

Opportunities for targeted HIV prevention in Kenya

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Patricia was my Co-Promotor until she peacefully passed away in Ghent on June 30th 2008. This doctoral thesis is some of the work that is built on the foundations that she laid at ICRH. Without her initiatives and determination, this work could not have been done.

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Preface

This must stop!

How immense the contrast can be. Wealthy and educated, parents and siblings alive, all living in prosperity; a secured job, a frequent flyer gold card, and two cars from which to choose one every morning. The car brings me to the office on Mombasa Island where I work with 100 hard-working colleagues on the prevention, treatment and care of reproductive health issues such as safe motherhood, bacterial vaginosis, human papilloma virus, and one that challenges all of us: human immunodeficiency virus (HIV). Between 10 and 40 percent of the people in our projects are infected with it, often living in a situation that Stephen Lewis described this way:

“Just a few weeks ago, we were taken to a rural village to see an “income generating project” run by a group of Women living With AIDS. They were gathered under a large banner proclaiming their identity, some fifteen or twenty women, all living with the virus, all looking after orphans. They were standing proudly beside the income generating projects....a bountiful cabbage patch. After they had spoken volubly and eloquently about their needs and the needs of their children (as always, hunger led the litany), I asked about the cabbages. I assumed it supplemented their diet? Yes, they chorused. And you sell the surplus at the market? An energetic nodding of heads. And I take it you make a profit? Yes again. What do you do with the profit? And this time there was an almost quizzical response as if to say what kind of ridiculous question is that...surely you knew the answer before you asked: “We buy coffins of course; we never have enough coffins”.

This is part of a speech by Stephen Lewis, former UN Special Envoy for HIV/AIDS in Africa, delivered at the Summit on Global Issues in Women’s Health. It is unbelievable that twenty-five years into the epidemic, still an estimated 2.5 million new infections occur each year.

This must stop!

We urgently need to prioritise prevention efforts.

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Introduction

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| The Global Pandemic | 1.1 |
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Photo credit: UNAIDS/G.Pirozzi

1.1 The Global HIV epidemic

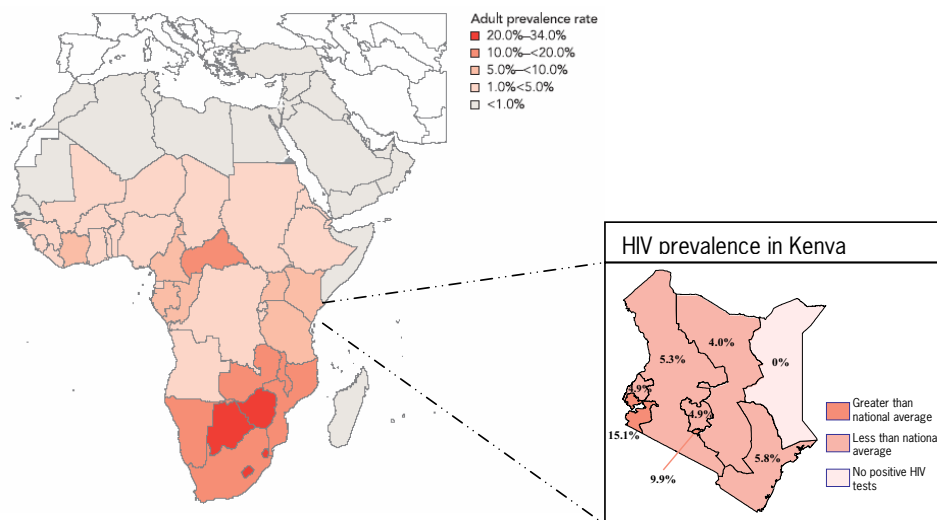
By 1985, with HIV cases reported in every region of the world, a group of scientists and health professionals came together under the auspices of the World Health Organization (WHO) to recommend a global strategy for AIDS prevention and control that was then endorsed by the World Health Assembly and the United Nations General Assembly. With the establishment of the Global Programme on AIDS in 1987 and the Joint United Nations Programme on HIV/AIDS (UNAIDS) in 1996, the United Nations moved to address AIDS, not as an isolated health problem but as a human development issue as significant as any facing the world today. At the 2001 Special Session of the UN General Assembly on AIDS, 189 nations agreed that AIDS was a national and international development issue of the highest priority, signing an historic Declaration of Commitment on HIV/AIDS that promised innovative responses, coordinated efforts and accountability for progress against the epidemic. The Declaration set a comprehensive list of time-bound targets to support the Millennium Development Goal of halting the spread and beginning to reverse the epidemic by 2015.

An estimated 33.2 million [30.6 million–36.1 million] people worldwide were living with HIV in 2007 and an estimated 2.5 million [1.8 million–4.1 million] became newly infected. That year, approximately 2.1 million [1.9 million–2.4 million] lost their lives to AIDS. (1) Sub-Saharan Africa is the worst affected region in the world.

HIV/AIDS has a major economic and social impact on individuals, families, communities and on society as a whole. AIDS threatens personal and national wellbeing by negatively affecting health, lifespan, and productive capacity of the individual; and by severely constraining the accumulation of human capital. Recent research across many severely affected, low-income countries, demonstrates that HIV/AIDS is a serious impediment to economic growth and development in such countries; there is no reason to expect Kenya is an exception. (2-4)

Although in most parts of the world women live longer than men, AIDS has driven female life expectancy below that of men in four countries: Kenya, Malawi, Zambia and Zimbabwe. (5) Women in sub-Saharan Africa are infected more often and earlier in their lives than men. Young women aged 15–24 are between two and six times as likely to be HIV-positive than men of a similar age. (1) Gender inequality, poverty, and women's lack of education are some of the reasons for women's increased vulnerability to HIV infection.

Figure 1: Adult HIV prevalence in Africa in 2005, and enlarged for Kenya.



1.2 HIV in Kenya

National adult (aged 15-49 years) HIV prevalence is estimated to have fallen from 10% in the late 1990s to about 7% in 2003 (6), to a prevalence of 5.1% in 2006. (Alloys Orago, Director National AIDS Control Program) High levels of HIV/AIDS related mortality and the saturation of infection among people most at risk appeared to be factors associated with the decline in HIV prevalence. (7) The Kenya AIDS Indicator Survey 2007, which assessed HIV status in a representative sample of 10,375 households with almost 18,000 participants, estimated the HIV prevalence in this age group at 7.8%. (8) As 95% confidence intervals are overlapping with previous estimates, no conclusions can be drawn on whether the higher HIV prevalence is indeed an increase in national prevalence or due to chance. Interpretation of a potential change is difficult as various factors besides changes in HIV incidence could impact on prevalence rates including access to ART and changes in HIV related mortality. An estimated 1,400,000 Kenyan adults are currently HIV infected despite a significant reduction in reported sexual risk behaviour in recent years. (8) The proportion of women reporting more than 1 sexual partner in the last 12 months decreased from 4.2% in 1998 to 1.8% in 2003.

For men, this decrease was more pronounced with 24.1% and 11.9% reporting more than 1 sexual partner in 1998 and 2003 respectively. (9) Condom use at last sex was reported by 15.1% of women and 42.5% of men in 1998, with corresponding figures of 23.9% and 46.5% in 2003. HIV prevalence of adult women in Kenya is 9.2%, as compared to 5.8% among men. This female to male ratio of 1.6 to 1 is higher than that found in other population-based studies in Africa. (8)

Figure 2: HIV prevalence among Kenyan adults of reproductive age (15-64 years).

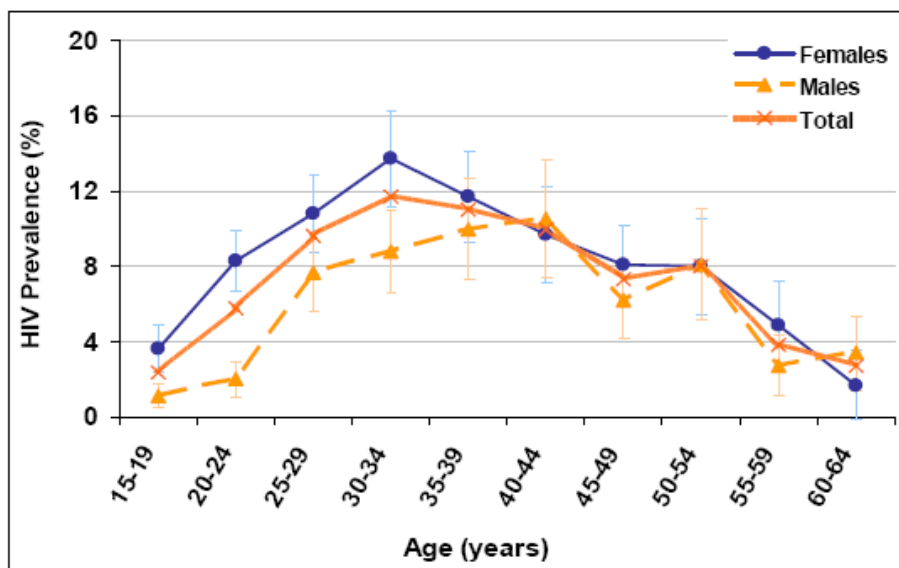


Figure 4. HIV prevalence and 95% CI among participants 15-64 years old by sex and 5-year age categories, KAIS 2007.

In the Kenya Demographic Health survey 2003, nearly three in four men and women knew someone personally who had AIDS or had died of AIDS. Similarly, most Kenyan adults knew that abstaining from sex, limiting sex to one faithful partner, using condoms, or both, are ways of reducing the risk of HIV infection.

1.3 Key populations targeted

The Kenya National HIV/AIDS strategic Plan 2006/2010 identifies the targeting of vulnerable groups as a core principle within the national response. (10) Sub-populations that play an important role in

fuelling the epidemic have been identified, and are among the most marginalized and discriminated people in society. Their behaviours put them at increased risk of becoming infected with, as well as spreading HIV to the population at large. Vulnerable groups include, but are not limited to, sex workers, men who have sex with men, orphans and vulnerable children, girls, migrant workers, uniformed services, victims of rape and sexual violence, intravenous drug users and discordant couples. (10) Targeting these groups is a key strategy for preventing HIV in both concentrated and generalized HIV epidemics. (1, 11-15) This thesis focuses on three key populations: sex workers; men who have sex with men; and people living with HIV.

1.3.1 Sex workers

While it is not possible to accurately count the number of people selling sex, it is estimated that sex workers may number in the tens of millions worldwide and their clients in the hundreds of millions. (1) While sex workers can be of all ages, most are young and the great majority are female; their clients (for both male and female sex workers) are mostly male. Although almost all countries in Africa criminalize sex work and thereby potentially subject the act of buying or selling sex for money to criminal sanction, sex workers have the same human rights as everyone else, particularly rights to education, information, the highest attainable standard of health, and freedom from discrimination and violence, including sexual violence. (1) Sex workers are at increased risk for HIV infection highlighting their social and economic vulnerability. This underlying vulnerability is driven by factors such as gender inequalities; inadequate or even harmful legislation and policies; limited access to health; education; social and legal services; inadequate access to information and HIV prevention commodities; stigmatization; marginalization; abuse; and exposure to factors such as population mobility and hazardous use of alcohol. Sex work takes place at a variety of settings, ranging from hotels, bars to roadside areas, beaches and their homes. In contrast to Asia where sex work is more organised from well-established brothels, in Africa, sex work mostly occurs in more informal settings within an unregulated working environment. In areas with economic and food insecurity, sex work is sometimes the sole option for women.

The sex industry is thought to be one of the key factors driving the spread of the epidemic. A study conducted in rural Zimbabwe among male mine and farm workers estimated that after adjusting for potential confounding factors, HIV was 1.5 times more likely in men who reported ever having had sexual contact with a sex worker. It was estimated that one fifth of HIV infection was potentially

attributable to sex worker contact. (16) Similar findings were presented among factory workers in Harare where men who had paid for sex were twice as likely to be infected with HIV as those who had not. (17) Kenya was among the first countries to identify female sex workers as an important core group in the epidemiology of HIV infection. (54) Initial studies in the 80-ties identified very high HIV prevalence rates of over 60% among sex workers. (55) A prospective study with over 1000 sex workers, whom were followed between 1985 and 1990, showed that an intervention to prevent HIV transmission consisting of counselling, condom promotion, and prevention and treatment of STIs would be cost-effective. (56) Already in the early stages of the epidemic, interventions aimed at most-at-risk groups (STD transmitter core groups) such as sex workers and long-distance truckers were identified as key interventions for preventing further spread of HIV because of their sexual behaviour as well as their highly mobile character. (54-60) Within each country of sub-Saharan Africa, areas most heavily affected by HIV are those linked with main transport routes or in border regions. Several studies have found that population mobility is associated with high-risk sexual behaviour and HIV among women. (18-20) Female sex workers on major highways in Kenya appear to be especially mobile. This is likely because sex work settings on transport routes don't remain stable and accommodation and leisure preferences of truckers change over time. (19) Using data collected among sex workers on the main road linking the Ugandan capital Kampala with Mombasa, the largest port in eastern Africa, modelling showed that raising condom use levels from the current 78% to levels of 90% would avert two thirds of the estimated 3,200 – 4,148 HIV infections which occur here each year. (20) These shifts in population and sex work settings complicate provision of services. Also, most clients operate in secrecy and do not wish to be identified.

1.3.2 Men who have sex with men

Men who have sex with men are found in all countries, yet are largely invisible in many places. Recent studies in several low- and middle-income countries indicate HIV infections attributable to men having sex with men (MSM) have previously been markedly underestimated. (21-26) Researchers reported an HIV prevalence of 21.5% among a snowball sample of 442 men who have sex with men in Senegal, where national HIV prevalence is 1.6%. (27, 28) A separate study of men who have sex with men risk behaviour in Senegal reported a large proportion of their sample had received money for sex, indicating that transactional or commercial sex may play an important role in some African MSM networks. (29) Researchers modelled the Kenyan HIV epidemic, and estimated that 4.5% of new

infections in Kenya in 2005 occurred through men having sex with men. (30) Preliminary results from a study in Kilifi, Kenya, report both high prevalence (up to 43%) and incidence rates (8.8 per 100 person-years of observation; 95% confidence interval=2.2 - 35.2) among a cohort of men who have sex with men, many of whom are sex workers. (31) Several, mainly western, studies show increased biological vulnerability to HIV among MSM due to highly efficient transmission inherent to exposure in anal sex and because this population group commonly has an extensive network of sexual partners. (32-34) For both men and women, HIV transmission during unprotected receptive anal sex is estimated to be about 10 times more efficient than unprotected vaginal intercourse. (35, 61) HIV programs among men who have sex with men in sub-Saharan Africa, has largely been neglected by governments and other HIV service organizations, due to denial of the existence of "African homosexuality", high levels of community stigma and discrimination, as well as the criminalization of same-sex behaviour in many countries. (36) In Kenya, sections 162 to 165 of the penal code criminalize homosexual behaviour and attempted homosexual behaviour between men, recommending sentences of 7 years. In addition to being penalized under sodomy laws in Kenya, male sex workers also break solicitation laws.

Limited data exist on how many men have sex with men, their motivations, or the characteristics of their risk behaviours. Further investigation to collect information on behavioural characteristics of MSM in and around Mombasa is needed, as the epidemiologic impact of MSM on HIV transmission in the Mombasa area may be substantial, particularly as the sexual networks of MSM in Kenya extend to women, and are not isolated from the general population. (37)

1.3.3 People living with HIV and AIDS

An estimated 1,4 million Kenyans were living with HIV/AIDS at the end of 2007. (8) Nationwide coverage of people who ever tested for HIV was estimated at 36%, somewhat higher among women (43%) as compared to men (25%). In the 2007 survey, among those tested HIV-infected, only 20% correctly new their HIV status. (8) Unprotected sex among HIV-infected persons is of concern because of the risk of HIV transmission to sero-discordant partners, or the risk of re-infection with new viral strains. It is estimated that over 400,000 married couples in Kenya are HIV discordant. This translates in 45% of married HIV-infected individuals have a partner who is currently not infected. (8) The majority of people who undergo HIV testing and become aware of their HIV status adopt safer

sexual behaviour, but a minority of people have difficulty implementing and sustaining these practices. (38-42, 62-67) There is particular concern among infected people receiving antiretroviral therapy (ART). ART significantly reduces morbidity and mortality and makes people feel healthier, which may lead to increased sexual activity and a reduction in preventive behaviours. This is being referred to as treatment optimism or behavioural disinhibition. People may experience “safer sex burnout” as they have difficulty sustaining safer sexual behaviours over a lifetime. On the other hand, people on ART may have increased contact with health care providers which may in turn encourage continuation of safe sex practices. A stochastic simulation based mainly on Ugandan data predicted declines in HIV incidence with the initiation of ART. However, despite decreasing incidence, the epidemic would continue to grow at a substantial rate, suggesting that ART alone cannot control the HIV epidemic. (43) When applied in the model, behavioural disinhibition could markedly offset the public health benefits.

In Europe and North America, data among men who have sex with men suggested an increase in the incidence of STIs including HIV since ART became more widely available. (44, 45). An increased risk of acquiring STIs, an epidemiological marker of unprotected sex, has also been reported among heterosexual HIV-infected persons receiving ART. (46) However, a more recent systematic review found that while people’s beliefs about lower infectivity with ART and undetectable viral loads promote unprotected sex, HIV-positive patients receiving ART did not exhibit increased sexual risk behaviour, even when therapy achieved undetectable viral loads. As of August 2006 an estimated eighty-eight thousand HIV-infected persons were receiving ART in Kenya. (47) If the described increase in risk behaviours is seen in Kenya, it has the potential to undo gains achieved by prevention and ART initiatives.

1.4 HIV Transmission and Prevention Strategies

The majority of HIV infections are through unprotected sexual contact, though transmission through blood contact does occur (blood transfusion, needle sharing etc). It has been estimated that in Kenya in 2005 there were approximately 82,369 new cases of HIV infection, with most of these in the general, low-risk population (30.1%), those having casual heterosexual sex (18.3%), among partners of those having casual sex (27.7%), and among men who have sex with men (4.5%).

The estimated average probability that an HIV infected person transmits the infection (transmission efficiency), during an unprotected sexual act (calculated for penile-vaginal sex) is between 0.0003

and 0.0012. (48) However, this estimated probability needs to be used with caution as the risk greatly varies depending on the stage of the HIV infection (e.g. acute HIV infection). Factors associated with increased risk of HIV transmission during unprotected sex have been well described in previous studies and include stage of HIV disease, viral load, presence of STI and genital ulcer disease, male circumcision, ART or other cofactors. (49-53)

Potential approaches to HIV prevention include voluntary counselling and testing, behaviour change interventions, barrier methods and interventions to reduce transmission efficiency such as circumcision, STI treatment, microbicides and vaccines. The government of Kenya, international donor partners, local and international non-governmental organizations, and many other facets of civil society are involved in activities and services to prevent HIV. Some of the activities implemented by these organizations include (in no particular order):

- Basic education and dissemination of information about HIV
- Communication about behaviour change
- Community mobilization to change social norms
- Mass media campaigns
- Participatory “edutainment” including drama and puppetry
- Training youth and adolescents in life skills and behaviour change
- Peer education and youth-to-youth initiatives
- Voluntary testing and counselling
- Prevention and treatment of other sexually transmitted infections
- Prevention of mother-to-child transmission of HIV
- Prevention of transmission in medical settings, including safe blood transfusion and proper infection control
- Condom education, promotion and distribution

Current approaches in women at high risk for HIV infection mainly include provision of voluntary testing and counselling (VCT), behaviour change interventions and the promotion of male condoms and their consistent and correct use. HIV prevention programs for men who have sex with men have been identified as an important component of a comprehensive HIV public health strategy. However, available data on the prevalence and characteristics of same-sex sexual activity in Kenya and in Africa is limited and needs further attention.

Better understanding is needed of the factors associated with increased sexual risk behaviour among these most-at-risk populations to more effectively develop and implement targeted interventions.

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Objectives

| | |
|---------------------|-----|
| General Objective | 2.1 |
| Specific Objectives | 2.2 |

2

Photo credit: Hugh Rigby/CCP

(ICASA), held in Nairobi, Kenya. (September 2003)

Youth demonstrate outside the 13th International Conference on AIDS and STIs in Africa

2.1 General Objective

The general objective of this work is to identify priorities in HIV prevention (acquisition and further transmission) and to assess targeted prevention strategies.

2.2 Specific Objectives

1 – To identify factors associated with unprotected sex among key populations in Mombasa, Kenya.

a – *To assess the association of heavy episodic drinking with unprotected sex acts among sex workers in Mombasa, Kenya.*

HIV prevention strategies have largely ignored the potential for alcohol to influence sexual behaviour. Effects of alcohol depend on total cumulative volume consumed, drinking patterns and drinking contexts. High-risk drinking patterns, especially heavy-episodic drinking is likely to be associated with unsafe sexual behaviour. If shown, targeted interventions assisting sex workers to adopt safer drinking patterns could potentially contribute to HIV prevention.

b – *To assess factors associated with unprotected anal sex among male sex workers who sell sex to men in Mombasa, Kenya.*

HIV prevention programs for men who have sex with men have been identified as an important component of a comprehensive HIV public health strategy. However, available data on the prevalence and characteristics of same-sex sexual activity in Africa is limited. Identification of risk factors among a sub-population of *male sex workers who sell sex to men* could guide HIV-1 prevention efforts.

c – *To assess factors associated with unprotected sex among HIV infected persons receiving ART in Mombasa, Kenya.*

Unprotected sex among persons receiving ART remains a concern because of the risk of HIV transmission to sero-discordant partners. If shown to be the case, targeted

interventions assisting persons receiving ART to adopt safer sexual behaviour could potentially make a marked contribution to HIV prevention.

2 – To assess the safety, acceptability and effectiveness of targeted HIV prevention strategies among most-at-risk populations in Mombasa, Kenya

a - To assess the long-term individual and subpopulation effects of five years of peer-mediated behaviour change interventions among female sex workers in Mombasa, Kenya.

Thus far, studies have evaluated the short-term effects of interventions on behaviour change, but, to date, limited information is available on their effectiveness in sustaining behaviour changes in the long-term.

b – To assess the impact and costs of adding female condoms to an existing male condom promotion and distribution peer education project for sex workers in Mombasa, Kenya

Male condoms are stigmatized in Kenya, even among men who are known to frequent sex workers. Adding the female condom to an existing male condom promotion and distribution project for sex workers could increase the proportion of sex workers reporting 100% condom use.

c – To assess the safety and acceptability of the diaphragm, a potential female-controlled method of preventing HIV and STI among sexually-active women in Mombasa, Kenya.

If proven acceptable, safe and effective, the diaphragm could be used as a female-controlled method of preventing both sexually-transmitted infections (STIs) and pregnancy.





Methods

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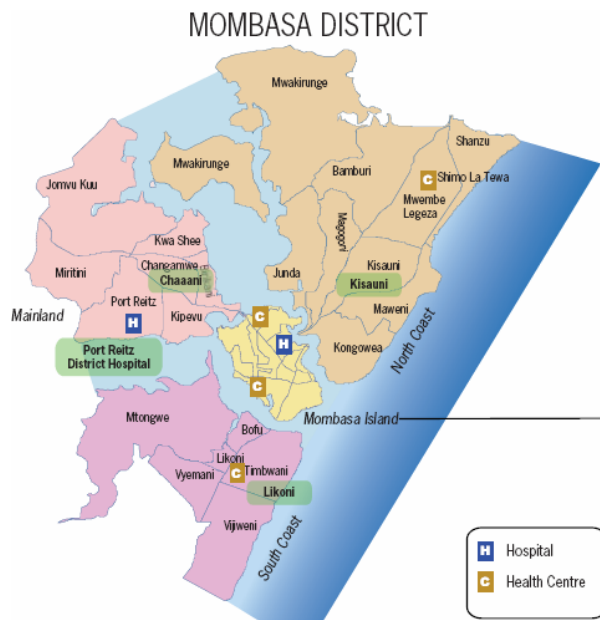
Photo credit: Stanley Luchters

3.1 Study Period

The thesis is a compilation of seven studies, all of which were conducted in the period between March 2003 and December 2006. Depending on the study design, studies took between 3 months and 3 years.

3.2 Description of the Study Sites and Population

Studies were conducted in Mombasa District in Kenya's Coast Province. Kenya is a former British colony and gained independence (Uhuru) on December 12th, 1963. The country has about 42 ethnic groups which are distributed throughout the country. Major tribes include the Kikuyu, Luo, Kalenjin, Luhya, Kamba, Kisii, and Mijikenda. The main religions in Kenya are Christianity and Islam. Mombasa has an estimated population of approximately one million people residing in the district area and covers approximately 100 square miles. Kenya's Coast Province, is a major regional economic centre, with important tourism, port, rail and industrial enterprises. As such, male and female commercial sex workers come from across the country, and elsewhere, to Mombasa. Mombasa consists of four divisions: Island, Changamwe, Kisauni and Likoni.



Mombasa Island, containing the city centre, is the oldest part of the district. Muslim communities are dominant in this part of Mombasa. The road linking the Mombasa seaport with the capital city Nairobi passes through Changamwe, which is largely inhabited by a migrant population, many of whom work at the nearby port, or as small scale traders, loaders and truck-drivers. This part of the city has a high burden of HIV and other STI, much of which is borne by sex workers. Kisauni Division borders the sea and is a popular tourist spot. It is characterized by many bars, guesthouses, and discos. Most of Mombasa's female sex workers live and work here. Likoni, south of the island is a multi-cultured community inhabited predominantly by the indigenous Digo Muslims and other ethnic communities from across the country.

Clinical and/or research sites where the studies were performed included:

Mombasa Island

- Coast Provincial General Hospital (CPGH): the provincial referral and teaching hospital.
- Mombasa drop-in centre: an ICRH run drop-in information and VCT centre mainly frequented by men who sell sex to men.

Changamwe

- Chaani clinic: a municipality run public-sector primary health clinic.
- Port Reitz District Hospital (PRDH): the second largest public hospital.
- Bomu Mkomani Clinic: a private, not-for-profit clinic.
- Magongo health centre: a municipality run public-sector primary health clinic.

Kisauni

- Kisauni drop-in centre: an ICRH run female sex worker drop-in centre.
- Bamburi health centre: a municipality run public-sector primary health clinic.

Likoni

- Likoni Health Centre: a Ministry of Health run health centre.

The study populations involved in the studies included female sex workers, male sex workers who sell sex to men, and HIV-infected men and women who could potentially infect an HIV-negative partner.

Female sex workers

Many female sex workers are active in Mombasa, though numbers vary depending on the season with more sex workers in the tourist season. Most sex workers are based at bars and nightclubs, and charge between \$5-55 per client. The majority of women are single or are separated / divorced after a steady relationship and have one or more children who are financial dependants. Sex work is often their only source of income, but part-time sex work is also practiced. Payment for sex is usually with cash money or a combination of cash and gifts, clothing or food. [1] ICRH has accumulated extensive experience in reproductive health interventions targeting female sex workers in and around Mombasa. As a component of Family Health International's (FHI) IMPACT (and more recently named APHIA-2) project in Kenya, the HIV Prevention, Care and Support Services project has been implemented by ICRH since 1999 and involved men and women at workplaces, youth and female sex workers. In order to acquire key baseline data for designing carefully targeted prevention activities, the project undertook a survey in the year 2000 assessing the sexual behaviour, knowledge and health status of sex workers. The subsequent project targeting female sex workers aims to reduce unprotected sex acts by increasing condom use and reducing the number of sexual partners; and secondly to empower FSW to control their working and social lives by increasing their knowledge of STI/HIV and condom negotiation skills. Finally it aims to reduce co-factors associated with HIV transmission by providing information on, and referrals for STI treatment, and HIV testing and counselling. The project mainly uses communication through peers, but also supported the initiation of drop-in centres in the community. Besides functioning as training and meeting facility, the drop-in centre was used for distributing information, education and communication (IEC) materials and condoms, and for voluntary counselling and testing (VCT) services. The peer education programme was developed in close collaboration with the community, with local chiefs, elders, and other local authorities to select their own educators for training. The selected peer educators receive intensive training through the 'Splash!' (Sensitivity-Provocative-Listening-Articulate-Speedback-Honest-Innovativeness) methodology. Training is organised such that after initial training, the peer educators are able to facilitate similar trainings to their peers while ICRH provides overall quality assurance. Trained peer educators are also given skills to lead group discussions on various elements of HIV/AIDS. This enables them to conduct at least four participatory education sessions each month in their specific environments - be it in the drop-in centres, or at sex workers' homes. They are also encouraged to take part in various outreach activities organised by ICRH, including mobile VCT

clinics, condom distribution, and community theatre. Those educators who demonstrate strong leadership skills and involvement are invited to attend advanced training on facilitation, project planning and advocacy skills. A number of sex workers have also been trained as counsellors, to conduct home visits and refer colleagues for medical care. Several educators have undergone refresher training to enable them to teach their peers about ARVs, opportunistic infections, female condom negotiation, prevention of mother-to-child transmission of HIV, and basic home-based care skills.

The peer network is set up so that each trained sex worker is encouraged to identify a friend with whom to share their lessons during an initial two-week period, after which the friend must find a second partner to pass on their training to - and so on. The project is divided into six geographical zones, each with its own smaller groups in which regular education sessions are conducted with bimonthly supervision from the ICRH field coordinators. Consultative meetings are also held with local chiefs and elders to review progress in each zone, and these leaders play an active role in the training workshops. A weekly radio show called Kati Yetu ('Between Us') supports the project by communicating sexual health messages through the mass media.

To date, more than 350 female sex worker peer educators have been formally trained by the project, further reaching an estimated 2,500 of their peers. The good links of ICRH with the target population and the local authorities has been crucial in the successful implementation of the research interventions. Female sex workers research participants were recruited from the larger population of sex workers in Mombasa.

Men who sell sex to men

The International Centre for Reproductive Health (ICRH) in collaboration with Population Council, University of Washington, the Kenya Medical Research Institute and the Ministry of Health conducted an enumeration of men who sell sex to men in and around Mombasa. (51) In the formative stage of this study, we mapped over 50 key contact locations where men who sell sex to men are known to search or wait for clients. During the enumeration training, additional sites were identified, and a total of 77 locations were categorized geographically and assigned to 12 zones in and around Mombasa District. These locations included bars (23 locations), nightclubs/ disco's (8 locations), beach areas and beach bars (5 locations), other private brothels, businesses, and estates (32 locations), and

public streets and parks (9 locations; table). Peak hours of contact were determined for each contact location and an enumeration scheme was established for each team, allowing for a defined observation period per location. It was agreed that Saturday afternoons and evenings would provide the largest probability to capture MSM who sell sex. Given that both sex work and sex between men is illegal in Kenya, approaching and confirming contacts as MSM who sell sex presented a unique challenge to the enumerators. Participatory discussion and role-playing revealed, however, that MSM consider themselves very good at visually identifying other MSM by evaluating a man's appearance, body language, and/or clothing. Other ethnographic research on MSM in Senegal supports this. (26) An enumerator would first visually identify, then approach and start casual conversation with the suspected MSM contact. Once the enumerator was confident that the contact's MSM status was confirmed, he would ask if the captured MSM was "seeking clients, or currently willing to sell sex in exchange for money and/or goods," i.e. if he was "on the market". Spoken in Swahili, *sokoni* refers literally to a local market. After it was established that an MSM was "on the market", therefore an MSM who sells sex, the enumerator would introduce himself as a peer educator, and offer an A5-size recruitment leaflet containing information in both Swahili and English about MSM, the risk of anal transmission of STD, including HIV, the benefits of regular HIV counselling and testing, and the location of the research clinic. Designed to be colourful and eye-catching, accepting the leaflet would effectively "tag", or capture each contact. To estimate the total population of MSM who sell sex, we applied a "capture-recapture" formula described in detail elsewhere. (52, 53) Capture 1 included 284 men (following the removal of 15 duplicates); 89 men refused to participate (table 1). Capture 2 included 484 men (following the removal of 35 duplicates); 75 men refused to participate. Of the 484 men in capture 2, 186 (re-captures) were also included in capture 1. These men are considered matches. Hence, the estimate of the population size is:

$$\frac{c1(284) * c2(484)}{m(186)} = 739 \text{ (95\% CI : 690 - 798)}$$

Table 1: Numbers and locations of men who sell sex to men that were “captured” in and around Mombasa, Kenya

| | First Count | Second Count |
|--|--------------------|---------------------|
| New captures | 284 | 298 |
| Bars (23 locations) | 95 | 71 |
| Nightclub/Disco (8 locations) | 57 | 76 |
| Beach areas/beach bars (5 locations) | 35 | 25 ¹ |
| Other private brothels, businesses, estates (32 locations) | 39 | 62 |
| Street areas/parks (9 locations) | 58 | 64 |
| Matches² | - | 186 |
| Bars (23 locations) | - | 36 |
| Nightclub/Disco (8 locations) | - | 23 |
| Beach areas/beach bars (5 locations) | - | 7 |
| Other private brothels, businesses, estates (32 locations) | - | 34 |
| Street areas/parks (9 locations) | - | 86 |
| Total captures | 284 | 484 |
| Tag (i.e. leaflet) refusals | 89 (22.9%) | 75 (12.6%) |
| Double-counted, or captured more than once | 15 (3.9%) | 35 (5.9%) |
| Total Contacts | 388 | 594 |

¹High tides during afternoon and evening hours limited capture probabilities at beaches during second count.

² Some locations had greater number of recaptures than the number of first count captures, reflecting high mobility.

We used a two-sample capture-recapture calculation to estimate that 739 MSM sell sex in and around Mombasa. In total, 582 MSM who sell sex were contacted through trained peer enumerators and an information leaflet about reducing HIV and STD transmission extended. Of these, 484 were contacted in a single day, offering avenues for HIV prevention.

Despite high community stigma and legal concerns, trust was established with a core group of men who sell sex to men. Our estimate of 739 MSM who sell sex in and around Mombasa is likely to be conservative. Thirty-seven enumerators could not provide permanent coverage at 77 locations, some felt that the time limits were too restrictive, and MSM working in private brothels or homes were not contacted efficiently. This study limited the enumeration to men who sell sex to men, because it was assumed that they are more likely to congregate at key areas to seek clients. However, men who sell

sex to men make up only a part of the larger population of MSM in this community, highlighting the potential importance of homosexual contact as a means of HIV transmission.

People living with HIV receiving ART

Over the last three years, Kenya has scaled up access to life saving ART. Currently, an estimated 190,000 HIV infected persons are on ART out of 500,000 who are receiving HIV care. (8) An estimated 14,400 men and women receive treatment in Coast Province (personal communication Dr Waudo, Provincial AIDS and STI coordinator). Study participants were recruited at three outpatient HIV treatment clinics in Mombasa: a provincial referral hospital, a district hospital, and a private, not-for-profit clinic. The participants were among the first patients to receive ART in Kenya and were participating in a randomized trial assessing the efficacy of modified directly-observed therapy (m-DOT) to improve adherence to ART. Adults living in Mombasa who were 18 years and older, ART naïve and with indications for ART as per the Kenyan national treatment guidelines were invited to participate.

3.3 Study Design

Several studies were implemented to reach the defined objectives. Qualitative and quantitative research methods were used as applicable. Qualitative methods included focus group discussion and in-depth interviews, whereas quantitative research data was obtained through prospective observational studies (single cross-sectional and repeated cross-sectional) and intervention studies (randomized controlled and before-after study designs). A specific study design was chosen depending on the research question that needed to be answered as well as the financial and logistical constraints.

Qualitative designs

1. Focus Group Discussion (chapter 5.5): This was one of the methods used to reach the specific objective 2c and is more extensively discussed in chapter 5.5. Focus group discussions permit discussion of issues that may be too sensitive for inclusion in survey questionnaires or even one-to-one ethnographic interviewing. It allows people to speak in more vague, third person terms even if describing their own personal experiences. Moreover, focus group discussions are a

particularly appropriate method to obtain perceptions through interaction and discourse in a group setting that one-to-one interviews may fail to generate (54). *Vikao* (same sex group discussions) are a popular activity amongst coastal Swahili people. Outside the domestic domain, men and women participate in a social environment in which same-sex group discussions are a significant forum for reinforcing group identification and increasing social cohesion. For our objective to assess the acceptability of the diaphragm, focus group discussion were an appropriate method to obtain information on perspectives of diaphragm users. Participants were selected who were most likely to provide detailed information and to share their experiences openly. Limitations are that this restricted the number of women and their partners (39 women and eight men), who provided personal perspectives on the use of the diaphragm and not necessarily a representative view of the population. Different themes may have emerged had selection of focus group participants been based on probability sampling, rather than the subjective views of study staff. Also, the data on men's perceptions is limited as few men participated and their views may not be generalizable to other men. A selection bias may have occurred as men who had negative experiences with the diaphragm may have chosen not to participate, potentially resulting in an under-representation of negative experiences in men. However, theoretical saturation was reached for the main themes covered in this paper and the users' perspectives presented here add information about the actual behaviours of women and men and the impediments to diaphragm use.

2. In-depth interviews (chapter 5.3; 5.5): To reach specific objective 2c also in-depth interviews were used. Selected individuals with specific experiences or when discussing sensitive subjects that are better not openly discussed in a group, in-depth interviews provide more detailed information. An in-depth interview was used to get better understanding of the woman's motivation to use a home-made diaphragm (chapter 5.3). This method was also used with five women who reported having experienced violent conflict with their partners (chapter 5.5). Advantages of the method include the possibilities to obtain very detailed information on a personal experience. A limitation is the lack of generalizability of the obtained information as this involves individual experiences. It also is especially prone to interviewer bias due to their own perceptions.

Quantitative observational designs

1. Cross-sectional (chapter 4.1; 4.2; 4.4): Specific objective 1 was reached using cross-sectional study designs in three separate studies. This design provides quantitative information from a defined population. Selected participants of this population are seen once by the researcher, and provide information from a single point or period in time. This allows for assessment of point- or period- prevalence and could determine associations between variables. As such, this methodology was used to investigate associations between certain factors and unprotected sex among male and female sex workers. A limitation of this study design is its inability to establish causality, making it difficult to interpret associations which are detected. The rapid availability of results at affordable cost makes this an attractive design, particularly among hidden and highly mobile populations such as commercial sex workers (male and female). The ability to interpret the findings can be increased by also assessing a control / comparison group. This can be done either by conducting a cross-sectional survey in the same population enrolling participants who do not have the exposure (chapter 4.4), or in the same population at a different point in time (chapter 5.1). The use of a control group using unexposed participants is described in more detail in chapter 4.4 where the control group was not exposed to antiretroviral treatment, but was anticipated to be similar with respect to other characteristics. The disadvantage of the design is the difficulty in assuring that the exposed and unexposed groups come from the same population. This could introduce a selection bias.

A repeat cross-sectional study at a later point in time, as described in chapter 5.1, allows for evaluation of changes that have taken place between the surveys and could provide valuable information about trends over time. This latter methodology was used to assess the changes in sexual risk behaviours before and after a five year intervention. As conclusions are drawn from one population, it is of utmost importance that both surveys select a representative sample. Therefore, the repeat survey should follow the design and methodology of the pre-intervention survey in the same population. Selection bias is a main concern in repeat cross-sectional studies. Limitations in the inability to establish causation in these studies remain.

Quantitative interventional designs

These also provide quantitative information from a defined population. However, participants are seen by the researcher at different points in time. As such, changes within participants can be

observed. Both prevalence and incidence measures can be assessed and causality can potentially be established. Disadvantages of the design are the high cost for the conduct of the study and the long duration. This study is less suitable when investigating rare outcome events.

1. Before-after design (chapter 5.2; 5.4): Two studies followed this design, where participants (mainly female sex workers) were enrolled and followed over time. The intervention was introduced after enrolment in the study (5.4) or after four months of follow-up (5.2). No control arm was available, but participants were their own control from before the intervention. Changes over time might in this case be due to the intervention or other external factors in the population. To reach specific objective 2b (chapter 5.2) a before-after design was chosen to investigate the impact of the addition of the female condom (intervention). Advantages included the lower cost as compared to a randomized controlled design, while maintaining the added value of cohort analyses. The design allowed us to assess each participant over time and the impact of use of the female condom. This reduced the challenges with selection bias as participants are their own control. Besides financial and potential ethical reasons, a randomized study was felt not to be feasible, as the female sex worker community is a close community and potential sharing of female condoms (intervention) would have been difficult to prevent.

To reach specific objective 2c (chapter 5.4), the same design was used to assess the safety and acceptability of the diaphragm. The design allowed for repeated evaluations of participants assessing safety and acceptability of the diaphragm over time. A control group could have allowed comparison of safety outcomes between women using and not using the diaphragm. However, a randomized controlled study design would have been too costly, logistically challenging and unnecessary as effectiveness of the intervention (diaphragm) in preventing HIV infection was not assessed.

2. Randomized controlled intervention study (chapter 4.3): To reach objective 1c, a secondary analysis was performed on an existing randomized controlled study. This is seen as the superior study design, but is also the most costly and time consuming. Participants are randomly assigned to two interventions and followed over time. The randomization ensures two equal study groups, with the only difference being the intervention under study. The secondary analysis within this study, as presented in chapter 4.3, did not benefit from this rigorous design as the randomized exposure did not have a direct relation to the objective of assessing predictors of unsafe sex. Therefore, a before-after analysis was preferred and performed on all participants.

The primary randomized controlled trial analysis is presented elsewhere and falls outside the scope of this thesis. (7)

Study specific limitations in interpretation of the study data as a result of the chosen design, is being discussed in the respective chapters and in the limitations section (6.2).

3.4 Sampling Procedures

Various sampling procedures were used depending on the target population that needed to be enrolled. The following procedures were used:

Qualitative research studies

Purposive sampling (chapter 5.3; 5.5) was used, aiming to select participant(s) who were most likely to provide detailed information and share their experiences openly. Study staff used their knowledge of study participant(s) to inform selection of suitable focus group members and one case report. Study staff asked women who had disclosed diaphragm use for permission to contact their male partners. Five focus group discussions took place with between seven and twelve participants (total of 39 women and 8 men). Each group comprised either female sex workers; unmarried women from sexual and reproductive health (SRH) clinics; married women from SRH clinics; women who had withdrawn from the study or missed the six-month study visit; or men. Additionally, five in-depth interviews were held with selected women.

Quantitative research studies

Non-probability convenience sampling (chapter 4.3; 4.4; 5.4): All participants following the study's inclusion criteria and seeking health services at the respective health facilities in Mombasa were invited to participate in the study until fully enrolled. For the randomized controlled study (chapter 4.3), computer generated random-number assignment was used, allocating an equal number of participants to treatment and control groups. Allocation concealment was maintained with sequentially numbered, opaque sealed envelopes. Participants were randomly assigned to study groups, in blocks of 40.

