>2.20</td>
<td>Cancer</td>
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<td>2.21</td>
<td>Eye trouble or visual changes</td>
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<td>2.22</td>
<td>Frequent headaches (&gt; 3/month)</td>
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<tr>
<td>2.23</td>
<td>Weakness or loss of sensation in extremities</td>
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<tr>
<td>2.24</td>
<td>Dizziness or fainting spells</td>
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<tr>
<td>2.25</td>
<td>Seizures</td>
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<tr>
<td>2.26</td>
<td>Depression</td>
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<tr>
<td>2.27</td>
<td>Psychiatric illness</td>
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<tr>
<td>2.28</td>
<td>Drug or alcohol addiction</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2.29</td>
<td>Other medical problems</td>
<td></td>
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</tbody>
</table>

Please specify:
Appendix V: Behavioural Assessment

Volunteer ID: ______________________  Visit Date: __/__/____  
DD/mmm/yyyy __/__/____

Visit Number:

☐ Enrollment  ☐ M1  ☐ M3  ☐ M6  ☐ Unscheduled: __________

The questions in this questionnaire will ask you about different activities in the past month.

Section 1: Douching and Lubricants

1.1 Do you wash or douche your genitalia?
☐ Yes
☐ No (Skip to 1.5)

1.2 How often do you wash or douche your genitalia?
☐ After every sex act
☐ Once a day
☐ Once a week
☐ Once a month
☐ Others, please specify: ________________________________

1.3 What do you use to wash or douche your genitalia? (Tick all that apply)
☐ Water only
☐ Water and detergent/ soap
☐ Lemon
☐ Soda
☐ Herbs
☐ Others, please specify: ________________________________

1.4 Why do you douche? ________________________________

1.5 Do you ever use lubricants?
☐ Yes
☐ No (Skip to Section 2)

1.6 What type of lubricants do you use? (Tick all that apply)
☐ Oil
☐ Crème
☐ Other, Specify: ________________________________

Section 2: Alcohol and Drug Use
2.1 Do you take alcohol?
☐ Yes
☐ No (Skip to 2.5)

2.2 How often do you drink alcohol?
☐ Often (Daily)
☐ Occasionally (once in a week)
☐ Rarely (once in a month)

2.3 What kind of alcohol do you usually drink?

2.4 How much alcohol do you usually consume at one time?
☐ 1-2 drinks
☐ 3-5 drinks
☐ 6 drinks

2.5 What drugs do you use commonly?
☐ Bhang
☐ None
☐ Cocaine
☐ Miraa
☐ Other, Specify

2.6 How often do you have sex while you are under the influence of a drug/alcohol?
☐ Always (100% of the time)
☐ Sometimes (about 50% of the time)
☐ Rarely (about 20% of the time)
☐ Never

Section 3: General Condom Use

3.1 Which type of condom do you and your partner prefer?
☐ Male
☐ Female

3.2 Which type of condom do you use most often?
☐ Male
☐ Female
3.3 What do you like about?
Female condoms? ____________________________________________________________

Male condoms?

3.4 What do you dislike about?
Female condoms? ____________________________________________________________

Male condoms?

3.5 Where do you go to get male condoms?
☐ Health clinic, Name of clinic _______________________________________________
☐ Pharmacy
☐ Public places
☐ Shops
☐ Other, Specify ____________________________________________________________

3.6 Have you ever used a female condom?
☐ Yes
☐ No
☐ Cannot remember

3.7 Where do you go to get female condoms?
☐ Health clinic, Name of clinic _______________________________________________
☐ Pharmacy
☐ Public places
☐ Shops
☐ Other, Specify ____________________________________________________________

3.8 When you buy condoms, how much do you typically pay?
___________ ksh per packet of male condoms
___________ ksh per female condom

Section 4: Sexual Activity
We will now discuss sexual activity in the past month. We will talk about vaginal sex or
sex where the penis touches the vagina; oral sex, or sex where the mouth touches
genitals; and anal sex, or sex where the penis touches the anus.

4.1 How much are you paid per sex act for
a. Vaginal Sex __________ ksh
b. Oral Sex __________ ksh
c. Anal Sex __________ ksh
4.2 From all sources, approximately how much money do you earn
a. Per day? ___ Ksh.
b. Per week? ___ Ksh

We will also discuss the different types of partners that you may have sex with. First, I will ask you about primary partners: these are your main partners like a boyfriend or a husband; Then, I will ask you about regular partners, or partners with whom you exchange money or goods for sex on a regular basis (for instance, a client with whom you have a once a week or once a month date); Finally, I will ask you about casual partners, or partners with whom you exchange money or goods for sex only once or twice. We will also ask you to specify the different types of sexual behaviour you might engage in with different partners.

