Use of Modified Respondent Driven Sampling Methodology to Enhance Identification and Recruitment of Most at Risk Persons into an HIV Prevention Trial in Kisumu, Western Kenya

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KEYWORDS

HIV/AIDS

Key Populations

HIV prevention

Modified respondent driven sampling

Men who have sex with men

Sex workers

Injecting drug users

People Living with HIV

Kisumu; Kenya

PREFACE

I declare that Use of Modified Respondent Driven Sampling Methodology to Enhance Identification and Recruitment of Key Populations into an HIV Prevention Trial in Kisumu, Western Kenya is my own work, that it has not been submitted for any degree or examination in any other university, and that all sources I have used or quoted have been indicated and acknowledged by complete references.

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Signed:

Date:

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I thank my supervisor, Professor Gail Hughes and co supervisor Professor Thandi Puoane for their guidance and support throughout this lengthy journey and I thank Dr Ernesta Kunneke who not only supervised my MPH but encouraged me to go on and enrol for this PhD. I would also not forget Dr Deborah A. Gust who not only encouraged me but took time to go through my thesis with a tooth comb to ensure 'I was saying what I meant to say and meaning what I was saying' and Eleanor McLellan-Lemal who always ensured I was on top of what I needed to be on top of. I would also like to thank my colleagues, family and friends who have encouraged me through the many highs and lows. Finally, I want to thank my wife Auma, my daughters Akinyi and Atieno and my son Odhiambo, for their understanding whilst I have been busy with this research and stealing their family time to complete this thesis.

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DEDICATION

This thesis is dedicated to my grandmother Adhiambo Ny'Ooko, nyar Yenga for her determination to outlive all of us and providing the motivation I needed as I observed her administer her homeopathic remedies and deliver uncountable babies in her hut in Kademba village. She gave me the motivation of agreeing to become a health worker and making the little changes needed in life to make this world a better place. And to say that she almost saw it to the end would be an understatement as she expired on 10th September 2014 after about 104 years of living life her way and on her terms.

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DEFINITION OF TERMS

ACASI	Audio-computer-assisted structured interview
AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine aminotransferase
AR	Action Research
CAPI	Computer-assisted Personal Interview
CDC	Centers for Disease Control and Prevention
CI	Cognitive Interview
CRC	Clinical Research Centre
SW	Sex Worker
DVD-RW	Digital Versatile Disc - Rewritable
HDSS	Health and Demographic Surveillance System
HIV	Human Immunodeficiency Virus
HSR	Health Systems Research
HSV-2	Herpes Simplex Virus type 2
ICF	Informed Consent Form
IDI	In-Depth Interview
IDU	Injecting Drug User
KEMRI	Kenya Medical Research Institute
KP	Key Populations
mRDS	modified RDS
MSM	Men who have Sex with Men
PDA	Personal Digital Assistant
PLHIV	People Living with HIV
PSC	Patient Support Centre
QA	Quality Assurance
RDS	Respondent Driven Sampling
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SQL	Structured Query Language
STD	Sexually Transmitted Diseases

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STI	Sexually Transmitted Infections
UNIM	University of Nairobi, Illinois and Manitoba program
VCT	Voluntary Counselling and Testing

Definitions:

Mature minor A mature minor is defined in the Kenya National VCT guidelines as a person less than 18 years of age who is pregnant, married, or a parent, and who is able to consent for themselves.

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ABSTRACT

This thesis presents research on the use of modified respondent driven sampling (mRDS) methodology to enhance identification and recruitment of key populations (KP) into an HIV prevention trial in Kisumu, western Kenya through a three phase mixed method study. The study was carried out in Kisumu, western Kenya within the Kenya Medical Research Institute (KEMRI) and the US Centers for Disease Control and Prevention (CDC) Research and Public Health Collaboration platform. The three phases included:

1. **PHASE I:** Identification and determination of categories of KPs and techniques of locating and motivating them to participate in HIV prevention trials.
2. **PHASE II:** Design and Implementation of a mRDS methodology in recruiting Ks into HIV prevention trials.
3. **PHASE III:** Evaluation of the mRDS in recruitment of KPs into an HIV incidence cohort study.