Time-location sampling: One study benefited from a capture-recapture enumeration exercise (chapter 4.2), identifying locations where men who sell sex to men seek clients. This activity yielded a database of 65 locations within Mombasa District containing estimates of men who sell sex to men present at each venue and the peak hours when they might be present. These locations served as the primary sampling units or clusters, and included bars, nightclubs/discos, beach areas/bars, public streets and parks, and other private brothels, businesses, and estates. All clusters were selected, and the number of participants selected at these locations was proportionate to the size of the clusters as identified in the enumeration phase. Participants were recruited consecutively until the planned number was reached at each venue (the total sample size was estimated at 360 enrolled participants). This sample design was assumed to be self-weighting, as the high mobility of the target population make it impossible to estimate fixed numbers at most venues.

Snowball sampling (chapter 4.1; 5.1; 5.2; 5.4): Snowball sampling is appropriate for locating difficult-to-reach populations, though this is classified as a non-random sampling technique. Initial respondents (seeds) were identified from bars, guest houses and the street, with subsequent participants recruited through these seeds. To limit potential for friendship bias, we restricted the maximum number of women recruited through one participant to 10. A comparable snowball strategy that we used (chapter 5.2), recruited participants through an existing HIV prevention peer education project (IMPACT) run by ICRH in Mombasa. Peer educators provided a list of 329 peer sex workers (out of a potential 2,382 sex workers identified by the program in Kisauni) with whom they had regular contact - snowballing. The study team then selected a random sample of 255 sex workers who were asked to come to the recruitment centre for screening. We enrolled the first 210 who were eligible according to study inclusion/exclusion criteria.

3.5 Data Collection, Management and Analysis

Depending on study design and available resources, different methods were used for data collection. Detailed information is presented in chapters 4 and 5 for each of the respective studies. In general, the following applied:

Qualitative research studies

Group discussions (chapter 5.5) and in-depth interviews (chapter 5.3 and 5.5) were tape recorded, transcribed verbatim, translated to English and analysed using MAX QDA2™ (Bonn, Germany). Transcripts were coded according to a coding structure developed after repeated review of the transcripts using text word searches. A coding report was generated that featured all the codes and associated text. Discussions between the authors led to the production of a narrative report.

Quantitative research studies

Where applicable, separate data collection tools were developed for clinical, non-clinical (e.g. semi-structured questionnaires capturing socio-demographic, economic and sexual behaviour information) and laboratory data. Apart from one study (chapter 4.2) in which survey interviews were administered using Perseus MobileSurvey 7 (Perseus Development Corporation, Braintree, MA, USA) software on Dell Axim X3 handheld computers, we used paper-based tools.

Data collection tools were pre-tested in the field before implementation and version controlled to ensure the correct tools were administered. Before implementation, research assistants and other study staff were at a minimum trained on applicable data collection tools, study protocol and human subjects' protection. Regular supervision by the study coordinator ensured that study activities were uniform across sites and between data collectors.

Development of the database including consistency checks was done by a trained data manager using either Microsoft Access (chapter 4.1; 4.3; 4.4; 5.2) or Epi Info (chapter 4.1; 5.1; 5.4). Paper-based data were double entered by separate trained data-entry clerks. Following data checking and cleaning, the final dataset was available for analysis.

Various software was used for data analysis of the studies including Intercooled Stata version 8.0 and version 9.2 (Stata Corporation, College Station, Texas, USA); SPSS 11.0 (SPSS, Inc., Chicago, IL, USA); and SAS version 8.01 and version 9 (SAS Institute, Cary, NC, USA).

3.6 Clinical and Laboratory Procedures

Clinical procedures including clinical examination and sample collection were performed by trained and qualified nurses, clinical officers and medical doctors. Since 2005, data was collected using

version controlled Standard Operating Procedures (SOP) to ensure comparability between researchers and between sites. Urine, blood and reproductive tract sampling was done at the above mentioned clinical sites

Processing and analysis of samples was done either at the clinical site (HIV rapid tests and urine pregnancy test), at the local ICRH research laboratory (HIV rapid tests, HIV ELISA, *Neisseria gonorrhoeae* gram stain and cultures, Reactive Protein Reagens, gram stain for bacterial vaginosis using Nugent scoring, wet mount for *Trichomonas Vaginalis*, KOH preparations for candidiasis, and Pap smear), or at a specialized external laboratory (Prostate Specific Antigen).

Since 2004, laboratory analysis were done using version controlled SOPs to ensure comparability between laboratory staff. An internal quality assurance monitor ensured that clinical and laboratory procedures were performed as per the SOPs and the protocol.

3.7 Research Ethics

Studies conducted received prior approval from the national Ethical Review Committees under Kenyatta National Hospital (chapter 4.1; 4.2; 4.3; 4.4; 5.1; 5.2; 5.3; 5.4; 5.5) or under KEMRI (chapter 4.1). For selected studies, additional approval was obtained from the ethical committee at Ghent University Hospital (chapter 5.3; 5.4; 5.5), Protection of Human Subjects Committee at Family Health International (chapter 5.1; 5.2) or Population Council's Institutional Review Board (chapter 4.2; 4.3; 4.4). Written informed consent was obtained from all study participants.

All study staff was trained on Human Subjects' Protection. In more recent studies, project staff was trained on International Conference on Harmonization - Good Clinical Practice Guidelines (ICH-GCP) and/or Good (Clinical) Laboratory Practice Guidelines (G(C)LP) depending on their responsibilities. An internal quality assurance monitor ensured that research ethics were maintained throughout the study and protocol was adhered to.

3.8 Data Dissemination

The following manuscripts have been published and provide the basis for this thesis:

1. **Luchters S**, Sarna A, Geibel S, Chersich M, Munyao P, Kaai S, Mandaliya K, Shikely KS, Rutenberg N, Temmerman M. Safer sexual behaviours after 12 months of antiretroviral treatment in Mombasa, Kenya: a prospective cohort. *AIDS Patient Care and STDs*. 2008, Jul;22(7):587-94 (A1, IF=2.007)
2. Geibel S, **Luchters S**, King'ola N, Esu-Williams E, Rinyiru A, Waimar T. Factors associated with self-reported unprotected anal sex among male sex workers in Mombasa, Kenya. 2007 *STD*, August 2008, Vol. 35, No. 8:746-752 (A1, IF=2.577)
3. **Luchters S**, Chersich MF, Rinyiru A, Barasa MS, King'ola N, Mandaliya K, Bosire W, Wambugu S, Mwarogo P, Temmerman M. Impact of five years of peer-mediated interventions on sexual behavior and sexually transmitted infections among female sex workers in Mombasa, Kenya. *BMC Public Health*, 2008 Apr 29;8:143 (A1, IF=1.603)
4. Sarna A, **Luchters S**, Geibel S, Kaai S, Munyao P, Shikely KS, Mandaliya K, van Dam J and Temmerman M. Sexual risk behaviour and HAART: A comparative study of HIV infected persons on HAART and on Preventive Therapy in Kenya. *Int J STD AIDS*, 2008 Feb;19(2):85-89 (A1, IF=1.274)
5. Okal J, Stadler J, Ombidi W, Jao I, **Luchters S**, Temmerman M, Chersich MF. Secrecy, disclosure and accidental discovery: perspectives of diaphragm users in Mombasa, Kenya. *Cult, Health Sex*. 2008 Jan;10(1):13-26. (A1, IF=0.889)
6. Chersich MF, **Luchters S**, Malonza IM, Mwarogo P, King'ola N, Temmerman M. Heavy episodic drinking among Kenyan female sex workers is associated with unsafe sex, sexual violence and sexually transmitted infections. *Int J STD AIDS*. 2007 Nov;18(11):764-769 (A1, IF=1.274)
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3.9 References

1. Hawken MP, Melis RD, Ngombo DT, Mandaliya K, Ng'ang'a LW, Price J, *et al*. Part time female sex workers in a suburban community in Kenya: a vulnerable hidden population. *Sex Transm Infect* 2002;78:271-273.
2. Geibel S, van der Elst EM, King'ola N, Luchters S, Davies A, Getambu EM, Peshu N, Graham SM, McClelland RS, Sanders EJ. "Are you on the market?" a capture-recapture enumeration of men who sell sex to men in and around Mombasa, Kenya. *AIDS* 2007 Jun 19;21(10):1349–1354.
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Results: Factors associated with unprotected sex among key populations

| | |
|------------------------------------|-------------|
| Female sex workers | 4.1 |
| Men who sell sex to men | 4.2 |
| HIV infected persons receiving ART | 4.3 and 4.4 |

4

Photo credit: International Centre for Reproductive Health. Peer education session: woman explaining the use of the female condom.

4.1 Heavy episodic drinking among Kenyan female sex workers is associated with unsafe sex, sexual violence and sexually transmitted infections.

Heavy episodic drinking among Kenyan female sex workers is associated with unsafe sex, sexual violence and sexually transmitted infections

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ABSTRACT

The study examined patterns of alcohol use and its association with unsafe sex and related sequelae among female sex workers in Mombasa, Kenya. A community-based cross-sectional study was conducted using snowball sampling. Binge drinkers (≥ 5 alcoholic drinks on ≥ 1 occasion in the previous month) were compared with non-binge drinkers. Of 719 participants, 22.4% were life-time alcohol abstainers, 44.7% non-binge and 33.0% binge drinkers. Compared with non-binge drinkers, binge drinkers were more likely to report unprotected sex (adjusted odds ratio (AOR) = 1.59, 95% confidence interval (CI) = 1.00 - 2.53; $P = 0.047$) and sexual violence (AOR = 1.85, 95% CI = 1.27 - 2.71; $P = 0.001$) and to have either syphilis, *Neisseria gonorrhoeae* or *Trichomonas vaginalis* infection (AOR = 1.56, 95% CI = 1.00 - 2.41; $P = 0.048$). HIV prevalence was higher among women having ever drunk (39.9%) than lifetime abstainers (23.2%; $P < 0.001$), but was not associated with drinking patterns. Interventions are needed to assist female sex workers adopt safer drinking patterns. Investigation is needed for the effectiveness of such interventions in reducing unprotected sex, sexual violence and sexually transmitted infections.

INTRODUCTION

Alcohol accounts for 4.0% of global death and disability compared with the 6.3% burden from unsafe sex.¹ In Africa, many areas carry a high burden of both HIV and alcohol-related morbidity and mortality.²⁻⁴ HIV and alcohol each increase underlying socioeconomic vulnerability. Moreover, studies in low-and middle-income countries have shown that alcohol use is associated with unprotected sex, early coital debut, multiple partners and sexually transmitted infections (STIs).⁵⁻¹¹ Some¹²⁻¹⁹ but not all^{18,20,21} studies in high-income countries have found an association between alcohol consumption and an increased number of sexual partners, regretted sexual relations, inconsistent condom use, condom failure and an increased incidence of STIs. Several studies have linked alcohol use with HIV incidence^{11,22,23} and prevalence.^{5,24-31}

Effects of alcohol depend on total cumulative volume consumed, drinking patterns and drinking contexts. Cumulative volume is causally linked with chronic social conditions like unemployment and chronic diseases such as liver cirrhosis.³² By contrast, drinking patterns, particularly heavy-episodic drinking (also referred to as binge drinking) with intoxication, predict acute social and acute medical consequences (interpersonal violence and accidents).³² High-risk drinking patterns, especially heavy-episodic drinking, is likely to mediate a relationship between unsafe sexual behaviour and alcohol. Low-risk drinking patterns typically occur in southern European countries, with low volume per drinking occasion and drinking with meals. Conversely, drinking patterns in much of Africa are characterized by sporadic heavy episodes of drinking, often in the form of weekend binge drinking.^{3,4} Therefore, in these settings, the predominant forms of alcohol-related morbidity and mortality are acute social and medical consequences.^{3,33} Despite high-risk drinking patterns and the substantial public health implications, little attention has been given to addressing effects of drinking patterns on unsafe sex and its sequelae. This study investigates whether binge-drinking patterns among female sex workers (FSW) are associated with unprotected sex, sexual violence and STI prevalence.

METHODS

This community-based cross-sectional study enrolled 719 FSW between October 2005 and January 2006 in Mombasa, Coast Province, Kenya. FSW were recruited using snowball sampling and gave

written informed consent. Women were eligible for the study if they had received money or gifts in exchange for sex in the last year, and were 16 years or older. The study was nested within an evaluation of a peer-education project. The Kenyatta National Hospital Ethics and Research Committee approved the study procedures.

Information on demographics, sexual behaviour, sexual violence and alcohol use was collected using a structured questionnaire administered in Swahili. A gynaecological exam was done, and blood, urine, Pap smear, and high vaginal and endocervical swabs were collected. A parallel algorithm was used for HIV testing with Uni-Gold™ HIV (Trinity Biotech plc, Bray, Ireland) and Determine™ HIV-1/2 (Abbott Laboratories by Abbott Japan Co Ltd, Minato-Ku, Tokyo, Japan). Syphilis infection was detected with a rapid plasma reagin test (Human GmbH, Weisbaden, Germany). To test for *Neisseria gonorrhoeae* infection, blood-agar culture plates (International Diagnostic Group, Lancashire, UK) were inoculated with endocervical swabs. Infection with *Trichomonas vaginalis* or candida was determined by wet mount and/or Pap smear slides. Where required, participants received treatment according to local guidelines or were referred to health services.

Measures of alcohol use

Drinking patterns were classified according to standard World Health Organization (WHO) categories: never drunk alcohol; non-binge drinkers (lifetime use of alcohol but less than five drinks on any occasion in the preceding month) or binge drinkers (\geq five drinks on \geq one occasion in the previous month).³⁴ To evaluate whether alcohol use and sexual behaviour were temporally paired, event-level measures were collected: sex while feeling drunk in the last seven days and condom use while drunk. Current frequency of alcohol intake (irrespective of volume per occasion) was categorized: secondary alcohol abstinence; one to three times a month; one to three times a week and almost every day or every day.

Other measures

Women with a curable STI (syphilis, gonococcus or trichomonas infection) were grouped together and compared with women with none of these infections. To assess sexual violence, women were asked whether any client had physically forced them to have sex without payment in the preceding

year. Self-reported condom use was dichotomized as always or inconsistent use. A history of condom bursting in the previous year was used as an indicator for condom accidents.

Data management and analysis

Data were double entered by separate clerks. Following data checking and cleaning, Intercooled Stata 8.0 (Stata Corporation, College Station, TX, USA) was used for statistical analysis. With univariate and bivariate analysis, we examined the effects of drinking patterns on sexual behaviours and related outcomes, comparing binge and non-binge-drinking patterns. This is the primary comparison as most interventions aim to assist binge-drinking women adopt safer drinking patterns rather than complete abstinence.³⁵ Though limited by study design, this comparison may provide an estimate of the potential benefit of such interventions. As a secondary analysis, outcomes among lifetime-alcohol abstainers were also compared with those who had ever consumed alcohol. Chi-square test was used for analysis of categorical variables and for continuous variables, an unpaired Student's t-test or Mann-Whitney U test for data with a normal and non-normal distribution. Using multivariate models, we investigated whether associations between drinking patterns and adverse outcomes were confounded by frequency of drinking or factors such as age and religion. Four multivariate logistic regression models were constructed, examining effects of drinking on condom use, history of sexual violence, prevalence of curable STI and prevalent HIV. For each regression analysis, variables associated with the outcome in univariate analysis were included in the initial model and retained if removal markedly altered the model's fit.

RESULTS

The mean age of participants was 30.4 years (standard deviation= 8.4 years). Most (627/719; 87.2%) women had one or more children, and were separated or divorced (332/716, 46.4%), or they had never been married (295/716, 41.2%; Table 1). Of 698 participants, 22.4% were lifetime alcohol abstainers, 44.7% non-binge and 33.0% binge drinkers. Compared with non-binge drinkers, binge drinkers were an average 2.2 years younger, more likely to work from a bar or nightclub than from home, had a higher income (\$20.3 versus \$13.5/week, $P= 0.007$) and were more likely to drink frequently (53.0% of binge-drinking women drink almost every day or every day).

Sexual risk behaviour

Binge-drinking patterns were associated with a higher number of sexual partners and increased risk of condom bursting (Table 2). An association between pattern of drinking and event-level data was detected (decreased condom use while using alcohol or drugs, and having sex while drunk). In multivariable analysis, after controlling for frequency of drinking and religion, women who binge drank were 1.59 times (95% CI= 1.00–2.53; $P= 0.047$) more likely to report inconsistent condom use than non-binge drinkers (Table 3). Frequency of drinking was also independently associated with condom use. Women who drank every day or almost every day were more likely to report inconsistent condom use than women who currently did not drink (AOR= 2.41, 95% CI= 1.25–4.66; $P= 0.009$).

Sexual violence

Sexual violence in the preceding 12 months was reported by 23.7%, 28.2% and 43.9% of women who never drank alcohol, non-binge drinkers and binge drinkers, respectively. Compared to non-binge drinkers, binge drinkers were significantly more likely to have experienced sexual violence (AOR = 1.85, 95% CI= 1.27–2.71; $P= 0.001$).

STIs and HIV

HIV infection was diagnosed in 37.3% (84/225) of binge drinkers, 41.8% (129/309) of non-binge drinkers and 23.2% (36/155) of lifetime-alcohol abstainers ($P = 0.3$). While a higher proportion of binge drinkers in the study were infected with syphilis, gonorrhoea, trichomoniasis and candida, no statistically significant associations were detected.

In the logistic regression model examining the relationship between drinking patterns and infection with a curable STI, an association between binge drinking and STI was detected (AOR = 1.56, 95% CI = 1.00–2.41; $P= 0.048$). Drinking patterns were not associated with prevalent HIV infection. In a secondary analysis, a multivariate model was constructed to explore the association between having ever drunk alcohol and HIV. After controlling for effects of age and religion, women who had ever drunk alcohol were 1.99 times more likely to be HIV infected than lifetime-alcohol abstainers (95% CI:1.31–3.03; $P= 0.001$).

Table 1: Demographic and socioeconomic characteristics of study participants

| Variable | All study participants* (A) | Women who have never drank (B) | Women who drink but don't binge (C) | Women who binge drink (D) | P value (B vs C+D) | P value (C vs D) |
|--|-----------------------------|--------------------------------|-------------------------------------|---------------------------|--------------------|------------------|
| Age , mean years (sd) n=718 | 30.4 (8.4) | 29.6 (8.7) | 31.5 (8.4) | 29.3 (8.0) | 0.21 | 0.003 |
| Education , median years at school (IQR) | 7 (5-9) | 7 (4-8) | 7 (5-10) | 8 (6-9) | 0.033 | 0.12 |
| Religion | | | | | | |
| Catholic | 32.4% (233/719) | 20.5% (32/156) | 30.5% (95/312) | 44.4% (102/230) | | |
| Protestant | 39.4% (283/719) | 37.2% (58/156) | 42.0% (131/312) | 34.8% (80/230) | | |
| Muslim | 26.3% (189/719) | 40.4% (63/156) | 26.6% (83/312) | 18.3% (42/230) | | |
| Other | 2.0% (14/719) | 1.9% (3/156) | 1.0% (3/312) | 2.6% (6/230) | <0.001 | 0.002 |
| Marital status | | | | | | |
| Never married | 41.2% (295/716) | 34.2% (53/155) | 40.3% (125/310) | 47.8% (110/230) | | |
| Married or cohabitating | 2.9% (21/716) | 4.5% (7/155) | 3.2% (10/310) | 1.7% (4/230) | | |
| Separated or divorced | 46.4% (332/716) | 51.6% (80/155) | 46.1% (143/310) | 41.7% (96/230) | | |
| Widow | 9.5% (68/716) | 9.7% (15/155) | 10.3% (32/310) | 8.7% (20/230) | 0.14 | 0.29 |
| Workplace | | | | | | |
| Bar or nightclub | 69.3% (498/719) | 46.8% (73/156) | 70.5% (220/312) | 81.3% (187/230) | | |
| Home | 20.6% (148/719) | 37.8% (59/156) | 20.2% (63/312) | 10.9% (25/230) | | |
| Street | 7.4% (53/719) | 13.5% (21/156) | 5.5% (17/312) | 5.7% (13/230) | | |
| Hotel, guest house or other | 2.8% (20/719) | 1.9% (3/156) | 3.9% (12/312) | 2.2% (5/230) | <0.001 | 0.016 |
| Income , median \$/week (IQR) | 13.5 (8.1-27.0) | 12.2 (6.8-20.3) | 13.5 (7.4-27.0) | 20.3 (9.5-27.0) | 0.001 | 0.007 |
| Age started sex work , median years (IQR) n=716 | 23 (19-28) | 23 (18-28) | 24 (20-29) | 22 (19-26) | 0.45 | 0.004 |
| Age started drinking alcohol [^] , mean (SD) n=557 | 22.2 (5.8) | NA | 23.0 (5.9) | 20.9 (5.3) | NA | <0.001 |
| Current drinking frequency [^] | | | | | | |
| Secondary abstinence | 15.1% (82/542) | | 26.3% (82/312) | 0% (0/230) | | |
| One to three times a month | 16.8% (91/542) | | 26.0% (81/312) | 4.4% (10/230) | | |
| One to two times a week | 38.2% (207/542) | NA | 34.9% (109/312) | 42.6% (98/230) | | |
| Almost everyday or everyday | 29.9% (162/542) | | 12.8% (40/312) | 53.0% (122/230) | NA | <0.001 |

SD=standard deviation; IQR=interquartile range; \$1=74 Kenya shillings; NA=not applicable; N=719 unless indicated; * information about drinking patterns is unavailable for 21; [^]Among women who have ever drank

Table 2: Univariate analysis of the association of alcohol use and binge drinking with high risk sexual behaviors, sexual violence and sexually transmitted infections

| Variable | Never drunk alcohol (A) | Non-binge drinkers (B) | Binge drinkers (C) | P-value (A vs B+C) | P-value (B vs C) |
|--|-------------------------|------------------------|--------------------|--------------------|------------------|
| Sexual risk behaviours | | | | | |
| Number of sexual partners in previous week, median (IQR) | 3 (2-6) | 3 (2-6) | 4 (2-7) | 0.046 | 0.002 |
| Always uses condoms | 39.1% (61/156) | 41.7% (130/312) | 23.4% (54/230) | 0.24 | <0.001 |
| Condom burst in preceding year | 26.7% (40/150) | 40.6% (124/305) | 58.0% (131/226) | <0.001 | <0.001 |
| Condoms not used due to alcohol or drugs | 1.3% (2/155) | 13.1% (41/312) | 25.8% (59/229) | <0.001 | <0.001 |
| Sex while feeling drunk in preceding week | NA | 35.2% (100/284) | 82.4% (183/222) | NA | <0.001 |
| Anal sex | 2.6% (4/156) | 2.6% (8/311) | 7.0% (16/230) | 0.29 | 0.014 |
| Sexual Violence | | | | | |
| Sexual violence in preceding year | 23.7% (37/156) | 28.2% (88/312) | 43.9% (101/230) | 0.009 | <0.001 |
| Sexually transmitted infections | | | | | |
| Current genital ulceration | 1.3% (2/156) | 1.3% (4/312) | 5.2% (12/230) | 0.25 | 0.007 |
| Syphilis infection | 2.6% (4/156) | 2.3% (7/310) | 4.9% (11/226) | 0.62 | 0.10 |
| Gonococcus infection | 0% (0/150) | 0.7% (2/305) | 1.4% (3/222) | 0.23 | 0.42 |
| Trichomoniasis infection | 23.2% (35/151) | 14.1% (43/305) | 17.9 (40/224) | 0.032 | 0.24 |
| Candida infection | 14.1% (21/149) | 12.8% (39/305) | 17.4% (39/224) | 0.84 | 0.14 |
| HIV infection | 23.2% (36/155) | 41.8% (129/309) | 37.3% (84/225) | <0.001 | 0.3 |

N=698 unless indicated (information about drinking patterns is unavailable for 21); IQR=interquartile range; NA=not applicable

DISCUSSION

Binge drinking, independent of frequency of drinking, was associated with inconsistent condom use, sexual violence and curable STI. Thus far, HIV prevention strategies and the related research agenda have largely ignored the potential for alcohol to influence sexual behaviour. While factors such as gender inequities and poverty continue to fuel the HIV epidemic, patterns of alcohol use may be an important mediating factor, especially episodes of acute intoxication. If that were true, targeted interventions assisting FSW adopt safer drinking patterns could potentially contribute to HIV prevention.

Several studies, including this study, have shown an association between alcohol use and having experienced sexual violence.^{36,37} A relationship between HIV infection and alcohol use could potentially act through sexual violence. Alcohol use has been associated with perpetrators and victims of such violence, and HIV has direct and indirect links with sexual violence.³⁶⁻³⁸

A study among men attending beer halls in Zimbabwe found an association between drinking patterns and HIV prevalence and incidence.²² By contrast, a study in Uganda showed that ever having drunk alcohol predicted HIV infection, although indicators of recent alcohol use were not significantly associated with HIV.³¹ Similar to the Uganda finding, in this study, having ever drunk alcohol was associated with HIV infection while recent binge drinking was not associated despite its relationship with HIV-risk factors. This finding may be explained by weaknesses inherent in cross-sectional studies making it difficult to evaluate whether current drinking patterns differ from drinking patterns at the time of HIV acquisition. It is also possible that knowledge of HIV status or even HIV-related ill-health influences drinking patterns or induces social desirability bias. A cohort study further investigating this association is underway among the same population.

Effects of alcohol on acute outcomes show considerable variation when compared with the more consistent findings for chronic outcomes like liver cirrhosis.³²

Accordingly, a relationship between drinking patterns and unsafe sex may vary between drinking contexts, population groups and other interacting factors. The intensity of alcohol use among FSW described in this study differs substantially from the general population in Kenya.³⁶ Substantiating a causal link between alcohol and acute social outcomes (such as unsafe sex) is difficult and is not possible with cross-sectional data. Although this study used standard measures of alcohol use,³⁴ obtaining accurate self-reported data has limitations, resulting in misclassification of drinking patterns. Further, alcohol-induced recall bias may occur, particularly following intoxication episodes.

Table 3: Multivariate analysis of the association between potential risk factors and condom use, sexual violence and sexually-transmitted infections

| Response variable | Risk factor | Crude odds ratio (95% CI) | P | Adjusted odds ratio (95% CI) | P |
|---|---|---------------------------|------------------|------------------------------|--------|
| Inconsistent condom use | Binge drinking pattern | | | | |
| | Binge vs. non-binge drinkers | 2.33 (1.58-3.43) | <0.001 | 1.59 (1.00-2.53) | 0.047 |
| | Frequency of drinking | | | | |
| | Secondary abstinence | 1.0 | | 1.00 | |
| | One to three times a month | 1.40 (0.77-2.56) | 0.27 | 1.39 (0.76-2.55) | 0.29 |
| One to two times a week | 2.40 (1.40-4.10) | <0.001 | 2.04 (1.16-3.60) | 0.014 | |
| Almost everyday or everyday | 3.20 (1.79-5.74) | <0.001 | 2.41 (1.25-4.66) | 0.009 | |
| Sexual violence | Religion | | | | |
| | Christian and other vs Muslim | 1.68 (1.11-2.54) | 0.013 | 1.70 (1.11-2.60) | 0.014 |
| | Binge drinking pattern | | | | |
| | Binge vs. non-binge drinkers | 1.99 (1.39-2.87) | <0.001 | 1.85 (1.27-2.71) | 0.001 |
| | Frequency of drinking | | | | |
| Secondary abstinence | 1.0 | | - | | |
| One to three times a month | 0.56 (0.27-1.14) | 0.10 | - | | |
| One to two times a week | 1.43 (0.82-2.49) | 0.20 | - | | |
| Almost everyday or everyday | 1.89 (1.06-3.35) | 0.028 | | | |
| Curable sexually transmitted infection | Religion | | | | |
| | Christian and other vs. Muslim | 1.36 (0.88-2.110) | 0.16 | 1.51 (0.94-2.42) | 0.09 |
| | Marital status | | | | |
| | Separated or divorced | 1.0 | | 1.00 | |
| | Married or cohabiting | 1.37 (0.44-4.24) | 0.59 | 2.05 (0.65-6.63) | 0.23 |
| | Never married | 1.59 (1.01-2.33) | 0.02 | 1.65 (1.10-2.48) | 0.016 |
| | Widow | 1.95 (1.05-3.63) | 0.03 | 2.26 (1.17-4.35) | 0.015 |
| | Number of sexual partners (per additional partner) | 1.12 (1.08-1.17) | <0.001 | 1.14 (1.09-1.19) | <0.001 |
| | Binge drinking pattern | | | | |
| | Binge vs. non-binge drinkers | 1.47 (0.95-2.27) | 0.082 | 1.56 (1.00-2.41) | 0.048 |
| Frequency of drinking | | | | | |
| Secondary abstinence | 1.0 | | - | | |
| One to three times a month | 0.84 (0.36-1.96) | 0.68 | - | | |
| One to two times a week | 1.44 (0.73-2.85) | 0.29 | - | | |
| Almost everyday or everyday | 1.39 (0.68-2.83) | 0.36 | - | | |
| Religion | | | | | |
| Christian and other vs Muslim | 1.52 (0.87-2.65) | 0.14 | - | | |
| Number of years of education (per additional year) | 0.95 (0.89-1.01) | 0.11 | 0.94 (0.89-1.00) | 0.073 | |

CI=confidence interval

Multiple endpoints were examined, each potentially influenced by the same set of explanatory variables. As this is a cross-sectional study, by nature exploratory, no corrections were made for multiple tests.

Research is warranted to evaluate the efficacy of alcohol-related harm reduction interventions in changing their drinking patterns and potentially risky sexual practices. Brief interventions have been shown to be highly effective in diverse settings and may be well suited.³⁹ These interventions typically motivate high-risk drinkers to shift the way they consume alcohol rather than promote abstinence.³⁵

Additional evidence showing that alcohol use is a risk factor for unsafe sex may lead to more robust efforts to control patterns of alcohol use. Overall, a discrepancy exists between the burden of alcohol-related disease, research findings about the effectiveness of alcohol control measures and the policy options considered by most governments.³⁵ This contrasts with robust control of other potentially harmful commodities such as tobacco (responsible for a similar proportion of the global burden of disease as alcohol[†]).

In sum, among FSW in Mombasa, high-risk drinking patterns appear intertwined with high-risk sexual behaviours. Breaking these links is likely to require a combination of effective measures addressing underlying socioeconomic vulnerability, alcohol availability, contexts and patterns of alcohol use as well as access to effective individual-level interventions.^{40,41} Studies are needed to examine the impact of these measures in reducing unsafe sexual behaviours and sexual violence in different cultural and socioeconomic contexts.

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4.2 Factors associated with self-reported unprotected anal sex among male sex workers in Mombasa, Kenya.

Factors associated with self-reported unprotected anal sex among male sex workers in Mombasa, Kenya

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ABSTRACT

Objectives: To identify social and behavioral characteristics associated with sexual risk behaviors among male sex workers who sell sex to men in Mombasa, Kenya.

Methods: Using time-location sampling, 425 men who had recently sold, and were currently willing to sell sex to men were invited to participate in a cross-sectional survey. A structured questionnaire was administered using handheld computers. Factors associated with self-reported unprotected anal sex with male clients in the past 30 days were identified and subjected to multivariate analysis.

Results: Thirty-five percent of respondents did not know HIV can be transmitted via anal sex, which was a significant predictor of unprotected anal sex [adjusted odds ratio (AOR) 1.92; 95% confidence interval (95% CI), 1.16–3.16]. Other associated factors included drinking alcohol 3 or more days per week (AOR, 1.63; 95% CI, 1.05–2.54), self-report of burning urination within the past 12 months (AOR, 2.07; 95% CI, 1.14–3.76), and having never been counseled or tested for HIV (AOR, 1.66; 95% CI, 1.07–2.57). Only 21.2% of respondents correctly knew that a water-based lubricant should be used with latex condoms.

Conclusions: Male sex workers who sell sex to men in Mombasa are in acute need of targeted prevention information on anal HIV and STI transmission, consistent condom use, and correct lubrication use with latex condoms. HIV programs in Africa need to consider and develop specific prevention strategies to reach this vulnerable population.

INTRODUCTION

HIV prevention programs for men who have sex with men (MSM) and men who sell sex to men (i.e., male sex workers who sell sex to men) are an important component of a comprehensive HIV public health strategy. [1,2] The inclusion of MSM or male sex workers in HIV programs in sub-Saharan Africa, however, has largely been neglected by governments and other HIV service organizations, because of denial of the existence of African homosexuality, high levels of community stigma and discrimination, and the criminalization of same-sex behavior in many countries. [3]

Available data on the prevalence and characteristics of same-sex sexual activity in Africa is limited. Within the past 5 years however, a limited yet growing body of literature has highlighted the existence of MSM in sub-Saharan Africa and their vulnerability to HIV. Researchers reported an HIV prevalence of 21.5% among a snowball sample of 442 MSM [4] in Senegal, where national HIV prevalence is 1.6%. [2] A separate study of MSM risk behavior in Senegal reported a large proportion of their sample had received money for sex, [5] indicating that transactional or commercial sex may play an important role in some African MSM networks. A population-based study in South Africa reports that among males aged 15 to 26 years, having had sex with a man was significantly associated with HIV seropositivity. [6]

Researchers modeled the Kenyan HIV epidemic, and estimated 4.5% of new infections in Kenya in 2005 occurred through men having sex with men. [7] In Nairobi, Kenya, MSM who self-identified as sex workers were significantly more likely to have experienced discrimination or violence than other MSM in the sample. [8] Results from a study in Kilifi, Kenya, report HIV prevalence of 24.6% among a cohort of 285 MSM around the Mombasa area, many of whom are sex workers. [9] A capture-recapture enumeration estimated that 739 male sex workers who sell sex to men were active in Mombasa District, Kenya, [10] confirming the existence of a highly vulnerable population insufficiently addressed in national and local HIV programming.

Mombasa is located on the coast of Kenya, with a population of approximately 1 million people residing in the district area. The district covers approximately 100 square miles, and the main industries are shipping and tourism. Both Kenyan and foreign tourism has been linked to the male sex trade in Kenya's Coast region, [11] but same-sex sexual relationships also exist in Mombasa that do not involve foreign partners, tourists, and/or sex work. [12]

Because of the evidence of large numbers of male sex workers in the Mombasa area, study investigators coordinated an intervention study in consultation with the Coast Provincial Medical

Office and the National AIDS Control Council, which cites MSM as a target group for behavior change communication in the Kenya National HIV/AIDS Strategic Plan. [13] Time-location sampling has been conducted successfully among MSM venues in the United States [14] and Thailand, [15] where application of this methodology to an MSM subgroup of male sex workers has also been documented. [16] We present here results from the first behavioral survey of male sex workers who sell sex to men in Africa using time-location or venue-based, sampling procedures.

METHODS

Sampling and procedures

This study benefited from a collaborative effort in May 2006 to map locations where male sex workers were believed to seek clients, identify male sex workers, and enumerate them via a capture-recapture procedure described previously. [10] This activity yielded a database including 65 locations within Mombasa District containing estimates of male sex workers who sell sex to men present at each venue and the peak hours when they might be present. These locations served as the primary sampling units or clusters, and included bars, nightclubs/discos, beach areas/bars, public streets and parks, and other private brothels, businesses, and estates. All clusters were selected at the first stage of sampling, and second stage selection was based on probability proportional to the number of male sex workers found at each venue in the enumeration database. This sample design was assumed to be self-weighting, as the high mobility of the target population make it impossible to estimate fixed numbers at most venues, and participants were recruited through a “take all” approach at the second stage until quotas were reached at each venue.

Twelve MSM key informants, all of whom were familiar with male sex work in Mombasa, were trained to assist with the identification and recruitment of male sex workers at the sampling venues. These MSM peer mobilizers were instructed by the study coordinator on which venues to go, and on how many “contacts” they were to confirm as male sex workers who sell sex to men. The confirmation process involved an initial visual identification, following which the peer mobilizer would approach and start casual conversation with the suspected male sex worker contact. Once the peer mobilizer was confident that the contact had a history of having sex with men, he would ask the contact if he had recently sold, and is currently willing to sell sex in exchange for money and/or goods. If the contact was confirmed as an male sex worker who sells sex to men, and was 16 years of age or older, the

peer mobilizer then gave a brief description and justification of the research activities, and offered to escort the contact to a central location where they were introduced to the study coordinator and interview team. Male sex workers who rejected the offer to participate were recorded as refusals.

Respondents were compensated 300 Kenya Shillings (KSH; about US \$4.50) for their time and return transportation. Concerns about confidentiality and safety were paramount to the recruitment process, hence the decision to conduct the interviews at central locations and not at the individual venues. Interviews were conducted person-to-person using handheld computers, and no personal identifications or measurements were recorded on the mobilizer forms or questionnaires.

The interview team was also trained to assess survey respondents, with the assistance of the handheld software, for possible need of medical treatment or HIV counseling. These respondents were given information about local clinics, and a research clinic located north of Mombasa where they could receive an initial needs assessment. Respondents who elected to engage in this needs assessment were given the choice of referral to linked community services or to participate in an MSM study cohort providing free comprehensive services. Free condoms were also offered to the survey participants following the interview.

Ethical approval

The Kenyatta National Hospital Ethics and Review Committee reviewed and provided local ethical approval to the study, which was supplemented by ethical review and approval by the Population Council's Institutional Review Board and administrative approval by the Coast Provincial Medical Office. All participants provided individual informed consent to participate.

Measures and statistical analysis

Data were collected on socio-demographic characteristics, sexual behaviors, prevention knowledge and practices, reported STI symptoms, discrimination, violence, and health service usage. The questionnaire adapted and combined indicators from both the female sex worker and MSM surveys developed by Family Health International for Behavioral Surveillance Surveys. [17] Survey interviews were administered using Perseus MobileSurvey 7 (Perseus Development Corporation, Braintree, MA) software on Dell Axim X3 handheld computers. The data were analyzed using Stata version 9.2 (StataCorp, College Station, TX). Variables from the data were initially examined using frequencies and descriptive techniques, and then chi-square tests were used to detect associations among

categorical variables and the Wilcoxon rank sum test was used to detect differences between medians.

Condoms are more effective for HIV prevention when used consistently, and people who never or inconsistently use condoms are at higher risk. [18,19] Therefore, the dependent variable used for this analysis is self-reported unprotected sex, that is, inconsistent or no condom use with male clients in the past 30 days. Condom use was measured using a 3-point scale (*"How often did you use a condom for anal sex with all of your male paying clients in the past 30 days: Always, sometimes, or never?"*). This variable was dichotomized into reported inconsistent or no use (sometimes or never) versus consistent (always) condom use with male clients. One respondent stated he "did not know," and was excluded from the analysis.

To determine factors associated with unprotected sex, independent categorical variables were assessed for distribution and content then recoded into dichotomous variables where applicable, and continuous variables were dichotomized based on their distributions at the median. Factors significant at the (<0.05) level in the binary logistic regression analysis were selected for inclusion in the initial multivariate logistic regression model. Variables not significant at the (<0.05) level were systematically removed from the model using the backwards stepwise method, after which model subset statistics were evaluated and tested for "fit" [20] and a final model identified. Standard errors in both the binary and multivariate logistic regression analyses were adjusted using Stata's svy procedures, [21] to account for cluster effects among males contacted at the same venues.

RESULTS

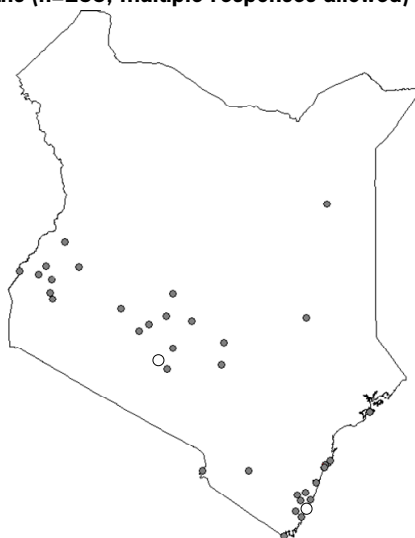
Sample characteristics

A total sample of 510 male sex workers were identified and contacted at the venues, and 425 survey interviews were completed, resulting in an 83.3% acceptance rate. Interviews were conducted from October to December 2006. As summarized in Table 1, most male sex workers were Kenyan (98.4%), with 6 respondents from Tanzania and 1 from Uganda. The majority of respondents were less than 30 years old, and approximately two-thirds of the sample had completed primary school. Religion was divided between Muslim respondents (48.0%) and the Christian Catholic (29.6%), and Protestant (19.3%) faiths. Sex work was the only source of occupational income for many (41.7%), whereas other income sources included street vending and casual labor. The median amount earned

from the last clients was KSH 1000 (about US\$ 15.00). At the same time, over one-half were currently providing financial support to partners, family, or other people. Over half of male sex workers reported typically drinking alcohol 2 days or more per week.

Most of the respondents (87.3%) reported having a male client within the past 7 days, and the median number of male clients reported in the past 7 days was 2. The majority of last paying male clients were Kenyan (80.9%). Over half of respondents reported selling sex outside Mombasa in the past year and identified 39 distinct locations within Kenya (Fig. 1), and 9 other locations in the Africa region, and 3 locations overseas. Noncondom use during anal sex with last male clients was reported by 42.1%, whereas 64.0% reported inconsistent (47.5%) or no (16.5%) use of condoms with all male clients in the past 30 days. Slightly more than one-half of respondents (57.6%) reported being only an insertive partner for anal sex with their last client. Physical abuse was reported by 12.2% of all respondents over the past 12 months, whereas 9.9% were victims of sexual violence or rape.

Figure 1. Locations in Kenya where male sex workers have sold sex to male clients outside Mombasa in the past 12 months (n=233, multiple responses allowed)



This figure utilizes mapping data courtesy of the Africover Initiative, Food and Agricultural Organization, United Nations, 2000.

One-quarter of respondents (25.2%) reported currently living with a male sexual partner. Sexual activity with women was also reported by a number of male sex workers; 67.1% had ever had sex

with a woman, 14.6% had a female paying client in the past 30 days, and 25.4% reported a nonpaying female sexual partner in the past 30 days. Additionally, 4.0% were currently living with a female wife, and 8.2% were living with a nonmarital female sexual partner. Some respondents were living concurrently with various partners, as overall 28.8% reported living with either a male or female sex partner.

Self-reported sexual identities were given in English and Kiswahili terminologies, including *basha*, king, *shoga*, queen, bisexual, gay, *kuchu*, and homosexual. Bashas or kings made up 51.3% of the sample, and were found to be characteristically and qualitatively distinct from the other groups. Bashas or kings were significantly more likely to be the insertive partner during anal sex with their last male client than those identified otherwise (97.7% vs. 14.8%, $P < 0.001$). They were also more likely to have had a nonpaying female sex partner in the past 30 days (44.7% vs. 27.8%, $P = 0.004$), to be providing financial support to someone (61.9% vs. 51.2%, $P = 0.026$), and to have had first sex with a man at a later age (median: 19 vs. 16 years, $P < 0.001$).