4.3 Do you have a primary partner?
☐ Yes
☐ No

(If respondent does not have primary partners, skip to 4.7).

4.4 How frequently do you have sex with your primary partner?
☐ Daily
☐ Weekly
☐ Monthly

4.5 When you have sex with a primary partner, how often do you have
a. Vaginal sex: ☐ Always (100%) ☐ Sometimes (50%) ☐ Rarely (20%) ☐ Never
b. Anal sex: ☐ Always (100%) ☐ Sometimes (50%) ☐ Rarely (20%) ☐ Never
c. Oral Sex: ☐ Always (100%) ☐ Sometimes (50%) ☐ Rarely (20%) ☐ Never

4.6 When you have sex with a primary partner, how often do you use a condom during
a. Vaginal sex: ☐ Always (100%) ☐ Sometimes (50%) ☐ Rarely (20%) ☐ Never
b. Anal sex: ☐ Always (100%) ☐ Sometimes (50%) ☐ Rarely (20%) ☐ Never
c. Oral Sex: ☐ Always (100%) ☐ Sometimes (50%) ☐ Rarely (20%) ☐ Never

Now, we will talk about regular partners. Remember that regular partners, are partners with whom you exchange money or goods for sex on a regular basis

4.7 On average, how many regular partners do you have per day_____? per week_____?
(For questions below, if respondent does not have regular, paying partners, skip to 4.10.)

4.8 When you have sex with regular partners, how often do you have
a. Vaginal sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never
b. Anal sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never
c. Oral Sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never

4.9 When you have sex with regular partners, how often do you use a condom during
a. Vaginal sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never
b. Anal sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never
c. Oral Sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never

Now, I will ask you about your casual partners. Casual partners are partners with whom you exchange money or goods for sex only once or twice.

4.10 On average, how many casual partners do you have per day? Per week?

4.11 When you have sex with casual partners, how often do you have
a. Vaginal sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never
b. Anal sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never
c. Oral Sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never

4.12 When you have sex with casual partners, how often do you use a condom during
a. Vaginal sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never
b. Anal sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never
c. Oral Sex: □ Always (100%) □ Sometimes (50%) □ Rarely (20%) □ Never

4.13 How often are you paid more to have sex without a condom?
□ Always (100% of the time)
□ Sometimes (about 50% of the time)
□ Rarely (about 20% of the time)
□ Never

4.14 How often are you paid more to have sex with a condom?
□ Always (100% of the time)
□ Sometimes (about 50% of the time)
□ Rarely (about 20% of the time)
□ Never

4.15 How often do you know the HIV status of the people you engage in sexual contact with?
□ Always (100% of the time)
□ Sometimes (about 50% of the time)
□ Rarely (about 20% of the time)
□ Never

4.16 Have you been diagnosed or treated for an STI or vaginitis somewhere other than the study site since your last visit?
□ Yes
□ No

4.17 If yes, provide details:
__________________________________________________________________________________
__________________________________________________________________________________

4.18 In the past one month have you experienced any form of physical or sexual assault?
□ Yes
□ No

4.19 If yes, please explain the events.
__________________________________________________________________________________
__________________________________________________________________________________

4.20 Where do you commonly have sex with your clients (*Do not read options and check all that apply*)
□ Home
□ Bar
□ Brothel
□ Other, Specify ________________________________________________________________

4.21 Is there other information about commercial sex work and your risk of HIV that you think we should know?
__________________________________________________________________________________
__________________________________________________________________________________

(Interviewer asks 4.22-4.24 only at Month 6 and if respondent reports having sex with clients at home, home is checked for 4.20.)