Methods

Phase I of the study included the conduct of in depth interviews which were used to identify different categories of persons considered to be KPs within Kisumu, identify strategies of locating the KPs and determine motivators and inhibitors of KPs participation in HIV prevention trials. Phase II on the other hand included the administration of a survey that had been refined in Phase I. The survey was used to design a mRDS methodology which was then implemented to recruit KPs into the survey. Phase III evaluated the success of the mRDS in recruiting KPs into an HIV prevention study by assessing the risk profiles for participants screened and enrolled into the Phase III study. Ethical approval for the study was sought from the ethics committee of the Kenya Medical Research Institute, the US CDC and the University of the Western Cape.

The study recruited 53 individuals into phase I and was able to 8 identify different categories of people considered to be KPs and the 4 salient strategies that could be used to recruit them into HIV prevention studies. The phase also identified 8 potential motivators and 9 potential inhibitors to participation in HIV prevention research. These categories and salient strategies were used in phase II to develop and pilot a mRDS methodology in recruiting 203 individuals into a survey. The survey was used as a validation tool for the risk levels of persons recruited by the mRDS using the variables of inconsistent condom use and having multiple partners. The

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validated mRDS was then applied in the recruitment of 1,292 participants in phase III of the study. These study participants had characteristics similar to those seen in similar studies and elucidated from phases I and II of the study. HIV seropositivity was used as the variable for validating risk levels of participants in this study and this was found to be higher that that seen in general population and comparable to that seen in other KPs groups in the region.

Results:

Overall the study was able to identify different categories of people considered to be at high risk of HIV acquisition. The groups identified included people who frequent bars (e.g. bar workers, drunkards, sex workers, businessmen), people who work in transportation (e.g. truck drivers, matatu drivers, motorcycle drivers, taxi drivers, bicycle taxi drivers), fishermen/fishmongers, MSM and hair salon workers. The study also identified using personal contact, link persons, peer mobilisers and leaders as strategies of identifying and locating KPs. The study used the mRDS successfully in recruiting participants with evaluation of inconsistent condom use and multiple sexual partnerships showing the participants to be of high risk behaviour. Of all the females in the study, only 3.3% were pregnant. The prevalence of Chlamydia was 2.9%, gonorrhoea was 5.0%, syphilis was 0.4% and HSV-2 was 46.0%. Those who tested positive for HIV were 26.2% with 42.3% of the HIV positive participants having CD4 counts of between 250 – 500 cells/ml.

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Recommendations and Conclusion:

The mRDS was successful in recruiting KPs in an HIV prevention trial. Majority of the participants reported inconsistent condom use and having multiple sex partners. In addition to MSM, SW and transport industry workers, fisherfolk, discordant couples, widowers, street youth, car washers and police also form part of KPs groups. The HIV prevalence was higher amongst these groups compared to general population with discordant couples having the highest HIV prevalence. The study recommends that mRDS should be used to identify and recruit KPs as it not only allows for faster recruitment of KPs, it also reduces the expense and complexity associated with coupon management in the standard RDS.

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1. CHAPTER 1: INTRODUCTION

1.1. Introduction

This chapter first defines the magnitude of HIV/AIDS from the worldview, to sub Saharan Africa and finally to Kenya and Nyanza region where Kisumu is found. Secondly the chapter defines people considered to be Key Populations (KPs) and briefly looks at the categories of people considered to be KPs. Thirdly it lays out the environment of HIV prevention and treatment programs within Kenya and explores specific programs targeting KPs. Fourth, it describes the geographic setting as well as the Kenya Medical Research Institute (KEMRI)/ United States Centers for Disease Prevention and Control (CDC) Research and Public Health Collaboration programme within which this research was conducted. Finally it presents the research problem and the rationale used to justify the research problem and carry out this research.