Although a large majority of respondents knew that consistent condom use prevents HIV transmission (86.6%), only 64.7% of male sex workers in Mombasa knew that HIV can be transmitted through unprotected anal sex. Slightly over one-half of male sex workers (55.8%) reported having ever received HIV counselling and/or testing. Some respondents also reported accessing MSM-friendly services at a drop-in centre or clinic in the past 12 months (22.1%). Approximately, one-third of respondents reported having burning urination in the past 12 months, whereas those reporting penile discharge (21.9%) and anal discharge (8.3%) were less.

Table 1. Characteristics of male sex workers who sell sex to men in Mombasa District (n=425)

| Variables | Percentage, or median (IQR) |
|--|-----------------------------|
| Socio-economic characteristics | |
| Kenyan citizen | 98.4 |
| Age in years (median, IQR) | 26 (22-31) |
| Completed primary school or higher | 68.5 |
| Religion | |
| Muslim | 48.0 |
| Catholic | 29.6 |
| Protestant | 19.3 |
| No religion | 3.1 |
| Sex work only source of income | 41.7 |
| Provides financial support to family, friends, or others | 56.7 |
| Consumes an alcoholic drink, days per week (median, IQR) | 2 (0-3) |
| Sexual networks and identities | |
| Ever had sex with a woman | 67.1 |
| Had a female paying client in past 30 days | 14.6 |

| | |
|--|-----------------|
| Had a non-paying female sex partner in past 30 days | 25.4 |
| Lives with a male or female sex partner | 28.8 |
| Lives with male sex partner | 25.2 |
| Lives with female wife | 4.0 |
| Lives with other female sex partner | 8.2 |
| Sexual self-identification | |
| Basha | 46.8 |
| Shoga | 16.5 |
| Queen | 10.8 |
| Bisexual | 7.1 |
| Gay | 6.1 |
| King | 4.5 |
| Kuchu | 2.8 |
| Homosexual | 1.6 |
| Others | 3.8 |
| Sexual practices | |
| Did not use condom during anal sex with last male client | 42.1 |
| "Never" or "sometimes" uses condoms during anal sex with male clients | 64.0 |
| Number of male clients in past seven days (median, IQR) | 2 (1-3) |
| Last paying male client a Kenyan citizen | 80.9 |
| Amount received from last male client in Kenya Shillings (median, IQR) | 1000 (500-2000) |
| Role during anal sex with last male client | |
| Insertive only | 57.6 |
| Receptive only | 34.8 |
| Both insertive and receptive | 7.6 |
| Exposure to violence in past 12 months | |
| Victim of physical abuse at least once | 12.2 |
| Victim of sexual abuse or rape at least once | 9.9 |
| Prevention knowledge | |
| Knows HIV can be transmitted via anal sex | 64.7 |
| Knows consistent condom use prevents HIV | 86.8 |
| Self-report of STI symptoms in past 12 months | |
| Burning urination | 33.4 |
| Penile discharge | 21.9 |
| Anal discharge | 8.3 |
| HIV testing and exposure to services | |
| Has ever been counseled or tested for HIV | 55.8 |
| Has ever visited an MSM-friendly centre or clinic | 22.1 |

STI, sexually transmitted infection; IQR, interquartile range
1 US\$ ~ 66 Kenya Shillings

Use of oil-based lubrications

Only 21.2% of respondents correctly knew that a water-based lubricant should be used with latex condoms. Vaseline or petroleum jelly was used by 36.2%, and 15.3% reported using a waterbased lubricant during anal sex with their last male client, whereas 28.6% reported using no lubrication. Among respondents who use condoms (n = 357), male sex workers who used an oil-based lubrication with their last male client were significantly more likely to have ever experienced condom breakage (48.4% vs. 35.6%, P=0.015).

Factors associated with inconsistent condom use

In table 2, we analyzed the bivariate associations between unprotected sex in the past 30 days and selected background characteristics, sexual identity and behaviors, reported STI symptoms, exposure to discrimination and violence, and exposure to HIV counseling and services. Key characteristics were associated with unprotected sex; male sex workers who engaged in frequent alcohol use (3–7 days per week), who self-identified as basha or king, and who received less money from their last male client (KSH 1000 or less) were significantly more likely to engage in unprotected sex with male clients. Incorrect knowledge about both HIV transmission via anal sex and consistent condom use as a prevention strategy were significantly associated with unprotected sex, as was self-reporting of burning urination or penile discharge in the past 12 months. Respondents who had never accessed key health services, including HIV counseling and testing or visiting an MSM-friendly drop-in centre or clinic, were also significantly more likely to report unprotected sex.

Table 2. Bivariate Logistic Regression - Factors associated with unprotected sex (inconsistent or no condom use) in the past 30 days for anal sex among male sex workers with male clients (n = 424)

| Bivariate associations | | | |
|---|----------------------------------|-------------------------|---------------|
| | Percent reporting ICU (n) | Crude odds ratio | 95% CI |
| Socio-economic characteristics | | | |
| Age | | | |
| 16–26 | 60.3 (224) | | |
| 27–60 | 68.5 (200) | 1.43 | 0.99-2.07 |
| Education | | | |
| Incomplete primary or less | 60.4 (134) | 1.26 | 0.80-1.98 |
| Completed primary or higher | 65.9 (290) | | |
| Religion | | | |
| Muslim | 62.1 (203) | | |
| Christian | 64.9 (208) | 1.13 | 0.68-1.88 |
| Employment | | | |
| Has other sources of income | 61.7 (248) | | |
| Sex work only source of income | 67.6 (176) | 1.30 | 0.84-2.00 |
| Financial support | | | |
| Does not give financial support | 65.8 (184) | 1.13 | 0.80-1.61 |
| Provides financial support to anyone | 62.9 (240) | | |
| Alcohol use | | | |
| Drinks none to two days a week | 60.0 (280) | | |
| Drinks three to seven days a week | 72.2 (144) | 1.73* | 1.13-2.66 |
| Sexual networks and identities | | | |
| Living situation | | | |
| Does not live with sex partner | 66.1 (277) | 1.27 | 0.91-1.77 |
| Lives with sex partner (male or female) | 60.5 (147) | | |
| Sexual identities | | | |
| Shoga, queen, bisexual, gay, all others | 58.3 (206) | | |
| Basha or king | 69.7 (218) | 1.65* | 1.07-2.55 |
| Sexual practices | | | |
| Number of male clients in past seven days | | | |
| None to two clients | 62.3 (292) | | |
| Three to ten clients | 68.2 (132) | 1.30 | 0.76-2.21 |
| Amount received from last male client | | | |

| | | | |
|---|------------|--------|-----------|
| 100 to 1000 Kenya Shillings | 69.6 (250) | 1.67* | 1.04-2.69 |
| 1001 to 20000 Kenya Shillings | 57.8 (166) | | |
| Role during anal sex with last male client | | | |
| Receptive only or both | 59.3 (177) | | |
| Insertive only | 67.8 (242) | 1.44 | 0.91-2.30 |
| Exposure to violence | | | |
| Physical abuse | | | |
| Not victimized | 62.9 (372) | | |
| Victim in past 12 months | 73.1 (52) | 1.60 | 0.80-3.20 |
| Sexual abuse or rape | | | |
| Not victimized | 63.6 (382) | | |
| Victim in past 12 months | 69.0 (42) | 1.28 | 0.69-2.36 |
| Prevention knowledge | | | |
| Knows HIV can be transmitted via anal sex | | | |
| Does not know or have correct knowledge | 74.7 (150) | 2.10** | 1.32-3.35 |
| Has correct knowledge | 58.4 (274) | | |
| Knows consistent condom use prevents HIV | | | |
| Does not know or have correct knowledge | 76.8 (56) | 2.01* | 1.06-3.82 |
| Has correct knowledge | 62.2 (368) | | |
| STI symptoms | | | |
| Self-reported burning urination | | | |
| Symptom not reported | 58.5 (282) | | |
| Burning urination in past 12 months | 75.4 (142) | 2.17** | 1.28-3.67 |
| Self-reported penile discharge | | | |
| Symptom not reported | 61.3 (331) | | |
| Penile discharge in past 12 months | 74.2 (93) | 1.81* | 1.01-3.24 |
| Self-reported anal discharge | | | |
| Symptom not reported | 63.4 (388) | | |
| Anal discharge in past 12 months | 71.4 (35) | 1.44 | 0.77-2.69 |
| HIV testing and exposure to services | | | |
| HIV counseling or testing | | | |
| Never been counseled/tested | 72.3 (188) | 1.92** | 1.26-2.93 |
| Has ever been counseled/tested | 57.6 (236) | | |
| Ever visited an MSM-friendly centre or clinic | | | |
| Has not visited | 67.1 (331) | 1.75** | 1.17-2.63 |
| Has visited | 53.8 (93) | | |

1 US\$ ≈ 66 Kenya Shillings

P value: * <0.05, ** <0.01

CI indicates confidence interval; OR, odds ratio.

Table 3 summarizes the results of multiple logistic regression of factors associated with unprotected sex after adjusting for all factors associated in bivariate analysis. Four variables were significant: not knowing HIV can be transmitted via anal sex [adjusted odds ratio (AOR), 1.92; 95% confidence interval (95% CI), 1.16–3.16]; drinking alcohol 3 or more days per week (AOR, 1.63; 95% CI, 1.05–2.54); self-report of burning urination within the past 12 months (AOR, 2.07; 95% CI, 1.14–3.76); and having never been counseled or tested for HIV (AOR, 1.66; 95% CI, 1.07–2.57). The factors in this model correctly classified consistent condom use or unprotected sex in the past 30 days for 67.0% of respondents, and the model was statistically significant ($F = 5.95$, $P < 0.001$).

DISCUSSION

This study characterizes the HIV risk behaviors of a mobile and highly vulnerable population. We documented high rates of unprotected sex and low levels of basic HIV understanding, which

emphasize the critical need to provide the most basic of HIV prevention messages and services for male sex workers in an African setting. Thirty-five percent of male sex workers in Mombasa were not aware that HIV can be transmitted via anal sex.

Table 3. Final Multivariate Model - Factors associated with unprotected sex (inconsistent or no condom use) in the past 30 days for anal sex among male sex workers with male clients (n = 424)

| | Adjusted OR | 95% CI |
|---|--------------------|---------------|
| Alcohol use: drinks > 2 days per week | 1.63* | 1.05-2.54 |
| Does not know HIV may be transmitted via anal sex | 1.92* | 1.16-3.16 |
| Self-reported burning urination in the past 12 months | 2.07* | 1.14-3.76 |
| Has never been counseled and/or tested for HIV | 1.66* | 1.07-2.57 |

P value: * <0.05

CI indicates confidence interval; OR, odds ratio.

After the survey was completed, male sex workers who participated in a focus group discussion rationalized this belief in 2 ways: anal sex was perceived to be a dry environment through which the HIV virus cannot move, and that anal sex as a risk behavior was never mentioned in Kenyan media campaigns or by health educators. Indeed, most HIV prevention programs in Africa operate under the assumption that vaginal sex is the only mode of HIV sexual transmission. This may be a concern for African women as well, as studies have documented anal sex practice among female sex workers in Kenya, [22,23] and among young South African males in heterosexual relationships. [24]

Male sex workers self-reported high levels of recent anal discharge, penile discharge, and burning urination—the latter significantly associated with unprotected anal sex. Furthermore, respondents reporting no exposure to HIV counseling and/or testing were significantly more likely to report unprotected sex. To improve access to STI treatment and counseling and testing programs, we recommend increasing outreach to male sex workers through peer education, and training health care providers to provide sensitive and appropriate counseling and care. These proposed interventions may help connect more male sex workers to services, despite high levels of community stigma.

We found that more frequent alcohol use was associated with unprotected sex and recommend further assessment of harmful or hazardous drinking among male sex workers, strengthening linkages to existing substance abuse programs in Mombasa, and establishing peer support groups. It

is also possible that low self-esteem and depression may be cofactors influencing both unprotected sex and substance abuse. This study did not systematically assess psychosocial disorders, and is recommended as a future priority for research with MSM in Africa.

Male sex workers in Mombasa are generally mobile and some sell sex throughout the country. A majority of their clients are Kenyan citizens, suggesting a sizable local population sexually attracted to men without foreign influence. The demographic and behavioral differences among self-described sexual identities highlight the importance of understanding identity to inform effective programming. Data from qualitative discussions conducted with male sex workers after this survey, however, suggest that some sexual behaviors and individual motives for engaging in sex work vary within identity subgroups. Further analysis of the relationships between identity, sexual desire, and financial motives among male sex workers in Kenya is needed.

Limitations of this study include, but are not limited to, differing skills of MSM as mobilizers may have led to variation in correct and efficient identification of men who sell sex to men, and the frequencies of individual respondent venue attendance were not accounted for in sampling or analysis, which may bias the results toward male sex workers who attend particular venues on a more frequent basis. [25] A research clinic 20 km north of Mombasa was actively providing risk reduction counseling, referral for treatment, and peer education activities for MSM during this research,[9] which may have resulted in a more well-informed survey population than that which may exist in other African cities.

Inconsistent or no condom use by male workers cannot be attributed to supply issues, as most reported condoms are very affordable and available at 10 KSH (packet of 3; about US\$0.15) or for free. Many respondents, however, reported using oil-based lubricants such as petroleum and baby lotion, and less than a quarter of respondents correctly knew that only water-based lubricants should be used with latex condoms. Water-based lubricants are available mainly at pharmacies and selected supermarkets in Mombasa, and are prohibitively expensive for many male sex workers. This study found a significant association between the use of oil-based lubricants and condom breakage, supporting findings of previous studies [26-28] and underscoring the need for education and provision of water-based lubricants to MSM as part of an integrated condom distribution strategy in Africa.

In summary, lack of knowledge of anal sex as an HIV risk behavior, frequent alcohol use, self-reported burning urination in the past year, and never having received HIV counseling or testing were significantly associated with unprotected anal sex among male sex workers who sell sex to men in

Mombasa District. The development of basic services, including the development of specifically tailored counseling, prevention, and treatment programs for this vulnerable population focusing on anal transmission are strongly recommended.

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4.3 *Effect of antiretroviral therapy on sexual behaviour among HIV-infected patients receiving ART in Kenya: findings from a longitudinal study.*

Effect of antiretroviral therapy on sexual behaviour among HIV-infected patients receiving ART in Kenya: findings: from a longitudinal study.

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ABSTRACT

Roll-out of antiretroviral treatment (ART) raises concerns about the potential for unprotected sex if sexual activity increases with wellbeing, resulting in continued HIV spread. Beliefs about reduced risk for HIV transmission with ART may also influence behaviour. From 09/2003 to 11/2004, 234 adults enrolled in a trial assessing the efficacy of modified directly-observed therapy in improving adherence to ART. Unsafe sexual behaviour (unprotected sex with an HIV-negative or unknown status partner) before starting ART and 12 months thereafter was compared. Participants were a mean 37.2 years (sd=7.9yrs) and 64% (149/234) were female. Nearly half (107/225) were sexually active in the 12 months prior to ART, the majority (96/107) reporting one sexual partner. Unsafe sex was reported by half of those sexually active in the 12 months before ART (54/107), while after 12 months ART, this reduced to 28% (30/107). Unsafe sex was associated with non-disclosure of HIV status to partner; recent HIV diagnosis; not being married or cohabiting; stigma; depression and body mass index <18.5kg/m². ART beliefs, adherence and viral suppression were not associated with unsafe sex. After adjusting for gender and stigma, unsafe sex was 0.59 times less likely after 12 months ART than before initiation (95% CI=0.37-0.94; *P*=0.026). In conclusion, though risky sexual behaviours had decreased, a considerable portion does not practice safe sex. Beliefs about ART's effect on transmission, viral load and adherence appear not to influence sexual behaviour but require long-term surveillance. Positive prevention interventions for those receiving ART must reinforce safer-sex practices and partner disclosure.

BACKGROUND

Access to antiretroviral therapy (ART) in Africa is expanding rapidly, providing life-sustaining treatment and demonstrating that high-quality services can be provided in low- and middle-income countries. It is estimated that 1.3 million people have initiated ART in sub-Saharan Africa.(55) Though this number is still less than a third of those who require ART, it is a marked improvement from a coverage of 2% in the region in 2004. The growing number of people living longer with HIV could form a potential source of transmission, and of the spread of drug resistant virus.(40, 56) It is thought that improvements in physical health and wellbeing with ART could be accompanied by an increase in sexual desire and activity, including unsafe sex.

There are concerns that increases in unsafe sexual practices occur as communities become aware that HIV is a manageable chronic illness.(57) This phenomenon has been referred to as treatment optimism or behavioural disinhibition. Also, changes in sexual practices may result from the perception among those receiving ART (or their partners) that they are no longer infectious, especially when the viral load is undetectable.(57-61)

Concerns about the potential impact of ART on sexual behaviour are supported by findings of several studies in high-income countries showing increases in risky behaviours.(62, 63) However, a meta-analysis of 25 studies among HIV-infected people showed that receiving ART (with or without viral suppression) was not associated with higher prevalence of unprotected sex.(57) The analysis, however, did demonstrate higher levels of unprotected sex among those who believed that receiving ART or having an undetectable viral load protects against HIV transmission. Similarly, unsafe sex was higher among those who believed HIV is a less severe or threatening disease due to the availability of ART. These studies were predominately among men who have sex with men and may not reflect changes in other settings and population groups.

Thus far, four studies in Africa provide information on changes in sexual behaviour with ART. Three of these studies were cross-sectional (64-66) and the longitudinal study included data only up to six months after ART initiation.(67) A systematic review including three of these studies, showed that access to ART was not associated with an increase in risky sexual behaviours.(68) The review also concluded that more studies were needed, especially to build an evidence base necessary to inform development of safer sex messaging and related interventions for people receiving ART in Africa.(69) In this study we evaluated factors associated with unsafe sexual behaviour as well as changes in sexual behaviour 12 months after initiating ART in Mombasa, Kenya.

METHODS

This study of sexual behaviours among patients receiving ART was part of a trial assessing the efficacy of modified directly-observed therapy (m-DOT) to improve adherence to ART. The study was conducted at two public sector hospitals and one private, not-for-profit clinic. Adults living in Mombasa who were 18 years and older, ART naïve and with indications for ART as per the Kenyan national treatment guidelines were invited to participate.

Study participants (149 women and 85 men) were randomly assigned to m-DOT and standard-of-care groups. Treatment and care were provided within routine services at HIV clinics within respective facilities. Prior to initiating ART, all participants attended three one-on-one counselling sessions with trained nurse counsellors. These counselling sessions included information on: the importance of adherence; the treatment regimen and dosing instructions; routes of HIV transmission; condom use; and the importance of disclosure and partner testing. Participants also received messages on positive prevention when starting ART and during routine follow-up visits.

Following initiation of ART, patients visited treatment centres every four weeks for clinical follow-up. In addition to receiving standard of care, those in the intervention arm had an m-DOT intervention for the first six months of treatment. This entailed twice-weekly visits to the health centre, where participants met with m-DOT observers (nurses) who observed the ingestion of one ART dose, performed pill-counts, collected used medication bottles, enquired about difficulties encountered and provided individualized adherence support. At m-DOT visits, medication was dispensed for the subsequent three or four days. Participants who missed visits or were unable to visit the health centre were traced by community workers. Adherence measures consisted of monthly clinic-based pill-counts. A summary measure of adherence over 12 months was calculated from the number of pills taken in this period divided by the number of pills expected to be taken. The result was dichotomised to $\geq 95\%$ and $< 95\%$ adherence. Additional details and trial results will be presented elsewhere.

Ethical approval for the study was obtained from the national Kenyan ethical committee (KNH-ERC) as well as the Institutional Review Board of the Population Council.

Data collection and outcome measures

Data on sexual behaviour were collected using structured questionnaires administered in Swahili by trained research assistants. Information was obtained at the start of treatment and after 6 and 12

months. The questionnaire captured information on: hetero- and homosexual contacts with regular, non-regular and commercial partners; condom use; disclosure of HIV status to partners and knowledge of their partner's HIV status; knowledge and attitudes towards ART and its effects on risk for HIV transmission; and history of STI. The recall reference period for most outcome measures was 12 months. Depression was assessed using Beck's Depression Inventory I[®]; the tool was culturally adapted and translated into Swahili. Perceived stigma was assessed using an adapted Berger scale with 16 items and categorized as minimal or low, moderate, or high stigma levels.

For study purposes, unsafe sex was defined as any unprotected sex act in the last 12 months with a partner of HIV negative or unknown status (primary outcome). A regular partner was defined as a spouse or sexual partner with whom the respondent lived or had a stable relationship. A non-regular partner referred to a partner with whom the respondent was not living or married to and only had sex with once or very rarely. Commercial partners were those who were given money or gifts in exchange for sex. Participants were asked two questions to assess their concern about HIV transmission while on ART at the 12 month visit: "Treatment with ARV medications can reduce the risk of transmission" and "HIV/AIDS has become less serious because of ARV medications". Agreeing with either one or both of these questions categorized them as having lower levels of concern about transmission. STI events were self-reported episodes in the past 12 months; laboratory confirmation of infection was not available.

Laboratory investigations

CD4 cell counts were determined at baseline, and months 6 and 12. PARTEC (Partec-GmbH, Münster, Germany) and FACS counters (Becton & Dickinson Immunocytometry Systems, California, USA) were used for enumerating CD4 cell counts. Plasma viral load (Roche Amplicor HIV-1 Monitor test version 1.5, Roche Molecular systems, Branchburg, New Jersey, USA) was measured at 12 months.

Data management and statistical analysis

Data were double-entered in a Microsoft Access 2003 database and analysed using Intercooled Stata, version 8.0 (Stata Corporation, College Station, Texas, USA). The chi-square test and Mann-Whitney *U* test were used for univariate comparisons of baseline characteristics for each gender. To assess factors associated with unsafe sex, a bivariate analysis was done, restricted to participants

who had been sexually active in the past 12 months at baseline and / or at 12 months follow up. Associations were assessed between unsafe sex and socio-demographic, HIV knowledge and beliefs, disclosure, health status and ART characteristics. Bivariate cross-sectional logistic regression models were constructed using generalised estimating equations (GEE), taking into account that observations were repeated on the same participant.

Participant's sexual behaviour before starting ART and after 12 months of treatment was compared using GEE. Multivariate models are presented for the primary outcome and for any sexual activity, unprotected sex at last sex act with any partner and self-reported STI. Variables associated with the primary outcome in the bivariate analysis described above or in similar studies were included in the model and retained if removal from the model markedly altered the model fit. Similar methods were used for constructing the other three multivariate models.

RESULTS

Between September 2003 and November 2004, 234 participants were enrolled and randomized to the m-DOT intervention or control group. The majority of those who met study eligibility criteria agreed to participate (234/249). At study entry, participants had a mean age of 37.2 years (sd=7.9 years; Table 1). ART was not initiated in seven participants who: withdrew from the study (two), died (three), were lost to follow up (one) or could not participate due to severe illness (one). In the year following ART initiation, 19 people died, 9 were lost to follow-up and 8 discontinued study participation (4 transferred to other hospitals and 4 discontinued ART).

While socio-economic characteristics were similar between women and men, women were more likely to be a widow (30%; 43/145 versus 12%; 10/84) or unemployed (85%, 123/145 versus 74%, 62/84; $P=0.041$). Median CD4 cell count was 99 (inter-quartile range (IQR)=49-147), similar for both genders.

Women perceived higher levels of stigma than men, and were less likely to have disclosed their HIV status to a regular partner or spouse. A substantial proportion of both women and men were mildly depressed (35%; 75/224), or had moderate to severe depression (32%; 71/224) at baseline.

Table 1: Baseline characteristics of women and men at initiation of antiretroviral treatment.

| Variable grouping | Variable | Total (N=234) | Women (N=149) | Men (N=85) | P-value [^] | |
|---------------------------|--|--|----------------|---------------|----------------------|------|
| Socio-demographic | Age: mean years (sd) | 37.2 (7.9) | 35.3 (7.5) | 40.4 (7.4) | <0.001 [£] | |
| | Highest education level: % (n/N) | | | | 0.50 | |
| | Never attended school | 6% (13/228) | 7% (10/145) | 4% (3/83) | | |
| | Primary education | 50% (113/228) | 50% (73/145) | 48% (40/83) | | |
| | Secondary or higher education | 45% (102/228) | 43% (62/145) | 48% (40/83) | | |
| Socio-demographic | Marital status: % (n/N) | | | | 0.002 | |
| | Never married | 14% (32/229) | 15% (22/145) | 12% (10/84) | | |
| | Married or cohabiting | 48% (111/229) | 39% (57/145) | 64% (54/84) | | |
| | Divorced or separated | 14% (33/229) | 16% (23/145) | 12% (10/84) | | |
| | Widowed | 23% (53/229) | 30% (43/145) | 12% (10/84) | | |
| Socio-demographic | Employment status: % (n/N) | | | | 0.041 | |
| | Employed | 19% (44/229) | 15% (22/145) | 26% (22/84) | | |
| | Unemployed | 81% (185/229) | 85% (123/145) | 74% (62/84) | | |
| Sexual Behaviour | Sexual partner(s) in past 12 months: % (n/N) | | | | 0.58 | |
| | Regular partner(s) / spouse | 93% (99/107) | 94% (62/66) | 90% (37/41) | | |
| | Non-regular partner(s) | 12% (13/107) | 11% (7/66) | 15% (6/41) | | |
| | Commercial partner(s) | 2% (2/107) | 0% (0/66) | 5% (2/41) | | |
| Sexual Behaviour | Number of sex partners in past 12 months (among sexually active): % (n/N) | | | | 0.068 | |
| | 1 partner | 90% (96/107) | 94% (62/66) | 83% (34/41) | | |
| | ≥ 2 partners | 10% (11/107) | 6% (4/66) | 17% (7/41) | | |
| HIV knowledge and beliefs | Duration since known HIV positive: % (n/N) | | | | 0.98 | |
| | < 1 year | 52% (118/226) | 52% (74/143) | 53% (44/83) | | |
| | 1 – 5 years | 38% (86/226) | 38% (55/143) | 37% (31/83) | | |
| | ≥ 5 years | 10% (22/226) | 10% (14/143) | 10% (8/83) | | |
| HIV knowledge and beliefs | Perceived stigma: % (n/N) | | | | 0.008 | |
| | Minimal or low | 31% (69/225) | 27% (38/143) | 38% (31/82) | | |
| | Moderate | 57% (129/225) | 57% (81/143) | 59% (48/82) | | |
| | High | 12% (27/225) | 17% (24/143) | 4% (3/82) | | |
| HIV status Disclosure | Disclosed status to regular partner/spouse: % (n/N) | | | | 0.059 | |
| | Yes | 42% (96/229) | 37% (54/145) | 50% (42/84) | | |
| | No | 58% (133/229) | 63% (91/145) | 50% (42/84) | | |
| HIV status Disclosure | HIV status of regular partner/spouses: % (n/N) | | | | 0.53 | |
| | HIV positive | 34% (55/161) | 38% (34/90) | 30% (21/71) | | |
| | HIV negative | 11% (18/161) | 10% (9/90) | 13% (9/71) | | |
| | Do not know | 55% (88/161) | 52% (47/90) | 58% (41/71) | | |
| Health status | Depression: % (n/N) | | | | 0.34 | |
| | No depression | 33% (75/224) | 30% (43/142) | 39% (32/82) | | |
| | Mild depression | 35% (78/224) | 35% (50/142) | 34% (28/82) | | |
| | | Moderate or severe depression | 32% (71/224) | 35% (49/142) | 27% (22/82) | |
| | Health status | WHO clinical HIV stage: % (n/N) | | | | 0.60 |
| Stage 1 | | 9% (20/228) | 10% (15/144) | 6% (5/84) | | |
| Stage 2 | | 21% (47/228) | 19% (27/144) | 24% (20/84) | | |
| Stage 3 | | 64% (145/228) | 64% (92/144) | 63% (53/84) | | |
| | Stage 4 | 7% (16/228) | 7% (10/144) | 7% (6/84) | | |
| Health status | Body mass index: % (n/N) | | | | 0.31 | |
| | < 18.5 kg/ m ² | 27% (59/215) | 30% (40/134) | 23% (19/81) | | |
| | • 18.5 kg/ m ² | 73% (156/215) | 70% (94/134) | 77% (62/81) | | |
| | CD4 cell count: median cells/mm ³ (IQR) | 99 (49 – 147) | 100 (50 – 152) | 93 (47 – 134) | 0.27 | |
| ART | Randomized intervention: % (n/N) | | | | 0.97 | |
| | Mod-DOT | 50% (116/234) | 50% (74/149) | 49% (42/85) | | |
| | Standard care | 50% (118/234) | 50% (75/149) | 51% (43/85) | | |

[^]Multiple responses possible. [^] chi-square test unless indicated. [£] Student t test.

Sexual behaviour

In the year preceding the initiation of ART, nearly half the participants (48%; 107/225) were sexually active, mainly with their regular partner or spouse (93%; 99/107). Sex with non-regular partners and commercial partners was reported by 12% (13/107) and 2% (2/107) of sexually-active participants, respectively. Men reported having sex with multiple partners more frequently than women (7/41, 17% versus 4/66, 6%; $P=0.068$). Only one man reported having had sex with another man. Over three quarters (77%; 82/107) of sexually-active participants reported having had unprotected sex with any partner in the 12 months preceding ART. The majority (54) of those had unprotected sex with people who were HIV negative or of unknown status and included regular, non-regular and commercial partners. Six sexually-active participants did not provide information on condom use in the past 12 months and were not included in the analysis of the primary outcome.

At the 12 month follow-up visit, 107 of 185 participants (58%) said they had been sexually active since initiating ART. They reported sex with regular (97 participants), non-regular (8 participants) and commercial partners (2 participants). Few reported more than one partner in the last 12 months (6%; 6/107). Unprotected sex was mentioned by 63% (67/107) of sexually-active participants, 30 of whom said this partner was HIV negative or of unknown status. Ten sexually-active participants, reporting sex with 2 positive and 6 negative partners or of unknown HIV status (2 missing), did not provide complete information on condom use at this visit.

Association of other factors with unsafe sex

To measure the effects of factors other than ART, GEE models assessed associations between potential risk factors and unsafe sex in the past year with a partner who was HIV negative or of unknown status (Table 2). After adjusting for intra-client clustering, unsafe sex was more likely among participants who had not disclosed their HIV status to their partner; were aware of their HIV status within the last year; were not married or cohabiting; had experienced moderate or high stigma; with moderate or severe depression, or with a body mass index below 18.5kg/m². In particular, non-disclosure of HIV status to a regular partner/spouse and high levels of perceived stigma were strongly associated with unsafe sex. No association was detected between gender and unsafe sexual behaviour. Study group was not associated with unsafe sex, even at the six month visit. Using pill count measures of adherence in the first 12 months of ART, 83.5% (182/218) of participants had

Table 2: Correlates of unsafe sex in the last 12 months with HIV negative or unknown status partners among sexually-active participants, adjusted for intra-client clustering.

| Variable Grouping | Variable | All measures | |
|--|---|---|---|
| | | Adjusted odds ratio (95% CI) | P-value |
| Socio-demographic characteristics | Sex: Female Male | 1.0 0.79 (0.44 – 1.43) | 0.43 |
| | Age: < 36 years ≥ 36 years | 1.0 1.12 (0.62 – 2.04) | 0.71 |
| | Baseline marital status: Never married Married or cohabiting Divorced, or separated Widowed | 3.06 (1.07 – 8.76) 1.0 2.59 (1.07 – 6.25) 2.35 (0.92 – 6.01) | 0.038 0.034 0.074 |
| | Baseline education level: Never attended school Primary education Secondary or tertiary education | 1.0 0.46 (0.12 – 1.74) 0.34 (0.09 – 1.29) | 0.25 0.11 |
| | Baseline employment status: Employed Unemployed | 1.0 0.67 (0.33 – 1.36) | 0.27 |
| | HIV knowledge and beliefs | Duration since known positive: < 1 year 1 – 5 years 5 or more years | 1.0 0.26 (0.15 – 0.46) 0.30 (0.11 – 0.80) |
| Concern of transmission risk: [†] Concern Lessened concern | | 1.0 1.66 (0.43 – 6.42) | 0.46 |
| Perceived stigma: Minimal or low Moderate High | | 1.0 3.11 (1.57 – 6.15) 5.20 (1.94 – 13.93) | 0.001 0.001 |
| Disclosure | Disclosed HIV status to regular partner / spouse: Yes No | 1.0 4.93 (2.51 – 9.69) | <0.001 |
| Health status | Depression: No depression Mild depression Moderate or severe depression | 1.0 1.65 (0.86 – 3.18) 2.62 (1.26 – 5.45) | 0.13 0.01 |
| | Body mass index: < 18.5 kg/m ² ≥ 18.5 kg/m ² | 1.0 0.26 (0.10 – 0.66) | 0.005 |
| | Pre-ART WHO clinical HIV stage: Stage 1 or stage 2 Stage 3 or stage 4 | 1.0 1.06 (0.57 – 1.96) | 0.86 |
| | CD4 cell count: < 100 cells/uL 100 - 350 cells/uL ≥ 350 cells/uL | 1.0 0.88 (0.45 – 1.71) 0.47 (0.18 – 1.24) | 0.71 0.13 |
| | Plasma viral load at 12 months: [†] Undetectable (< 400 cps/mL) Detectable (≥ 400 cps/mL) | 1.0 0.64 (0.16 – 2.58) | 0.53 |
| ART | Adherence to ART: [‡] < 95% adherence ≥ 95% adherence | 1.0 1.21 (0.30 – 4.84) | 0.79 |

[†]Variable only measured at 12 months, not adjusted for intra-client clustering.
[‡] Summary of adherence (pill count measures) over 12 month period, not adjusted for intra-client clustering

taken \geq 95% of their pills in this period. Levels of adherence were not associated with unsafe sex. Also, no association was observed between unsafe sex and decreased concern about HIV transmission with ART or plasma viral suppression.

Effect of antiretroviral treatment on sexual behaviour

The effect of ART on sexual behaviour was assessed comparing data collected at baseline and after 12 months of treatment (Table 3). With adjustment for intra-client clustering, sexual activity increased in the 12 months after ART initiation (OR =1.44, 95% CI=1.07-1.94; $P=0.017$). However, in a multivariate model, no difference was detected in levels of sexual activity after 12 months of ART, adjusting for intra-client clustering, gender, marital status and stigma (AOR=1.30; 95% CI=0.86-1.96; $P=0.21$).

For the primary outcome (unprotected sex with a person with HIV negative or unknown status in the past 12 months), adjusted odds ratios were calculated, including gender, disclosure of status to regular partner/spouse as well as intra-client clustering. In this multivariate model, after 12 months of ART as compared to before starting ART, unsafe sex was 0.59 less likely (95% CI=0.37–0.94; $P=0.026$) among the whole study population (including sexually-active and non-active participants). No adjustments were done for body mass index and depression as these were highly correlated with ART exposure (co-linear). Also, after 12 months follow-up, the duration of which participants were aware of their HIV status had surpassed the 1 year period and this variable was not included in the final model.

Among sexually-active participants, a decrease was noted in unsafe sex from 50% (54/107) in the 12 months preceding ART to 28% (30/107) in the subsequent 12 months. The odds ratio adjusted for intra-client clustering, gender, disclosure to regular partner/spouse and stigma was 0.52 (95% CI=0.32-0.87; $P=0.012$). These findings were consistent with changes in reported condom use at last sex act.

Using self-reported sexually-transmitted infections as a proxy for unprotected sex, a decrease was noted over the course of the study in the total population (AOR=0.37; 95% CI=0.20-0.67; $P=0.001$), as well as among sexually-active participants (AOR=0.20; 95% CI=0.09-0.43; $P<0.001$).

Table 3. Effect of 12 months of antiretroviral treatment on the sexual behaviour in Mombasa, Kenya: multivariate generalised estimating equations

| Variable | Baseline, % (n/N) | 12-months FU % (n/N) | Crude odds ratio (95% CI) | Adjusted odds ratio (95% CI) [*] | P-value |
|--|----------------------|-------------------------|------------------------------|--|---------|
| All participants | | | | | |
| Sex in last 12 months | 48% (107/225) | 58% (107/185) | 1.44 (1.07 – 1.94) | 1.30 (0.86 – 1.96) | 0.21 |
| Unprotected sex with negative / unknown partner in past year | 24% (54/225) | 16% (30/185) | 0.61 (0.38-0.96) | 0.59 (0.37 – 0.94) | 0.026 |
| Unprotected sex at last sex act | 22% (49/225) | 6% (11/185) | 0.22 (0.12 – 0.43) | 0.23 (0.12 – 0.44) | <0.001 |
| Self-reported STI | 20% (44/220) | 8% (15/184) | 0.34 (0.19 – 0.62) | 0.37 (0.20 – 0.67) | 0.001 |
| Sexually active participants | | | | | |
| Unprotected sex with negative / unknown partner in past year | 50% (54/107) | 28% (30/107) | 0.37 (0.23 – 0.60) | 0.52 (0.32 – 0.87) | 0.012 |
| Unprotected sex at last sex act | 46% (49/107) | 10% (11/107) | 0.14 (0.08 – 0.27) | 0.16 (0.08 – 0.32) | <0.001 |
| Self-reported STI | 31% (32/104) | 8% (9/106) | 0.19 (0.09 – 0.41) | 0.20 (0.09 – 0.43) | <0.001 |

FU: follow up. *Models included the following variables:

All participants

Sex in last 12 months: gender, marital status and disclosure to regular partner/spouse

Unprotected sex with negative / unknown partner: gender and stigma

Unprotected sex at last sex: gender

Self-reported STI: gender, disclosure to regular partner/spouse and stigma

Among sexually active participants

Unsafe sex with negative / unknown partner: gender, disclosure to regular partner/spouse and stigma

Unprotected sex at last sex: gender and disclosure to regular partner/spouse

Self-reported STI: gender and disclosure to regular partner/spouse

DISCUSSION

This study showed no evidence of increased risky sexual behaviours among those receiving ART for 12 months. Specifically, a substantial reduction in risk taking were seen when examining unprotected sex with HIV negative or unknown HIV status persons, condom use at last sex act, number of sexual partners or reported STI. Similar findings were reported in previous studies in sub-Saharan Africa.(64, 65, 67)

Risk factors for unsafe sex among people receiving ART were similar to those found in previous studies.(65) A few studies have examined ways of increasing disclosure rates and assessed negative and positive outcomes of disclosure.(70-74) However, additional efforts are needed to increase disclosure rates to sexual partners in Africa (73), making this a more routine practice, while protecting the rights of persons with HIV.(69)

No association was detected between plasma viral suppression or adherence and risky behaviours. While having an undetectable plasma viral load does not eliminate the possibility of transmitting HIV, those with detectable viral levels are at substantially higher risk for transmitting HIV.(47, 75, 76) Similarly, those with poor adherence may have a greater likelihood of transmitting HIV, especially drug resistant strains. High levels of adherence were noted in this study, as in previous reports from resource-constrained settings.(77-79) Several other studies of m-DOT among diverse population groups have also reported high adherence levels (80-82), though not all.(83) In this study, the lack of an association between viral suppression or adherence and sexual behaviour may be important from a public health perspective. However, the study has limited power to detect these effects. Caution is therefore required in the interpretation of these findings.

This study could assist in guiding development of prevention messages for this population. These messages need to reinforce their safer-sex practices, assisting to prevent potential long-term 'safer sex fatigue'. In addition, contextual and socio-cultural factors (such as gender roles, stigma, social norms and economic status) need to be considered as individual behavioural changes do not occur in isolation.(84, 85) While evidence is accruing that prevention interventions can reduce HIV risk behaviour among people living with HIV in high-income countries (86), little is known about these interventions in resource-constrained settings, or whether these interventions are efficacious among people receiving ART. Encouragingly, a cohort study in rural Uganda found that partner VCT, prevention counselling and condom provision together with home-based ART reduced risky sexual behaviour by 70%.(67) The reduction in risk observed among ART patients may not be solely attributable to ART *per se*, but rather to more frequent encounters with health workers and improvements in counselling, condom provision and other services associated with ART introduction. With our study design, it is not possible to disaggregate the relative effects of these interventions and of ART on changes in risk behaviour over time. Interestingly, those in the m-DOT study arm who had more contact with health services for the first six months of ART, had similar changes in sexual behaviour to the control group.

It may also be necessary to establish mechanisms for tracking changes in community-level beliefs about the effects of ART on risk for HIV transmission, which may occur as public awareness increases that HIV is a manageable disease and that risk of transmission is reduced with an undetectable viral load. In high-income countries, several studies among men who have sex with men have suggested that since ART became available, the prevalence of unprotected sex and incidence

of STIs, including HIV, have increased.(63, 87, 88) This increase in unprotected sex – regardless of HIV status – has been causally linked with the belief that HIV is a less severe or threatening disease since ART became available.(60) Potentially, treatment optimism at a population level may be more important than treatment optimism among HIV-positive individuals.

This study reports changes in sexual behaviour up to one year after initiating ART, in a population with relatively advanced immune suppression at initiation of ART. It is possible that there is a critical threshold of time after starting ART at which increases in unprotected sex will occur. Persons with symptomatic disease may have less interest in sex or adverse effects of ART could diminish sexual desire. While it is not possible to predict changes in sexual behaviour in the longer term from this study, it is encouraging to note that those with higher CD4 cell counts or less advanced clinical disease were not more likely to have unsafe sex. Moreover, the finding that people who were aware they were HIV infected for more than one year had safer practices may indicate that changes in behaviour with knowledge of HIV status are sustained or improved over time.(65)

Study outcomes are self-reported, mostly sexual behaviours, which are subject to both recall and social-desirability bias. Ensuring that the interviewers were not the same people as those who provided positive prevention counselling aimed to reduce this bias. The study also lacks a control group, limiting its rigor.

In conclusion, using several outcomes measures, ART was associated with reduced sexual risk behaviour. Other studies have shown that once people become aware they have HIV infection they reduce behaviours that place others at risk for HIV acquisition.(89, 90) This phenomenon, together with regular contacts with the health system for ART follow up may facilitate safer sexual behaviour among those receiving ART. Nevertheless, a considerable proportion still do not consistently practice safer behaviours and remain a cause for concern. Moreover, it may be difficult to sustain safer behaviours over a lifetime, making longer-term studies essential to examine changes in social and behavioural outcomes in the long run. Overall, evidence of the influence of ART on behaviours in resource-constrained settings is limited, nevertheless, the evidence from this study and information from other settings can be used to design interventions to promote and sustain safer behaviours for those receiving ART.

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4.4 *Sexual risk behaviour and HAART: A comparative study of HIV infected persons on HAART and on Preventive Therapy in Kenya.*

Sexual risk behaviour and HAART: A comparative study of HIV infected persons on HAART and on Preventive Therapy in Kenya

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SUMMARY

Unprotected sex (UPS) among persons receiving HAART remains a concern because of the risk of HIV transmission. A cross-sectional study comparing the sexual risk behaviour of 179 PLHA receiving HAART with that of 143 PLHA receiving preventive therapy (PT) with cotrimoxazole / isoniazid was conducted in Mombasa, Kenya.