4.22 How often do you have sex with clients at home?
□ Always (100% of the time)
□ Sometimes (about 50 % of the time)
Rarely (about 20% of the time)
Never

4.23 Are there challenges to conducting sex work in your home?
Yes
No

1.24 Please explain these challenges.

Form Completed by: ________________ Date: ________________
        dd/mmm/yyyy
Form Entered by: ________________ Date: ________________
        dd/mmm/yyyy
Appendix VI: Health Care Provider Interview Guide

Principal Investigator: Prof. JJ Bwayo, PhD, MD

Co-Investigator: Sabina Wakasiaka, MPH

Sponsor's Name: US Centers for Disease Control Foundation

Introduction: You are being asked to be part of a research study. The study will be carried out by the Kenya AIDS Vaccine Initiative (KAVI) of the University of Nairobi and Emory University School of Medicine, Atlanta, GA, US. Please take your time deciding whether to join the study. Carefully consider the following information and ask the study co-investigator (Sabina Wakasiaka) any questions you may have.

You will be told the purpose of the study and what would be expected of you. If you agree to be in the study, you will be asked to sign on this consent form, and will be given a copy to keep. It is important that you know the following: Your taking part is entirely voluntary you may decide not to take part in the study without affecting your opportunity to be in other studies or HCP programs.

Interviewer: ________________________________

Interviewee: ________________________________

Date: ________________________________

Time interview begins: ________________________________

Time interview ends: ________________________________

Introductory Script: Thank you for taking time to participate in this research study. Our goal is to gather information from health care providers that will help us to develop effective methods to prevent HIV and other STI. This information is critical because the
percentage of women infected with HIV (the virus that causes AIDS) around the world continues to rise, particularly in developing countries, where most women contract HIV through vaginal sex with men. Because many men are unwilling to use condoms, women urgently need a method of HIV prevention that they can control themselves in order to decrease their risk of HIV infection. Microbicides, or drugs that can kill the virus upon contact, are one such method of HIV prevention being studied. Microbicides can be delivered in gels or creams that a woman could insert in her vagina before sexual intercourse. Another method of delivery is an 'intravaginal ring.' This device is a flexible, doughnut-shaped, silicone ring about two inches wide that a woman would place in her vagina. There the ring would slowly release a drug that could stop the HIV virus from entering her body.

Before we continue to develop this device as a method of HIV prevention, however, we need to make sure that it would be useful and accepted in the countries where it is most needed. To do so, we need to understand common sexual practices in the communities you serve, as well as your opinion as a health care provider about the potential effectiveness of various methods of HIV prevention. Because sexual behaviours often vary a great deal between cultures, often time's sexual practices that are considered the norm in some places are considered taboo in others. For this reason, it is important that we try not to judge but to understand these similarities and differences. Please remember that our conversation here today is completely confidential.

This first set of questions concerns sexual behaviour and terminology:
1. What words do *you* use, and what words do *your patients* use to refer to the following: Male and female genitalia? Penile-vaginal sex? Oral sex or any oral/mouth contact with genitals? Anal sex or any oral or genital contact with the anus?

2. In your perception, which of these sex acts are most and least common in the communities you serve?

3. Are there ever a time when having sex is considered inappropriate amongst the populations that you serve?

Thank you for your thoughtful answers to those questions. This section concerns your opinions about specific methods of HIV prevention:


6. What is your opinion on the use of a microbicide gel or cream placed in the vagina as a method of HIV prevention for commercial sex workers?

**Now let's turn our attention to the microbicide ring.** [Show healthcare provider a prototype of the ring]:

7. What do you think about the microbicide ring?

8. What do you think about its size?

9. Do you have any safety concerns about this device as a health care provider? Please describe.
10. Do your female patients ever use preparations or products to cleanse or tighten the vagina? Which ones? How do you think that these preparations would affect the use of a microbicide ring?

11. Do you think that women would have any problem touching their genitals to insert this device? Do you think that all women could insert it by themselves? Would factors such as female circumcision or excess weight make it difficult for some women to use the ring?

12. Are there any other factors or barriers to the use of intravaginal rings in the general populations that you serve (Probe: such as cultural, religious or anatomical?)

13. Presuming that it was safe and effective to leave this device in for an extended period, how long do you think that women would be comfortable leaving the device in? One month? Six months? One year?

14. Would women be comfortable leaving the device in during their menstrual period?

15. How comfortable do you think it would be to leave it in during sexual intercourse? Would it affect one’s sexual pleasure? Would a woman’s partner notice the device?

16. What is your opinion on the use of an intravaginal ring as a method of HIV prevention for commercial sex workers?

17. What would a woman’s paying sex partner think about her using an intravaginal ring? Would it affect her profits? Would it affect her safety?