1.2. HIV/AIDS Magnitude

The number of People Living with HIV (PLHIV) has been increasing steadily since the first diagnosis of HIV was made in 1981 with an estimated 36.9 million PLHIV globally in 2014 (UNAIDS, 2015). This increase is probably as a result of the high numbers of people newly infected with HIV along with significantly expanded access to antiretroviral therapy (ART) with a resultant fewer deaths (UNAIDS, 2009, UNAIDS, 2010, UNAIDS, 2013b, UNAIDS, 2015). Of these, adults accounted for 32.1 million PLHIV with women accounting for 17.7 million PLHIV and children below the age of 15 accounting for 3.3 million PLHIV (UNAIDS, 2013a). There has been a decrease in the HIV incidence with 2.0 million new HIV infections globally in 2014 down from 3.4 million in 2001 showing a 34% decline. Of these, 2.0 million were adults and 260,000 were children below the age of 15 years (UNAIDS, 2013a, UNAIDS, 2013b, UNAIDS, 2015). During the same period there was a decline in the number of AIDS deaths from 2.3 million in 2005 to 1.6 million AIDS deaths in 2012 with the number of adults who died being 1.4 million while children below 15 years were 210,000 (UNAIDS, 2013b, UNAIDS, 2013a). The figure below illustrates the trend of new HIV infections, AIDS global deaths and PLHIV between the year 2001 and the year 2012.

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Figure 1.2.1: Number of People Living with HIV, new HIV Infections, and AIDS deaths, 2001-2012, Globally

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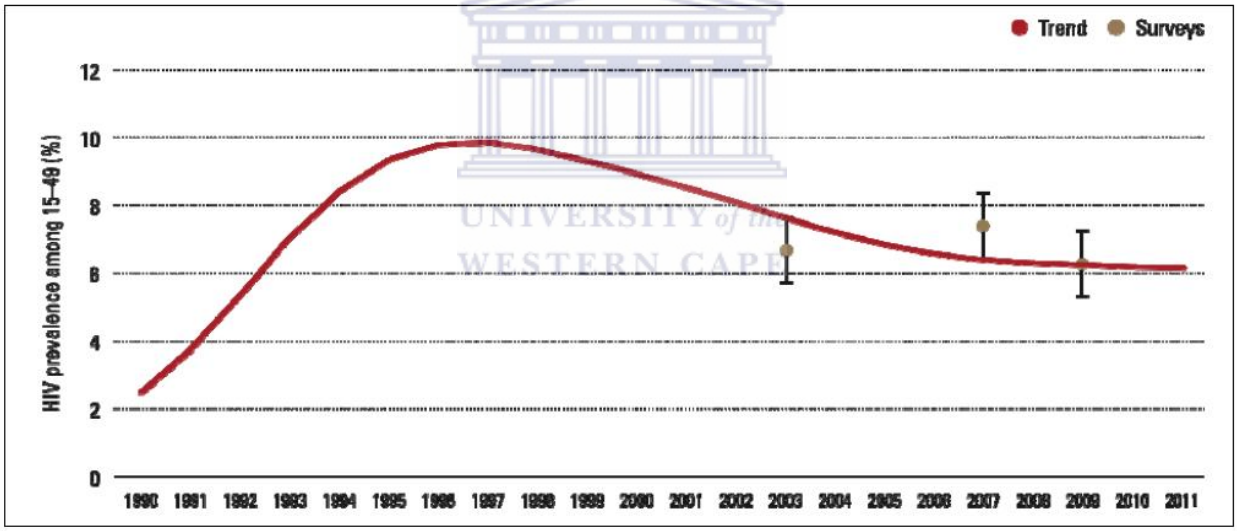
Sub-Saharan Africa, even though a home to 10% of the world's population, still bears an inordinate share of the global HIV burden. Although HIV incidence has decreased, the number of PLHIV continues to rise with 25.0 million PLHIV in 2012, representing 71% of the global total (UNAIDS, 2013b). Of these, 22.1 million were adults and 2.9 million were children aged less than 15 years. The region was home to 1.6 million new infections with adults accounting for 1.4 million new infections and children below the age of 15 accounting for 230,000 new infections (UNAIDS, 2013b). In the same duration, there were 1.2 million global AIDS deaths with 1.01 million and 190,000 deaths occurring in adults and children below the age of 15 years respectively (UNAIDS, 2013a, UNAIDS, 2013b). Provision of ART has also been on the rise in sub-Saharan Africa with an estimated 6.2 million of the 10.9 million people needing ART getting it in this region by 2010 (WHO, 2010), a further increase to 7.5 million in 2012 (WHO, 2013).