Forty-five percent of all participants were sexually active in the last six months. Participants receiving PT were more likely to report ≥ 2 partners (13% versus 1%; $P = 0.006$). Participants receiving PT reported more unprotected sex with regular partners (Odds Ratio (OR): 3.9; 95% confidence interval (CI): 1.8 - 8.4) and also more STI symptoms (OR: 1.7; 95% CI: 1.0 - 2.8; $P = 0.059$). More than 40 percent of all participants did not know the HIV-status of regular partners. Therefore, HAART was not associated with increased sexual risk behaviours though considerable risk of HIV-transmission remains. HIV care services need to emphasize partner testing and consistent condom use with all partners.

INTRODUCTION

With increased access to highly active antiretroviral therapy (HAART) there has been dramatic decline in morbidity and mortality from HIV disease.⁽¹⁾ As of August 2006 eighty-eight thousand HIV-infected persons were receiving antiretroviral therapy (ART) in Kenya.⁽²⁾ Unprotected sex (UPS) among persons receiving HAART is of concern because of the risk of HIV-transmission to sero-discordant partners, possibly with resistant viruses, or the risk of re-infection with new, drug resistant viral strains.⁽³⁾ An increase in risk behaviours has the potential to undo gains achieved by prevention and ARV initiatives. There is widespread concern that a reduction in preventive behaviours may occur among HIV-infected persons once they feel better with ART. UPS and the incidence of sexually transmitted infections (STI) including HIV have increased among men who have sex with men (MSM) since HAART became more widely available.⁽⁴⁻⁵⁾ Among HIV-infected MSM receiving ART, risk behaviour was associated with immunological and virological improvements, related in part to a perception of lower infectivity due to lower viral loads.⁽⁶⁾ An increased risk of acquiring STIs, an epidemiological marker of UPS, has been also reported among heterosexual HIV-infected persons receiving ART.⁽⁷⁾ A recent review found that while people's beliefs about lower infectivity with ART and undetectable viral loads promote UPS, HIV-positive patients receiving ART did not exhibit increased sexual risk behaviour, even when therapy achieved undetectable viral loads.⁽⁸⁾ Currently limited evidence is available from resource poor settings.⁽⁹⁻¹¹⁾

Our study examines the sexual risk behaviour of HIV-positive persons accessing care and whether HAART is associated with increased sexual risk behaviour in Mombasa, Kenya.

METHODS

This cross-sectional study compares the sexual risk behaviour of HIV-infected adults ≥ 18 years of age who were receiving either HAART or preventive therapy (PT) with cotrimoxazole and/or isoniazid without HAART.

Study setting and subject recruitment

Participants receiving HAART comprised of adult HIV-infected persons completing six-months on ART; five persons refused the interview. Treatment naïve HIV-infected persons with CD4 cell counts < 200 cells/mm³ were eligible to receive ART in the newly introduced government ARV programme in

Mombasa. All patients initiating ART were invited to participate in a longitudinal adherence study within which this study was nested. Participants receiving PT comprised of HIV-infected persons who were not yet eligible to initiate ART and completed at least five-months on preventive therapy; there were no refusals. The PT programme was in place prior to the introduction of the ARV program, and was phased out once the ARV programme was stabilised. At the time of the study the two programmes were running in parallel and patients participating in the two programmes were mutually exclusive. Participants were recruited as they came for follow-up services.

Participants in both groups were in regular contact with health workers through monthly visits to the HIV-clinics. All patients received messages on positive prevention at the time of HIV testing, when starting their respective treatments and during follow-up; information provided consisted of routes of transmission, condom use, disclosure and partner testing. Those receiving HAART also had intensive counselling on treatment adherence.

Data collection

A structured questionnaire was used. Face-to-face interviews were conducted (September 2003 and June 2005) in English or Swahili as per patient preference. Interviewers were trained in rapport building and non-judgmental information gathering. The reference period for all measures was six-months. Study participants provided written informed consent. Ethical approval for the study was obtained from the Kenyatta National Hospital Ethical Research Committee and the Ethical Review Committee of the Population Council.

Study variables and measures

A regular partner was defined as a spouse or cohabiting sexual partner. A casual partner referred to a partner with whom the respondent had sex infrequently and was not living with or married to. A sex worker was a partner to whom money was paid in exchange for sex. Condom use at last sex referred to the most recent sexual act in the last six-months. Consistent condom use was defined as always using condoms in the past six-months; it was assessed as 'always', 'sometimes', 'never' and excluded last sex. UPS was defined as condoms not used at last sex or inconsistent condom use in the last six-months. STIs were self-reported episodes of genital discharge (GD) or genital ulcer (GU) in the past six-months; laboratory confirmation of STI was not available. Respondents were asked to report whether they knew their partner's HIV-status and whether they had disclosed their own HIV-status to

their partners. Economic status was derived from type of housing and ownership of assets; the scores were categorised into quartiles (Q).

Statistical methods

SPSS 11.0 (SPSS, Inc., Chicago, IL, USA) was used for statistical analysis. Chi-square tests were used to compare socio-demographic characteristics and behaviours between groups. Logistic regression analysis was undertaken to determine predictors of sexual activity and UPS in the last six-months. Variables found to be associated with sexual activity and UPS by having odds ratios that reached significance ($P < 0.05$) on univariate analysis were included in multivariate models.

RESULTS

Socio-demographic characteristics

We interviewed 179 HIV-infected persons six-months after initiating HAART (first line regimen: stavudine, lamivudine plus nevirapine or efavirenz) and 143 HIV-infected persons receiving PT with cotrimoxazole and/or isoniazid for median of six-months (IQR:5, 7). Mean age of participants was 37 years (SD:8 years). There were no differences between groups with regard to age, marital status, sex or educational level (Table 1). Participants receiving PT were more likely to be employed ($P=0.007$) and belong to higher economic status ($P=0.01$) than those receiving HAART. For participants receiving HAART, the median CD4 cell-count at start of treatment was 100cells/mm³ (IQR:50, 152) and median increase in CD4 cell-counts over six-months was 216cells/mm³ (IQR:128, 334). CD4 cell-counts were not available for those receiving PT.

Sexual activity

Forty-five percent of study participants reported sexual intercourse in the reference period. There was no difference in self-reported sexual activity between participants receiving HAART and those receiving PT (44% and 47%; $P=0.476$). Sex, education, employment and study group were not associated with sexual activity. On multivariate analysis, age and marital status emerged as independent predictors of sexual activity. Older participants were less likely to report sex than younger patients (OR:0.94 per unit increase in age; 95%CI:0.91-0.97; $P=0.001$). Married or

cohabiting respondents were 8.3 times more likely to report sex than single/divorced/widowed respondents (95%CI=4.96-14.14; $P<0.001$)

Table 1: Socio-demographic characteristics of participants receiving HAART and participants receiving PT at HIV care clinics in Mombasa

| | HAART % (n=179) | PT % (n=143) | P-value |
|------------------------------|--------------------|-----------------|---------|
| Age (years) | | | |
| <30 | 24 (42) | 28 (40) | |
| 31-40 | 45 (81) | 45 (64) | |
| >41 | 31 (56) | 27 (39) | 0.585 |
| Sex | | | |
| Male | 35 (63) | 34 (49) | |
| Female | 65 (116) | 66 (94) | 0.862 |
| Education level | | | |
| Never attended school | 7 (13) | 14 (20) | |
| < 7 years school | 47 (84) | 39 (55) | |
| 8-12 years school | 40 (71) | 41 (59) | |
| College/technical/university | 6 (11) | 6 (9) | 0.181 |
| Marital status | | | |
| Married/cohabiting | 48 (86) | 45 (64) | |
| Single | 12 (21) | 12 (17) | |
| Widowed/separated | 40 (72) | 43 (62) | 0.830 |
| Employment | | | |
| Yes | 18 (33) | 32 (45) | |
| No | 82 (146) | 69 (98) | 0.007 |
| Economic status | | | |
| Lower ES (Q1) | 18 (33) | 7 (10) | |
| Middle ES (Q2) | 55 (99) | 61 (87) | |
| Higher ES (Q3&4) | 26 (47) | 32 (46) | 0.010 |

Sexual partners

The majority of sexually active study participants reported sex with one partner (136/146). Patients receiving HAART were less likely to report multiple partners than those receiving PT ($P=0.006$) (Table 2). The majority of respondents reported sex with regular partners. No male-to-male sex was reported. More participants receiving HAART reported sex with regular partners ($P=0.044$) and fewer with casual partners ($P<0.001$) than those receiving PT.

Over 40 percent of respondents in both groups were unaware of the HIV-status of their regular partners. There was no difference between groups with regard to knowledge of partner's status or

disclosure of HIV-status to regular partners (Table 2). Similarly, the majority of respondents in both groups did not know the HIV-status of and did not disclose their HIV-status to their casual and sex worker partners (Table 2).

Table 2: Sexual risk behaviour variables by study group

| Variable | HAART % (n/N) | PT % (n/N) | P-value |
|-------------------------------|------------------|---------------|---------------------|
| Number of partners (n=146) | | | |
| One | 99 (77/78) | 87 (59/68) | 0.006 ¹ |
| > two | 1 (1/78) | 13 (9/68) | |
| Type of partners (n=146) | | | |
| Regular | 97 (76/78) | 88 (59/68) | 0.044 |
| Casual | 2 (2/78) | 23 (15/68) | <0.001 ¹ |
| Sex-worker | 1/78 | 1/68 | |
| Knowledge of partner status | | | |
| Regular (n=135) | | | |
| HIV-positive | 45 (34/76) | 36 (21/59) | |
| HIV-negative | 13 (10/76) | 24 (14/59) | |
| Unknown | 42 (32/76) | 41 (24/59) | 0.248 |
| Casual (n=17) ² | | | |
| HIV-positive | - | 4/15 | |
| HIV-negative | - | 2/15 | |
| Unknown | 2/2 | 9/15 | - |
| Sex-worker (n=2) ² | | | |
| Unknown | 1/1 | 1/1 | - |
| Disclosed status to | | | |
| Regular (n=135) | 82 (62/76) | 73 (43/59) | 0.228 |
| Casual (n=17) ² | 0/2 | 10/15 | - |
| Sex-worker (n=2) ² | 1/1 | 0/1 | - |
| Condom use with | | | |
| Regular (n=135) | | | |
| At last-sex | 93 (71/76) | 77 (45/59) | 0.012 |
| Consistently last 6-months | 53 (40/76) | 22 (13/59) | <0.001 |
| Casual (n=17) ² | | | |
| At last-sex | 2/2 | 5/15 | - |
| Sex-worker (n=2) ² | | | |
| At last-sex | 0/1 | 0/1 | - |

¹Fisher's exact test; ²Absolute numbers, statistical testing not undertaken

Condom use with partners

Participants receiving HAART were more likely to report condom use at last sex (OR:4.1; 95%CI:1.37-12.28) and consistent condom use (OR:3.9; 95%CI:1.83-8.43) with regular partners than those receiving PT (Table 2). More participants receiving HAART reported consistent condom use with HIV-positive partners (56%vs.14%; $P=0.004$) and partners of unknown status (56%vs.16%; $P=0.004$) than those receiving PT. There was no difference between groups with regard to HIV-negative partners (30%vs.42%).

Participants receiving HAART were more likely to report condom-use with casual partners; there was no difference with regard to sex-workers (Table 2)

Sexually transmitted infections (STI)

Participants receiving PT were more likely to report STI symptoms (22%vs.13%; OR:1.7; 95%CI:0.98-2.81; $P=0.059$) than those receiving HAART (GU: 27%vs.18%; OR:1.9; 95% CI:1.41-3.45; $P=0.03$; GD:15%vs.9%; $P=0.12$). Women respondents were more likely to report STI symptoms (30%vs.8%; OR:4.91;95% CI:2.33-10.31; $P<0.001$) compared to men (GU: OR:3.05; 95%CI:1.43-6.51; $P=0.005$; GD: OR:22.310; 95%CI:3.01-165.21; $P<0.001$). There were no differences between groups in seeking treatment (82%vs.76%) and informing partners about the STI (59%vs.58%).

Factors associated with unprotected sex with regular partners

Sixty-percent of respondents reported UPS with regular partners in the last six-months. Patients receiving PT were more likely to report UPS than those on HAART (78%vs.47%; $P<0.001$).

On univariate analysis, male respondents, married respondents and those receiving PT were more likely to report UPS. Partner's HIV-status, disclosure of HIV-status, number of partners, reporting an STI were not found to be associated with UPS. On multivariate analysis, married or cohabiting respondents were three times more likely to report UPS with regular partners. After controlling for marital status and therapy, gender was no longer a significant predictor for UPS. Patients receiving PT were four times more likely to report UPS than those receiving HAART when adjusted for marital status and gender ($P<0.001$).

Table 3: Multivariate analysis of predictors of unprotected sex with regular partners (n=135)

| Variable | Univariate OR (95% CI) | P-value | Multivariate OR (95% CI) | P-value |
|---|------------------------|---------|--------------------------|---------|
| Age (years) ¹ | | | | |
| <30 (n=44) | 1.0 | | | |
| 31-40 (n=62) | 0.997 (0.455-2.204) | 0.994 | | |
| >41 (n=29) | 0.892 (0.343-2.321) | 0.815 | | |
| Sex | | | | |
| Female (n=80) | 1.0 | | 1.0 | 0.111 |
| Male (n=55) | 2.097 (1.012-4.349) | 0.047 | 1.934 (0.860-4.349) | |
| Marital status | | | | |
| Single/widowed/divorced (n=32) | 1.0 | | | |
| Married/cohabiting (n=103) | 3.535 (1.547-8.081) | 0.003 | 3.067 (1.251-7.519) | 0.014 |
| Education (years) ¹ | | | | |
| <7 (n=68) | 1.0 | | | 0.915 |
| >7 (n=67) | 1.038 (0.520-2.072) | | | |
| Number of sexual partners ¹ | | | | |
| One (n=127) | 1.0 | | | |
| ≥2 (n=8) | 2.009 (0.390-10.337) | 0.404 | | |
| Partner's HIV-status ¹ | | | | |
| HIV-positive (n=55) | | | | |
| HIV-negative (n=24) | 1.111 (0.414-2.981) | 0.834 | | |
| Unknown (n=56) | 1.030 (0.482-2.205) | 0.939 | | |
| Disclosure of own HIV-status ¹ | | | | |
| Yes (n=105) | 1.0 | | | 0.348 |
| No (n=30) | 0.675 (0.298-1.532) | | | |
| STI ¹ | | | | |
| No (n=101) | 1.0 | | | |
| Yes (n=34) | 1.253 (0.559-2.810) | 0.585 | | |
| HAART (n=76) | 1.0 | | | |
| PT (n=59) | 3.932 (1.834-8.430) | <0.001 | 1.0 | 0.005 |
| | | | 4.269 (1.902-9.581) | |

¹ not included in multivariate model. Logistic Regression Analysis

DISCUSSION

There has been widespread concern that providing antiretroviral therapy to HIV-infected patients may lead to an increase in sexual activity and sexual risk behaviour. Fifty-five percent of our study population was sexually inactive; the proportions were similar among patients receiving ART and those receiving PT. Despite marked improvements in health status of patients on HAART (mean CD4 cell count increase: 239 cells/mm³) there was no difference in self-reported sexual activity between the two groups six-months after treatment. Our findings are similar to those reported from Uganda⁽⁹⁾ and Cote d'Ivoire.⁽¹¹⁾

We found fewer multiple partners and fewer casual partners among PLHA receiving HAART compared to those receiving PT, consistent with findings from Cote d'Ivoire.⁽¹¹⁾ Overall twelve percent of our sexually active participants reported casual partners; Bateganya (2005) report a much higher proportion (around 35% among ART-experienced and ART-naïve respondents).⁽⁹⁾ Our findings are also consistent with those reported from Uganda⁽⁹⁾ and Cote d'Ivoire⁽¹¹⁾ with regard to a higher proportion of participants on HAART reporting condom use with regular partners compared to those not receiving HAART.

Although sexual risk behaviour was lower among patients receiving HAART compared to those receiving PT, it is important to emphasize that risk of HIV-transmission remains. More than forty percent of respondents in both groups reported regular partners of unknown status and between 13-24 percent of respondents reported HIV-negative regular partners. Overall sixty percent of respondents reported UPS with regular partners, a third with casual partners and all with sex workers in the last six months. Importantly, almost half the respondents receiving HAART (14/32) and more than four-fifths (20/24) receiving PT who had regular partners of unknown status did not use condoms consistently; and around two-thirds of respondents receiving HAART (7/10) and those receiving PT (8/14) who had HIV-negative regular partners did not use condoms consistently. Although disclosure rates to regular partners were slightly higher in patients receiving HAART, almost a fifth of the sexually active respondents did not disclose their HIV-status to regular partners, and more than two-thirds to casual and sex-worker partners. Lack of knowledge of partner's serostatus and low levels of disclosure of HIV-status, coupled with inconsistent condom use sets the stage for HIV transmission to sero-discordant partners, especially in regular partner relationships. Bunnell (2006) reports from Uganda that 85 percent⁽¹⁰⁾ of risky sexual acts occurred within married couples.⁽¹⁰⁾ In such a setting the risk of HIV-transmission of resistant viral strains and re-infection with new strains

poses a serious public health risk.⁽⁶⁻⁷⁾ UPS can also carry the risk of unwanted pregnancy and subsequent HIV-transmission to the child.

STIs are often used as epidemiological markers of UPS. In our study patients receiving PT were more likely to report STI symptoms in the last six-months than patients on HAART. We also found that women were more likely to report STI symptoms than men. In the absence of confirmatory laboratory results it is difficult to assess how many of the reported GD/GU were actual STIs.

Although prevention is stressed during counselling around HIV-testing and at the time of initiating ART, most counselling in HIV care services is directed toward treatment adherence. Patients on HAART in this study received at least three preparatory counselling sessions on adherence followed by ongoing support. This emphasis on adherence may have contributed to the differences between groups. Additionally patients receiving HAART may perceive the seriousness of their illness differently, which could modify sexual behaviour.

Traditionally, the focus of HIV prevention programs has been on high-risk groups. For HIV-positive persons' counselling on prevention occurs mostly around HIV-testing, at the time of initiating ART and PMTCT services for women. Prevention messages emphasizing sero-status disclosure, partner-testing, and consistent condom use with all partners are needed on an ongoing basis in HIV care services.

This study has limitations. A cross-sectional study does not address the change in sexual behaviour over time. Although well trained research staff, unlinked to the health facility, interviewed patients, recall and social desirability biases may have occurred. Our study used self-reports to elicit information on sexual behaviours; however we feel that this does not unduly influence our results as almost sixty-percent of sexually active respondents reported UPS in the last six months. Reviews of validity and reliability of HIV research have found that sexual behaviour data are fairly consistent and self-reported data on sexual acts and condom use are reasonably congruent especially for infrequent acts and relatively short recall periods.⁽¹²⁾ We did not distinguish between types of sexual intercourse (vaginal or anal) but limited the enquiry to penetrative sexual intercourse.

The study design is strengthened by the fact that we had a comparison group and that the patients in that group (receiving PT) were exposed to health workers, received prevention messages and some form of treatment making them comparable to the HAART group and thereby minimizing biases.

In conclusion we found that sexual risk behaviour is a concern among HIV-positive persons accessing HIV-care services although treatment with HAART is not associated with higher sexual risk behaviour. Prevention interventions targeting HIV-positive persons are needed on an ongoing basis in HIV care services.

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Results: Safety, acceptability and effectiveness of HIV prevention strategies among most-at-risk populations

- Assessment of peer-mediated behaviour change intervention 5.1
- Assessment of female condom intervention 5.2
- Assessment of diaphragm intervention 5.3, 5.4 and 5.5



Photo credit: ICRH. "HIV Prevention Edutainment" conducted by the International Centre for Reproductive Health in Mombasa, Kenya.

5.1 Impact of five years of peer-mediated interventions on sexual behaviour and sexually transmitted infections among female sex workers in Mombasa, Kenya.

Impact of five years of peer-mediated interventions on sexual behaviour and sexually transmitted infections among female sex workers in Mombasa, Kenya

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ABSTRACT

Background: Since 2000, peer-mediated interventions among female sex workers (FSW) in Mombasa Kenya have promoted behavioural change through improving knowledge, attitudes and awareness of HIV serostatus, and aimed to prevent HIV and other sexually transmitted infection (STI) by facilitating early STI treatment. Impact of these interventions was evaluated among those who attended peer education and at the FSW population level.

Methods: A pre-intervention survey in 2000, recruited 503 FSW using snowball sampling. Thereafter, peer educators provided STI/HIV education, condoms, and facilitated HIV testing, treatment and care services. In 2005, data were collected using identical survey methods, allowing comparison with historical controls, and between FSW who had or had not received peer interventions.

Results: Over five years, sex work became predominately a full-time activity, with increased mean sexual partners (2.8 versus 4.9/week; $P < 0.001$). Consistent condom use with clients increased from 28.8% (145/503) to 70.4% (356/506; $P < 0.001$) as well as the likelihood of refusing clients who were unwilling to use condoms (OR = 4.9, 95%CI = 3.7-6.6). In 2005, FSW who received peer interventions (28.7%, 145/506), had more consistent condom use with clients compared with unexposed FSW (86.2% versus 64.0%; AOR = 3.6, 95%CI = 2.1-6.1). These differences were larger among FSW with greater peer-intervention exposure. HIV prevalence was 25% (17/69) in FSW attending ≥ 4 peer-education sessions, compared with 34% (25/73) in those attending 1-3 sessions ($P = 0.21$). Overall HIV prevalence was 30.6 (151/493) in 2000 and 33.3% (166/498) in 2005 ($P = 0.36$).

Conclusions: Peer-mediated interventions were associated with an increase in protected sex. Though peer-mediated interventions remain important, higher coverage is needed and more efficacious interventions to reduce overall vulnerability and risk.

BACKGROUND

Despite 25 years of HIV prevention, in many settings HIV incidence remains high in the general population and especially among most-at-risk groups [1]. In particular, women in sub-Saharan Africa remain disproportionately affected by HIV, which reflects and reinforces underlying gender inequities. Female sex workers (FSW), estimated to number tens of millions worldwide [2], are highly vulnerable to acquiring and transmitting sexually-transmitted infections (STI) including HIV [3]. Targeting most-at-risk groups such as FSW is a key strategy for preventing HIV in both concentrated and generalized HIV epidemics [2,4,3].

Preventing HIV among FSW requires implementation of evidence-based interventions, adapted to local circumstances [5,6]. Data supports the effectiveness of FSW interventions which address the conditions and context of sex work, including targeted condom promotion and distribution; skills development (such as condom negotiation); STI/HIV education; and STI treatment [7-13]. Though several studies have shown peer-educators can effectively deliver these interventions [3,14-16], additional evidence is needed of the impact of outreach and peer-networks in diverse settings, and sustainability over longer periods of time. Using a before-after design with a baseline cross-sectional survey in 2000 and repeated in 2005, we aimed to evaluate the impact of five years of peer-mediated STI/HIV prevention interventions among FSW in Mombasa, Kenya. Historical and internal controls are compared to evaluate changes in HIV-related knowledge and attitudes, behavior, and STI/HIV prevalence.

METHODS

Setting and population

Mombasa, in Kenya's Coast province, is a major economic centre in the region, with important tourism, port, rail and industrial enterprises, as well as a large FSW population. The study took place in a division of Mombasa, Kisauni, which has around 250 000 inhabitants, 70 000 households and a population density of 2 278 inhabitants/km² [17]. More than half the population of Kenya lives on less than \$2 a day and the Gross Domestic Product per person is an estimated \$547 [18]. The population studied consisted of FSW, defined as any woman who reported having received money or gifts in exchange for sex in the past year. Sex workers are either full- or part-time, and work from bars, hotels, streets and homes. They frequently also are involved in other small businesses,

including selling foodstuffs, vegetables, and in some areas, local brew on the roadside. Commonly the clients of sex workers are employed at local factories or are *matatu* (minibus taxi) touts [19].

Intervention project

Between 2000 and 2005, the International Centre for Reproductive Health in collaboration with Family Health International (FHI) implemented a peer-mediated FSW intervention in Mombasa (IMPACT project). This aimed to reduce unprotected sex acts by increasing condom use and reducing the number of sexual partners; and secondly to empower FSW to control their working and social lives by increasing their knowledge of STI/HIV and condom negotiation skills. Finally it aimed to reduce co-factors associated with HIV transmission by providing information on, and referrals for STI treatment, and HIV testing and counseling.

Sixty-two FSW from Kisauni division were selected and trained as peer educators in 2000; 57 of whom were retained throughout the five-year period. Peer educators were selected through key informants (bar maids, patrons) at identified hotspots in the area. Study staff aimed to select FSW who were willing to be a peer leader, had a substantial network of peers, were likely to remain in the area for an extended period, and had some knowledge of the key topics. Those selected, attended a five-day training course on STI/HIV signs and symptoms; STI/HIV prevention and treatment; promotion and distribution of male and female condoms; and teaching of safe sex negotiation skills. Six-day advanced and three-day refresher training was provided midway in the project. Peer educators acted as links between the local FSW community and the project, facilitating local involvement and participation. They conducted one-on-one or weekly-group sessions, mostly in the houses of FSW or at a drop-in centre based within the community. Besides functioning as training and meeting facility, the drop-in centre was used for distributing information, education and communication (IEC) materials and condoms, and for voluntary counselling and testing (VCT) services. Diverse mediums were used to transfer knowledge and health promotion messaging, such as peer-mediated drama, role playing exercises, use of picture codes (visual images used for engaging discussion on sensitive topics) and video sessions. Peer-led activities occurred throughout the five-year period at a relatively constant rate. Peer educators also led monthly community gatherings with active participation of FSW, youth and other community members. These provided HIV education, condom promotion and other risk-reduction activities and were accompanied by mobile VCT services, facilitating entry to HIV testing. A field coordinator updated peer educators on

new developments in HIV prevention and regularly attended peer-education sessions to monitor the accuracy of information given and to assist in responding to questions.

Study design

Over a two-month period, in February-March 2000 and October-November 2005, we conducted pre- and post-intervention cross-sectional surveys. To enhance comparison, the repeat survey adhered to the design and methodology of the pre-intervention survey, detailed previously [20]. In brief, initial respondents (seeds) were identified from bars, guest houses and the street, with subsequent participants recruited using snowball sampling. To limit potential for friendship bias, we restricted the maximum number of women recruited through one participant to 10. Eligible participants were self-reported FSW, older than 16 years and working within Kisauni. Peer educators were excluded from participation in the repeat survey.

Study procedures were performed by qualified staff at the drop-in centre. These procedures included structured questionnaires; VCT; collection of blood plasma and urine samples; and gynecological examination, with speculum insertion and collection of endocervical and high vaginal swabs. Where indicated, FSW received STI treatment as per the Kenya STI guidelines free of charge. Women were encouraged to learn their HIV status and offered same day HIV testing and counseling, using on-site serial testing. Those who tested positive for HIV were referred to a comprehensive HIV care clinic where antiretroviral treatment is provided at no cost for those requiring it.

Laboratory investigations

Investigations for HIV, syphilis, *Neisseria gonorrhoeae* and *Chlamydia trachomatis* were performed in 2000, with methods previously described [20]. In the repeat survey, parallel rapid HIV testing was done in the laboratory with Determine™ HIV-1/2 (Abbott Laboratories by Abbott Japan co Ltd, Minato-Ku, Tokyo, Japan) and Uni-Gold™ HIV (Trinity Biotech plc, Bray, Ireland). For five discordant HIV results, an enzyme-linked immunosorbent assay was performed as tie-breaker (all five were HIV seronegative). A rapid plasma reagin test (Human GmbH, Weisbaden, Germany) was used for syphilis screening. Endocervical secretions were tested for gonococcus using gram stain and culture with blood agar (International Diagnostic Group, Lancashire, United Kingdom). Chlamydia was not analyzed in the 2005 survey due to financial constraints, but additional tests were performed,

including a wet mount preparation to identify candida and *Trichomonas vaginalis*, as well as a gram stain to detect bacterial vaginosis (diagnosed with Nugent's criteria).

Data management and statistical analysis

Data were double entered by separate clerks. Following data checking and cleaning, Intercooled Stata 8.0 (Stata Corporation, College Station, Texas, USA) was used for statistical analysis. A standard WHO framework was used to assess risk measures within three categories: unprotected sex (number of partners and condom use); empowerment of sex workers (knowledge and condom negotiation); and HIV transmission efficiency (when condoms fail or are not used) [5]. Reproductive tract infections (RTI) such as syphilis and gonococcus were considered important co-factors of HIV transmission efficiency and analyzed within this category. This strategic framework provides a systematic means of assessing desired outcomes of HIV prevention services for FSW. Sexual partners of FSW were categorized as: emotional partners (husband/boyfriend) or clients (regular clients and casual one-time clients).

Analysis included descriptive statistics of the distribution and central values of socio-demographic and sex work characteristics, and indicators of sexual behavior. Significance testing was done to compare differences in participants' characteristics using chi-square and unpaired Student's *t* tests.

To evaluate overall effects of the project (assuming that peer-mediated interventions influence norms in the whole population), we compared outcomes in the 2005 sample of FSW with those in 2000. Odds ratio's (OR) with 95% confidence intervals (CI) were calculated.

Using the 2005 data set, effects of individual-level exposure to peer interventions were determined by comparing women who had ever attended a peer-education session with those who had not. To determine whether the number of peer-education sessions attended had an effect on outcomes, we compared women who had attended four or more peer education sessions in the past six months with those who had attended fewer sessions. Logistic regression models were constructed to control for potential confounding, giving adjusted odds ratios (AOR) of the association between exposure to peer-mediated services and outcome variables. Age, marital status, education and place of work were included in multivariable models.

Ethical approval

Written informed consent was obtained from all participants before study entry. For both surveys, ethical approval was obtained from the Kenyan national ethics committee at Kenyatta National Hospital (Ethics and Research Committee) and from the Protection of Human Subjects Committee of FHI, USA.

RESULTS

The number of study participants was 503 in 2000 and 506 in 2005. Comparing the population in 2000 and 2005, relatively small differences were seen in age and income (Table 1). Larger changes had occurred in marital status, proportion of women in full-time sex work and workplace (from homes and guest-houses in 2000 to mainly bars and nightclubs in 2005). While the proportion of single women remained unchanged, in 2000 a substantial proportion (39.4%) were married or cohabiting, compared with only 2.5% in 2005. Sex work had changed from a predominately part-time to full-time activity; women with an alternative source of income decreased from 67.0% to 37.7% ($P < 0.001$). Most women in 2005 reported usually receiving payment for sex with cash (86.6%; 438/506), with the remainder receiving a combination of cash and gifts, clothing or food. In both time periods, about 90% of FSW had one or more children.

In the 2005 survey, 28.7% (145/506) reported having attended peer-mediated interventions at least once. In the past six months, 78.6% (114/145) of these women had attended peer-education sessions, a median of four times (IQR = 2–7). Eighty four percent of FSW who attended peer education had one-on-one sessions with peer educators (122/145). In a multiple-response question, women reported having participated in peer-mediated drama (43%; 62/145), role plays (41%; 59/145), picture code (32%; 47/145) and video sessions (3%; 4/145). About half (55%; 80/145) the women who received peer interventions reported that a peer educator had referred them to HIV testing.

Population-level effects, comparing female sex workers in 2000 and 2005

Unprotected sex

With more women reliant solely on sex work for their income in 2005, the mean number of sexual partners increased from 2.8 to 4.9 per week ($P < 0.001$). Merely 7.0% of women had four or more one-time clients per week in 2000; this increased to 33.2% in 2005 (OR = 6.6, 95%CI = 4.4–10.2; P

< 0.001; Table 2). These changes were accompanied by marked increase in condom use with clients, in last sex act (47.3% versus 85.8%; $P < 0.001$) as well as in consistent use, from 28.8% to 70.4% (OR = 5.9, 95%CI = 4.4–7.8; $P < 0.001$). No improvements were achieved with emotional partners, where still 80% of women did not use condoms consistently.

Table 1. Participant's socio-demographic and socio-economic characteristics

| | N | 2000 survey | | N | 2005 survey | | P-value* |
|---|-----|-------------|--------|-----|-------------|--------|----------|
| Age, mean years (sd) | 503 | 31.0 | (8.8) | 504 | 29.5 | (7.5) | 0.004 |
| Marital status, % (number of women) | 503 | | | 506 | | | |
| Single | | 43.9% | (221) | | 43.1% | (218) | |
| Married / cohabiting | | 39.4% | (198) | | 2.8% | (14) | |
| Separated / divorced | | 15.1% | (76) | | 46.6% | (236) | |
| Widowed | | 1.6% | (8) | | 7.5% | (38) | <0.001 |
| Education, % (number of women) | 502 | | | 506 | | | |
| None | | 19.3% | (97) | | 10.1% | (51) | |
| Primary level | | 60.0% | (301) | | 60.3% | (305) | |
| Secondary level | | 18.5% | (93) | | 27.1% | (137) | |
| Tertiary level | | 2.2% | (11) | | 2.6% | (13) | <0.001 |
| Religion, % (number of women) | 502 | | | 506 | | | |
| Catholic | | 17.1% | (86) | | 28.9% | (146) | |
| Muslim | | 55.2% | (277) | | 32.4% | (164) | |
| Protestant | | 26.7% | (134) | | 37.2% | (188) | |
| Other | | 1.0% | (5) | | 1.6% | (8) | <0.001 |
| Number of living children, % (number of women) | 503 | | | 506 | | | |
| 0 | | 7.6% | (38) | | 12.9% | (65) | |
| 1 | | 22.9% | (115) | | 28.1% | (142) | |
| 2-3 | | 38.0% | (191) | | 41.5% | (210) | |
| > 3 | | 31.6% | (159) | | 17.6% | (89) | <0.001 |
| Weekly income from sex work alone, mean USD (sd) | 503 | 19.9 | (16.9) | 506 | 22.5 | (15.8) | 0.01 |
| Alternative source of income, % (number of women) | 503 | | | 506 | | | |
| None | | 33.0% | (166) | | 62.3% | (315) | |
| Formal employment | | 1.8% | (9) | | 1.4% | (7) | |
| Informal trade | | 61.6% | (310) | | 31.6% | (160) | |
| Other | | 3.6% | (18) | | 4.7% | (24) | <0.001 |
| Where clients usually obtained, % (number) | 502 | | | 506 | | | |
| Home | | 47.8% | (240) | | 15.9% | (81) | |
| Hotel / guest house | | 40.0% | (201) | | 0.8% | (4) | |
| Bar / nightclub | | 9.4% | (47) | | 75.5% | (382) | |
| Street / beach | | 2.2% | (11) | | 7.5% | (38) | |
| Other | | 0.6% | (3) | | 0.2% | (1) | <0.001 |

* P-value was calculated using chi-square test for categorical and unpaired Student's *t* test for continuous variables.

Exchange rate of 1USD: 74 Kenya Shillings

Table 2. Sexual behavior and reproductive tract infections among female sex workers in 2000 and 2005, and a comparison between those in 2005 who had or had not received peer-mediated interventions

| | 2000 survey | 2005 survey | OR* (95%CI) | Non peers | Peers | AOR** (95%CI) |
|--|-----------------|-----------------|-----------------|-----------------|-----------------|----------------|
| UNPROTECTED SEX | | | | | | |
| Total years in sex work, mean (sd) | 9.2 (7.8) | 5.6 (7.0) | - | 5.5 (4.7) | 6.1 (5.1) | - |
| ≥ 4 sexual partners in past week | 29.2% (147/503) | 48.0% (243/506) | 2.2 (1.7-2.9) | 50.7% (183/361) | 41.4% (60/145) | 0.8 (0.5-1.1) |
| ≥ 4 casual onetime clients in past week ^s | 7.0% (33/472) | 33.2% (148/446) | 6.6 (4.4-10.2) | 35.9% (115/320) | 26.2% (33/126) | 0.7 (0.5-1.2) |
| Used a condom with last client | 47.3% (238/503) | 85.8% (434/506) | 6.7 (4.9-9.2) | 82.6% (298/361) | 93.8% (136/145) | 3.5 (1.6-7.4) |
| Always used a condom with clients | 28.8% (145/503) | 70.4% (356/506) | 5.9 (4.4-7.8) | 64.0% (231/361) | 86.2% (125/145) | 3.6 (2.1-6.1) |
| Always used a condom with boyfriend / husband ^d | 20.3% (66/325) | 20.1% (60/298) | 1.0 (0.7-1.5) | 17.6% (37/210) | 26.7% (24/90) | 1.7 (1.0-3.1) |
| SEX WORKER EMPOWERMENT | | | | | | |
| Own idea to use the condom at last sex | 89.9% (214/238) | 90.3% (392/434) | 1.0 (0.6-1.8) | 88.3% (263/298) | 94.9% (129/136) | 2.3 (1.0-5.5) |
| Provided the condom at last sex herself | 72.7% (173/238) | 71.2% (309/434) | 0.9 (0.6-1.3) | 68.5% (204/298) | 77.2% (105/136) | 1.6 (1.0-2.6) |
| HIV-related knowledge and attitudes | | | | | | |
| Thinks a client might be HIV-infected | 22.1% (111/502) | 30.6% (154/504) | 1.5 (1.2-2.1) | 30.0% (108/360) | 31.3% (45/144) | 1.2 (0.8-1.8) |
| Knows people with HIV can look healthy | 95.6% (481/503) | 94.2% (474/503) | 0.7 (0.4-1.4) | 92.8% (334/360) | 97.2% (141/145) | 3.0 (1.0-9.1) |
| Mentions advantage to knowing HIV status | 78.3% (393/503) | 94.4% (475/503) | 4.7 (3.0-7.6) | 93.0% (334/359) | 97.9% (142/145) | 3.2 (0.9-11.3) |
| Knows ≥2 symptoms of STI in women | 81.9% (412/503) | 66.4% (336/506) | 0.4 (0.3-0.6) | 61.2% (221/361) | 79.3% (115/145) | 2.7 (1.6-4.3) |
| Cited ≥2 ways to prevent STI | 43.9% (221/503) | 30.4% (154/506) | 0.6 (0.4-0.7) | 23.8% (86/361) | 46.9% (68/145) | 2.8 (1.9-4.3) |
| Ever refused client unwilling to use condoms | 41.4% (208/503) | 77.7% (393/506) | 4.9 (3.7-6.6) | 75.4% (272/361) | 83.5% (121/145) | 1.7 (1.0-2.8) |
| TRANSMISSION EFFICIENCY | | | | | | |
| Awareness of own HIV status | 5.2% (26/503) | 40.2% (203/505) | 12.3 (7.9-19.8) | 38.2% (138/361) | 44.8% (65/145) | 1.4 (0.9-2.1) |
| Self reported history of RTI in past year | | | | | | |
| Excessive or foul smelling vaginal discharge | 20.9% (105/503) | 47.2% (239/506) | 3.4 (2.5-4.5) | 48.8% (176/360) | 43.5% (63/145) | 0.8 (0.5-1.2) |
| Genital ulcer | 11.1% (56/503) | 19.6% (99/505) | 1.9 (1.3-2.8) | 21.1% (76/361) | 16.6% (24/145) | 0.8 (0.5-1.3) |
| RTI prevalence | | | | | | |
| Syphilis infection | 2.0% (10/500) | 2.0% (10/498) | 1.0 (0.4-2.4) | 2.5% (9/235) | 0.7% (1/142) | 0.3 (0.04-2.3) |
| Chlamydia infection | 4.2% (21/502) | - | - | - | - | - |
| Gonorrhoeal infection | 1.8% (9/502) | 1.0% (5/484) | 0.6 (0.1-1.9) | 1.2% (4/432) | 0.7% (1/142) | 0.6 (0.7-5.9) |
| Trichomonas vaginalis infection | - | 20.4% (100/490) | - | 21.8% (76/348) | 16.9% (24/142) | 0.7 (0.5-1.2) |
| Bacterial vaginosis infection | - | 46.5% (205/441) | - | 47.8% (149/312) | 43.4% (56/129) | 0.9 (0.6-1.3) |
| Candida infection | - | 22.4% (110/491) | - | 21.0% (73/348) | 25.9% (37/143) | 1.5 (0.9-2.3) |

Notes to Table 2:

RTI reproductive-tract infection. Cells contain %, n/N unless indicated.

[^]Sexual partners are classified: boyfriend/husband, regular clients and one-time clients

[§]Among those women having had a one-time client in the past week

[£]Among those women who reported having a boyfriend / husband

[†]H₀:odds ratio=1

^{**}AOR, odds ratio adjusted for age, marital status, education and place of work. Associations in the category "Sex worker empowerment" were also adjusted for education. Logistic regression was used to calculate AOR.

Sex worker empowerment

Among women reporting to have used a condom during last sex with a paying client, approximately 90% in both surveys mentioned this was their idea, and around 70% provided the condom themselves. The proportion of women who mentioned there is an advantage to knowing once HIV status was higher in 2005 (94.4% versus 78.3%; $P < 0.001$). An increase was also seen in the proportion of women who had ever refused one or more clients unwilling to use condoms from 41.4% to 77.7% (OR = 4.9, 95%CI = 3.7–6.6; $P < 0.001$). Still, of the 150 women in 2005 who reported inconsistent condom use with clients, 93 (62.0%) cited 'client refusal' as the reason for inconsistent use.

Reduced transmission efficiency

Being aware of HIV status increased markedly from 5.2% in 2000 to 40.2% in 2005. Syphilis prevalence remained unchanged, though increases had occurred in history of genital ulcer disease or abnormal vaginal discharge.

Individual-level effects, comparing those who had or had not received peer-mediated interventions

Those who had received peer-mediated interventions (peers) had a similar age, marital status, education and income to women who had never received peer interventions (non peers) (data not shown). However, compared with non-peers, peers were more likely to be muslim (42.8% versus 28.3%; $P = 0.019$) and to work from home (24.8% versus 12.5%; $P = 0.002$).

Individuals exposed to peer education had more consistent condom use with clients (86.2% versus 64.0%; $P < 0.001$; Table 2). After adjusting for age, marital status, place of work and education, peers were 2.3 times more likely to suggest condom use (95%CI = 1.0–5.5; $P = 0.05$) and 1.7 times more likely to refuse clients unwilling to use condoms (95%CI = 1.0–2.8; $P = 0.04$). Peers had higher levels of knowledge on HIV and STI than non-peers. Specifically, 79.3% (115/145) of peers compared with 61.2% (221/361) of non-peers knew ≥ 2 symptoms of STI in women, 46.9% (68/145) of peers cited ≥ 2 ways to prevent STI, compared with 23.8% (86/361) of non-peers. These differences were statistically significant ($P < 0.001$).

When comparing STI in peers with non-peers, no significant differences were noted, but all differences were in the same direction. Curable STI (infection with syphilis, gonorrhea or trichomoniasis) were detected in 18.3% (26/142) of FSW who had received peer-mediated interventions, compared with 24.4% (85/348) in those unexposed ($P = 0.14$).