18. Do women come to your clinic/dispensary with complaints that are possibly caused by STI’s? How do the women describe these complaints? How do you usually treat such complaints?
19. If condoms, vaginal creams/gels or vaginal rings were all equally effective and available as methods to prevent HIV. Which method would be preferred in the communities you serve, and why?

20. If microbicide rings were available, what do you think would be the best method for distributing them?

21. Are there any other issues that we should take into consideration in order to develop an effective Microbicide ring?

22. In closing, are there any questions that you have for us?

Facilitator: Thank the health care provider again for taking time to participate in the study.
APPENDIX VIII
VOLUNTEER RECRUITMENT
SOP01, Version 1.0

The signatures below constitute the approval of the SOP 01; version 1.0, dated 24th Nov. 2006 called ‘Volunteer Recruitment, Stage One -Initial Contact’, and provides assurance that the study was conducted in accordance with these procedures.

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<tr>
<th>Prepared by</th>
<th>Date prepared</th>
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<tr>
<td>Sabina Wakasiaka</td>
<td>24th Nov 2006</td>
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FLOW DIAGRAM FOR INITIAL CONTACT WITH POTENTIAL IVR VOLUNTEERS

Initial Contact

KAVI team members make appointments with local administrators to seek community consent and create awareness of IVR study

1.0.1 First

PI and Coordinator hold community seminars in designated village Barasa.

Second Contact

FCSW are then invited to attend detailed IVR information seminars at Alice Nursing Home. Each village had a seminar schedule; this gave Volunteers equal opportunity to participate. At this point it was emphasized that FSW who participated in the FGDs were not be eligible for study.

VCT Visit Service

Interested FSW were invited to have VCT service at Alice Nursing Home. Those testing negative were given a

1.0.2 Third

Informed Consent information was discussed at the first one on one session with the nurse. There was ample time for question and answer session. Whenever the nurse was sure that participant had understood relevant information regarding the study she then booked participant for the screening visit.
3.1 Initial contact with local community leaders

KAIVI team members made appointments with local administrators to seek community consent and create awareness of IVR study. These meetings included the chief, area counselor, village elders and the district officer.

3.1.1 Contact with local communities/organizations

Study team contacted local communities and target populations such as local government representatives, bar managers, CBOs and health professionals, to make an appointment to discuss the study with a member/employee representative. The aim of the appointment was to seek permission to discuss the study with members of their organization at a pre-arranged time.

3.2 First contact with Potential Volunteers (prior to an Information Seminar)

Once agreed with the institution/community, a seminar was scheduled and conducted at the community level. During the seminar general information about HIV/AIDS was given, this included methods of prevention and the role of preventive vaccine and Microbicide, thus introducing the topic of an Intra Vaginal Ring.

3.3 Second contact (Unit Seminars)

Following a negative HIV test, Potential Volunteers were booked for a one-on-one counseling session where the nurse discusses Informed Consent information in detail. Volunteers were also informed that FGD participants would not be eligible for study. When the nurse was sure that the participant had understood relevant information regarding IVR study she then booked the participant for the screening visit.
The signatures below constitute the approval of the SOP 02, version 1.0, dated 24th. Nov. 2006, called 'Volunteer screening', and provides assurance that the trial will be conducted in accordance with these procedures.

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| Effective date            | 30th Nov. 2006      |
2. Flow diagram for Volunteer Screening

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<th>Pre-screening Visit</th>
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<tr>
<td>The nurse reviews Informed Consent document and administers test of understanding tool. Potential volunteers are required to score over 90% of the set questions before proceeding for the screening visit. Questions that the volunteer failed to answer are discussed and clarification before volunteer moves to the next step.</td>
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<th>SCREENING VISIT</th>
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<tr>
<td>Study physician reviewed Informed Consent Information with volunteer, confirms understanding then obtains written Informed Consent.</td>
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<td>Potential Volunteer was then registered on a Screening Log and screening number assigned</td>
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<tr>
<td>Administration of baseline, demographic, behavioural and medical history questionnaire was done by trial nurse.</td>
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<tr>
<td>The study physician conducted General Physical Examination and filled out the eligibility checklist.</td>
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<tr>
<td>Blood, urine and vaginal samples were obtained as indicated</td>
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<td>Appointment for day 0 visit was made with eligible volunteers.</td>
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3.1 Pre-screening Visit

This session could occur a day earlier or on the screening visit day. The nurse administered test of understanding tool. Potential volunteers were required to score over 90% of the set questions before proceeding for the screening visit. Questions that the volunteer failed to answer were discussed and clarification made as needed.