Effects of number of peer-education sessions attended

Women who had attended four or more peer education sessions in the past six months reported less sexual partners and higher levels of protected sex than women who attended fewer sessions (Table 3). These women had a lower prevalence of all STI (including HIV), but these differences were not statistically significant. Prevalence of curable STI among those attending only one to three peer education session was 22% (16/73), compared with 14% (10/69) in those attending more sessions ($P = 0.25$). Similar findings were noted when number of peer session attended was analyzed as a continuous variable (data not shown).

HIV prevalence

When comparing HIV prevalence in 2000 and 2005, a non-significant increase was noted: 30.6% (151/493) versus 33.3% (166/498; $P = 0.36$). No difference was seen among younger women 15–19 years (15%, 4/27 versus 15%, 4/26; $P = 0.95$). HIV infection increased with age to a peak in women 25–29 years in 2000 and then declined with increasing age. In 2005, this peak occurred in older women, 35–39 years. Though not significantly different, HIV prevalence was lower in peers (29.6%; 42/142) compared with non-peers (34.8%; 124/356; $P = 0.26$). HIV prevalence was 25%

(17/69) in FSW who attended four or more peer-education session, compared with 34% (25/73) in those attending one to three sessions ($P = 0.21$).

Table 3: Effects of number of peer education sessions attended on sexual behavior and reproductive tract infections

| | One to three peer education sessions in past six months | Four or more peer education sessions in past six months | AOR** (95%CI) |
|--|---|---|-----------------|
| UNPROTECTED SEX | | | |
| Total years in sex work, mean (sd) | 5.9 (4.4) | 6.4 (5.7) | - |
| ≥ 4 sexual partners in past week | 53% (39/74) | 30% (21/71) | 0.4 (0.2-0.9) |
| ≥ 4 one-time clients in past week [§] | 34% (23/68) | 17% (10/58) | 0.4 (0.1-1.0) |
| Used a condom with last client | 89% (66/74) | 99% (70/71) | 7.2 (0.8-64.4) |
| Always used a condom with clients | 80% (59/74) | 93% (66/71) | 3.3 (1.0-10.8) |
| Always used a condom with boyfriend / husband [£] | 20% (10/50) | 35% (14/40) | 1.9 (0.7-5.7) |
| SEX WORKER EMPOWERMENT | | | |
| Own idea to use the condom at last sex | 92% (61/66) | 97% (68/70) | 2.9 (0.5-18.4) |
| Provided the condom at last sex herself | 79% (52/66) | 76% (53/70) | 0.6 (0.3-1.6) |
| HIV-related knowledge and attitudes | | | |
| Thinks a client might be HIV-infected | 28% (21/74) | 35% (25/71) | 1.8 (0.8-4.0) |
| Knows people with HIV can look healthy | 97% (72/74) | 97% (69/71) | 1.5 (0.1-15.8) |
| Mentions advantage to knowing HIV status | 97% (72/74) | 99% (70/71) | 0.4 (0.01-11.1) |
| Knows ≥ 2 symptoms of STI in women | 77% (57/74) | 82% (58/71) | 1.1 (0.4-2.6) |
| Cited ≥ 2 ways to prevent STI | 33% (25/74) | 61% (43/71) | 3.9 (1.8-8.7) |
| Ever refused client unwilling to use condoms | 85% (63/74) | 82% (58/71) | 1.2 (0.4-3.3) |
| TRANSMISSION EFFICIENCY | | | |
| Awareness of own HIV status | 43% (32/74) | 46% (33/71) | 1.2 (0.5-2.4) |
| Self reported history of RTI in past year | | | |
| Excessive or foul smelling vaginal discharge | 47% (35/74) | 39% (28/71) | 0.7 (0.3-1.4) |
| Genital ulcer | 20% (15/74) | 13% (9/71) | 0.7 (0.2-1.9) |
| RTI prevalence | | | |
| Syphilis infection | 1% (1/73) | 0% (0/69) | - |
| Gonorrhoeal infection | 1% (1/73) | 0% (0/69) | - |
| Trichomonas vaginalis infection | 19% (14/73) | 14% (10/69) | 0.8 (0.3-2.3) |
| Bacterial vaginosis infection | 42% (28/66) | 44% (28/63) | 1.3 (0.6-2.9) |
| Candida infection | 29% (21/73) | 23% (16/70) | 1.1 (0.5-2.6) |

Notes to Table 3:

RTI reproductive-tract infection. Cells contain %, n/N unless indicated. ^Sexual partners are classified: boyfriend/husband, regular clients and one-time clients; [§]Among those women having had a one-time client in the past week; [£]Among those women who reported having a boyfriend / husband; **AOR, odds ratio adjusted for age, marital status, education and place of work. Logistic regression was used to calculate AOR.

DISCUSSION

The study aimed to evaluate overall and individual-level effects of five years of peer-mediated interventions among FSW, using a standard framework of outcome measures [5]. Societal changes over time and the presence of other HIV prevention initiatives make it difficult to ascertain the proportion of change attributable to the peer intervention. More can be drawn from the differences noted between women who received peer-mediated interventions and those who had not. Further, behavioral changes were more marked in women with increased exposure to peer education, providing additional supportive evidence for the effectiveness of these interventions. These findings are encouraging and consistent with previous studies which evaluated the ability of peer-mediated interventions to facilitate behavior change among high-risk groups [21,3,22,23], (though not all) [24].

Effect on HIV prevalence

Though the burden of HIV in the general population in Kenya has declined in recent years, it is not known whether such changes are mirrored among FSW and other high-risk populations [1,25]. Complex behavioral changes occurred between the two periods and, disappointingly, HIV prevalence remains high in this population, even among younger age groups (a useful proxy for recent infection). Improved survival with wider access to antiretroviral treatment and care may make a minor contribution to this finding. Several other studies have also shown weak correlation between behavioral changes and HIV risk [9,24,26]. Most notably, a community-randomized trial in Uganda found that changes in behavior and an STI treatment intervention did not reduce HIV incidence [26]. Interestingly, FSW who attended peer-education sessions more frequently did show a trend towards lower HIV prevalence, though study design, sample size and potentially confounding factors limit the ability to draw firm conclusions.

Behavior changes

Condom use during last sex act was about seven times more likely in 2005. Consistent use with clients increased to 70%, similar or higher than seen in other studies in Africa, but, as elsewhere, remained disappointingly low with boyfriends and husbands [27,12,13]. Increased condom use among FSW has been shown to reduce HIV prevalence and incidence [14,21,22,27,28]. However, the best marker of risk for less infectious STI such as HIV, is the total number of unprotected sex acts [29]. Messages about reducing the number of sexual partners were not effective. This is likely

due to the close link between number of partners and income, and women have limited alternative sources of income to replace that lost from a reduction in partner number. Overall, it is uncertain whether the balance between higher number of partners and increased condom use reduced the total number of unprotected sex acts.

Women showed stronger condom negotiation skills with high levels of initiation and provision of condoms. An increase in self determination is also suggested as women in 2005 were five times as likely to refuse clients unwilling to use condoms as those in 2000. These are proxy indicators of FSW empowerment at an individual level, while changes in social attitudes and legal status as well as collective associations or networks are needed for more comprehensive empowerment of FSW [5,30] However, for those FSW who use condoms inconsistently, client's refusal remains the most common reason, suggesting that a subset of FSW remains particularly vulnerable. Importantly, only a minority of clients initiated condom use, again highlighting the need for interventions targeting clients of sex workers and the contexts in which they work [31].

Compared with the first time period, women had favorable attitudes towards HIV testing. The marked increase in women knowing their HIV status is an important finding in this study, though some women reported being fearful of HIV testing during interviewing.

Study limitations

The study design and the absence of prospective controls limit the ability to quantify the effectiveness of the intervention. This is particularly important since marked changes occurred in the study population, possibly resulting from an expansion in tourism and number of bars, with concomitant FSW in-migration. Many new women are likely to have entered female sex work and women reached by peer education left. Over half (278/502) of study participants in 2005 only started practicing sex work in the last five years. An especially notable change over the five years is the decline in number of FSW who are married or cohabiting, which warrants further investigation. Though snowball sampling is appropriate for locating difficult-to-reach populations, this non-random sampling may have contributed to differences noted. The sample size was intended to mitigate such effects.

Over the study period, other interventions have promoted sexual behavior change such as mass-media education, increased availability of widely-promoted VCT services and an HIV prevention study in 2004 which introduced the female condom[13] These concurrent interventions are likely to have

impacted on self-reported knowledge of HIV status, the desire to know once HIV status and possibly also on condom use. A further limitation is that many outcomes were self-reported, subject to social-desirability bias [26,32,33]. Nevertheless, observational designs like controlled before-and-after studies can provide strong plausibility support that positive impact has occurred, and highlight aspects that require further development [34,35].

Policy recommendations

Study findings will be used to inform design of future peer-mediated interventions in this population, with an increased focus on building negotiation skills for women whose clients refuse condom use, strengthening efforts to promote condom use with emotional partners, and early recognition and treatment of STI. Further interventions are required to impact on the gender norms in this setting and to reduce economic dependency. Such interventions were not the focus of this study, which predominately addressed biomedical risk factors. Overall effectiveness may be improved by engaging peer educators from subgroups which had low levels of peer-education coverage, as well as by using qualitative research methods to inform further modification of the intervention [7].

CONCLUSIONS

About 90% of peer educators were retained over five years and were able to reach nearly one third of the target population. These levels of peer educator retention are high, possibly due to rigorous selection procedures and ongoing supportive supervision for their work. Though uncertainty of the effects of the intervention remains, study findings suggest that peer-mediated interventions can change sexual behavior in FSW, but this did not lower the HIV prevalence among FSW, even among younger age groups. Promising results were achieved among FSW who attended peer sessions more frequently, suggesting that effectiveness of peer education is related to intensity of the intervention. Of note, the lack of impact of these peer sessions on condom use among relationships of FSW with boyfriends and husbands remains a major concern. These results also suggest that additional strategies are needed to improve coverage and impact of peer interventions. While peer-mediated strategies remain important for reaching vulnerable groups and improving their self-efficacy, additional HIV prevention technologies and a reduction in socio-economic vulnerability are urgently needed to increase their ability to control risk for HIV acquisition.

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTION

The study was conceived and designed by SL, PM, NK and SW. SL, NK, AR, MB, KM and WB made substantial contributions to acquisition of data. SL analysed study data and drafted the article. MC assisted with the data analysis and revised the article critically for important intellectual content. MT provided overall supervision and revised the article for important intellectual content. All authors assisted in interpretation of data and they read and approved the final manuscript.

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5.2 A prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa.

A prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa, Kenya

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ABSTRACT

Objective: To assess the impact and costs of adding female condoms to a male condom promotion and distribution peer education programme for sex workers in Mombasa, Kenya.

Design: A 12 month, prospective study of 210 female sex workers.

Methods: We interviewed participants about their sexual behaviour every 2 months for a total of seven times and introduced female condoms after the third interview. We also collected cost data and calculated the cost and cost effectiveness of adding the female condom component to the existing programme.

Results: Introduction of the female condom in an HIV/AIDS prevention project targeting sex workers led to small, but significant, increases in consistent condom use with all sexual partners. However, there was a high degree of substitution of the female condom for male condoms. The cost per additional consistent condom user at a programme level is estimated to be \$2160 (£1169, €1711) (95% CI: 1338 to 11 179).

Conclusions: The female condom has some potential for reducing unprotected sex among sex workers. However, given its high cost, and the marginal improvements seen here, governments should limit promotion of the female condom in populations that are already successfully using the male condom. More research is needed to identify effective methods of encouraging sex workers to practice safer sex with their boyfriends.

INTRODUCTION

Condom use is widely recognized as the primary mode of HIV prevention among high risk populations. However, male condoms are stigmatized in Kenya, even among men who are known to frequent sex workers.¹ Male condom use with regular clients and boy friends of female sex workers is particularly low.^{2,3}

The female condom has been proposed as an alternative to the male condom for couples who do not wish to use the male condom. Numerous studies have indicated that sex workers find the device an acceptable, and sometimes preferable, method to the male condoms.⁴⁻⁷ Recent qualitative research in Mombasa, Kenya, revealed that sex workers were willing and able to introduce the female condom to partners with whom they do not consistently use male condoms, such as regular clients and boyfriends (Toroitich-Ruto, Brelsford, Thomsen, unpublished manuscript). However, because female condoms cost more, if they substitute for male condoms, the overall costs of a prevention programme would increase without increasing the overall proportion of protected acts and averting infections.⁸ We carried out a 12 month prospective study of the effects and costs of adding female condoms to an existing male condom promotion and distribution project for sex workers in Mombasa, Kenya.

METHODS

Design

We used a prospective design with three pretests (O_1-O_3) and four post-tests (O_4-O_7). We did not have a control group because the sex worker population in Mombasa is a relatively small, enclosed community. Therefore, there was a high risk that individuals in a control group would obtain female condoms from their colleagues.

Study site

Participants lived and/or worked in the Kisauni division of Mombasa District, a major sea port and trucking centre on the Trans-East African highway. Kisauni, a popular tourist spot, is characterized by many bars, guesthouses, and discos. Most sex workers are street or bar based, and charge between \$5 and \$55 per client. Their regular clients (someone who they see on a regular basis and

who is usually expected to pay for sex) and boyfriends (don't pay for sex) are often employed in local factories or are matatu (minibus) touts.⁹

Population

We recruited participants through an existing HIV prevention peer education project run by the International Centre for Reproductive Health in Mombasa. Peer educators provided a list of 329 peer sex workers (out of a potential 2382 sex workers identified by the programme in Kisauni) with whom they had regular contact. The study team then selected a random sample of 255 sex workers who were asked to come to the recruitment centre for screening. We enrolled the first 210 who were eligible according to study inclusion/exclusion criteria. Written informed consent was obtained at study entry.

The ethics committees of Kenyan National Hospital and the sponsoring institution in the United States approved the study.

Procedures

Peer educators asked the selected potential participants to come to a community resource centre for sex workers in Kisauni. Women who fulfilled the inclusion criteria were interviewed on their sexual behaviours every 2 months for 1 year. At the first and last interviews, trained nurses instructed them to self swab for vaginal fluids, which we later analysed for prostate specific antigen and compared them with self report of condom use. The results of these analyses are presented elsewhere.¹⁰

Intervention

The intervention consisted of female condom education through peer education and IEC (information, education, communication) materials, as well as the provision of female condoms. Four months after enrolment in the study, each participant received 20 female condoms per month for 8 months free of charge via her peer educator. Additional condoms were distributed by study personnel during interviews when it was discovered that the participant had run out or had not received her quota from the peer educator.

The female condom was introduced into an existing peer education programme with female sex workers, where activities included weekly group and spontaneous individual education on sexual and

reproductive health topics. IEC materials were developed to highlight the role of male and female condoms in STIs, including HIV, and pregnancy prevention. In particular, sex workers were encouraged to always use a condom, even with a steady partner, and to first use a male condom, but to try a female condom if that did not work.

Study Outcomes and Analyses

The primary out come was consistent condom use (every sex act protected) with all sexual partners in the 7 days before each interview. This outcome was chosen because of the importance of 100% condom use among populations at high risk for HIV, such as sex workers. The 7 day time period was chosen because of previous work with this population, which indicated that sex workers could comfortably count clients back this far, but not farther.¹¹ Secondary out comes of interest were the number and proportion of protected sexual acts with different partner types.

The homogeneity of the proportion of consistent condom use with all partners before the introduction of the female condom and at the end of the intervention (visits O₃ and O₇), was tested in a one sided McNemar test with 0.05 significance level. The odds of consistent condom use in the last 7 days during the post-intervention period relative to the pre-intervention visits were estimated in bivariable and multivariable logistic models for repeated measures. Covariates included age, type of sexual partners (casual, regular, or boyfriend), having ever been pregnant, use of condoms for contraceptive purposes, and numbers of partners at baseline. Odd ratios and their 95% confidence intervals were calculated.

Significance tests were two sided (unless noted otherwise) at the 0.05 level. The statistical package used was SAS, version 9.

Cost data

The cost analysis was designed to determine (a) what additional resources would be required to support provision of female condoms through an existing peer promotion programme, and (b) the cost effectiveness of the intervention. In consultation with programme personnel, we identified the resources used during the intervention and assigned a cost to each resource. We used this information to first compute the cost of the study intervention serving the study participants and then estimated the annual cost of serving the 2382 sex workers identified in Kisauni. This included

annualizing capital expenses and scaling up the supplies to reach a larger population. This estimate was used to assess the cost effectiveness of adding female condoms at the programme level. (Equipment and training costs were annualized using expected useful life of investment (3–10 years depending upon type of equipment and 3 years for training) and a discount rate of 8.9% representing the treasury bill rate from the Central Bank of Kenya during the intervention (www.centralbank.go.ke/treasurybills/results.asp). Data were analysed using MS-Excel spreadsheets.

RESULTS

Analysis Population

A total of 210 sex workers were recruited in the study from January to February 2004. At 12 months 92% (195/210) were followed up. Present at both O_3 and O_7 were 151 (71.9%) who were included in the McNemar test for primary analysis of consistent condom use. All participants who were present at O_1 and at least one other visit were included in the bivariable and logistic models for consistent condom use (n=196; 93.3%).

Background characteristics

The average study participant was 29 years old, had been pregnant, and was using at least one method of contraception (data not shown). Of these, the majority used male condoms for contraception (76%), one third used injectables, and 23% used oral contraceptives. In the 7 days before study enrolment, study participants reported having, on average, coitus with five casual clients, two regular clients, and one boyfriend. Almost 11% reported having been physically assaulted by a sexual partner in the last 12 months. There were no differences in baseline characteristics between the included and excluded primary or secondary analysis populations with regard to age, marital status, parity, contraceptive use, or self report of STIs.

Consistent Condom Use

Of the 151 participants at O_3 and O_7 , 149 participants had consistency condom data. In this group, the proportion of participants reporting consistent condom use with all partners increased from 59.7% (89/149) (table1) just before female condoms were introduced, to 67.1% (100/149) at the last visit ($P=0.04$). This increase was because 42% (25 of 60) of the previously inconsistent condom

users became consistent users at the final visit. Of those who were previously consistent condom users, 16% (14 of 89) reported inconsistent condom use at the last visit. Within specific partner types, we only saw a change in consistent condom use with regular clients (94–99%; $P=0.05$). Eight women reportedly never used condoms.

Table 1. Number and percentage of study participants with consistent/inconsistent condom use in the last 7 days before and after female condom (FC) introduction by time period and type of partner including test of homogeneity over time.

| Type of Partner | Before FC Introduction (O ₃) | After Female Condom Introduction (O ₇) | | | McNemar test statistic | P-value* |
|-----------------------|--|--|---|---------------|------------------------|----------|
| | | Inconsistent (any act unprotected), No (%) | Consistent (all acts protected), No (%) | Total, No (%) | | |
| All | Inconsistent | 35 (23%) | 25 (17%) | 60 (40%) | 1.55 | 0.04 |
| | Consistent | 14 (9%) | 75 (50%) | 89 (60%) | | |
| | Total | 49 (33%) | 100 (67%) | 149† (100%) | | |
| Casual Clients | Inconsistent | 0 (0%) | 1 (1%) | 1 (1%) | NA | NA |
| | Consistent | 0 (0%) | 109 (99%) | 109 (99%) | | |
| | Total | 0 (0%) | 110 (100%) | 110 (100%) | | |
| Regular Clients | Inconsistent | 0 (0%) | 5 (6%) | 5 (6%) | 1.33 | 0.05 |
| | Consistent | 1 (1%) | 72 (92%) | 73 (94%) | | |
| | Total | 1 (1%) | 77 (99%) | 78 (100%) | | |
| Non-paying Boyfriends | Inconsistent | 34 (43%) | 9 (11%) | 43 (54%) | 0 | 0.5 |
| | Consistent | 9 (11%) | 27 (34%) | 36 (46%) | | |
| | Total | 43 (54%) | 36 (46%) | 79 (100%) | | |

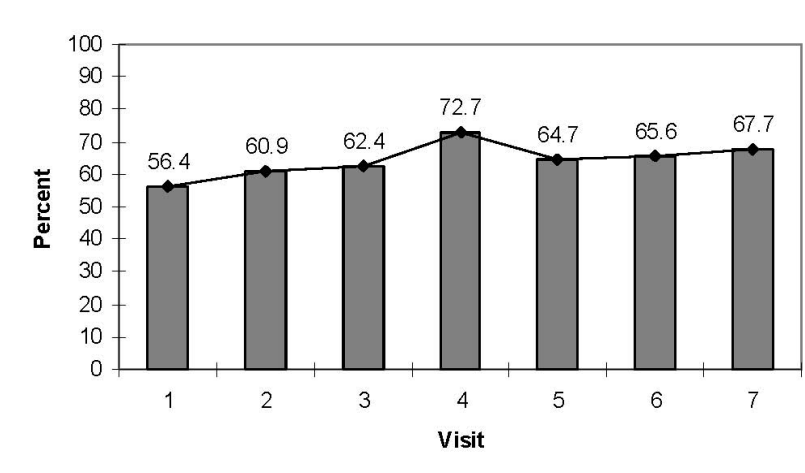
*One-sided p-value for the extent of agreement between condom use before and after female condom introduction.

† Two participants are excluded due to unavailable consistency data with all partners at O₇.

In the logistic model for consistent condom use the likelihood (odds ratio) that a participant would become a consistent condom user after the introduction of the female condom was 1.7 (95%CI:1.4 to 2.2). Figure 1 shows the percentages used in the logistical models.

Comparing the women who reported inconsistent condom use at the end of the study (n=50) with reported users (n=116), we found inconsistent users to be more likely to have a boyfriend or a larger number of partners than the consistent condom users.

Figure 1: Percentage of participants reporting consistent condom use with all partners by study visit^{1,2}



¹ The female condom was introduced immediately after visit 3.

² Adjusted OR for consistent condom use after female condom introduction was 1.7 (95% CI: 1.4 - 2.2) unadjusted estimate was 1.5 (95% CI: 1.2-1.9).

Number of clients

The mean number of casual clients in the 7 days before the interviews decreased steadily from 4.9 during recruitment to 2.5 a year later (table 2). This decrease was statistically significant ($P < 0.001$). Similarly, the mean number of regular clients decreased from 1.9 at recruitment to 1.3 at the last visit ($P < 0.001$). There was a steady downward trend over the whole study for both of these decreases. The average number of sexual partners who were boyfriends remained around one during the study.

Unprotected Sex Acts

Study participants reported a declining mean number of unprotected coital acts with all partners overtime: 1.7 before the female condom introduction to 1.4 after ($P = 0.01$) (table 2). Similarly, the mean number of coital acts decreased from 13.3 during the three pre-intervention observations to 10.1 during the post-intervention visits ($P < 0.001$). The trend over the whole study period (before and after female condom introduction) was steadily downward.

In looking at specific types of partners, the mean number of total and unprotected coital acts with casual and regular partners, but not boyfriends, declined overtime. The observed decreases all followed the same downward trend starting in the male condom phase of the study.

Male vs. Female Condom Use

The proportion of sex acts protected by male condoms decreased from 84.3% before the introduction of the female condom to 56.5% after ($P < 0.001$) (Table 2). The declines in male condom use were offset by the increases in female condom use. However, female condom use did experience a steady downward trend after its introduction (from 34.9% to 29.4%).

Costs

The total cost of the 9 month intervention was \$54,139 (£29,453, €42,622.8) or approximately \$258 per participant (table 3). When scaled up to reach the 2,382 sex workers in the Kisauni division, the annual cost for female condom promotion is estimated to be \$380,081 or about \$160 per person.

Using the increase in the number of sex workers reporting consistent condom use after the introduction of the female condoms as the effectiveness measure (and adjusting the observed increase in consistent condom users from 11 to 16 to simulate no loss to follow up in a non-study population) (the 95% confidence interval for this increase is three to 25 additional consistent condom users), we calculated cost effectiveness. The first row in table 3 shows the incremental cost per additional consistent condom user, which was \$3,384. When the intervention is scaled up to include the whole programme in Kisauni (row two), the estimated incremental cost per additional user is \$2,160. The majority of costs for the female condom promotion programme are for the female condom commodities. Therefore, the cost of the programme is sensitive to the extent of substitution of female condoms for male condoms. The third row of this table shows a hypothetical situation whereby the number of female condoms required is reduced by 50%, owing to less substitution, reducing the estimated incremental cost per additional consistent condom user (row three) to \$1,140.

Table 2: Mean number of clients, coital acts, and unprotected coital acts (SD), by partner type and study visit, and percentage of coital acts protected by male and female condoms in the last 7 days, by study visit.

| Covariates | Study Visit | | | | | | | | | | | | | | P-value | | |
|---|----------------|-------------|----------------|------------|----------------|------------|----------------|------------|----------------|------------|----------------|------------|----------------|------------|--------------------------------|------------|----------|
| | O ₁ | | O ₂ | | O ₃ | | O ₄ | | O ₅ | | O ₆ | | O ₇ | | O ₄ -O ₇ | | No |
| | No | | No | | No | | No | | No | | No | | No | | No | | |
| Number of subjects | 196 | | 191 | | 196 | | 185 | | 186 | | 179 | | 184 | | 193 | | |
| Number of clients in last 7 days | 4.9 (5.61) | 4.5 (4.61) | 3.3 (4.08) | 3.5 (4.22) | 2.7 (2.71) | 2.4 (2.83) | 2.5 (3.09) | 1.9 (2.34) | 1.6 (1.98) | 1.3 (1.31) | 1.1 (1.18) | 1.3 (1.41) | 1.3 (1.41) | 1.1 (1.2) | 0.7 (0.56) | 0.7 (0.56) | 0.0009* |
| Casual | 1.9 (2.34) | 1.6 (1.98) | 1.2 (1.2) | 1.3 (1.31) | 1.1 (1.2) | 1.1 (1.18) | 1.3 (1.41) | 1.9 (2.81) | 0.8 (0.69) | 0.7 (0.55) | 0.7 (0.56) | 0.7 (0.56) | 0.7 (0.56) | 1.1 (1.2) | 0.7 (0.56) | 0.7 (0.56) | <0.0001* |
| Boyfriend | 14.2 (0.93) | 15.0 (1.00) | 10.7 (0.66) | 11.3 (0.6) | 10.2 (0.59) | 9.9 (0.56) | 9.0 (0.63) | 8.7 (0.77) | 8.2 (0.68) | 6.6 (0.54) | 5.1 (0.44) | 5.0 (0.45) | 5.0 (0.45) | 5.5 (0.45) | 5.1 (0.44) | 5.0 (0.45) | 0.109* |
| Number of coital acts | 8.7 (0.77) | 8.2 (0.68) | 6.3 (0.53) | 7.7 (0.39) | 7.7 (0.39) | 6.6 (0.54) | 6.6 (0.54) | 8.7 (0.77) | 8.2 (0.68) | 6.6 (0.54) | 5.1 (0.44) | 5.0 (0.45) | 5.0 (0.45) | 5.5 (0.45) | 5.1 (0.44) | 5.0 (0.45) | <0.0001† |
| Casual | 4.9 (0.32) | 4.9 (0.40) | 3.5 (0.23) | 3.5 (0.22) | 3.3 (0.22) | 3.3 (0.19) | 3.3 (0.25) | 4.9 (0.32) | 4.9 (0.40) | 3.5 (0.22) | 3.3 (0.19) | 3.3 (0.25) | 3.3 (0.25) | 3.3 (0.22) | 3.3 (0.19) | 3.3 (0.25) | <0.0001† |
| Regular | 3.7 (0.26) | 4.4 (0.29) | 3.8 (0.25) | 3.4 (0.21) | 3.9 (0.23) | 4.1 (0.25) | 3.7 (0.30) | 3.7 (0.26) | 4.4 (0.29) | 3.4 (0.21) | 4.1 (0.25) | 4.1 (0.25) | 3.7 (0.30) | 3.9 (0.23) | 4.1 (0.25) | 3.7 (0.30) | 0.217† |
| Boyfriend | 1.7 (0.23) | 1.7 (0.24) | 1.5 (0.20) | 1.1 (0.17) | 1.4 (0.20) | 1.6 (0.24) | 1.3 (0.21) | 1.7 (0.23) | 1.7 (0.24) | 1.1 (0.17) | 1.6 (0.24) | 1.6 (0.24) | 1.3 (0.21) | 1.4 (0.20) | 1.4 (0.10) | 1.4 (0.10) | 0.015† |
| Number of unprotected coital acts | 0.4 (0.18) | 0.1 (0.04) | 0.0 (0.01) | 0.0 (0.00) | 0.2 (0.06) | 0.2 (0.06) | 0.0 (0.00) | 0.4 (0.18) | 0.1 (0.04) | 0.0 (0.00) | 0.0 (0.02) | 0.0 (0.02) | 0.0 (0.0) | 0.0 (0.02) | 0.0 (0.1) | 0.0 (0.1) | 0.0003† |
| Casual | 0.3 (0.08) | 0.2 (0.09) | 0.2 (0.08) | 0.0 (0.00) | 0.0 (0.00) | 0.0 (0.00) | 0.0 (0.00) | 0.3 (0.08) | 0.2 (0.09) | 0.0 (0.00) | 0.0 (0.02) | 0.0 (0.02) | 0.0 (0.03) | 0.0 (0.00) | 0.0 (0.01) | 0.0 (0.01) | <0.0001† |
| Regular | 1.7 (0.19) | 2.1 (0.26) | 2.0 (0.26) | 1.5 (0.23) | 2.0 (0.26) | 2.0 (0.26) | 1.5 (0.23) | 1.7 (0.19) | 2.1 (0.26) | 1.5 (0.23) | 2.1 (0.30) | 2.1 (0.30) | 1.9 (0.29) | 2.0 (0.26) | 1.9 (0.13) | 1.9 (0.13) | 0.260† |
| Boyfriend | 84.8 | 84.5 | 83.6 | 55.6 | 57.2 | 56.7 | 56.6 | 84.8 | 84.5 | 83.6 | 55.6 | 56.6 | 56.6 | 57.2 | 56.5 | 56.5 | <0.0001† |
| % All coital acts protected by male condoms | 0.6 | 0.8 | 0.0 | 34.9 | 29.1 | 27.4 | 25.7 | 0.6 | 0.8 | 0.0 | 34.9 | 25.7 | 25.7 | 29.1 | 29.4 | 29.4 | <0.0001† |

* P-value for the difference across visits.

† P-value for the difference between the average of visits O₁-O₃ and the average of visits O₄-O₇.

DISCUSSION

Introducing the female condom in to a male condom programme resulted in a small, but significant, increase in the proportion of sex workers reporting 100% condom use with all partners. This result replicates what has been found in other sex workers,¹²⁻¹³ and high risk populations¹⁴⁻¹⁶— namely, that complementing male condom promotion programmes with the female condom increases reported condom use. However, these increases have not always been accompanied by decreases in sexually transmitted infections.¹³⁻¹⁶ This discrepancy usually gives rise to a discussion on the validity of self reported condom use.¹⁷ Our analyses of the prostate specific antigen (PSA) samples at baseline and the final follow up indicated that although there was under-reporting of unprotected sex, these levels remained constant during the study, implying that the changes that we witnessed in consistent condom use were real.¹⁰

While over-reporting of protected sex may not have influenced the consistent condom use outcome, it is possible that contact with the research staff could have been responsible for some of the other positive effects of the intervention that we observed. For example, the reported number of casual and regular clients decreased by 50%, and 30%, respectively, during the study, although this was not a specific objective of the intervention. Similarly, the reported total number of coital acts and the number of unprotected acts with all partners decreased overtime by 25% and 20%, respectively. Discussions with the sex workers after the study revealed that the participants may have been positively influenced by their numerous contacts with study personnel, both because the process of counting sex acts raised their awareness of how much (sometimes unpaid) sex they were having, and because study personnel also provided information on sexual health after the interviews were completed, according to the study protocol. This fact, combined with the fact that most of the downward trends started before the introduction of the female condom, raises questions about the degree to which the female condom was instrumental in the decline of some of these risky behaviours. However, it cannot be denied that a sharp drop in the number of unprotected coital acts, and a sharp increase in consistent condom use, was observed directly after the introduction of the female condom, indicating some effectiveness.

Other limitations to this study were the small study size and the pre-post intervention design. The small study size was a result of budgetary constraints in a study where participants come from a highly mobile population, and thus need to be followed up every 2 months in order for them not to go

missing. It is because of this intensive follow up carried out by the research assistants that we were able to retain 92% of the participants over the 12 month study period.

Condom Migration

In our study, about 30% of male condom use before female condom introduction was replaced by female condoms despite messages emphasizing its use only when using a male condom was not possible. Such “condom migration” does not seem to lead to more sexually transmitted infections,¹⁸ but it has cost implications. The cost of the female condoms alone - \$108 per sex worker over 9 months - would represent a substantial investment by the Kenyan Ministry of Health, which spent \$70 per capita on health in 2002. Therefore, it seems unlikely that the female condom intervention could be expanded without donor assistance. In addition, because female condoms are currently much more expensive than male condoms, whenever the majority of female condoms are used as a substitute for a male condom there is limited public health impact from the intervention but there is a marked increase in cost.

The great uptake of female condoms by women who were already successfully using (mostly free) male condoms maybe explained by several factors. Firstly, our monitoring reports revealed that peer educators’ distribution of male condoms dropped by about half in the last 4 months of the study, which was probably because of the arrival of the Muslim holy month of Ramadan and a shortage of Ministry of Health condoms. Thus, study participants may have been “replacing” male condoms with female condoms because they did not have enough male condoms. Secondly, there is the novelty effect. It is not uncommon for a new product to take over a portion of an existing market, to be followed by a subsequent decline after the novelty wears off (as we saw here). Finally, in our formative research phase, Mombasa sex workers told us that they could secretly use the female condom with unsuspecting clients who would pay more for (seemingly) condom less sex. Thus, the female condom may have been picked up by sex workers as much for its money making potential as for its protective effects.

Continuing ‘Condom Gap’ with Boyfriends

Although our formative research indicated that the female condom had a potential role in filling the “condom gap” with sex workers and their emotional partners, introducing the female condom did not result in an increase in protected sex with boyfriends. A low risk perception with regular clients and

boyfriends, and thus less insistence on condom use, is not uncommon in sex worker populations.^{2 19} Further, few male condom promotion programmes have been successful in increasing these levels, indicating limitations to peer education programmes that cannot be over come simply by introducing a new device.¹³ The fact that consistent condom users in this study were less likely to have a boyfriend supports this conclusion.

Table 3: Incremental cost-effectiveness analysis of female condom introduction

| | Incremental Cost | Increase in number of consistent condom users after female condoms introduced (95% CI) | Incremental cost per year per additional consistent condom user (95% CI) |
|--|------------------|--|--|
| Intervention | \$54,139 | 16* (3 to 25) | \$3,384 (\$2,166 to \$18,046) |
| Scaled-up program† | \$380,081 | 176 (34 to 284) | \$2,160 (\$1,338 to \$11,179) |
| Scaled-up program with 50% reduction in number of female condoms required | \$200,597 | 176 (34 to 284) | \$1,140 (\$706 to \$5,900) |
| <p>* This figure has been altered from the actual increase found in the study to indicate the number that would have become consistent condom users if there was no loss to follow-up [(0.6711 x 210) – (0.5973 x 210) = 16]. Assumes those lost to follow-up had same behaviours as those who stayed in study.</p> <p>† Figures reflect increases from the study sample (n=210) to all sex workers in the Kisauni program (n=2,382). The cost of scaling up the intervention assumed that besides additional condoms required to serve a larger group (91% of scale-up costs) that there would also be increased communication costs and office supplies proportional to the increase in persons served in order to document the increased activities. We assumed that personnel costs would not increase since program staff are already contacting these persons with the male condom promotion messages.</p> | | | |

CONCLUSIONS

The female condom shows limited promise in increasing consistent condom use. Whether or not the increases seen here are programmatically significant is best judged by programme planners and policy makers in individual countries, depending on the public health priorities of those countries. However, one consideration that should be taken into account is the cost. Although some replacement is to be expected with a new product, the reduction of male condom use by 30% is problematic because of the high cost of the female condom. If female condom programmes are to be expanded, the messages surrounding their introduction should be fine tuned to avoid promoting this product where the male condom is already used.

In addition, alternatives for promoting safer sex with boy friends of sex workers, including the use of male or female condoms, need to be explored. Suggestions provided by the sex workers themselves for narrowing this “condom gap” included promoting the female condom as a family planning method, empowering women financially to reduce their dependence on boyfriends, and encouraging men to go for voluntary HIV counselling and testing to help them better understand their own risk of infection.

Key messages

- The female condom shows some limited promise in increasing consistent condom use among sex workers and their partners
- Because of the relatively high cost of female condoms, and the likelihood of sex workers substituting them for male condoms, they should be promoted only where male condoms are not currently being used 100% of the time
- More strategies are needed to encourage sex workers to protect themselves when having sex with this category of partner

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CONTRIBUTORS

SCT designed and oversaw the study, she also wrote the major portions of the introduction, results, and discussion; WO was the research coordinator and wrote a portion of the methods section; ELW

directed the development and implementation of the statistical analysis plan and contributed in writing the results section; HOT implemented the statistical analysis programming; CT-R supervised the conduct of the study; RH was the study economist and conducted all economic analyses; NK supervises the sex worker peer education programme; SL was the principal investigator for the study. All authors were involved in the design of the study and the review of the manuscript.

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5.3 Use of homemade diaphragm for dual protection against pregnancy and sexually-transmitted infections: case report.

Use of self home-made diaphragm for protection against pregnancy and sexually-transmitted infections: case report

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SUMMARY

This is a case report of a 44-year old woman who used a home-made diaphragm for 16 years to protect herself from pregnancy and sexually-transmitted infections. The woman stitched a piece of cloth with folded polythene inside. This case report provides a vivid illustration of the limitations of available methods of protection for women. It consists of an introduction to the topic, a description of her experiences using her home-made diaphragm and a discussion of the significance of the case. This report supports the need for additional research on female-controlled methods of protection against sexually-transmitted infections, methods that can be used without male knowledge and co-operation, such as vaginal microbicides and cervical barriers against infection, including the diaphragm.

INTRODUCTION

About 40% of Kenyan women of reproductive age are currently using contraception (1). However, the existing contraceptive method mix does not fully address the needs of women, many of whom have an unmet need for family planning and for protection against HIV and other sexually transmitted infections (STI). Although both male and female condoms provide dual protection against pregnancy and STI, they require male co-operation, and acceptability and uptake of these methods remains poor. In response to these concerns, research initiatives have increasingly focused on female controlled methods that may be used without male knowledge and/or co-operation, such as vaginal microbicides and cervical barriers including the diaphragm (2). Limited evidence from observational studies suggests the diaphragm provides protection against STI and their sequelae, including gonorrhoea, pelvic inflammatory disease, tubal infertility and cervical dysplasia (3). This is biologically plausible as the cervix is a primary site of entry for several STI, including HIV and human papilloma virus. The cervical columnar epithelium is thinner than the vaginal epithelium and, in addition, expression of CD4-cell and CCR5-chemokine receptors is higher in the cervix than vagina (3). The diaphragm, formerly a widely used contraceptive method, is currently not available in family-planning services in Kenya. We report a case of a 44-year old Kenyan woman who used a homemade diaphragm since 1977 for protection against pregnancy and STI.

CASE REPORT

The woman, a participant in a study investigating diaphragm acceptability among women in Mombasa, Kenya, completed nine years of school, is divorced, and has had three first-trimester miscarriages and four live births. She earns about 80 US\$ per month from baking and selling foodstuffs and, following her divorce, as a female sex worker. She developed a home-made diaphragm in response to a number of factors: she feared she may acquire an STI as several of her friends had; negotiating condom use was often unsuccessful; and no alternatives were available for simultaneous protection against STI and pregnancy. Based on knowledge of female anatomy learnt at school, she created a physical barrier to cover the cervix and prevent both 'sperm entering the uterus' and STI. The woman stitched a piece of cloth with folded polythene plastic inside to form an 8 cm by 8 cm device (see figure 1). She tested the device by placing cotton wool behind it and pouring

ink, mimicking semen, onto it. On noting the cotton wool was unstained and ink had not penetrated through her home-made diaphragm, she assumed it would provide adequate protection. Prior to each sexual act she inserted the diaphragm, without using lubricant or spermicide. Her device was treated as a disposable item, being removed and discarded immediately following intercourse, unless she anticipated more than one sexual act that day when it was left in place for a few hours. It was used during menstruation and absorbed menstrual flow, enabling her to have sex without her partner knowing she was menstruating. She used it during all sexual acts for a total of 16 years. Condoms were not used during this time. None of her sexual partners ever reported feeling the device during intercourse, enabling her to use it without their knowledge. She never disclosed its use to her husband or other partners. For a period of time she discontinued using it as she wished to conceive. After her fourth child she reinitiated use of the home-made diaphragm. Not wishing to disclose its use to her husband, she had an intrauterine device (IUD) inserted so she could show him the family planning clinic card. After her divorce she had the IUD removed and continued using only her diaphragm. She gave several samples of the home-made diaphragm to women in her community, some of whom were reportedly reluctant to use it, fearing it would 'enter their stomach'. She reports that while using the device she did not become pregnant, acquire an STI or have a urinary tract infection. After counselling, the woman accepted HIV testing, which was negative. Cervical cytology was carried out; no intraepithelial lesion or malignancy was noted on Pap smear. She recently switched to the latex diaphragm, provided through the above-mentioned diaphragm acceptability study. Although the latex diaphragm is harder to remove than her device and she is concerned its smaller size provides less protection against STI infection, overall she prefers the latex diaphragm as it causes less discomfort during sex and is easier to insert.

DISCUSSION

Physical barriers covering the cervix have been used for centuries to prevent pregnancy. Ancient texts document use of lemon halves, beeswax plugs and crocodile-dung (4). Mass production of the diaphragm began more than a hundred years ago and by the 1940s, it was the most commonly used contraceptive method in several countries (4). With development of more effective and coitus-independent contraception, diaphragm use decreased markedly and, at present, is not included in the contraceptive method mix in many countries. In these settings, little is known about use of homemade diaphragms. Recent studies of diaphragm acceptability in eastern and southern Africa have reported high continuation rates (5,6). However, cultural beliefs about objects entering the stomach through the uterus could potentially decrease uptake of the diaphragm and related technologies. Peer educators in Kenya reported these beliefs hindered enrolment in the diaphragm study. Prospective studies investigating effectiveness of the diaphragm in preventing infection with HIV and other STI are underway in African countries including Kenya, Madagascar, South Africa and Zimbabwe.

Figure 1: Self home-made diaphragm for protection against pregnancy and sexually-transmitted infections



CONCLUSION

This case report further demonstrates that women have an unmet need for dual protection against pregnancy and STI, and benefit from female controlled methods. Though an isolated report, it adds to existing evidence that the diaphragm is potentially an invaluable technology for women, protecting against unintended pregnancy and possibly against STI. Inclusion of the diaphragm in the contraceptive method mix should be reconsidered, particularly if ongoing studies demonstrate the diaphragm to be effective in reducing acquisition of HIV and other STI. This would assist women in high-HIV burden areas to protect themselves against HIV and other STI, although existing cultural beliefs have to be considered during promotion of the diaphragm and similar devices.

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5.4 Acceptability of the diaphragm in Mombasa Kenya, a six month prospective study.

Acceptability of the diaphragm in Mombasa Kenya: A 6-month prospective study

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ABSTRACT

Objective: If proven acceptable, safe and effective, the diaphragm could be used as a female-controlled method of preventing both sexually-transmitted infections (STIs) and pregnancy. This study's aim was to assess the acceptability and safety of the diaphragm among sexually-active women in Mombasa, Kenya.

Methods: We conducted a 6-month prospective study among female sex workers (FSWs), and women attending sexual and reproductive health services. Diaphragm acceptability was assessed using continuation rates and factors associated with acceptability. Safety evaluations included colposcopy findings and incidence of urinary tract infections (UTIs) and STIs.

Results: Half the 185 participants were FSWs who had less schooling and were less likely to be married than other women. After 6 months, 55% (56/102) of sexually-active women reported having used the diaphragm each sex act during the preceding month. Women liked using the diaphragm (95%, 104/109), and 96% (125/130) reported willingness to continue using it. Colposcopy did not reveal significantly more vaginal or cervical lesions. Use of the diaphragm was not associated with an increase in bacterial vaginosis or UTIs. A pregnancy rate of 12 per 100 women/years was observed.

Conclusion: After 6 months of diaphragm use in this setting, continuation rates were sustained, user satisfaction was high and adverse effects were few.

INTRODUCTION

Women are biologically more susceptible to infection with HIV and other sexually-transmitted infections (STIs) than men. In many settings, social, cultural and economic imbalances further increase their vulnerability. (1) This, together with the lack of female-controlled protection methods, hinders efforts to prevent transmission of HIV and other STIs. Recent research has focused on female-controlled methods such as vaginal microbicides and cervical barriers. (2,3) These methods are not intended to replace condom use, but rather to increase existing options. (4) Observational studies suggest that cervical barriers protect against some STIs such as gonococcal endocervicitis, as well as their sequelae, including cervical dysplasia, pelvic inflammatory disease (PID) and tubal infertility. (5) This is biologically plausible as the cervix is an entry site for several agents of STIs including HIV, gonococcus, Chlamydia trachomatis and the human papilloma virus (HPV). (5,6) If proven to be a safe, effective and acceptable method, the diaphragm would have an added value, allowing women to protect themselves in case condom use is not an option. This prospective study investigated the acceptability and safety of the diaphragm in Mombasa, Kenya.

METHODS

The study took place from January 2004 to July 2005 at a public-sector primary health clinic in Chaani. The road linking the Mombasa seaport with Nairobi passes through the area, inhabited largely by a migrant population, many of whom work at the nearby port or as truck drivers. Two groups of women were included in the study: female sex workers (FSWs), and women attending sexual and reproductive health services (SRH), such as family planning clinics. Fourteen peer educators made contact with FSWs in bars, guesthouses and other community settings. Female sex workers were defined as women having exchanged sex for money or goods, either as an added income or on a full-time basis. Women eligible for the study were 18 years or older, resided within the defined study area for at least 1 year, and were likely to remain in the area for the next 6 months. All women enrolled in the study had shown interest in using the diaphragm. Women who were pregnant, planning a pregnancy in the next 6 months, allergic to latex or had undergone a hysterectomy were excluded from the study. Written informed consent was obtained at study entry. The Kenyatta National Hospital, Ethics and Research Committee and the ethics committee of Ghent University, Belgium, approved the study. A latex diaphragm (CMD, The Netherlands) was provided

after being fitted by a medical doctor. Women were instructed that the diaphragm should be inserted up to 30 min before intercourse, left in place for 6 h thereafter, and removed within 24 h of insertion. No spermicide or lubricant was provided as use of the spermicide nonoxynol-9 has been associated with greater risks of developing genital lesions and, as a consequence, of acquiring HIV infection. (7) Women were discouraged from using spermicide-containing products. A trained nurse or counsellor emphasized the importance of male condom use at enrolment and each subsequent visit. Women were informed that the protective efficacy of the diaphragm against HIV/STIs is unknown. At enrolment and subsequent visits, male condoms were promoted and distributed free of charge. Particular efforts were made to identify women with a decrease in male condom use since the last visit to allow for additional targeted counselling. Peer educators made specific efforts to reach study participants in the community and provide them with condoms. Participants were referred for HIV testing and counselling within the health centre. Participants were also told that the diaphragm offers some protection against pregnancy, but were strongly encouraged to use more effective methods of contraception while participating in the study. Following enrolment, monthly study visits were scheduled for 6 months. Each visit comprised a structured interview, urine collection and a gynaecological examination, including speculum insertion with endocervical and high vaginal swab collection. A Gram-stained endocervical smear was used to identify Gram-negative diplococci for the diagnosis of *Neisseria gonorrhoeae*. Nugent's criteria were used for diagnosis of *bacterial vaginosis*. Infections with *Trichomonas vaginalis* or candidiasis were detected using a wet preparation, and a dipstick identified leukocytes in the urine. When indicated, STI treatment was provided by study staff, according to national STI guidelines. At the 6-month visit, a colposcopy was done to examine the cervix, and the vaginal walls for disruptive lesions and nondisruptive lesions, such as erythema and abrasions potentially associated with diaphragm use. Focus group discussions with diaphragm users, partners of diaphragm users, and women who withdrew from the study provided complementary information on benefits and disadvantages of diaphragm use in our setting.

Data management and analysis

Data collected during structured interviews and laboratory investigations were double entered using EpiData version 3.0 (The EpiData Association, Odense, Denmark). For analysis of categorical variables, chi-square test and Fisher's exact test were used; for continuous variables, we used an unpaired Student's t-test or Mann-Whitney U-test for normally and non-normally distributed data,

respectively. Multivariable logistic regression models were constructed to investigate factors associated with diaphragm acceptability. The primary outcome variable in this model is diaphragm continuation at 6 months, defined as diaphragm use with all sex acts in the last month among sexually-active women. Variables associated with diaphragm use in bivariate analysis or in similar studies were included in the initial model, and retained if removal markedly altered the model fit. Explanatory variables were tested for interaction. The likelihood ratio test was used to examine evidence for interaction between the effects of exposures and the two groups of women.

RESULTS

In total, 185 women were enrolled in the study, of whom 152 (82%) had at least one follow-up visit and 135 (73%) completed the 6-month study period. Nine women were willing to participate in the study, but did not fulfil eligibility criteria. Ninety-five women (51.4%) were FSWs, who had fewer years of schooling and were less likely to be married than participants from SRH services (Table 1). Only 12% (11/94) of FSWs had no monthly income compared with 32% (27/84) of other study participants ($p \leq 0.001$). FSWs reported an unexpectedly low number of sexual partners; at baseline, about half of them indeed had none or only one partner in the previous three months. Most of these women are part-time sex workers, as shown in previous studies in Mombasa. (8) Only eight of the 94 women (9%) who reported exchanging money or goods for sex cited sex work as their main source of income. At least three attempts were made to trace women who did not return for study visits. Baseline characteristics of women completing the 6-month study visit were compared with those of women lost to follow-up. Age, education, income, self-reported sex work, and condom and contraceptive use were similar between these groups (data not shown).

Acceptability of the diaphragm

At the 6-month visit, 55% (56/102) of women reported having used the diaphragm each time they had sex during the previous month. At each visit, about half of the sexually-active women reported that they had used the diaphragm with every sex act in the previous month. Around 8% (range: 3–16%) never used the diaphragm. The potential impact of non-response bias was estimated at the 6-month visit, assuming all women who did not attend follow-up were sexually active and never used the diaphragm. In this scenario, 37% (56/152) of women used the diaphragm with all sex acts and

Table 1: Baseline characteristics at study entry

| Variable | All study participants (n=185) | Female sex workers (n=95)* | Women attending SRH services (n=86)* | p-value |
|---|--------------------------------|----------------------------|--------------------------------------|---------------------|
| <u>Age, mean years (sd)</u> | 31.3 (7.6) | 31.2 (7.7) | 33.0 (7.3) | 0.11** |
| <u>Socio-economic characteristics</u> | | | | |
| Marital status, % (n) | | | | |
| Never married | 28% (51/184) | 39% (37/95) | 15% (13/85) | |
| Married | 39% (71/184) | 15% (14/95) | 65% (55/85) | |
| Widowed, separated or divorced | 34% (62/184) | 46% (44/95) | 20% (17/85) | <0.001 [‡] |
| Religion, % (n) | | | | |
| Christian | 84% (153/182) | 83% (77/93) | 85% (72/85) | |
| Muslim | 16% (29/182) | 17% (16/93) | 15% (13/85) | 0.73 [‡] |
| Education, mean years of schooling (sd) | 7.9 (3.4) | 6.8 (3.7) | 9.1 (2.6) | <0.001** |
| Income, Ksh/month (USD), % (n) | | | | |
| None | 21% (39/182) | 12% (11/94) | 32% (27/84) | |
| <2000 (\$27) | 29% (52/182) | 38% (36/94) | 18% (15/84) | |
| 2001-10 000 (\$27-136) | 46% (83/182) | 45% (42/94) | 46% (39/84) | |
| >10 000 (>\$136) | 4% (8/182) | 5% (5/94) | 4% (3/84) | 0.001 [‡] |
| <u>Sexual behaviour characteristics</u> | | | | |
| Age at first sexual intercourse, median years (IQR) | 16 (15-19) | 16 (15-18) | 18 (16-20) | <0.001* |
| Sexual partners in last 3 months, % (n) | | | | |
| 0 | 6% (11/184) | 6% (6/94) | 6% (5/86) | |
| 1 | 70% (128/184) | 50% (47/94) | 91% (78/86) | |
| 2 or more | 25% (45/184) | 44% (41/94) | 4% (3/86) | <0.001 [‡] |
| Condom use, % (n) | | | | |
| Never | 47% (86/183) | 26% (24/94) | 71% (60/85) | |
| Inconsistent | 36% (65/183) | 49% (46/94) | 20% (17/85) | |
| Always | 17% (32/183) | 26% (24/94) | 9% (8/85) | <0.001 [‡] |
| <u>Current contraception use, % (n)</u> | | | | |
| None | 53% (98/184) | 66% (63/95) | 38% (33/86) | |
| Any method | 47% (86/184) | 34% (32/95) | 62% (53/86) | <0.001 [‡] |
| Diaphragm | 0% (0/86) | 0% (0/32) | 0% (0/53) | 1.0 [†] |
| Injectable contraceptive | 57% (49/86) | 63% (20/32) | 53% (28/53) | 0.38 [‡] |
| Pill | 19% (16/86) | 9% (3/32) | 25% (13/53) | 0.083 [‡] |
| Intrauterine device (IUD) | 5% (4/86) | 0% (0/32) | 8% (4/53) | 0.29 [‡] |
| Male condom | 15% (13/86) | 22% (7/32) | 11% (6/53) | 0.19 [‡] |
| Female condom | 1% (1/86) | 0% (0/32) | 2% (1/53) | 1.0 [†] |
| Other | 3% (3/86) | 6% (2/32) | 2% (1/53) | 0.55 [†] |

*Information on female sex work practices is not available for four women.

Statistical tests compare FSWs to women attending SRH services: [‡]chi-square test; [†]Fisher's exact test; **unpaired Student's t-test, ^ΩMann-Whitney U-test.

Table 2. Factors associated with consistent diaphragm use at six months using logistic regression model

| Study population | Variable | Unadjusted odds ratio | 95%CI | P-value | Adjusted odds ratio | 95%CI | P-value | |
|---|---|-----------------------|-----------|---------|---------------------|------------|---------|--|
| Female sex workers | Age (per increase in year) | 1.00 | 0.94-1.06 | 0.97 | - | - | - | |
| | Education (per increase in year of schooling) | 1.14 | 1.01-1.30 | 0.04 | 1.17 | 0.99-1.39 | 0.058 | |
| | <u>Marital status</u> | | | | | | | |
| | Never married | 1.0 | | | 1.0 | | | |
| | Married | 0.86 | 0.15-5.0 | 0.86 | 1.77 | 0.25-12.5 | 0.57 | |
| | Widowed, separated or divorced | 1.95 | 0.55-6.95 | 0.30 | 3.07 | 0.76- 12.3 | 0.12 | |
| | Income (per increase in income category) | 1.04 | 0.54-2.0 | 0.90 | - | - | - | |
| | <u>Condom use at study entry</u> | | | | | | | |
| | Never or inconsistent use vs. always | 1.88 | 0.54-6.54 | 0.32 | 1.36 | 0.85-2.18 | 0.20 | |
| | <u>Contraceptive use at study entry</u> | | | | | | | |
| Women attending sexual and reproductive health services | None vs. current use | 1.07 | 0.34-3.32 | 0.91 | - | - | - | |
| | Age (per increase in year) | 0.99 | 0.91-1.07 | 0.77 | - | - | - | |
| | Education (per increase in year of schooling) | 0.93 | 0.74-1.16 | 0.52 | 0.82 | 0.59-1.14 | 0.24 | |
| | <u>Marital status</u> | | | | | | | |
| | Never married | 1.0 | | | 1.0 | | | |
| | Married | 0.29 | 0.03-2.9 | 0.26 | 0.13 | 0.11-1.45 | 0.12 | |
| | Widowed, separated or divorced | 0.14 | 0.01- 2.1 | 0.10 | 0.06 | 0.03-0.90 | 0.04 | |
| | Income (per increase in income category) | 0.55 | 0.31-0.98 | 0.04 | 0.40 | 0.17-0.92 | 0.031 | |
| | <u>Condom use at study entry</u> | | | | | | | |
| | Never or inconsistent use vs. always | 1.31 | 0.21-8.11 | 0.77 | - | - | - | |
| <u>Contraceptive use at study entry</u> | | | | | | | | |
| None vs. current use | 0.62 | 0.17-2.22 | 0.46 | 0.28 | 0.056-1.36 | 0.11 | | |

43% (66/152) never used the diaphragm in the last month. After 6 months, 95% (104/109) of women currently using the diaphragm reported liking it. Women reported to like the diaphragm because it 'allows them to be in control' (40%), is easy to use (8%), and procures a feeling of being protected against infections (78%). Nearly all women (96%) said they would use it again. One woman reported difficulties storing the diaphragm. In the focus group discussions, women mentioned few difficulties with diaphragm insertion and removal. Further analysis of these discussions highlighted the importance of covert use of the diaphragm during sex work or with casual partners. However, women in long-term relationships often wished to disclose its use, but found the process of disclosure very difficult. Several of the women reported that their partners criticized their use of the diaphragm as it indicated that they did not trust their partner, or that they did not trust themselves. In the discussion groups, a few women reported that their partners had accidentally discovered they were using the diaphragm. This often resulted in partner conflict. At the six-month visit, 54% (65/121) of women reported to have disclosed their use of the diaphragm to their partners; 81% (52/64) of the partners of these women were willing to give the device a try. The main reasons for non-disclosure (n=47) were fear for their partner's reaction in 81% (38/47), and feelings that disclosing was unnecessary in 19% (9/47). Factors associated with diaphragm use appeared to differ for FSWs and women attending SRH services, each requiring a separate multivariate model (Table 2). Among FSWs, diaphragm use was associated with the number of years of school attended, with an adjusted odds ratio (AOR) of 1.17 per year of schooling (95% CI: 0.99–1.39; $P=0.058$). Women attending SRH clinics who had a higher income (AOR=0.40 per increase in income category; 95% CI: 0.17–0.92; $P=0.031$) or were widowed, separated or divorced were less likely to use the diaphragm (AOR=0.06; 95% CI: 0.17–0.92; $P=0.031$).

Contraceptive and condom use

Contraceptive prevalence (including women using the diaphragm with all sex acts) increased from 47% (86/184) at baseline to 61% (81/133) at 6 months ($P=0.013$). With the addition of the diaphragm to the available contraceptive method mix, the relative contribution of the male condom changed from 15% (13/86) at baseline to 10% (8/81) at the 6-month visit ($P=0.31$). During the 6 months the study lasted, reported consistent condom use did not change (range: 8–17%; $P=0.94$). Eight participants conceived during the study, giving a pregnancy rate of 12.2% per year. All these women reported inconsistent use both of the diaphragm and alternative contraceptive methods.

Safety of the diaphragm

At the 6-month visit, bacterial vaginosis, trichomoniasis, candidiasis and urinary tract infections (UTIs) were diagnosed in, respectively, 25%, 10%, 16% and 28% of women who did not use the diaphragm in the preceding month, and 32%, 4%, 18% and 27% among women who did use the diaphragm (Table 3). Colposcopy examination identified disruptive lesions in 3% of women in both groups and non-disruptive lesions in 20% (13/66) and 9% (3/34) of women having used and not used the diaphragm in the preceding month, respectively ($P=0.16$). Among sexually active women, the incidence rate for gonococcal infection in women who always used the diaphragm was 28.6 per 100 person-years of observation compared to 48 per 100 person-years in women who inconsistently used the diaphragm during the study (rate ratio 0.60; 95% CI: 0.17–1.87; $P=0.34$).

DISCUSSION

Continuation rates at 6 months and user perspectives indicate high acceptability of the diaphragm in this setting. High levels of diaphragm continuation have also been reported in similar studies elsewhere. (9,10) In addition to being a female-controlled method not necessarily requiring male co-operation, the diaphragm has several advantages for women:

- minimal interference with sexual spontaneity;
- absence of drug-related side effects;
- immediate contraceptive reversibility.

Compared with the male condom, the diaphragm has less impact on sexual pleasure and spontaneity, both features being important for male acceptability. Skills needed for diaphragm use were easily acquired, consistent with other reports. Studies in India, Colombia, the Philippines and Turkey found that women with low education and income were able to successfully use the device and to overcome potential obstacles such as limited privacy for its insertion and removal. (11,12) Women attending SRH services in this study who had a low income were even more likely to continue diaphragm use than women with higher incomes. Among FSWs, low levels of education were associated with decreased diaphragm use. Possibly, women with low levels of education require additional information and counselling about female anatomy before diaphragm use. It has been reported by FSW peer educators and participants that some women are reluctant to use the

Table 3. Diaphragm safety evaluations at 6 months assessing the occurrence of UTI, STIs and colposcopic abnormalities with diaphragm use in the preceding month

| Variable | Baseline All participants % (n/N) | Six months | | P-value * |
|----------------------------|---|--|---|-----------|
| | | Diaphragm not used in preceding month % (n/N) | Used diaphragm in preceding month % (n/N) | |
| Urine leukocytes positive | 31% (53/169) | 28% (11/40) | 27% (22/83) | 0.91 |
| Bacterial vaginosis | 37% (58/155) | 25% (10/40) | 32% (26/82) | 0.45 |
| Trichomoniasis | 6% (10/173) | 10% (4/39) | 4% (3/82) | 0.15 |
| Candida | 6% (10/172) | 16% (6/38) | 18% (15/82) | 0.74 |
| <u>Colposcopy Findings</u> | Not available | | | |
| Any disruptive lesion | | 3% (1/34) | 3% (2/66) | 1.0 |
| Ulcer | | 3% (1/34) | 3% (2/66) | |
| Abrasions | | 0% (0/34) | 0% (0/66) | |
| Any non-disruptive lesion | | 9% (3/34) | 20% (13/66) | 0.16 |
| Erythema | | 3% (1/34) | 3% (2/66) | |
| Oedema | | 0% (0/34) | 3% (2/66) | |
| Petechiae | | 6% (2/34) | 6% (4/66) | |
| Papule | | 0% (0/34) | 5% (3/66) | |
| Pustule | | 0% (0/34) | 3% (2/66) | |

*Chi-square test.

diaphragm because they feared it would 'enter their stomach'. When making sexual and reproductive choices, in addition to assessing the positive and negative characteristics of a method, women need to consider both their family planning needs and risk of contracting STIs. Overall, diaphragm acceptability and use are, therefore, likely to be determined, amongst other things, by its effectiveness in protecting against pregnancies, as well as against STIs. Introduction of the diaphragm led to a significant increase in contraceptive prevalence to 61% (81/133) at 6 months. The diaphragm and male condom have a similar contraceptive efficacy, with about 15% of typical users becoming unintentionally pregnant within the first year of using either method. Despite widespread promotion and provision of the male condom, its acceptability and continuation rates remain low. (13) Only about 15% of women consistently used condoms during the study despite extensive counselling. Although women received repeated counselling and information about the uncertain protective efficacy of the diaphragm against some STIs, the majority perceived this device as giving them some protection. This is similar to findings of a South African microbicide trial, where many participants believed the candidate agent helped to prevent HIV and other STIs. (14) These

observations indicate that, in the future, researchers need to take steps to ensure participants comprehend the uncertain efficacy of an investigational product. Also, during research activities and programme implementation, one should ensure that condoms are not replaced by less effective methods of protection against HIV and other STIs. Though it is not possible within this small study to comment on the effectiveness of the diaphragm in preventing infection of the cervix by agents of STIs, we found that sexually active women who always used the diaphragm during the study were 40% less likely to acquire gonorrhoea than those who used the diaphragm inconsistently. In contrast with previous studies, this cohort study provides evidence of the safety of using the diaphragm without spermicides. Previous investigations on diaphragm safety pertained mostly to women using the diaphragm with a spermicide, making it difficult to distinguish adverse events related to diaphragm use from those due to the spermicide. We observed no increased risk of *bacterial vaginosis*, trichomoniasis, candidiasis or UTIs with diaphragm use. Nondisruptive cervical and vaginal lesions seemed more common with diaphragm use, but the difference was not statistically significant. The importance of these lesions in relation to HIV acquisition is not known and further research is needed to investigate whether lesions occur with longer-term use of the diaphragm. The diaphragm may also serve for administering microbicides, potentially providing synergistic protection against HIV and other STIs. Once available, such a female-controlled dual protection against STIs and pregnancies could have an important impact especially in settings with high rates of STIs, HIV and unintended pregnancies. Evidence of diaphragm's acceptability may influence its role in future microbicides research. The number of women attending each monthly visit differed. Therefore, as different women attended each visit, it is difficult to draw firm conclusions about changes in diaphragm and condom use over the months. Non-response bias may have occurred with a retention rate of 73%. The baseline characteristics of this group were similar to those completing follow-up. With the exception of five women who cited partner disapproval, reasons given for leaving the study were unlikely to be related to diaphragm acceptability. In the past, the diaphragm was very commonly resorted to for contraception (15), but its use diminished rapidly with the introduction of more effective contraceptives that do not interfere with sexual spontaneity, especially hormonal contraceptives and intrauterine devices. Worldwide, by 2003, only an estimated 0.5% of women of reproductive age were using the diaphragm and related methods. (16) Nowadays, most women of reproductive age and health care workers are not familiar with the diaphragm. Lack of health provider familiarity with this contraceptive and lack of expertise in fitting it may limit future provision.

(17) The diaphragm is at present an underutilized and under-researched technology. Acceptance and use of the diaphragm were high in our setting. If current studies demonstrate its protective effect against HIV and other STIs, it could provide a means of prevention for women whose partners refuse to use condoms.

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5.5 Secrecy, disclosure and accidental discovery: perspectives of diaphragm users in Mombasa, Kenya.

Secrecy, disclosure and accidental discovery: perspectives of diaphragm users in Mombasa, Kenya

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ABSTRACT

The diaphragm is receiving renewed attention, as a promising female-controlled method of preventing HIV and other sexually-transmitted infections (STI). It is anticipated that female-controlled technologies will reduce women's biological susceptibility and assist in counteracting their socio-cultural vulnerability to HIV. Understanding the subjective experiences of diaphragm users in different settings may inform development and promotion of such methods. This paper explores perspectives of female sex workers and women attending sexual and reproductive health services in Mombasa, Kenya. Data are reported from focus group discussions and in-depth interviews with women and men, following a prospective study investigating diaphragm continuation rates over six months. Discussions highlighted covert use of the diaphragm during sex work or with casual partners, and coital independence as favourable attributes. These features were especially pronounced compared with male condoms. Few difficulties with diaphragm use were reported, although its insertion and removal occasionally presented problems. Many women – especially those in long term partnerships – wished to disclose its use, but found the disclosure process highly problematic. Accidental discovery often resulted in partner conflict. Although future uptake of the diaphragm may be high in this setting, its use may be limited to certain types of relationships and relationship contexts.

INTRODUCTION

There is a long-neglected unmet need for female-controlled methods for preventing HIV and other sexually-transmitted infections (STIs) (UNAIDS/UNFPA et al. 2004, UNAIDS/WHO 2004). Women are biologically more susceptible to infection with STIs than men. Moreover, social and economic factors increase their vulnerability, especially in settings with stark gender and economic inequities (UNAIDS/WHO 2004). Increased vulnerability together with a lack of prevention options for women limits the impact of current initiatives to reduce transmission of HIV and other STIs. In response to this, concerted efforts are being made to develop technologies that are under the control of women and can potentially be used without their partner's knowledge.

Research has focused on vaginal microbicides and cervical barriers, such as the diaphragm, which may be used without male co-operation and/or knowledge (Harvey et al. 2003, Minnis and Padian 2005). These methods are not intended to replace condom use, but rather to augment existing options as it is likely that female and male condoms will long remain the most effective individual-level method of protection (Foss et al. 2003).

Limited evidence from observational studies suggests the diaphragm protects against man's STIs and their sequelae, including gonorrhoea (Austin et al. 1984, Rosenberg et al. 1992), pelvic inflammatory disease (Wolner-Hanssen et al. 1990) and cervical dysplasia (Becker et al. 1994). This is biologically plausible—the cervix being a primary entry site for STIs such as HIV, *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and the *human papilloma virus* (Moench et al. 2001). Ongoing trials aim to determine its protective efficacy against HIV.

The diaphragm is one of the oldest contraceptive methods and was formerly quite widely used. It was often used with a spermicide and studies to date have largely investigated the contraceptive efficacy of the diaphragm and spermicide together. Less evidence is available of unintended pregnancy risks with the use of the diaphragm alone; however, a recent Cochrane review comparing contraceptive efficacy of the diaphragm with and without spermicide found no difference in efficacy (Cook et al. 2003). In recent years, the diaphragm has not been included in the method mix in family planning services in many countries, including Kenya (United Nations 2003). Therefore, at present, most women and health providers are not familiar with it. However, in recent times spermicide use among women at high risk for HIV has been discouraged, since nonoxynol-9 was found to be associated with increased risk of genital lesions which may increase the risk of acquiring HIV infection (Wilkinson et al. 2002).

The perspectives of diaphragm users and population-level uptake are likely to be context specific, as trade-offs between positive and negative attributes are shaped by social and cultural practices. Diaphragm uptake will also depend on available options for contraception and for protection against HIV and other STIs, as well as on the degree of protection the device confers. The aim of this paper is to explore the subjective experiences of women and men following diaphragm use in Mombasa, Kenya. Documenting user perspectives in diverse settings may inform the design of diaphragm studies, the tailoring of diaphragm promotion and the future development of female-controlled prevention technologies.

METHODS

Study setting

The study took place from January 2004 to July 2005 in a public-sector primary health clinic in Chaani, Mombasa. Mombasa, on Kenya's Coast province, is a major regional economic centre, with important tourism, port, rail and industrial enterprises. The road linking the Mombasa seaport with the capital city Nairobi passes through Chaani, which is largely inhabited by a migrant population, many of whom work at the nearby port or as small scale traders, loaders and truck-drivers. This part of the city has a high burden of HIV and other STIs, much of which is borne by female sex workers (Luchters et al. 2006).

Study participants

Two groups of women were invited to participate: women sex workers approached by peer educators in bars, guesthouses and other community settings; and women recruited from sexual and reproductive health (SRH) services at Chaani clinic. Women attending such services were informed about the study during the morning health talks and patient encounters. In these interactions, trained health workers outlined study procedures, showed women the device and asked them to decide if they were interested in participating. Those interested, received more detailed information from nurses at the clinic and were referred to study staff.

To be eligible for the study, women had to be aged 18 to 49 years, sexually active, resident within the study area for at least one year and considered likely to remain in the area for the next six months. All those enrolled had expressed willingness to try using the diaphragm. Women who were

pregnant, planning a pregnancy in the next six months, allergic to latex or had a previous hysterectomy were excluded from the study.

This study consisted of two phases. Phase 1, a six-month cohort study, assessed diaphragm continuation rates and factors associated with diaphragm use. Thereafter, qualitative research methods were used to examine diaphragm users' perspectives (Phase 2). These form the basis of this paper. Written informed consent was obtained at study entry and prior to the qualitative phase. The Kenyan ethics and research committee and the ethics committee of Ghent University, Belgium, approved the study.

Phase 1

Following enrolment, participants were fitted with a latex diaphragm and received practical guidance on its insertion and removal. Women were instructed that the diaphragm should be inserted up to 30 minutes before intercourse, left in place for six hours after intercourse and removed within 24 hours of insertion. They were discouraged from using lubricants or spermicide-containing products and were told to use only water during insertion and cleaning of the diaphragm.

Study participants received individualised counselling to assist them to reduce their risk of acquiring HIV and other STIs, and were offered HIV testing and counselling. At enrolment and subsequent visits they were informed that the protective efficacy of the diaphragm against STIs (including HIV) was unknown. Male condoms were promoted and provided free of charge at enrolment and at each subsequent visit. At study visits, women whose male condom use had decreased were identified and received additional counselling. Peer educators made specific efforts to reach study participants in the community and provide them with condoms. Although women were informed that the diaphragm offers protection against pregnancy, they were encouraged to use more effective contraceptive methods.

Structured interviews were used to collect demographic, behavioural and clinical data. At follow-up visits, the use of the diaphragm, condoms and contraception was assessed. Women reporting intimate-partner violence during the study were linked with a local service that provides confidential counselling and other supportive interventions.

Of the 185 study participants, 97 were sex workers and 88 were women enrolled at SRH clinics. None of the participants had previously used the diaphragm. Women were a mean 31.3 years (standard deviation=7.6 years). Sex workers were less likely to be married and had fewer years of

schooling compared with women from SRH clinics (6.8 years versus 9.9 years; $P < 0.001$). Median age at sexual debut was 16 years (inter quartile range=15–19 years) for sex workers and 18 years (inter quartile range=16–20 years) in the other study group ($P < 0.001$). Eighty-two percent of women (152/185) had at least one follow-up visit and 73% (135/185) completed the six-month study period. At the six-month visit, 55% (56/102) of the sexually-active women reported using the diaphragm with all sex acts in the previous month. No change was detected in the proportion of participants reporting consistent condom use at each visit. After six months, fewer sex workers than women from SRH clinics reported having disclosed diaphragm use to their partners (42%, 26/62 versus 67% 38/57; $P = 0.007$). More detailed results and data on factors associated with diaphragm use, effects of diaphragm use on contraceptive method mix, and diaphragm safety and effectiveness are presented elsewhere (Luchters et al. 2007)

Phase2

After Phase 1, all participants were contacted and asked if they were willing to participate in focus group discussions. Of the 135 women who completed six-months follow up, 119 (88%) agreed to participate. Having interacted closely with participants during the preceding six months, study staff had got to know many participants well. Based on this, they made a subjective assessment of which participants were most likely to provide detailed information and to share their experiences openly. Study staff asked women who had disclosed diaphragm use for permission to contact their male partners. Thirty men were contacted and invited to participate in a focus group discussion, eight of whom arrived on the scheduled date.

Groups were separated according to marital status, gender and site of recruitment. By increasing the homogeneity within groups, we aimed to encourage discussion of shared experiences and to reduce inhibitions. Five focus group discussions took place with between seven and 12 participants (total of 39 women and eight men). Each group comprised either sex workers; unmarried women from SRH clinics; married women from SRH clinics; women who had withdrawn from the study or missed the six-month study visit; or men. The age of focus group participants ranged from 20–45 years. Additionally, study investigators were concerned that violence may be related to diaphragm use and in-depth interviews were held with the five women who reported having experienced violent conflict with their partners during Phase 1. These interviews explored the underlying reasons for the conflict and a potential relation with diaphragm use.

During group discussions, participants were given name tags with nicknames, to protect confidentiality. Discussants were requested to use the nickname or say 'my colleague' when referring to other participants. Participants were asked to avoid discussing proceedings after the sessions. Electronic data are stored on a password-protected computer and contained no identifying information.

Generally, participants took an active role in the discussions. They spoke freely and displayed interest in the issues. Focus group discussions are a particularly appropriate method of data collection in Mombasa. They succeed in producing data through interaction and discourse in a group setting that one-to-one interviews may fail to generate (Kitzinger 1995). Vikao (same sex group discussions) are a popular activity amongst coastal Swahili people. Outside the domestic domain, men and women participate in a social environment in which same-sex group discussions are a significant forum for reinforcing group identification and increasing social cohesion.

Trained researchers facilitated the group discussions in Swahili, the common language of the coastal region of Kenya. A standardized interview schedule was used, with open-ended questions followed by specific probes. Topics covered included perspectives on diaphragm use, sexual pleasure, gender relations, partners' response to the method and concerns about HIV, STIs and pregnancy. Group discussions were tape-recorded, transcribed verbatim, translated to English and analysed using MAX QDA2™ (Bonn, Germany). Transcripts were coded according to a coding structure developed after repeated review of the transcripts using text word searches. A coding report was generated that featured all the codes and associated text.

RESULTS

The content analysis highlighted several themes concerning women and men's subjective experiences with the diaphragm. These included the convenience of the diaphragm from a practical perspective; its perceived efficacy; the pivotal role of sexual pleasure in decisions about protection; and secrecy and disclosure. Many of these themes are underscored by gender power issues and reveal how sexuality and family planning decisions in this setting are often areas of contestation between men and women.

Convenience of the diaphragm

Very few women experienced difficulties with the practical attributes of the diaphragm (insertion, removal, cleaning and storage). However, the timing of inserting and removing the diaphragm in relation to women's daily activities was raised as an important issue. Agnes, a 26-year-old married woman, described her difficulties with timing diaphragm insertion while at the same time maintaining its secrecy:

'The bad thing about the diaphragm is that when my husband comes home and he is ready, and you want to use it [the diaphragm], you are expected to insert it earlier. So when he comes and you have not inserted, it becomes difficult, because he might find out.'

Others, such as Lillian (29 years old), also reported problems with timing the removal of the diaphragm and the constraints of her workplace:

'Personally, I have a problem with diaphragm, you know I go to work and sometimes I leave the house at six o'clock. I cannot remove it in the morning while bathing since I can get an infection or get pregnant because there is a fixed time that it should remain inside. I am forced to go to work while I have it inside. So, I go to work in the morning and wait up to around 10.00am to go back to the house and remove, wash and store it. So I feel for those of us who leave for work very early.'

Christine, a 33-year-old unmarried woman, experienced a similar problem:

'Some work places don't have good toilets. For example, the company that I work for sometimes has no water in the toilet. So what happens when one has to remove the diaphragm there, will I leave it dirty? There's always that worry of how it will be at work when it's time to remove it.'

Like many others, Christine raised concerns about personal hygiene, highlighting her discomfort in leaving the diaphragm in place for six hours after intercourse. Having semen in the vagina caused women to feel uncomfortable and unclean. Mary, a school teacher, believed that this was the reason many of her female colleagues shunned the diaphragm:

'They say it is unclean to use it since the diaphragm traps semen inside the body....They say it

is dirty, because you insert your fingers at night and in the morning also to remove it.'

Perceived efficacy in preventing sexually-transmitted infection and in enhancing sexual pleasure.

Group discussions with women highlighted the diaphragm's perceived efficacy against STI, but also its contribution to sexual pleasure.

Some women thought the diaphragm had been highly effective in minimising their risk of infection. For example, a 26-year-old female sex worker reported decreased STI and associated this with diaphragm use:

'When I was using condoms only, I got infections but since I started using the diaphragm I have not been infected. If you find me sick, it will not be an STI, it will be something else. For me the diaphragm is good. Before I got it, I used to get infected with gonorrhoea because I am a sex worker and I have multiple sexual partners who I hook up with in clubs. Sometimes the condom bursts just as he is about to ejaculate and at other times the clients refuse to put on the condom. You may try to shake him off, but he may be too strong for you. But since I started using it [diaphragm] I have not had such problems.'

The diaphragm, as she noted, provided an additional protective option to condoms, which were unreliable and unfeasible in some of her sexual relationships.

While perceived protection against STIs was an important aspect of the diaphragm— particularly for women who saw themselves as at high risk—the implications for sexual pleasure received more attention in the focus groups. Both sex workers and women from SRH clinics appeared to place a higher emphasis on men's pleasure than their own.

Women in long-term relationships often reported that their partners experienced heightened sexual feelings when using the diaphragm:

'When I insert it he tells me he gets more pleasure than before. You know he is young, so when he feels it inside, he tells me that he did not feel like that previously.'

The only criticism of the diaphragm voiced by men was that it restricted their depth of penetration:

'When I asked him how he feels he said it is the same, but when he penetrates he feels there is something blocking him, so he does not reach where he always reaches when there is no diaphragm.'

In their focus group, men tended to agree that the diaphragm did not interfere with sexual pleasure; many simply felt that there was no difference when the diaphragm was used.

The diaphragm was viewed most positively by both men and women in comparison to the condom. Kazungu, a 37-year-old married man described his initial reaction to the diaphragm and how this had changed:

'I really criticized it [the diaphragm]. She told me that instead of the condom we use the diaphragm. But later when I tried it I realized that it was even better than the condom. Because with the condom you don't get as much enjoyment, but with the diaphragm you really enjoy since you know you are using something that gives you "flesh to flesh" contact.'

The absence of the condom allowed men to experience a greater degree of intimacy. Unprotected sex was described as unrestricted; enabling their partners to experience a sensation of unrestricted sex. This was important for the clients of sex workers, but also for non-paying, emotional partners. Men also stressed the importance of ejaculating inside a woman—something the condom prevented. Karisa, a married 31-year-old man, explained why:

'The condom does not have pleasure, a woman does not feel pleasure so it will be difficult to convince her to use it. For most women the pleasure is to feel the semen, because when you ejaculate and she does not feel anything then it is just like when you come out without ejaculation.'

These ideas were supported by women who regarded the sensation of ejaculation as pleasurable, and even therapeutic, as Mercy (41 years old and married) noted:

'Some women believe that they cannot stay for a year without a man to lubricate her. There are some women who refuse when their husbands want to use the condom. They will say "I cannot have sex without my husband ejaculating in me. That is medicine for my body".'

The positive associations of the diaphragm versus the negative associations of the condom were not

surprising. Informants raised the all too familiar concerns with the condom; particularly that it undermined trust within a relationship. Condoms were regarded as very necessary in extramarital relationships but inappropriate within more permanent relationships, where they symbolized a lack of trust. Given the particular difficulties with using condoms with boyfriends and husbands, women felt the diaphragm provided a useful alternative. Although the diaphragm had distinct advantages over the male condom, it did not necessarily escape some of the same criticisms that were levelled at the condom. Most significantly, diaphragm use also symbolised a lack of trust within long-term relationships, perhaps even more so because the diaphragm was a virtually invisible device and could be used secretly. Mary, a school teacher, said:

'My colleagues who are teachers say it is for prostitutes, someone with a husband cannot use that, what for?'

Several of the women in the focus groups reported that their partners' criticized their use of the diaphragm as it indicated that they did not trust their partners, or that they did not trust themselves. This concern—amongst others—introduces us to the apparent importance of the clandestine use of the diaphragm.

Secrecy and disclosure

A recurrent theme in discussions with women was their ability to use the diaphragm covertly, without their partner's knowledge. This was an advantage for women whose partners objected to contraceptive or condom use. Josephine, 28 years old, emphasised this aspect:

'The diaphragm is good because I use it secretly. First he doesn't want me to use the pills. He says that they cause high blood pressure. He cannot wear a condom. So I took the diaphragm. I am happy with the diaphragm because even if he doesn't want me to use it, I insert it and when we have intercourse he doesn't even know.'

For Josephine, like many others, the diaphragm provided an invisible method of contraception, allowing her to take control over her own fertility. Twenty-seven-year-old Jane had a similar viewpoint:

'In order to protect yourself, you don't even need to tell him, you can just use the diaphragm without his knowledge, if you don't intend to have more children. I don't see the need of telling

him, because when you tell him he will have so many reasons for not using contraception. I don't even think he can feel the diaphragm when you have inserted it, so it is up to you as a woman to stay with your secret.'

The secrecy afforded by the diaphragm not only imparted power in sexual decision making, but a sense of empowerment in general. Amina, a 40-year-old married woman elaborated:

'First you should know that women have secrets; they can keep secrets even from their husbands. So, because we were born secretive, women can use the diaphragm to protect themselves without telling men. My secret is my own, alone. The man who will ever discover that I used the diaphragm; it will be up to him and his God.'

In the discussion groups, most women supported the idea of using the diaphragm secretly and withholding knowledge of it from their partners. They particularly liked the idea that this enabled them to avoid negotiating its use, thereby minimising potential conflict with their partners. Women who had paying clients were particularly enthusiastic about using the diaphragm as they felt it allowed them to have protected sex without having to negotiate condoms.

As a secretive device the diaphragm was especially beneficial for women who may be coerced into having unprotected sex. Grace, a 26-year-old married woman recounted her experiences:

'My husband is a drunkard and he would not allow me to use a condom or a diaphragm. The diaphragm is my secret, when you think you have had sex flesh to flesh, you do not get my flesh. So I try to protect myself even if it [diaphragm] is not one hundred percent. That is why it is my secret.'

Yet, although secrecy was imperative for some women, in many relationships disclosure of the diaphragm was desired and/or inevitable. Disclosure was often exceptionally problematic.

Women who informed their partners that they intended to use the diaphragm once they had enrolled in the study often experienced resistance from their partners. Aisha, a married woman aged 40 years, decided to opt out of the study due to her husband's reaction:

'I tried the diaphragm but my husband became very harsh with me so I decided that there is no need to destroy my family so I left it. At the moment I don't use any family planning methods, I

just depend on God.'

Mwanaisha, a 37-year-old woman, explained that her husband initially agreed but later refused to allow her to use the diaphragm:

'When I first told my husband about the diaphragm he agreed and said that if it is a method of family planning, then there was no problem. But when he saw it he said "what kind of thing is this? Don't ever use it". So I kept it till now. He said that it was a female condom and I could not wear it. He felt that if I start wearing the diaphragm then I could get out of the house and see other men.'