3.2 Procedures Required Prior to the Clinical Examination and Specimen Collection

Baseline Questionnaire was completed by the trial study nurse or trial physician. If the Questionnaire results indicated that the potential Volunteer was not eligible for the trial, the trial physician then informed volunteers the reasons for ineligibility. Referral was made as required to either Kenyatta National Hospital or a facility of their choice. Finally the physician appreciated volunteers for their interest in the trial.

3.3 Clinical Assessments

- Medical history was recorded in the baseline demographic form and any medication that the Volunteers were taking was documented.
- Physical examination and vital signs were recorded on the Physical Exam Form. Pelvic exam was included in the physical exam form.
- Genital swaps were taken as indicated. (Refer to SOP3)
3.4. Laboratory Sample Collection (refer to SOP 3)

The following specimens were collected during a Screening Visit.

- Blood samples for RPR and HSV-2 Ab.
- Urine samples for pregnancy test.
- Cervical swaps were taken for STI and Vaginitis.

3.5 Final Procedures completed before the Volunteer left the study site.

The physician completed the eligibility checklist, dated and signed it. The nurse and physician completed the Screening Visit Checklist to ensure that all screening procedures were carried out.

- Before leaving the clinic the trial nurse did offer the Volunteer a copy of the signed and dated Screening Consent Form and the Consent Information Sheet for the study. If the Volunteer does declined to take their copy, this was then recorded on the Screening Visit Checklist.
- Appointment was made for day 0.
APPENDIX X
SAMPLE COLLECTION
SOP03, Version 1.0

The signatures below constitute the approval of the SOP 03, version 1.0, dated 24\textsuperscript{th} Nov. 2006, called ‘Sample Collection, and provides assurance that the trial will be conducted in accordance with these procedures.

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1. **Purpose**

To establish standard operating procedures for taking blood, urine and genital specimens.

2. **Responsible persons**

This SOP applied to all study nurses and doctors responsible for taking blood, urine and genital specimens. In general, the study nurse was responsible for taking blood and urine specimens; the study doctor was responsible for taking genital specimens.

3. **Procedures for Taking Blood Samples**

A Laboratory Requisition Form was completed requesting for blood samples to be taken from a volunteer. The original form was provided to the laboratory with the samples, and a copy was placed in the volunteer’s file with the Data Collection Forms. The expiry date on each item of blood collection equipment including blood tubes was checked prior to its use. No equipment was used after its expiry date. All sample collection equipment was prepared and ready for use prior to venepuncture.
3.1. Equipment Required

- Appropriate blood sample tubes as required by protocol
- Vacutainer needle size 21 G (or as appropriate)
- Vacutainer needle holder
- Pair of clean, non-sterile gloves
- Alcohol swab
- Tourniquet
- Micropore tape
- Spot plaster
- Labels for blood sample tubes
- Laboratory Requisition Form
- Plastic tray
- Biohazardous waste container/'sharps' box

3.2 Preparation of Assembled Blood Collection Equipment

Visit checklist was checked to ascertain what samples are required at the volunteer's visit.

The nurse ascertained that the participant had breakfast and/or a cup of tea/coffee prior to venepuncture. If not, tea, coffee or a carbonated drink was offered, after which the volunteer was given another 5-10 minutes before proceeding.
The procedure was explained to the Participant to allay any anxiety and answer any questions that may be asked. Participant Sat or lay on a couch according to the volunteer's preference. Hands were washed thoroughly and dried

3.3 The Standard Procedure

Put on gloves. Assemble all blood tubes and blood collection equipment onto plastic tray. Take the needle out of the pack; leave the needle cover in situ. Attach the Vacutainer needle to the needle holder. Prepare a short length of micropore tape. The cubital fossa was examined for suitable venous access. Having selected and palpated the suitable vein, all equipment positioned for easy access. A pillow was placed under the fully extended selected arm for comfort, a tourniquet was put on the arm, placing it 5-8cm above the suitable vein and tightened to expose the vein. the skin was cleaned with an alcohol swab with a downward movement and allowed to dry. Taking the needle, with the bevel uppermost, having removed the needle cover, it was slided into the vein at an angle of 30 degrees. Holding the Vacutainer needle holder, the first Vacutainer blood collection tube was pressed into the clear shield. The rubber seal of the tube passed over the valved end of the needle and the vacuum allowed the requisite quantity of blood to flow. When the blood begun to flow the tourniquet was released. When the first tube had filled, it was removed and the process repeated until all the appropriate tubes were filled. The tourniquet was then opened, and then gently the needle was withdrawn from the vein, immediately the puncture site was covered firmly with a swab and the Participant was asked to press firmly on the puncture site. The needle and its attachments was disposed off into a ‘sharps’ box. The site of the venepuncture was then checked for bleeding, if it
had stopped the spot plaster applied. If the site was still bleeding, pressure was applied continuously for a further 5 minutes. All efforts were made to make sure the Participant feels well before leaving. Laboratory Requisition Form was then completed, ensuring that all tests required by the protocol were indicated on the form.