In contrast, those women who were in relationships in which reproductive and sexual health issues were discussed relatively openly, disclosure was not a critical issue. Lillian, a 37-year-old married woman, initiated a discussion about the diaphragm with her husband before she started to use it:

'I have taken pills [oral contraception] for a long time. I am now tired since I gave birth to my last child born in 1991. When I came to know about the diaphragm, I did not hide from my partner, I told him "look at this thing, it is used like this and now I am tired of using these pills for all those years, let us try and see if it will work". January, it was okay, February, it was okay, March, it was okay until now. To tell the truth I don't use any other method besides the diaphragm. I told him this, "I want to stop using the oral contraceptives, I want to use this thing and see if it will suit me for family planning. If it suits me, I will stop the oral contraceptive pills". So I continued using it until now. He is grateful because he was the one who was buying the pills.'

Although Lillian's case was not the norm, several women eventually disclosed to their partners after having used the diaphragm in secret for some time. Katama, a 38-year-old man recalled:

'When my wife came with it for the first time she could not find a way of telling me, so she decided to use it secretly. After using it secretly, she tried seducing me in every way to get me to agree to use the diaphragm. It took me a long time before I agreed to it.'

However, in several cases accidental discovery pre-empted disclosure. For example, as mentioned earlier, some men were able to feel the diaphragm, especially when having sex from behind.

Maintaining secrecy of the diaphragm in the long run was difficult, particularly with co-residential partners where accidental discovery of the diaphragm could occur. This sometimes had negative consequences and could result in partner conflict. However, all the reported incidents of violence following accidental discovery of the diaphragm occurred within relationships that had long-standing high levels of conflict, often including physical violence. Below are three excerpts from in-depth interviews detailing women's experiences after accidental discovery. Christine, a 29-year-old married woman, recalled what happened when her husband discovered her diaphragm:

'One day as my husband was looking for his clothes in the wardrobe he came across the diaphragm. He asked me what it was used for. I explained to him that it is a diaphragm for protection against sexually transmitted infections and contraception. He was furious. He said "Oh, so you think I am promiscuous". He then shouted and argued with me, eventually we had a fight.'

In other cases, men responded more violently. Mary, a 37-year-old resident of Chaani, had been married for five years with two children. She used the diaphragm for several months until the device was discovered by her husband. According to Mary, he said:

'So you have other men and they are so many that you have to use this thing [diaphragm] with them'.

He then reported Mary's actions to his mother who accused Mary of being a prostitute. Infuriated, Mary separated from her husband. Although the discovery of the diaphragm seemed to be the main reason for their break up, it appears that it only precipitated the end of an unhappy relationship. Mary reported that her husband was 'a drunkard and was ready to beat me up'. Adhiambo (33 years old) had a similar experience. When her husband discovered that she had been using the diaphragm for several months he beat her severely. In these situations the diaphragm itself sometimes became the main object of the dispute. Liz was 30 years old and had two children. She recounted in an in-depth interview that her husband was aware that she was using the diaphragm and had initially supported her using it as she had experienced adverse side-effects with hormonal contraception. Yet when their youngest child became severely ill, Liz's husband decided that they should have another baby. Liz refused and continued to use the diaphragm:

'When we quarrelled he burnt the diaphragm and we continued having unprotected sex because telling him to wear a condom would have made him ask me if I am his prostitute. He burnt the diaphragm intentionally so that I could conceive, because he said that before the end of the year he wanted me to have another baby...and now that I am pregnant he is satisfied. Maybe I can use it later.'

DISCUSSION

Experiences with new female-controlled methods for preventing HIV continue to reflect the barriers women face in carrying out safer behaviour choices such as condom use and postponing or limiting the number of pregnancies. These difficulties are particularly pronounced in situations where men strive to exert control over decisions about fertility, sexual pleasure and HIV prevention. New prevention methods like microbicides and cervical barriers are intended to be invisible and, by extension, clandestine and therefore empowering for the women who use them. In the context of an HIV epidemic where younger women bear the burden of HIV, female-controlled methods may be a crucial part of strategies to reduce infections (Minnis and Padian 2005). They would provide those women who have no means of combating a possibly deadly infection with a form of protection that is hidden, thereby allowing them to take increased control.

The data presented in this paper underline the importance of the clandestine use of the diaphragm, especially in relationships in which sexual negotiations are limited (sex workers and women who experience intimate-partner violence) or where partners differ over decisions about fertility. With casual partners or paying clients, women did not feel it necessary to disclose diaphragm use. However, as in a Ugandan study (Green et al. 2001), we showed that clandestine use was not always desirable or feasible; in many situations women willingly disclosed to their partners. In particular, married women or those in a long-term relationship often wished to disclose. Their dilemma was how to introduce the diaphragm to their partners. The type and nature of the relationship appears to be of major influence on the desire to disclose diaphragm use, but also on the complexity of the disclosure process. As with disclosing HIV status to partners, disclosure of diaphragm use was often a process rather than a single event. Among partners who communicate openly about sexual health, couple counselling could potentially be a useful means of introducing the diaphragm. For some couples, this

may obviate the need for complex disclosure processes and assist in delivery of accurate information for men. Further investigation of strategies to facilitate beneficial disclosure may also be important for microbicide products as it is possible that similar issues emerge with use of microbicides.

Accidental or belated disclosure of diaphragm use can have important negative implications within married or long-term relationships. Though secretive methods negate the need for discussion, this can create distrust and result in negative consequences for women when discovered. The same social context that necessitates the need for women to use covert methods of protection may also precipitate adverse consequences upon discovery of undisclosed use of the diaphragm, microbicides or related technologies.

The meanings of diaphragm use were also very different depending on the type of relationship, for example paid sexual encounters and long term partnerships. Diaphragm use in stable partnerships symbolised distrust and infidelity, similar to reactions to female and male condoms. Within regular partnerships, method use may depend on the dyadic relationship, with couple-decision making generally taking precedence over the individual's attitude to the product. Evidence from this paper suggests that, as with male condoms, women in casual and commercial sex relationships, rather than those in marital or regular relationship found it easier to use the diaphragm.

As expected (Severy and Newcomer 2005), women reported making tradeoffs between the diaphragm and available contraceptive and HIV-preventive methods. Though women viewed the diaphragm as an additional protective option in circumstances where condoms were unfeasible, it appears that it also replaced condom use in some couples. However, as the proportion of women using condoms remained unchanged throughout the study, it is possible that the decrease in condom use among some couples may have been counterbalanced by increased use in other women due to condom-promotion activities. Similarly, women reported substituting more effective contraceptive methods with the diaphragm. This migration occurred despite repeated counselling about its relatively high contraceptive failure rate and the unknown protective efficacy of the diaphragm against STIs. It is intended that new technologies will address unmet needs rather than replace existing methods. Re-introducing the diaphragm in Kenya would broaden the current contraceptive method mix and may increase the overall contraceptive prevalence. However, it is possible that the presence of an alternative to condoms may undermine the incentive for women to undertake difficult condom negotiations. Moreover, the lack of condom migration seen thus far in clinical studies (Foss

et al. 2003; Behets et al. 2005; van der Straten et al. 2005) may not be mirrored in real-life situations, where women have a range of methods to choose from and health providers have marked impact on method selection.

On the other hand, a shared interest between men and women is sexual pleasure. As commonly described (Hart et al. 1999; Pool et al. 2000; Thomsen et al. 2004), men and women concur that condoms are undesirable and hinder sexual pleasure. In this study the diaphragm was regarded as a way of increasing sexual intimacy and liberating sexuality from the constraints of condoms. The extent to which protective methods intrude into sexual pleasure and spontaneity is a key factor in determining whether they will be used consistently and correctly, especially in the 'heat of the moment' (Severy and Newcomer 2005). As previously shown (Albarracin et al. 2000), methods that are highly coital dependent are more likely to be used inconsistently. Compared with the condom, diaphragm insertion is relatively coitus independent. Increases in the recommended time that the diaphragm can remain in situ may accentuate this aspect. Recently developed cervical barriers can be worn up to 72 hours, allowing for near continuous diaphragm use. This may also address some difficulties with the timing of its insertion and removal. However for some women, the option of removing the diaphragm sooner than the recommended six hours after coitus may improve diaphragm acceptability. This issue was also described in a similar study in Kenya (Sharma et al. 2006) and warrants investigation.

Several factors limit the ability to draw conclusions from this study and to generalize its findings. Different themes may have emerged had selection of focus group participants been based on probability sampling, rather than the subjective views of study staff. Further, data on men's perceptions is limited as few men participated and their views may not be generalizable to other men. Men who had negative experiences with the diaphragm may have chosen not to participate, potentially resulting in an under-representation of negative experiences in men. Levels of male participation in this study illustrate the difficulties faced with increasing men's involvement in reproductive health services and the low acceptability of such service for men. Nevertheless, including men's perspectives provided valuable information and is important for predicting sustained use of the diaphragm (Thomson and Hoem 1998).

As we intentionally selected women who had discontinued diaphragm use and those who experienced violence, study results may over-represent negative experiences of women. This is evidenced by the fact that about half of women used the diaphragm for six months without disclosing its use to their

partners. However these data, even from women who experienced violence, may be useful in understanding the more typical experiences of women in this setting. Though theoretical saturation was reached for the main themes covered in this paper, having only five focus groups limited the ability to explore further sub-themes.

The users' perspectives presented here add information about the actual behaviours of women and men and the impediments to diaphragm use. Findings also caution that differential continuation rates may be observed in the long run, depending on relationship type or gender-power distribution. The value of such findings again illustrates the difficulties with predicting sustained use of a new product on the basis of only continuation rates (Reproductive Health Matters for the World Health Organisation 1997). Analysis of the experiences of women and men provide a more vivid picture of the comfort and difficulties with the diaphragm, issues not captured by continuation rates, particularly those in a study setting. If trials confirm protective efficacy of the diaphragm, issues described here should be taken into account during diaphragm promotion. Promotion strategies may need to specifically address particular groups of women and types of relationships.

Moreover, realistic assessment is needed of the extent to which a woman's control over diaphragm insertion is able to counter gender-power imbalances within long-term relationships.

Resumen

Se está volviendo a prestar más atención al diafragma como un método eficaz controlado por las mujeres para evitar el contagio del VIH y otras infecciones de transmisión sexual. Se prevé que las tecnologías controladas por las mujeres reducirán su susceptibilidad biológica y ayudarán a contrarrestar su vulnerabilidad sociocultural frente al virus del sida. Si entendemos las experiencias subjetivas de las usuarias de diafragmas en diferentes entornos podremos informar sobre el desarrollo y el fomento de tales métodos anticonceptivos. En este ensayo analizamos las perspectivas de las trabajadoras sexuales femeninas y las mujeres que utilizan los servicios de salud sexual y reproductora en Mombasa, Kenia. Tras un estudio prospectivo en el que se investigaron las tasas del uso continuo del diafragma en un periodo de seis meses se recabaron datos a partir de grupos de discusión y entrevistas exhaustivas con mujeres y hombres. En las charlas se destacaron como atributos favorables el uso encubierto del diafragma durante el trabajo sexual o con compañeros casuales y la independencia coital. Estas características se especificaron especialmente en comparación con los preservativos masculinos. Se informaron que el uso del diafragma causaba pocas dificultades aunque a veces era un problema insertarlo y sacarlo. Muchas mujeres, especialmente las que tienen relaciones estables durante mucho tiempo, deseaban confesar que lo usaban, pero creían que si lo hacían les iba a ocasionar muchos problemas. De hecho si casualmente era descubierto por el compañero, creaba tensiones entre la pareja. Aunque en el futuro el uso del diafragma pueda ser alto en este ambiente, podría estar limitado a ciertos tipos de relaciones y contexto relacionado.

Résumé

En tant qu'outil prometteur de prévention du VIH et d'autres infections sexuellement transmissibles (IST) à maîtrise féminine, le diaphragme bénéficie d'un regain d'intérêt. Il est attendu des technologies à maîtrise féminine qu'elles réduisent la vulnérabilité physiologique des femmes par rapport au VIH et qu'elles les aident à contrecarrer leur vulnérabilité socioculturelle au VIH. La compréhension des expériences subjectives des utilisatrices de diaphragmes dans des environnements divers devrait permettre de documenter le développement et la promotion de ces méthodes. Cet article explore les points de vue de professionnelles du sexe et d'autres femmes fréquentant des services de santé sexuelle et reproductive à Mombasa, au Kenya. Les données sont issues de groupes cible et d'entretiens en profondeur avec des femmes et des hommes, suite à une étude prospective qui a évalué le taux d'utilisation continue du diaphragme pendant une période de six mois. Les discussions ont mis l'accent sur la possibilité d'utiliser le diaphragme secrètement pour le commerce du sexe ou les rapports sexuels occasionnels, et sur « l'indépendance coïtale », comme caractéristiques favorables du diaphragme. Ces caractéristiques sont particulièrement soulignées par comparaison avec celles du préservatif masculin. Peu de difficultés concernant l'usage du diaphragme ont été signalées, bien que

son insertion et son retrait aient épisodiquement posé quelques problèmes. Beaucoup de femmes – en particulier celles qui sont engagées dans des relations à long terme – souhaitaient en révéler l'usage à leurs partenaires mais considéraient les processus pour y parvenir trop problématiques. La découverte fortuite de l'usage du diaphragme entraînait souvent des conflits avec les partenaires. Bien que l'acceptation future du diaphragme ait des chances d'être élevée dans cet environnement, son usage pourrait se limiter à certains types de relations et au contexte de ces relations.

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Discussion

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Photo credit: Hugh Rigby/CCP

A billboard promotes condoms on the road from Nairobi to Kampala, Kenya. The text says "Let's talk." (2001)

6.1 Discussion of research findings

This thesis aims to identify priorities in HIV prevention and to assess some potential prevention strategies among selected key populations. More specifically, this was done by identifying factors associated with unprotected sex among female sex workers, men who sell sex to men, and HIV infected individuals receiving ART. Additionally, we assessed acceptability and effectiveness of potential HIV prevention interventions including a peer-mediated behavioural change intervention, the female condom and the diaphragm.

Factors associated with unprotected sex among key populations

Sex workers and alcohol use

Previous studies have identified various factors associated with unprotected sex among sex workers including marital status, amount charged for sex, knowledge on transmission of HIV, knowledge of own HIV status, condom negotiating skills, substance abuse, and client refusal. (1-9)

Use of alcohol among clients and sex workers at the time of purchasing sex is common. Motivations for alcohol use among men is often recreational and for social purposes and is encouraged by their peers. (10) However, women report more often an abusive environment and dysfunctional families as a motivation for alcohol consumption. (10) Research in South Africa found that alcohol and other drugs are commonly used prior to sex work, to lower inhibitions and give women courage to approach clients. (11, 12) Many of these women also explained that they always used condoms, except when intoxicated. In addition to affecting sexual decision making and judgement, alcohol use also influences condom negotiation skills. Effects of alcohol depend on total cumulative volume consumed, drinking patterns and drinking context. Drinking patterns in much of Africa are characterized by episodes of heavy drinking, mostly in the weekend. (13, 14) Our research identified that female sex workers in Mombasa who binge drink were 1.6 times more likely to report inconsistent condom use than non-binge drinkers. Frequency of drinking was also associated with condom use, with women who drink everyday or almost every day being more likely to report inconsistent condom use than women who currently don't drink. Among the men who sell sex to men in Mombasa, an association between frequency of drinking and unprotected anal sex was also noted. Previous studies from low- and middle-income countries have shown that alcohol use is associated

with unprotected sex, early coital debut, multiple partners and STIs. (15-21) Some, (22-30) but not all (28, 31, 32) studies in high-income countries have found an association between alcohol consumption and an increased number of sexual partners, regretted sexual relations, inconsistent condom use, condom failure and an increased incidence of STI. Several studies have linked alcohol use with higher HIV incidence (21, 33-35) and prevalence. (15, 36-43) Despite high-risk drinking patterns and the substantial public health implications, little attention has been given to addressing effects of drinking patterns on unsafe sex and its sequellae.

Men who sell sex to men

Formative research in 2002 in Mombasa indicated that men who sell sex to men are at high risk for becoming infected with and transmitting HIV and other sexually transmitted infections (STIs). Reported risk factors included high numbers of sexual partners, inconsistent condom use, poor knowledge of STI prevention, and high alcohol and drug use. Men who sell sex to men were found to be engaging in high-risk sexual practices with male clients, and some also with females. Our recent research among men who sell sex to men in Mombasa identified that men who self-identified as *basha* or king (insertive male partner), and who received less money from their last male client (KSH 1000 or less) were more likely to have unprotected anal sex (inconsistent or no condom use) in bivariate analysis. In multivariate analysis, after adjusting for all factors associated in bivariate analysis, four variables remained significantly associated with unprotected anal sex in the past 30 days with male clients: not knowing HIV can be transmitted via anal sex, drinking alcohol 3 or more days per week, self-report of burning urination within the past 12 months, and having never been counselled or tested for HIV. While a large majority of respondents knew that consistent condom use prevents HIV transmission (86.6%), only 64.7% of men who sell sex to men in Mombasa knew that HIV can be transmitted through unprotected anal sex. Consistent condom use during anal sex with a man was reported by 36% of respondents. A prospective vaccine preparedness cohort study of men who have sex with men in Coast province showed high rates of HIV prevalence and HIV incidence. (44, 45) It was concluded that the high prevalence of HIV-1 in Kenyan MSM is probably attributable to unprotected receptive anal sex, which was more common among men who reported sex with men exclusively. (45)

People Living with HIV/AIDS

Among HIV infected persons receiving antiretroviral therapy (ART), we explored factors associated with unprotected sex. Access to ART for HIV-infected individuals in Africa has increased in recent years, resulting in better quality lives among people living with HIV. With improved and sustained health, HIV-infected men and women have increased opportunities to transmit HIV to sero-discordant partners in their communities if safe sex practices are not followed. Currently, limited evidence is available on correlates of unsafe sexual behaviour among HIV-infected individuals in resource constrained settings. Previous studies from sub-Saharan Africa include one prospective before-after study with 6-months interval, and two cross-sectional studies. (46-48) Overall, these studies showed no evidence for increased sexual risk taking with the introduction of ART. Approximately half the respondents receiving ART reported sexual activity in the three studies. In the two cross-sectional studies, however, this was reported for all HIV positive respondents, regardless of ART status. In the before-after study, the percentage of ART patients who were sexually active in the previous 3 months did not change from baseline to follow-up. Condom use was significantly higher among ART patients compared to non-ART patients in both cross-sectional studies. In Ivory Coast, Moatti found that condom use at last sex, regardless of partner type, was 80.2% for ART patients versus 58.8% for non-ART patients ($P < 0.001$). Bateganya reported that, in Uganda, condom use at last sex with a spouse was 71% among ART patients versus 47% among non-ART patients. In the before-after study, condom use at last sex with HIV-negative or unknown partners increased significantly from 63% at baseline to 85% at 6-months (AOR=3.3; 95% CI=1.7-6.4). Limitations of these studies include reliance on self-report of sexual behaviours, convenience sampling, choice of control arms, and short duration of ART among the participants. Social desirability bias may have been exacerbated in the study by Bunnell due to the fact that counsellors who provided the ongoing risk-reduction counselling, also administered the interviews.

Our Mombasa study includes two evaluations assessing sexual behaviour of patients receiving ART. One cross-sectional evaluation compared patients receiving 6 months of ART with patients receiving prophylactic treatment of either co-trimoxazole (advanced HIV disease (WHO stage 3 or 4) or WHO stage 2 with history of oral thrush) or tuberculosis prophylaxis (all HIV infected persons). In contrast with previous studies, this study compared with non-ART patients also attending regular care services, which enables this design to better assess the effect of ART alone. Approximately half the respondents in both groups reported to be sexually active in the reference period. Participants

receiving ART were more likely to report condom use at last sex with their regular partner (93% versus 77%; OR=4.1; 95%CI=1.37-12.28). A second before-after analysis in the same population of patients receiving ART assessed sexual behaviour before and after 12 months of ART. Sexual activity increased from 50% at baseline to 58% after 12 months (AOR=1.44; 95% CI=0.95-2.18; P=0.09). Unprotected sex at last sex with a negative or unknown partner significantly decreased from 46% to 10% respectively (AOR=0.16; 95% CI=0.08-0.32; P<0.001). Nevertheless, a considerable proportion (28%) of sexually active participants reported unprotected sex with a negative or unknown status partner in the past year, which remains a cause for concern.

Safety, acceptability and effectiveness of HIV prevention strategies among most-at-risk populations

Three studies assessed the safety, acceptability and effectiveness of HIV prevention strategies among female sex workers in Mombasa, Kenya.

One study (chapter 5.1) assessed the long-term individual and sub-population effects of five years of peer-mediated behaviour change interventions among female sex workers in Mombasa, Kenya. These findings are encouraging and consistent with previous studies which evaluated the ability of peer-mediated interventions to facilitate behaviour change among high-risk groups. (49-57) Though promising as an intervention, a greater sub-population effect might have been achieved in our study if more peers were reached. This could potentially be done by employing peer educators from subgroups which had lower levels of peer-education coverage, and by the ongoing training of new peer educators. These efforts are hampered by the high mobility of the population. This study was limited by its design (before-after evaluation). A prospective study design could have assessed the effectiveness of the intervention more accurately, but would not have been able to assess the situation in this sub-population. Unpublished data, from a prospective cohort study among 277 HIV uninfected female sex workers from the same area, showed an HIV incidence rate of 1.14 per 100 person-years of observation. This low incidence in a sex worker population with 34.9% HIV prevalence could potentially be partially contributed to a reduction in sexual risk behaviour, though many other external factors should be considered. A further limitation of the study is that many outcomes were self-reported and therefore prone to recall and social-desirability bias. This issue is discussed separately. The studies show the importance of peer-mediated behaviour change

interventions, but these should ensure sustained widespread coverage, especially among highly mobile sub-populations such as female and male sex workers.

In addition to behaviour change interventions for prevention of HIV transmission, there is a need for female controlled barrier methods. We assessed the acceptability and effectiveness of the female condom (chapter 5.2). Introducing the female condom into a male condom program resulted in a small, but significant, increase in the proportion of sex workers reporting 100% condom use with all partners. This result replicates what has been found in other sex worker, and high-risk populations, namely, that complementing male condom promotion programs with the female condom increases reported condom use. (22, 58-61) No formal effectiveness of the female condom in preventing HIV has been performed, though female condoms have successfully reduced STI transmission (59, 62), and there is biological plausibility for HIV prevention. Laboratory test have shown that polyurethane female condoms also provide an effective physical barrier. (63) However, in a cross-over trial comparing male and female condoms, increased semen exposure and self-reported mechanical difficulties were noted, which might suggest lower effectiveness of female condoms for HIV prevention. (64) Female condoms empower women by enabling them to negotiate safer sex, by promoting healthier behaviour, and by increasing self effectiveness and sexual confidence. A simulation model in South Africa concluded that a well-designed female condom programme for sex workers would be highly cost-effective. (65) Female condoms do not need an erect penis, are reusable and can be inserted ahead of time and left in after sex. Since they are made of polyurethane, female condoms can be used with water-based or oil based lubricants. Female condoms are acceptable, but major difficulties include cost and poor availability. In our study, about 30% of male condom use prior to female condom introduction was replaced by female condoms despite messages emphasizing its use only when using a male condom was not possible. Such “condom migration” has cost implications. The cost of the female condoms alone – \$108 per sex worker over nine months – would represent a substantial investment by the Kenyan Ministry of Health, which spent \$70 per capita on health in 2002. Therefore, it seems unlikely that the female condom intervention could be expanded without donor assistance, or unless prices would considerably be reduced. Furthermore, because female condoms are currently much more expensive than male condoms, whenever the majority of female condoms are used as a substitute for a male condom there is limited public health impact from the intervention but there is a marked increase in cost. However,

broadening the prevention method mix and availing a female controlled prevention method has considerable benefits at the individual level. Still, alternatives need to be explored for promoting female and male condoms with boyfriends of sex workers. Suggestions provided by the sex workers themselves for narrowing this “condom gap” included promoting the female condom as a family planning method, empowering women financially to reduce their dependence on boyfriends, and encouraging men to go for voluntary HIV counselling and testing to help them better understand their own risk of infection.

Another study (chapter 5.3, 5.4 and 5.5) describes the safety and acceptability of another potential female-controlled method of preventing HIV and STI: the diaphragm. Continuation rates at six months and user perspectives indicate high acceptability of the diaphragm in this setting. In addition to being a female-controlled method not requiring male cooperation, the diaphragm has several advantages for women: minimal interference with sexual spontaneity, absence of drug-related side effects, and immediate contraceptive reversibility. Compared with the male condom, the diaphragm has less impact on sexual pleasure and spontaneity, both features being important for male acceptability. When making sexual and reproductive choices, in addition to assessing the positive and negative characteristics of a method, women need to consider both their family planning needs and risk of contracting STIs. Overall, diaphragm acceptability and use are therefore likely to be determined, amongst other things, by its effectiveness in protecting against pregnancies as well as against STIs. In the past, the diaphragm was very commonly used for contraception (66), but its use diminished rapidly with the introduction of more effective contraceptives that do not interfere with sexual spontaneity, especially hormonal contraceptives and intrauterine devices. The diaphragm is at present an underutilized and under-researched technology, despite acceptance and use of the diaphragm being high in our setting.

Although women received repeated counselling and information about the uncertain protective efficacy of the diaphragm against some STIs, the majority perceived this device as giving them some protection. This is similar to findings of a South African microbicide trial, where many participants believed the candidate agent helped to prevent HIV and other STIs. (17) These observations indicate that, in the future, researchers need to take steps to ensure participants comprehend the uncertain efficacy of an investigational product. Also, during research activities and programme implementation, one should ensure that condoms are not replaced by less effective methods of

protection against HIV and other STIs. Similar constraints were observed in the Mira study: the largest randomized controlled trial assessing the effect of provision of latex diaphragm, lubricant gel, and condoms (intervention), compared with condoms alone (control) on HIV sero-incidence in women in South Africa and Zimbabwe. (67) The Mira study was an open-label, randomised controlled trial in HIV-negative, sexually active women recruited from clinics and community-based organisations, who were followed up quarterly for 12–24 months (median 21 months). All participants received an HIV prevention package consisting of pre-test and post-test counselling about HIV and sexually transmitted infections, testing, treatment of curable sexually transmitted infections, and intensive risk reduction counselling. Overall HIV incidence was 4.0% per 100 woman-years: 4.1% in the intervention group (n=2472) and 3.9% in the control group (n=2476), corresponding to a relative hazard of 1.05 (95% CI 0.84–1.32, intention-to-treat analysis). However, the proportion of women using condoms was significantly lower in the intervention than in the control group (54% vs 85% of visits, $P<0.0001$). The study observed no added protective benefit against HIV infection when the diaphragm and lubricant gel were provided in addition to condoms and a comprehensive HIV prevention package. The observation that lower condom use in women provided with diaphragms did not result in increased infection merits further research. Although the intervention seemed safe, the findings did not support addition of the diaphragm to current HIV prevention strategies.

6.2 Limitations

Methodological challenges

Various methodological challenges occur in conducting sexual behaviour studies among key populations and some of the main limitations are discussed here.

Sample size

An essential part of planning a study involves the determination of the sample size. Unfortunately, in many cases, sample size is guided by the availability of funds and on logistical grounds. Small samples might lead to the problem that some secondary research questions lack adequate power. In the study described in chapter 5.4, the limited number of participants resulted in an inability to conclude whether the diaphragm was safe to use, based on colposcopy data. In the analysis, we compared 34 women who did not use the diaphragm in the preceding month with 66 who did use it.

In doing this we had 18% power (probability of achieving this significance level) to show with 95% confidence that there is no difference between the two arms. To have 80% power, we would have required 178 participants in each group.

Sampling challenges

Sampling of most-at-risk populations, including male and female sex workers, has many challenges as they are highly mobile and all too often their behaviours are stigmatized and/or criminalized. Due to this, these marginalized populations are difficult to access and make probability sampling challenging and costly. Existing community interventions in Mombasa involving the female (and to a lesser extent male) sex worker populations allowed easier access to, and trust with the participants. Despite this, sampling methods needed to be adapted and included strategies such as snowball sampling and time-location sampling which are non-random convenience sampling methods. Though these methods are appropriate for locating difficult-to-reach populations, this non-random sampling may have contributed to a selection bias and may result in findings that are not representative of the wider target population.

In particular, the study as described in chapter 5.1 which consisted of two cross-sectional studies five years apart, was challenged by a change in population characteristics, despite having used the same methodology for identification and enrolment of participants. The changes observed could be due to the non-random sampling, and/or as a result from societal changes. This limited the ability to interpret the study results.

In the study assessing the sexual risk behaviours of people receiving ART (chapter 4.3 and 4.4) a systematic sampling was used by recruiting consecutive patients attending the Comprehensive HIV Care Clinic. The participants were among the first people receiving ART from a public hospital. This could have introduced a selection bias as potentially patients with more advanced disease were enrolled first, which could limit the validity of generalizing the results to the people who initiate ART at a less advanced stage of HIV disease.

Study design

Various study designs were used in reaching the objectives of this thesis. Some of the advantages and disadvantages of these designs are discussed in chapter 3.3.

A limitation in study design was encountered in a repeat cross-sectional study as described in chapter 5.1. A repeat cross-sectional study, at a later point in time, allows for evaluation of changes, potentially due to the intervention, that have taken place between the surveys. This methodology was used to assess the changes in sexual risk behaviours before and after a five year intervention. After five years, a marked change occurred in the demographics of the study population, possibly resulting from an expansion in tourism and number of bars, with concomitant FSW in-migration. Many new women are likely to have entered female sex work and some women reached by peer education left. Over half (278/502) of study participants in 2005 only started practicing sex work in the last five years. The absence of prospective controls limited the ability to quantify the effectiveness of the intervention. Also, over the study period, other interventions have promoted sexual behaviour change such as mass-media education, increased availability of widely-promoted VCT services and an HIV prevention study in 2004 which introduced the female condom [chapter 5.2]. These concurrent interventions are likely to have impacted on self-reported knowledge of HIV status, the desire to know one's HIV status and possibly also on condom use.

Given the highly mobile nature of sex work, limiting the loss to follow-up of participants was a challenging, time consuming and costly effort. One study, as described in chapter 5.2, managed to limit the loss to follow-up of participants to 8%. This was due to the intensive follow-up procedures from study staff and female sex worker peer educators. One other study, as described in chapter 5.4, did not benefit from an extensive peer-network in that sex worker's community which resulted in a retention rate of merely 73%. Non-response bias may have occurred, though the baseline characteristics of this group were similar to those completing follow-up.

Limitations have also occurred when choosing the control group. In chapter 4.4 we describe a study where we aimed to select controls from the same population, but without the intervention (receiving ART) to assess the association between ART and sexual risk behaviour. Similar to the patients receiving ART, we recruited HIV-infected controls from the same health facilities, who were accessing HIV care services at regular intervals. Comparison of the characteristics revealed that there were no differences between groups with regard to age, marital status, sex or educational level. However, participants receiving preventive therapy were more likely to be employed ($P=0.007$) and belong to a higher economic status ($P=0.01$) than those receiving ART. Participants receiving ART were likely to have lower CD4 cell counts and/or have a more advanced HIV disease stage, though marked improvements in health status of patients on ART (mean CD4 cell count increase: 239 cells/mm³)

were observed at the time of the evaluation. This should be taken into account when interpreting the results as HIV disease stage could be associated with the outcome and was not controlled for in the analysis.

Reverse causality

Establishing causality is the major limitation of all the cross-sectional studies included here. The study as described in chapter 4.1 assessed the association between heavy episodic drinking and unprotected sex. However, using this design, it was not possible to determine if a causal relationship between alcohol and unprotected sex exists. An equally plausible explanation is that people with high risk sexual behaviour are more likely to drink as a result of their situation (reverse causality). Observation of a dose-response showing that people who drink more frequently are also more likely to report unprotected sex, does strengthen the association. A prospective study would have been able to investigate the causal relation.

Confounding

Confounding variables include those factors that are both associated with the outcome as well as the exposure variable. As such, confounding could result in an association between an exposure and outcome, based on the unequal distribution of the confounding variable. It is therefore required to control for these factors either at the study design stage (randomized study design), and/or analysis stage (stratification or controlling for confounders). (68) Residual confounding could remain, as often not all confounders are known, they may be difficult to measure, or the information may not have been collected. This played an important role in our study presented in chapter 5.1 when comparing the survey from 2000 and 2005. Due to the unavailability of the full dataset of the 2000 survey (3), it has not been possible to perform a multivariate analysis to account for the changes in the populations. This indeed is a limitation in the comparison of the two surveys and has implications for interpretation. Therefore, more can be concluded from the behaviour differences noted between women who received peer-mediated interventions and those who had not.

Validity of self-reported measures

Self-reported measures of HIV risk

Measuring incidence of HIV has many challenges. Therefore, related outcome variables including HIV prevalence, STI incidence/prevalence, and behavioural measures such as (self-reported) unprotected sex (e.g. changes in condom use, frequency of unprotected sex), number of sex partners, and sexual violence are often used as surrogate markers in prevention studies. (69-72) The last decade has seen a spirited debate between those advocating the use of behavioural versus biological endpoints for evaluating interventions to prevent HIV transmission. (73) Both behavioural (e.g. self-reported condom use) and biological endpoints (e.g. sexually transmitted infection [STI] incidence) have been used to evaluate the effectiveness of condoms in preventing infection transmission.

Peterman et al reported that no single measure of sexual behaviour appeared to be a strong predictor of STI/HIV incidence. (74) Selective behaviour changes, which take into account the perceived riskiness of the partner, could be one reason why measured STI/HIV incidence did not closely match any of the sexual behaviour outcomes. Validity of behavioural outcomes as surrogate markers was also assessed by Pinkerton et al showing that the number of unprotected sex acts is the superior marker of HIV risk, whereas changes in the proportion of sexual acts protected by condoms and the changes in number of partners were only weakly associated with HIV risk. (75)

Additionally, self-reported data related to coitus are limited by uncertain validity due to recall and social desirability bias. (76-83) We assessed the validity of self-reported unprotected sex among female sex workers in Mombasa, Kenya, by comparing their reports of recent behaviours with the identification of prostate-specific antigen (PSA), whose detection in vaginal fluid by solid-phase enzyme-linked immunosorbent assay (ELISA) serves as a biological marker of recent exposure to semen. (84-88) This was a sub-study to the prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa, presented elsewhere in this thesis. (chapter 5.2) Of the 210 women enrolled in the study, 167 contributed PSA and self-reported data for both the enrolment and 12-month visit. The remainder of the study population did not have laboratory data at the enrolment (n=16) or laboratory or questionnaire data at the 12-month visit (n=27).

We found PSA in 11% of self-collected vaginal swabs from female sex workers in Mombasa who reported either protected sex only or no sex for the past 48 hours. Among sex workers reporting

only protected sex for the past 48 hours, 12.9% of samples (n=248) tested positive for PSA and for women reporting no sex during this time period, this was 6.2% of samples (n=81).

In previous research, Macaluso et al. collected vaginal specimens after inseminating 40 women with 1mL of their partner's semen. Most women (71%) tested negative for PSA at 24-hours post-insemination and almost all (97%) were negative at 48-hours after the exposure. (88) This high test specificity at 48 hours suggests that most discrepancies found in the present study (i.e., women with PSA identification and self-reports of either protected sex only or no sex) cannot be attributed to false positive laboratory values. Furthermore, our findings probably are underestimations of misreports of semen exposure since PSA begins to clear immediately after exposure. In addition, unknown factors, such as menstruation, douching or exercise, theoretically could affect marker detection or clearance. Although incorrect condom use (e.g., used for less than entire act) or condom malfunctions could lead to female exposure to semen, we would expect that the amount of semen transmitted through these events would be less than that from unprotected sex.

A range of unidentified factors – related to the participant, interviewer, study procedures or interventions – could affect the genuineness of participant responses. Bias in self-reporting is likely to be different between study groups because participants in the intervention arm could be more motivated to alter their responses as a result of self-presentation bias or to please the interviewer. Interviewers might even contribute unconsciously to this difference between groups if they cannot remain completely neutral during data collection. Thus, any improvement in self-reported protected sex could be attributed to differential misclassification rather than the intervention under study. Furthermore, even if bias were assumed to be non-differential, this could lead to substantial loss of study power. (89) All studies presented in this thesis are to some extent prone to the above mentioned bias. Another shortcoming of these findings is the limited generalizability. It is unknown how well this information translates to men who sell sex to men or non-sex worker populations such as people living with HIV/AIDS. In conclusion, the effectiveness of an intervention to reduce HIV transmission should, whenever possible, be based on both self-reported behavioural information and biomedical outcomes. The use of different data collection formats such as ACASI or other new technologies that could reduce social desirability bias need to be examined. Standardisation of questions and recall period to assess sexual risk behaviours would improve comparability and reliability of data. Identification of biomarkers with higher sensitivity of semen exposure over a longer period of time would greatly benefit future behaviour research.

Self-reported measures of Sexually Transmitted Infections symptoms

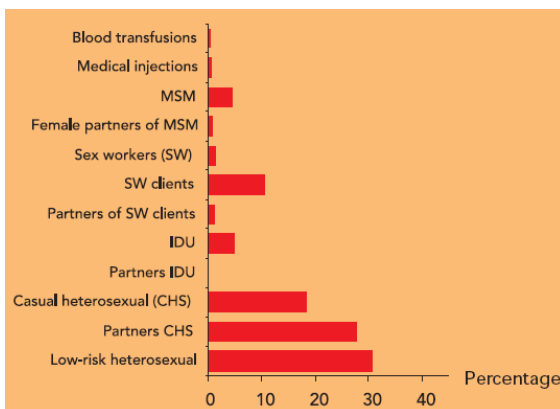
Self-reported symptoms of STI among men and women was a variable used in three of the studies in this thesis (chapter 4.2, 4.3 and 4.4). In our study among men who sell sex to men, we documented self-reported burning on urination and penile discharge to assess the association with unprotected anal sex. Self-reported incidence of urethritis in men is one of the reproductive health indicators recommended by WHO and is defined as a penile discharge with or without burning sensation or pain during urination in the past 12 months. (90) Self-reported incidence of STI raises a number of issues regarding definitions and recall of events. One of the largest challenges with self-reported STIs is that a large proportion of STI are asymptomatic. Compared with women, symptoms in men are usually more easily recognizable, and symptoms of gonorrhoea/chlamydia (penile discharge) may be distinguishable from syphilis (sores, ulcerations). Nevertheless, even in males many infections are asymptomatic. Moreover, respondents may not differentiate between the terms used in the investigation. The most important limitation is the interpretation and validity of the reported symptoms. Some studies have demonstrated considerable discrepancies between reported and observed symptoms (91) and there might well be recall bias, leading to underreporting. More importantly, the presence of asymptomatic gonococcal or chlamydial infection in males seriously limits the usefulness of this indicator, even as a proxy for STI prevalence or incidence. (92) Therefore, self-reported symptoms should be used with caution in assessing the impact of preventive and treatment services.

Harrington et al conducted a prospective, randomized controlled clinical trial of STI/HIV prevention for African American females, aged 14 to 18, in Birmingham (USA) to determine the accuracy of self-reported STI test results in female adolescents. (80) Of 479 adolescents who completed baseline STI testing and follow-up surveys, 28% had positive test results for at least one disease: 4.8% for gonococcal infection, 17.1% for chlamydial infection, and 12.3% for trichomoniasis. Of the adolescents with negative STI test results, 98.8% were accurate in their self-report of STI status, as compared with 68.7% of the adolescents with positive results. In South Africa, reporting of prompted STI symptoms (after a few simple questions from the health care worker) had a sensitivity of 78.5%, specificity of 52.9%, PPV of 80.4% and NPV of 50.0%. (93) Further studies assessing the validity attributed to self-reported measures of sexually transmitted infections among men and women are needed.

6.3 Recommendations for targeted interventions in Kenya

Kenya is among the countries with a generalized HIV epidemic, indicating that HIV prevalence among the general population is at a sufficient level to drive the epidemic. (94) However, increased HIV prevalence rates, with concentrated sub-epidemics, occur among specific key populations including sex workers and men who have sex with men. These groups play an important role in fuelling the epidemic. Many countries, including Kenya, have committed to providing universal access to Comprehensive HIV prevention, treatment, care and support by 2010. (95)

Access to ART has increased significantly over the last 5 years, but prevention efforts have lagged behind. UNAIDS estimates that each year another 2.5 million new HIV infections occur worldwide. (96) It is clear that improvements in HIV prevention strategies are urgently needed. Committed, strong and well informed leadership and coordination is required to make such efforts work. Furthermore, to have an impact on HIV incidence, interventions must be directed to those populations and behaviours that are driving the epidemic in that country. A recent analysis by Gouws et al (97) showed that most new infections in Kenya occur in populations usually defined as 'low risk', such as cohabitating couples. This suggests that there is a specific need to address the general population, particularly discordant couples, in addition to identified high-prevalence populations such as sex workers, sexual partners of sex workers, and men who have sex with men. Effective HIV prevention programmes should prioritize those most affected by and those most vulnerable to HIV infection.



Source: Gouws E et al. (2006). Short term estimates of adult HIV incidence by mode of transmission: Kenya and Thailand as examples. STI, 82 (Suppl. 3): iii51 – iii55. (97)

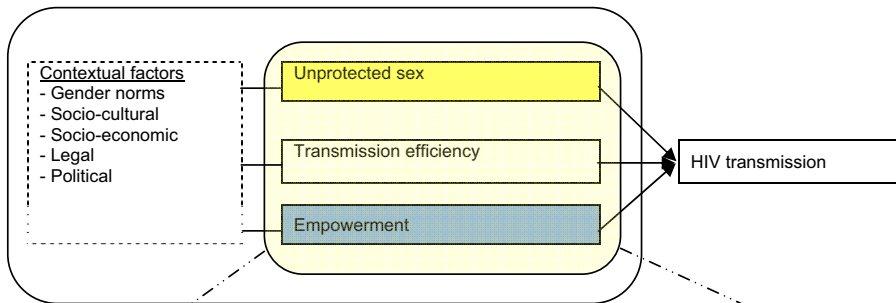
HIV prevention efforts can be broadly categorized in three groups: behavioural change, biomedical, and structural approaches (social, justice and human rights interventions). For HIV prevention strategies to have an impact, it has become clear that not one of the approaches alone can curb the epidemic, and that a combination of strategies is required. (98-100) Moreover, integration of behavioural, biomedical, and structural HIV prevention strategies together with HIV treatment is needed. This has recently been termed: highly active HIV prevention. (101)

This thesis focuses on three key audiences that have been identified as priority groups for targeted HIV prevention interventions: female sex workers, men who sell sex to men, and people living with HIV. Targeted HIV prevention interventions, relevant for the three identified key populations, will be discussed following a framework of interventions to reduce HIV transmission: reducing the number of unprotected sex acts, reducing HIV transmission efficiency, and increasing empowerment of key populations (figure 1). (102)

6.3.1 Unprotected Sex

Current approaches to reducing unprotected sex mainly include increasing condom use and scaling up of counselling and voluntary testing. The male condom is the most effective and most accessible available technology for reducing sexual transmission of HIV. (103) The female condom is a known effective and available prevention method, but unfortunately remains expensive and often not available. Ways of reducing the cost could be through development of new technologies for making female condoms or through increased production (economies of scale). (104) Health economists have developed models to estimate the relative benefit of female condom investment compared with other costs of STI/HIV prevention and treatment. In one such model commissioned by the Female Health Company, substantial cost savings to the health sector were estimated based on different use scenarios in South Africa and Brazil of their new female condom, FC2. For example, the model estimated that in South Africa, assuming a low uptake of 4 million (at an estimated unit cost of US\$0.77 for product, distribution, training, and education) the female condom would prevent 1,740 HIV infections, with a net savings to the health care system of about \$980,000. These types of models suggest that female condom programs can be highly cost-effective and offer significant protection to women and men. Wider availability of the female condom would also provide women with a choice of HIV prevention methods. Therefore, the female condom is an important prevention

Figure 1: Framework of risk factors and interventions to reduce HIV transmission in female sex workers, men who sell sex to men and persons living with HIV receiving ART.



| Risk factors | Targeted Highly active HIV prevention* interventions |
|--|---|
| Unprotected sex Number of sexual partners <i>Alcohol use (4.1)</i> <i>Knowledge of HIV status (4.2)</i> Adherence to biomedical strategies <i>Sexual disinhibition* (ART) (4.3 & 4.4)</i> Number of unprotected sex acts | <i>Behavioural change</i> Peer education & professional education (5.1) Brief alcohol harm reduction interventions PITC / CITC <i>Biomedical Strategies</i> Male condom consistent and correct use (5.2) Female condom consistent and correct use (5.2) Cervical barriers* (diaphragm) (5.4 & 5.5) |
| Transmission efficiency Concurrent sexual partnerships Type of sex (anal, receptive) Vaginal Practices Biological susceptibility Viral load <i>Sexually Transmitted Infections (4.2)</i> <i>Bacterial vaginosis*</i> | <i>Behavioural change</i> Peer education & professional education (5.1) <i>Biomedical Strategies</i> Post-exposure with ART (following sexual violence) Pre-exposure with ART* Microbicides* (Antiretroviral) Microbicides* (Antimicrobial products) Vaccines* Male circumcision* (Not PLHA) <i>Treatment Strategies</i> ART treatment STI control |
| Empowerment Knowledge of HIV/STI (5.3) Knowledge of HIV transmission (4.2) Condom negotiation skills Disclosure (4.3) | <i>Behavioural change</i> Peer education & professional education (5.1) Skills learning (5.1) |

*This term is attributed by Prof King Holmes, University of Washington School of Medicine, Seattle, USA
 *Terms in *italic* include potential risk factors and interventions that require further confirmation

Figure adapted from: WHO. Toolkit for targeted HIV/AIDS prevention and care in sex work settings. In; 2005, ISBN 92415966 (102)

tool, and its use along with antiretroviral therapy is one way to efficiently and effectively combine prevention and treatment. These methods should be made available free or at low cost for key populations. All stakeholders have a role to play in maximising availability and use of condoms.

A systematic review by Foss showed condom promotion among female sex workers to be particularly effective, more so than with other population groups. (105) Other successful interventions described in the review and elsewhere, involved combinations of peer or other health education, condom provision and/or STI testing and treatment. (174) Peer mediated education programmes have shown to successfully promote condom use. (56, 106) Our study, reported in chapter 5.1, showed consistent condom use, with levels as high as 86% after a 5-year peer-mediated condom distribution intervention. (107) The main obstacle to consistent condom use remains refusal on the part of male clients. A randomised trial among sex workers in Madagascar demonstrated that the addition of clinic-based counselling to peer education reduces STI prevalence. (108) The counselling intervention lasted about 15 minutes and covered: risk assessment; information on STI and HIV, and dual protection; condom negotiation skills; and promotion of a ‘no condom no sex’ policy. After six months, more than half of the sex workers in the intervention arm reported 100% condom use with clients in the past month. Increases in condom use with a non-paying partner were also observed, though levels remained low. A reduction in STI compared with controls showed that the impact of male condom programmes for FSW can be further heightened by more intensive counselling on risk reduction. Several long-term studies among FSW have found that declines in high-risk behaviour and HIV incidence occur over time, possibly due to the ongoing risk-reduction counselling provided as part of study activities. (109, 110)

Among men who sell sex to men, consistent condom use during anal sex with a male client was reported by 36% of respondents in our study in Mombasa. (111) The lack of knowledge on HIV prevention was one of the main findings, with over 35% reporting that they did not know that HIV can be transmitted through unprotected anal sex. This highlights the urgent need for condom promotion and distribution specifically targeting this sub-population. Peer-mediated interventions among men who sell sex to men could well be an effective strategy, though limited evidence is available.

Of HIV positive people receiving ART in Mombasa, 66% reported to have a negative or unknown status partner. (112) Consistent condom use with these partners was reported by 72% of participants with similar findings reported in Uganda and Ivory Coast. (46-48) Each of these

unprotected sex acts among HIV-infected individuals potentially have a risk of HIV transmission. Integration of HIV prevention counselling in a home-based antiretroviral therapy programme in Uganda, combined with voluntary HIV counselling and testing for the partners of persons on antiretroviral therapy, resulted in a 70% drop in unprotected sex, including an 85% reduction in unprotected sex among married couples. (47) Amongst others, the Centers for Disease Control and Prevention (CDC) are now expanding prevention programs, specifically targeting persons living with HIV, to include a focus on reducing the risk of transmission as a supplement to current programs that primarily focus on reducing the risk of acquisition of the virus. CDC has developed a prevention intervention package entitled “HIV prevention in care and treatment settings” as part of their broader prevention programme for positives. The intervention has been adapted for HIV positive persons accessing care and treatment services (ART) and is delivered at the end of every routine clinic visit giving patients multiple exposures to the same prevention messages.

Besides condoms, other barrier methods have been under evaluation, but with no proven effectiveness it is too early to make recommendations for any targeted HIV prevention intervention. However, the diaphragm or other cervical barrier methods may serve for administering microbicides, potentially providing protection against both HIV and pregnancies. Once available, such a female-controlled dual protection against STIs and pregnancies could have an important impact especially in settings with high rates of STIs, HIV and unintended pregnancies.

It is also necessary to provide services to address the specific factors which undermine use of barrier methods, such as use of alcohol and other substances. HIV prevention strategies have largely ignored the potential for factors such as alcohol to influence sexual behaviour. Sex workers with hazardous or harmful alcohol use have a higher risk of unprotected sex and therefore a greater need for support. Alcohol adversely affects their sexual decision making, and their skills to negotiate condom use and to use them correctly. Targeted interventions assisting sex workers to adopt safer drinking patterns could significantly contribute to HIV prevention. Despite research demonstrating the effectiveness of alcohol control measures, few interventions have been implemented thus far in Kenya and other African countries. While it is recognized that control of alcohol is difficult and politically charged, increased efforts are needed at the level of national and provincial governments, but also at an individual level. The health care sector has an important part to play in mitigating

alcohol-related harm. Overall, these interventions to reduce harm are likely more effective than promoting total abstinence. Harm reduction interventions targeting individual behaviour change need not be complex or expensive. Use of brief interventions targeting particular subgroups of the drinking population are cost effective and lead to public health gains (113, 114), although they have not been broadly disseminated or utilized in resource-constrained settings. One small randomized trial from South Africa assessed an adapted empowerment-based HIV intervention designed to reduce sexual-risk, substance use and victimization among underserved women. (115) Comparison was made between provision of the intervention in groups or individually. A significant reduction in alcohol (and other substance use) and sexual risk behaviours was seen one month after the intervention, though no difference between the two formats of administering the intervention was seen. Brief Interventions together with peer support groups could make a substantial change to patterns of alcohol use among key populations, and potentially reduce their sexual risk taking.

Scaling up of HIV testing and counselling

HIV testing and counselling has become an integral component of HIV prevention and care strategies. Several studies conducted in developing countries assessed the impact of VCT on the behaviours of people who sought the service at a free-standing VCT. (76, 116-122) Overall, data from these studies provide varied results. The study with the strongest design, a randomized controlled trial, showed that VCT had a clear impact on specific risk behaviours for individuals and couples. Moreover, participants who received VCT experienced more than a 25% reduction in certain risk behaviours compared to individuals and couples who received health information. (116) A community based study conducted in Uganda, did not find any differences in risk behaviours between participants who learned their HIV test result and those who did not. (121) Across studies, few participants experienced negative consequences after receiving VCT. It is also important to note that none of the studies contained data showing a significant increase in participant's reports of sexual risk behaviours after VCT. Despite increases in the availability of testing services, many sex workers remain unaware of their status. A cohort study in Mombasa Kenya showed that female sex workers who acquire HIV infection report fewer sexual partners and higher condom use than when they were uninfected. (123) In another study, almost half of sex workers knew their status from testing during pregnancy. (1) Implementation of Provider Initiated Counselling and Testing (PITC) services should be integrated within all health services, also to support changes in behaviour, especially among those

testing positive. In addition to other benefits of knowing one's HIV status, the purpose of PITC is to enable specific clinical decisions to be made and/or specific medical services to be offered that would not be possible without knowledge of the person's HIV status. In generalized epidemics it is recommended to test all clients, and not only high risk populations, attending health facilities irrespective of whether they have signs or symptoms suggestive of HIV. (124) WHO and UNAIDS also recommend that known and innovative approaches be used to scale up and expand access to Client Initiated Testing and Counselling (CITC). (124) Offering repeat HIV testing at pre-determined intervals potentially has several advantages, including increasing the likelihood of detecting acute HIV infection, which is a vital period of HIV transmission. Peer outreach programmes offer an opportunity to encourage testing and to link sex workers with local testing and or mobile services. (124) Partner testing is also vitally important, particularly among those infected. Persons diagnosed HIV-positive should be encouraged and supported to disclose their HIV status to their sexual partners and/or others at risk.

6.3.2 Transmission efficiency

The most developed intervention to reduce the transmission efficiency of HIV includes the treatment and prevention of sexually transmitted infections. Currently, many other biomedical interventions are in various stages of development such as pre-, and post-exposure prophylaxis, microbicides and vaccines.

STI prevention and treatment

STIs increase HIV shedding in the genital tract and increase susceptibility to infection by disrupting mucosal barriers. (125-129) The presence of STI in women also increases risk for HIV infection by recruiting HIV-susceptible inflammatory cells to the genital tract. (130) In addition, STIs such as herpes simplex virus type 2 (HSV-2), may increase the HIV plasma viral load in coinfecting persons. (131, 132) Community intervention trials have evaluated the effect of STI control on HIV acquisition with mixed results. (133-135) A randomized placebo-controlled trial among HIV-uninfected female sex workers in Nairobi, Kenya, assessed the effect of monthly antibiotic prophylaxis on HIV-incidence. (136) In this trial, monthly presumptive treatment significantly reduced the incidences of cases of infection with *Neisseria gonorrhoeae*, *Chlamydia trachomatis* and *Trichomonas vaginalis*, most of

which were asymptomatic. However, there was no effect of prophylaxis for STIs on the incidence of HIV infection.

HSV-2 infection is a leading cause of genital ulcerative disease and has shown to be highly associated with HIV infection. (137) Two trials have assessed whether antiviral treatment has an effect on HIV acquisition among women and men who have sex with men. (138, 139) No evidence was observed for a protective effect of acyclovir on HIV incidence. The potential effect of antiviral treatment for HSV-2 infection among HSV-2/HIV-1 co-infected individuals to reduce HIV transmission is currently under evaluation.

STI control strategies will have the greatest effect on an HIV epidemic when they address specific high-risk populations, specific STIs, and when they take into account the stage of the HIV epidemic. (140-142) WHO recommends that STI services are critical for controlling the HIV epidemic, especially among populations at higher risk for HIV transmission. In a generalized epidemic such as in Kenya, STI treatment interventions targeting key populations including sex workers, MSM, and HIV positive persons should be implemented, and be supported by behavioural, structural and social components as not one intervention is effective by itself and synergistic combinations are needed, at several levels, to have maximum impact. (143)

Oral antiretroviral prevention

For people infected with HIV, antiretroviral therapy markedly decreases HIV related morbidity and mortality. Antiretroviral therapy reduces the viral load in the blood and in genital secretions of both men and women, and the drugs can be found in semen and vaginal and cervical secretions. It is therefore likely that it also reduces infectiousness. Much has been learned from studies assessing antiretroviral prophylaxis for the prevention of mother-to-child transmission. These lessons suggest the impact of viral suppression on HIV infectiousness is likely to be marked. For example, a study in Gauteng, South Africa compared the risk of transmission between women with low CD4 cell count receiving ART and women receiving a short-course intervention only, as ART was not clinically indicated. It showed that, despite their advanced disease stage, women receiving ART were significantly less likely to transmit HIV to their newborn infant. (144) More recently, after review of the medical literature and extensive discussion with experts, a statement on behalf of the Swiss Federal Commission for HIV/AIDS mentioned that: an HIV-infected person on antiretroviral therapy with

completely suppressed viraemia (effective ART) is not sexually infectious if the person infected with HIV consistently adheres with the ART; the person infected with HIV has a VL during ART that has been below the limits of detection (blood plasma level <40 copies/ml) and has been so for at least six months; and the person infected with HIV has no additional STI present. (145) This controversial statement is currently being opposed by various organizations including UNAIDS and WHO who have come out strongly in favour of recommending continued use of a comprehensive package of HIV prevention approaches, including correct and consistent use of condoms. (146) However, early initiation of ART among HIV-infected persons might well be an interesting approach to reduce infectiousness, especially among populations reporting high-risk sexual behaviour. (147)

Antiretroviral drugs have also been extensively used for prevention of sexual transmission in cases of non-occupational sexual exposures and after occupational injuries. Case-control studies have shown the effectiveness of Post-Exposure Prophylaxis (PEP), mainly after occupational exposures. (148, 149) Recommendations are to initiate medication as soon as possible after the exposure and continue for one month with one or a combination of drugs depending on the risk of HIV exposure. Studies assessing the effectiveness of PEP after sexual violence are limited, despite sexual violence being very common, especially among sex workers. In our studies in Mombasa, one third (32.4%) of female sex workers and 10% of MSM reported sexual violence in the past year. (111, 150) Accessibility to post-exposure antiretroviral prophylaxis needs to be improved.

For continuous sexual exposures, there is currently no recommendation regarding use of antiretrovirals, but studies are underway to assess the use of antiretroviral pre-exposure chemoprophylaxis (PrEP). Pre-exposure prophylaxis is under investigation in various trials and involves a daily single or combination of drugs, with the first study results expected from 2009. PrEP can have a substantial impact in the reduction of HIV, especially persons at high-risk for HIV acquisition could benefit from this intervention if shown effective. (151, 152) Concerns with the intervention include potential toxicity associated with long-term use, development of drug resistance, and changes in sexual risk behaviour (behavioural disinhibition). Especially among populations where condom use is currently high, changes in sexual behaviour could diminish or even reverse the effect of the condom intervention. (153)

Microbicides (antimicrobial & antiretroviral)

Microbicides are products designed to prevent the sexual transmission of HIV and other disease pathogens. (154-157) Potentially, they can be applied vaginally or rectally. They may also offer back-up protection in the event that condoms fail. In addition, they may be used by HIV-discordant couples who wish to bear children. Current compounds consist of topical creams, gels, films, or suppositories and have a range of working mechanisms. As of now, no effective microbicide is available, but various new generation products are in advanced stages of development. (158) So far, only one compound has completed a phase III trial, but it did not show efficacy against HIV acquisition. (100, 159) Newer generation microbicides include those containing antiretrovirals, which are likely to be more promising as they specifically target HIV replication. Main challenges in microbicides trials include the lack of biological efficacy markers, the need for large and expensive efficacy trials, the risk for drug resistance development, and the patient's adherence to product use before or during coitus. However, once shown effective and available, microbicides could become a critical female-controlled method for HIV-uninfected high-risk women. Also, if shown effective against rectal transmission, men who have sex with men could add this method to the available prevention technologies. As with most prevention interventions, it is unlikely that one method will be able to provide 100% protection, and a combination of various methods will likely remain the most promising approach.

Vaccines

A safe and effective vaccine remains the best hope for ending the HIV/AIDS pandemic, however the timeline for developing and making available a safe and effective HIV/AIDS vaccine to communities affected by the pandemic remains unclear. Moreover, multiple prevention strategies are likely to be most effective in combating HIV, especially with first generation vaccines that may not be fully protective.

Male circumcision

Current evidence from randomized controlled trials undertaken in Kenya, South Africa and Uganda, show that male circumcision reduces the risk of heterosexual transmission of HIV infection from women to men by approximately 58%. (160-162) Male circumcision is an important HIV prevention method as part of a comprehensive package of HIV prevention interventions, particularly in settings

with a generalized epidemic, though likely not as a targeted intervention among the key populations discussed in this thesis. There is currently inconclusive evidence regarding the effect of male circumcision on HIV transmission to a woman or between men. (163-165) However, women might benefit indirectly if the HIV prevalence decreases among men in the population. Among HIV-infected men, circumcision is currently not recommended as they may be more likely to transmit if they resume sexual activity before wound healing has completed. (166) Excluding HIV positive men from a potential country-wide intervention will however be challenging.

6.3.3 Empowerment

Empowerment of key populations can occur through provision of information and education; increasing knowledge of HIV status; reducing stigmatization; improving access to health services; providing skills to support disclosure and condom negotiation; addressing sexual and gender-based violence; and building support networks. Provision of information, education and skills learning can occur when attending health services and - more importantly - through regular outreach and peer education efforts, as well as activities in community drop-in centres. Building condom negotiation skills in male and female sex workers is a central component of condom programming and includes assisting sex workers to negotiate condom use with clients, to avail condoms at time of sex and, if needed, to refuse clients unwilling to use condoms.

Female sex workers typically have high levels of knowledge of key features of the infection, though of concern, half the sex workers in one study thought that individuals who appear healthy are uninfected with HIV (49). Low levels of knowledge and poor risk perception have been reported in other studies. (167) Among men who sell sex to men in Mombasa, only 64.7% knew that HIV can be transmitted through unprotected anal sex. Importantly, higher levels of knowledge are associated with higher condom use. (1) Improving sex worker knowledge of STI symptoms and of the importance of accessing STI services should they have such symptoms is critical and can be provided through peer education. (107) Materials should be simple, clear, consistent, non-judgemental, attractive and culturally sensitive. (56) In addition to printed materials, other educational mediums have been successfully used, including peer-led drama, slides, video sessions, and role-playing exercises. (51, 107) Building skills to negotiate safer sex, and to refuse a sexual partner unwilling to use a condom increases the ability to avoid risks for HIV acquisition. Many women and men in sex work experience

sexual and gender based violence, while at work or in their personal lives. Efforts to eliminate violence towards sex workers need to involve law enforcement agencies, the judiciary and health services. At an individual level, educational strategies can help women reduce violence by providing safety tips and creating awareness of legal protection options. (168)

Vulnerability is highest where populations lack a social support network. This is often due to stigma and criminalization of their status and/or way of life. Lack of a support network means that the collective power is reduced. Peer support and community mobilisation can facilitate social cohesion, mutual support and development of self-help groups and networks. Having key populations lead and run interventions themselves may assist in developing HIV risk reduction interventions.

6.3.4 Sexual disinhibition with prevention interventions

One of the challenges involving all of the HIV prevention interventions includes sexual disinhibition: an increase in sexual risk behaviour as a result of (less effective) alternative ways of protection against HIV. Sexual disinhibition is based on perceptions of protection or acceptable risk-taking, or as a result of accessibility to more acceptable alternative methods. Examples of potential sexual disinhibition include the increased sexual risk taking due to the availability of ART (treatment optimism), a reduction in condom use (condom migration) or changes in sexual risk taking due to alternative prevention methods, such as female condom, diaphragm, male circumcision, PrEP, PEP and microbicides. Condom effectiveness is estimated to be between 60% and 95% in a meta-analysis among discordant couples reporting consistent condom use. (169) It is currently unknown what effectiveness can be expected from many of the alternative biomedical prevention methods on HIV transmission. Importantly, the effect of a method on preventing HIV transmission depends not only on its efficacy, but also on the adherence of users with the product. With statistical modelling using a potential microbicides intervention, Foss et al. concluded that the maximum amount of condom migration that can be tolerated is greater for higher levels of microbicide efficacy and consistency of use, but also for lower initial levels of consistent condom use. (170)

In our study, about 30% of male condom use before female condom introduction was replaced by female condoms despite messages emphasizing its use only when using a male condom was not possible. Similarly, the Mira study as earlier discussed in chapter 6.1 showed a significantly lower proportion of condom use among those women using the diaphragm as compared to the control

arm. (67) In the male circumcision trials, no sexual disinhibition was seen from the trials in Uganda and Kenya, though in South Africa circumcised men reported a higher number of sexual partners as compared to the control arm. (160-162)

Sexual disinhibition needs serious consideration in future prevention trials as well as before implementation of an efficacious intervention on a larger scale.

Antiretroviral “treatment optimism” has been described to occur among HIV positive individuals receiving ART as well as among HIV negative and those with unknown HIV status. (171-173) This was however not seen among our cohort of HIV-infected participants receiving ART in Kenya, similar to reports from Uganda and Ivory Coast. (46, 48) There is limited evidence on treatment optimism among HIV-uninfected people in sub-Saharan Africa. The statement by the Swiss Federal Commission for HIV / AIDS mentioned earlier in chapter 6.3.2 could enable people to justify high-risk sexual behaviour with partners receiving ART. Caution is needed and clear information needs to be communicated to persons receiving ART, their partners and the community at large.

6.4 Future research

Based on the research presented in this thesis various future research priorities remain:

- Research is needed to evaluate the efficacy of alcohol-related harm reduction interventions in changing their drinking patterns and potentially sexual practices among female and male sex workers who sell sex to men. Brief Interventions together with peer support groups could make a substantial change to patterns of alcohol use among key populations, and potentially reduce their sexual risk taking. For individuals, evidence-based interventions are needed to change the way alcohol is drunk, to shift hazardous drinking patterns to safer patterns. Research is needed to assess alcohol use among HIV positive persons and how this affects sexual risk behaviour.
- Knowledge of HIV status has shown to be associated with improved sexual risk behaviour. Scaling up of targeted VCT through innovative approaches such as home-based VCT, for instance through door-to-door testing, or provided to household members of people initiating ART, could increase coverage. Among HIV positives, additional ways need to be identified to increase disclosure rates to sexual partners, while protecting the rights of persons with HIV as well as emphasizing on partner testing.

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- Interventions targeting men who sell sex to men are rare and only starting to be implemented. High HIV prevalence and incidence rates combined with lack of HIV prevention knowledge and low consistent condom use make interventions a public health priority. Therefore, provision of basic services; including the development of specifically tailored voluntary counselling testing services, behaviour change interventions, promotion of male condoms with appropriate lubricants, and other harm reduction programmes focusing on anal transmission are strongly recommended. ICRH in collaboration with Population Council is currently implementing such an intervention in Mombasa, based on information obtained in the survey and together with selected men who sell sex to men. Activities include the formation of a MSW Drop-in Centre, training of MSW peer educators, training of MSW leaders in basic counselling skills, condom distribution, training of medical practitioners in treatment of STI and opportunistic infections, and psychosocial support for MSW. If shown feasible, acceptable and effective, such interventions need to be scaled up to other areas in sub-Saharan Africa.
 - Although our study evaluated ART treatment effects on unsafe sex over a longer period than previous studies, 12-months remains relatively short considering ART is a lifelong treatment and potential treatment optimism or “safer sex burnout” are particularly expected after sustained periods of treatment. Prospective studies are needed assessing the impact of sustained ART use (>2 years) on people’s sexual risk behaviour. Also, treatment optimism among the HIV uninfected population needs to be assessed. With various new technologies in development, careful evaluation of potential sexual disinhibition will be needed.
 - Assessment of the feasibility, acceptability and effectiveness of a “Highly active HIV prevention intervention” among the general population as well as key populations in Kenya.
 - Targeted interventions assisting HIV-infected persons to adopt safer sexual behaviour could further contribute to HIV prevention. Acceptability and effectiveness of such interventions at the health facility as well as the community level need to be assessed. Given that patients in regular contact with health providers still report high rates of unprotected sex, questions and concerns arise regarding sexual risk behaviour among HIV infected persons in the community who do not receive any treatment and thus have limited or no contact with the health system. The CDC prevention programme for positives is also developing an intervention package targeting PLWH who are in the community and not accessing services. Acceptability and effectiveness of these interventions in the target population are still to be assessed.

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- Better outcome measures for HIV acquisition and transmission need to be used in prevention studies. This would include both the assessment of the change in the number of unprotected sex acts, as well as the use of reliable biomarkers. Biomarkers for semen exposure are being assessed and fall into two broad categories: a) biomarkers of seminal plasma; and b) biomarkers of spermatozoa and other cells present in semen. The best characterized marker of seminal plasma is prostate-specific antigen (PSA), but also includes semenogelins, and various isozymes (lactate dehydrogenase, creatinine phosphokinase etc.). Markers of spermatozoa and other cells include sperm cells, Y-chromosome DNA, gender differentiating alleles, Gamete-specific nuclear proteins, and sperm-specific antigens. Further research is needed to identify a sensitive, specific, easy to assay, reliable, and validated biomarker of semen.
 - Correct and consistent use of male condoms has been shown to prevent HIV transmission, but women are often unable to ensure that their male partners use condoms. Our studies assessing female controlled barrier methods including the female condom and the diaphragm showed weaknesses, but highlight the urgent need for the development of female controlled methods. Acceptability studies of female controlled methods among men are needed.
 - While the search for an HIV/AIDS vaccine continues, research must be conducted to develop and test non-vaccine strategies to prevent the transmission of HIV. Since the majority of new infections are transmitted through sexual contact, there is a clear and urgent need for new technologies to prevent the sexual transmission of HIV. The search for alternative prevention technologies such as microbicides, PrEP and early ART initiation, that are effective and user friendly should remain high on the agenda. Although the findings of Mira study did not support addition of the diaphragm to current HIV prevention strategies, the diaphragm or other cervical barrier methods may serve for administering microbicides, potentially providing synergistic protection against HIV and pregnancies.

6.5 Conclusions

HIV prevention remains a Kenyan and global public health priority, requiring strong and well informed leadership and coordination. In a generalized epidemic such as in Kenya, it is important that prevention efforts are directed to the general population, but targeted programmes for key

populations, including male and female sex workers, men who have sex with men and HIV positive persons remain important. Prevention programmes should be integrated with HIV treatment programmes and consist of a targeted, evidence-based combination prevention package of structural, behavioural, and biomedical approaches, also described as “highly active HIV prevention”. Preventing HIV among female and male sex workers who have sex with men requires implementation of interventions, adapted to local circumstances. Data supports the effectiveness of interventions which address the conditions and context of sex work, including targeted male and female condom promotion and distribution with appropriate lubricants; integrated provider-initiated testing and counselling in all health services; specifically tailored voluntary counselling testing services; alcohol harm reduction; STI/HIV education and treatment; and skills development (such as disclosure and condom negotiation). Among men who sell sex to men, targeted interventions are urgently needed and focussing on anal transmission is strongly recommended.

For persons living with HIV, targeted male and female condom promotion and distribution with appropriate lubricants; skills development (such as disclosure and condom negotiation); alcohol harm reduction; and STI/HIV education are important to prevent further transmission of HIV. Increasing access to health services providing ART, care and support for all people living with HIV, including quality STI treatment, should not be hampered by fear of sexual disinhibition.

Additional research is needed to identify new opportunities for targeted HIV prevention, and to improve implementation of existing interventions. New biomedical prevention technologies such as new female condom, diaphragm, PrEP, microbicides, and vaccines are under development and it is anticipated will soon add to the highly active HIV prevention package for key populations.

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Summary

In 2007, an estimated 2.5 million [1.8 million - 4.1 million] persons became newly infected with HIV, most of these infections occurred in sub-Saharan Africa. Sub-populations that play an important role in fuelling the epidemic have been identified, and are among the most marginalized and discriminated people in society. Their behaviours put them at increased risk of becoming infected with HIV as well as spreading HIV to the population at large. Vulnerable groups include, but are not limited to, sex workers, men who have sex with men, orphans and vulnerable children, girls, migrant workers, uniformed services, victims of rape and sexual violence, intravenous drug users and discordant couples. Targeting these groups remains a key strategy for preventing HIV in both concentrated and generalized HIV epidemics. This thesis focuses on three of these key populations: sex workers; men who have sex with men; and people living with HIV.

Currently, a better understanding is needed of the factors associated with increased sexual risk behaviour among these key populations to more effectively develop and implement targeted interventions. Also, assessment of existing interventions remains needed.

The general objective of this work is to identify priorities in HIV prevention (acquisition and further transmission) and to assess prevention strategies among key populations. More specifically, the research aimed to identify factors associated with unprotected sex among key populations, and to assess the safety, acceptability and effectiveness of HIV prevention strategies among most-at-risk populations in Mombasa, Kenya. Taken together, seven studies were conducted in the period between March 2003 and December 2006, in Mombasa district, Kenya.

Factors associated with unprotected sex

The studies identified that among female sex workers in Mombasa, women who binge drink (≥ 5 alcoholic drinks on ≥ 1 occasion in the previous month) were more likely to report inconsistent condom use than non-binge drinkers. Frequency of drinking was also associated with condom use. Women who drink everyday or almost every day were more likely to report inconsistent condom use than women who currently don't drink. Among the men who sell sex to men, alcohol use three or

more days per week was also associated with unprotected anal sex. Targeted interventions assisting sex workers to adopt safer drinking patterns could contribute to HIV prevention.

In addition, thirty-five percent of men who sell sex to men in Mombasa did not know HIV can be transmitted via anal sex, which was a significant predictor of unprotected anal sex. Provision of basic services; including HIV/STI education, the development of specifically tailored voluntary counselling testing services, behaviour change interventions, promotion of male condoms with appropriate lubricants, and other harm reduction programmes focusing on anal transmission are strongly recommended.

Among HIV infected individuals, unsafe sex (unprotected sex with an HIV-negative or unknown status partner) was reported by half of those sexually active in the 12 months before ART, while after 12 months ART, this reduced to 28%. Unsafe sex was associated with non-disclosure of HIV status to partner; recent HIV diagnosis; not being married or cohabiting; stigma; depression and body mass index $<18.5\text{kg/m}^2$. ART beliefs, adherence and viral suppression were not associated with unsafe sex. Increasing access to health services providing ART, care and support for all people living with HIV should not be hampered by fear of sexual disinhibition. However, positive prevention interventions for those receiving ART must reinforce safer-sex practices and partner disclosure.

Safety, acceptability and effectiveness of HIV prevention strategies

The research evaluated peer-mediated interventions among female sex workers that promote behavioural change through improving knowledge, attitudes and awareness of HIV serostatus, and aim to prevent HIV and other sexually transmitted infections (STI) by facilitating early STI treatment. Impact of these interventions was evaluated among those who attended peer education and at the FSW population level. Peer-mediated interventions were associated with an increase in protected sex. The impact of the female condom was assessed in a separate study and showed to have some potential for reducing unprotected sex among sex workers. However, given its high cost, and the marginal improvements seen here, there is limited use among populations that are already successfully using the male condom. However, new female condom technologies and large-scale promotion and implementation in the general population could significantly reduce cost of the female condom and provide women with a proven effective HIV prevention method.

The safety and acceptability of the diaphragm was evaluated as it was thought that the diaphragm could be used as a female-controlled method of preventing both sexually-transmitted infections (STIs)

and pregnancy. After 6 months of diaphragm use, continuation rates were sustained, user satisfaction was high and adverse effects were few. Users highlighted covert use of the diaphragm during sex work or with casual partners, and coital independence as favourable attributes. Few difficulties with diaphragm use were reported, although its insertion and removal occasionally presented problems. Many women – especially those in long term partnerships - wished to disclose its use, but found the disclosure process highly problematic.

In conclusion, in a generalized epidemic such as in Kenya, it is important that prevention efforts are directed to the general population, but programmes for key populations, including male and female sex workers, men who have sex with men and HIV positive persons remain important. This thesis emphasises that prevention programmes should be evidence-based and targeted to specific populations and entail a combination prevention package of behavioural, structural and biomedical approaches, also described as “highly active HIV prevention”.

Data supports the effectiveness of interventions which address the conditions and context of sex work, including targeted condom promotion and distribution with appropriate lubricants; specifically tailored voluntary counselling testing services; alcohol harm reduction; STI/HIV education and treatment; and skills development (such as disclosure and condom negotiation). Among men who sell sex to men, targeted interventions also focusing on anal transmission is strongly recommended. Interventions assisting persons living with HIV to adopt safer sexual behaviour and disclose the status to sexual partners will contribute to prevention of further HIV transmission. Increasing access to ART, care and support for all people living with HIV, including quality STI treatment will improve quality of life and reduce HIV infectiousness.

New biomedical prevention technologies such as new female condom, diaphragm, PrEP, microbicides, and vaccines are under development and it is anticipated will soon add to the highly active HIV prevention package for key populations.

Samenvatting (Dutch language)

In 2007 werd een geschat aantal van 2.5 miljoen [1.8 miljoen - 4.1 miljoen] mensen geïnfecteerd met het HIV virus. Sub-Sahara Afrika blijft het meest getroffen gebied. Bepaalde groepen, die een belangrijke rol spelen bij de verspreiding van het virus onder de bevolking zijn geïdentificeerd. Deze groepen omvatten de meest gemarginaliseerde en gediscrimineerde groepen in de samenleving. Hun gedrag of situatie maakt dat ze een verhoogde kans hebben om zowel zelf geïnfecteerd te raken, als anderen binnen de samenleving te infecteren met het HIV virus. Geïdentificeerde groepen zijn onder meer mannelijke en vrouwelijke prostituees, homoseksuele mannen, weeskinderen, meisjes, migranten, intra-veneuze druggebruikers, slachtoffers van seksueel geweld, en relaties waarbinnen er reeds een persoon geïnfecteerd is. Preventie-interventies, speciaal gericht op deze groepen zijn een belangrijk onderdeel van de strategie om verdere verspreiding in de bevolking te beperken. Dit geldt voor zowel geconcentreerde als gegeneraliseerde epidemieën. Deze thesis richt zich met name op drie van deze groepen: vrouwelijke prostituees, mannen die sex verkopen aan andere mannen, en mensen die al geïnfecteerd zijn en het virus kunnen verspreiden naar anderen. Een beter begrip is nodig van de factoren die invloed hebben op hun seksueel gedrag om meer gerichte interventies te ontwikkelen en te implementeren. Tevens is het belangrijk om bestaande interventies te evalueren.

Het doel van dit werk is om in deze specifieke groepen de prioriteiten in HIV-preventie te identificeren (zowel de besmetting als de verspreiding), en om bestaande preventie strategieën te evalueren. Meer specifiek zal dit onderzoek trachten belangrijke factoren te identificeren die geassocieerd zijn met onbeschermd seks, alsook bestaande HIV preventie strategieën te evalueren op hun veiligheid, aanvaardbaarheid en effectiviteit in Mombasa, Kenia. In totaal zijn zeven studies uitgevoerd in de periode tussen maart 2003 en december 2006 in het district van Mombasa.

Factoren geassocieerd met onbeschermd seks

Het onderzoek toonde aan dat prostituees in Mombasa die meer dan vier alcoholische dranken op één of meer momenten in de afgelopen maand nuttigden, vaker inconsistent condoomgebruik rapporteerden dan prostituees die dat niet deden. De frequentie van het nuttigen van alcoholische dranken was ook geassocieerd met condoomgebruik. Vrouwen die iedere dag of bijna iedere dag

alcohol nuttigden, rapporteerden vaker inconsistent condoomgebruik. Ook bij mannen die sex verkochten aan mannen in Mombasa was de frequentie van het gebruik van alcohol gerelateerd aan onbeschermd anale seks. Gerichte interventies die sekswerkers inzetten om minder en minder vaak alcohol te nuttigen, zouden een positief effect kunnen hebben op de preventie van HIV overdracht.

Daarnaast rapporteerde 35% van de mannen die seks verkopen aan mannen in Mombasa, dat zij niet wisten dat het HIV virus via anale seks kan worden overgedragen. Dit tekort aan kennis was sterk geassocieerd aan het rapporteren van onbeschermd anale seks. Het is daarmee sterk aan te raden dat interventies worden geïmplementeerd specifiek gericht op educatie, gedragsverandering, promotie van condoomgebruik, en promotie van HIV-testen onder mannen die seks hebben met mannen.

Van de personen die reeds besmet zijn met het HIV virus, rapporteerde de helft van de seksueel actieve personen dat zij onbeschermd seks hadden met partners die niet geïnfecteerd zijn of waarvan zij niet wisten of deze besmet zijn. Na 12 maanden gebruik van antiretrovirale medicijnen rapporteerde nog 28% dit gedrag. Onbeschermd seks met voornoemde partners was geassocieerd met het niet onthullen van de HIV infectie status, een recente diagnose van HIV infectie, niet getrouwd zijn of niet samenwonen, stigma, depressie, en een BMI (body mass index) van $<18.5 \text{ kg/m}^2$. In interventies, die gericht zijn op HIV geïnfecteerde personen die antiretrovirale therapie gebruiken, moet meer aandacht worden besteed aan het promoten van beschermd seks en het onthullen van de HIV status aan een partner. Echter, terughoudendheid met de implementatie van antiretrovirale behandelingsprogramma's met het oog op "behandelings-optimisme" lijkt niet nodig.

Veiligheid, aanvaardbaarheid en effectiviteit van HIV preventie strategieën.

Een onderzoek evalueerde "peer-mediated" interventies bij prostituees die gedragsveranderingen promoten door middel van het verbeteren van de vakkennis en de attitude, alsook het verhogen van de kennis van de HIV-status. De peer-mediated interventies waren geassocieerd met een verhoogd percentage van vrouwen die seksuele contacten beschermden met een condoom.

Een aparte studie die de impact van het vrouwencondoom evalueerde, gaf aan dat tot op zekere hoogte er een verhoging was van het aantal beschermd seksuele contacten na de invoering van het vrouwencondoom in een groep van prostituees, maar de hoge kosten van het vrouwencondoom belemmert het optimale gebruik. Nieuwe technologieën in de ontwikkeling van het vrouwencondoom

en wijdverspreide implementatie kan de kosten verminderen en zou vrouwen een alternatief geven dat bewezen effectief is om HIV te voorkomen.

Een mogelijk alternatief voor het condoom om zowel HIV als zwangerschappen te voorkomen is het pessarium. De veiligheid en acceptabiliteit hiervan werd geëvalueerd in Kenia in een studie waarbij vrouwen het pessarium voor zes maanden gebruikten. Na zes maanden was het gebruik goed onder de deelnemers en vermeldden de gebruikers tevreden te zijn met het produkt en weinig bijwerkingen te hebben ondervonden. Bij het onderzoek kwam naar voren dat het een voordeel was dat gebruik van het pessarium niet altijd aan de partner vermeld hoefde te worden. Tevens werd het als een voordeel gezien dat het pessarium van te voren kan worden ingebracht en dat er geen handelingen zijn tijdens de seks zoals met het condoom. Enkele van de genoemde nadelen waren het inbrengen en de verwijdering van het pessarium en de moeilijkheid van het onthullen van het gebruik aan een partner.

Concluderend, preventie activiteiten in de algemene Keniaanse bevolking zijn belangrijk, maar extra aandacht voor mannelijke en vrouwelijke prostituees, mannen die sex hebben met mannen, en reeds geïnfecteerde personen blijft nodig. Dit proefschrift benadrukt de nood aan gerichte interventies die een combinatie van preventiestrategieën gebruiken inclusief gedragsveranderings-, structurele-, en biomedische interventies.

Preventie interventies met aangetoonde effectiviteit zijn die interventies die rekening houden met de context en situatie waarin sex-werk zich afspeelt, inclusief gerichte condoom promotie en distributie met het juiste glijmiddel; aangepaste dienstverlening van counseling en testen op HIV; voorts interventies om minder, en minder vaak alcohol te nuttigen; educatie en behandeling van seksueel overdraagbare aandoeningen; en aanleren van bekwaamheden, zoals het kunnen onthullen van de HIV status, en onderhandelen over condoom gebruik. Daarnaast is het belangrijk om voor mannen die sex verkopen aan mannen, interventies te implementeren die gericht zijn op anale sex. Voor reeds geïnfecteerde personen moet additionele hulp geboden worden om hun HIV status te onthullen aan seksuele partners. Toegang tot antiretrovirale middelen, behandeling van seksueel overdraagbare aandoeningen, en gerichte zorg in het algemeen zal ook het risico op verdere verspreiding verminderen.

Nieuwe biomedische technologieën zoals een nieuw vrouwencondoom, pessarium, orale antiretroviral prophylaxe, microbiciden, en HIV vaccinaties zijn in ontwikkeling en zullen hopelijk snel bijdragen aan het pakket van preventieve middelen.

List of Publications

1. Steegen K, **Luchters S**, De Cabooter N, Reynaerts J, Mandaliya K, Plum J, Jaoko W, Verhofstede C, Temmerman M. Evaluation of two commercially available alternatives for HIV-1 viral load testing in resource-limited settings. *J Virol Methods*. 2007 Dec;146(1-2):178-187
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Abbreviations

| | |
|---------------|--|
| AIDS | Acquired immunodeficiency syndrome |
| AM | Ante Midday |
| ART | Antiretroviral therapy |
| CDC | Centers for Disease Control and Prevention |
| CITC | Client-initiated HIV Testing and Counselling |
| (co)-Promotor | A wise person sharing her/his knowledge |
| CPGH | Coast Provincial General Hospital |
| ELISA | Enzyme-linked immunosorbent assays |
| G(c)LP | Good (Clinical) Laboratory Practice |
| HAART | Highly active antiretroviral therapy |
| HIV | Human Immunodeficiency Virus |
| ICH – GCP | International Conference on Harmonization - Good Clinical Practice |
| ICRH | International Centre for Reproductive Health |
| IMPACT | Implementing HIV/AIDS Prevention and Care project |
| KEMRI | Kenya Medical Research Institute |
| KOH | Potassium hydroxide |
| MARP | Most-at-risk populations |
| Monk, the | Eowyn Lucy Luchters, daughter |
| MSM | Men who have sex with men |
| PEP | Postexposure Prophylaxis |
| PrEP | Preexposure Prophylaxis |
| PhD | Doctorate in philosophy (not used in thesis) |
| PITC | Provider-initiated HIV Testing and Counselling |
| PLWH | People living with HIV |
| PRDH | Port Reitz District Hospital |
| PSA | Prostate Specific Antigen |
| SOP | Standard Operating Procedures |

| | |
|--------|----------------------------------|
| SRH | Sexual and reproductive health |
| STI | sexually transmitted infections |
| UN | United Nations |
| UNAIDS | United Nations AIDS organization |
| VCT | Voluntary testing and counseling |
| WHO | World Health Organization |

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