4. Procedures for Taking Urine Samples

A Laboratory Requisition Form was completed requesting for urine samples taken from a volunteer. The original form was provided to the laboratory with the samples, and a copy placed in the volunteer’s file with the Data Collection Forms. The same form was used for all samples at a visit.

Equipment Required

- Urine collection bottles, 20mls

4.2. Preparation of Assembled Urine Collection Equipment

The procedure was explained to the volunteer. The urine collection bottle was be labeled as highlighted below.

4.3 Procedure. A clean catch mid-stream urine sample was collected. The participant was instructed to pass an initial stream of urine, then collected at least 10 mls of urine. This was not a sterile sample.

5. Procedures for Taking Genital Samples

A Laboratory Requisition Form was completed requesting for collection of urine samples from a volunteer. The original form was provided to the laboratory with the samples, and a copy was placed in the volunteer’s file with the Data Collection Forms. The same form was used for all samples at a visit.
Equipment Required

- Speculum
- Lamp
- Drape for exam table and participant
- Chlamydia/gonorrhea kit with swab (Dacron)
- Trichomoniasis In-Pouch TV culture packet
- Regular small swabs (3)
- Small tube with cap, filled with 1ml saline
- Glass microscope slide

5.2 Preparation of Assembled Specimen Collection Equipment

The procedure was explained to the volunteer. The sample containers and glass plate were labeled as detailed below.

5.3 Procedure

The participant reclined on exam table in position for a pelvic exam, with lower half of the body draped. External genitalia were examined and findings recorded on physical exam form. The Speculum was lubricated with sterile water or saline as desired. The Speculum was carefully inserted into vagina and opened to visualize the cervix. The vagina and cervix were examined and record findings on physical exam form.

To obtain specimens. Chlamydia/gonorrhea PCR tests: Chlamydia/gonorrhea Dacron swab 1 cm was Inserted into cervical os and rotated. Swab was removed and inserted
into test kit container, breaking off swab handle and leaving swab tip in container. The Cap was then screwed onto container.

**Candida:** A small swab was used to gently collect vaginal secretions from lateral vaginal wall or anterior fornix. Swab tip was placed into the glass tube with saline and stirred. Swab and cap lid were then removed. Wet prep was prepared at KAVI lab.

**Bacterial Vaginosis:** One small swab used to gently collect vaginal secretions from lateral vaginal wall or anterior fornix. Swab tip rolled across the clean plate. The specimen was allowed to air dry. No heat fix was done. Once dry, it was placed in slide carrier. Gram stain and Nugent's score for bacterial Vaginosis was performed at KAVI. The disposable speculum was removed and placed in dirty equipment bag to return to KAVI lab for disposal.

**6.0 Labeling**

At the visit, the nurse/counselor or laboratory personnel prepared the relevant set of labels, and then the nurse/counselor attached labels to all blood tubes, sample containers and glass slides. All the blood tubes/urine bottles/sample containers/glass slides were labeled as appropriate e.g. with the date and time of collection, the volunteer's ID number and initials.
Ref: KNH-ERC/ 01/ 3202

Prof. Job Bwayo
Dept of Medical Microbiology
Faculty of Medicine
University of Nairobi

Dear Prof Bwayo

RESEARCH PROPOSAL: “ACCEPTABILITY OF INTRAVAGINAL RINGS TO PREVENT HIV IN KENYA” (P109/7/2005)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and approved revised version of your above cited research proposal for the period 16th January 2006 – 15th January 2007. You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

PROF A N GUANTAI
SECRETARY, KNH-ERC

cc. Prof. K.M.Bhatt, Chairperson, KNH-ERC
The Deputy Director CS, KNH
The Dean, Faculty of Medicine, UON
The HOD, Medical Records, KNH