The HIV prevalence in Kenya reached its peak of 10.5% in the 1995 to 1996 period, followed by a decline of about 40% to approximately 6.7% in 2003 after which it generally stabilised (Figure 1.2.2). This decline that occurred between 1995 and 2003 has been attributed to the high AIDS

related mortality while the stabilisation between 2003 to date is largely attributed to the rapid scale up of ART and a reduction in incidence (National AIDS and STI Control Programme, 2014). HIV prevalence in Kenya varies considerably by geographical region, age, sex, location and socio-economic status. Of all adults and adolescents aged 15-64 years, 5.6% were infected with HIV in 2012. The prevalence was higher among urban residents (6.5%) compared to their rural counterparts (5.1%). Peak prevalence was 9.4% among ages 45–49 years in rural areas and 11.8% among ages 35–39 years in urban areas. The prevalence was higher in women than in men in both rural and urban areas with women more likely to be infected than men (6.9% vs. 4.4%, respectively). Regional variation was evident with prevalence being 2.1% in North Eastern compared to 15.1% in Nyanza representing 40% of all HIV infections in the country (National AIDS and STI Control Programme, 2014).

Figure 1.2.2: Trends in HIV Prevalence in Kenya



The antenatal surveillance projected the antenatal HIV prevalence of 7.4% in 2011 (National AIDS and STD Control Programme, 2011). In 2012 the HIV incidence was 0.5 new infections per 100 persons per year, representing an estimated 106,000 new infections with the incidence being seen as stable between 2007 and 2012 in general and across age and sex (National AIDS Control Council and National AIDS and STD Control Programme, 2012, National AIDS and STI Control Programme, 2014). Persons in marital or cohabiting relationships had the highest number of new infections (44.1%), followed by those engaged in casual heterosexual sex (20.3%) and KPs with KPS accounting for more than a third of new infections (PEPFAR, 2014)

1.3. Defining Key Populations

Several behavioural risk factors have been documented to be associated with high risk for acquisition of HIV. Several studies in sub Saharan Africa (Bailey et al., 2007, Gray et al., 2007, Mmbaga et al., 2007a, Mermin et al., 2008, Amornkul et al., 2009, Landman et al., 2008, Morris and Kretzschmar, 1997, Shelton et al., 2005, Halperin and Epstein, 2007, Meekers et al., 2003, Hearst and Chen, 2004, UNAIDS, 2010) have shown that female sex work, marital status, number of sex partners, concurrent sexual partnerships, age, men having sex with men, gender, HSV-2 seropositivity, reported sexually transmitted infections (STI), non condom use, circumcision status, religious persuasion, injecting drug use and alcohol use during sex to be among behavioural risk factors associated with HIV acquisition. These behavioural risk factors therefore form a basis for objective criteria for determining those who may be considered as KPs.

KPs have been defined differently in different areas, but are mostly said to include sex workers (SW), men who have sex with men (MSM), injecting drug users (IDU) and truck drivers (International HIV/AIDS Alliance, 2010, National AIDS Control Council, 2009a, UNFPA, 2008, Dutta and Maiga, 2011). The Kenyan Government through the 2nd Kenya National AIDS Strategic Plan period (2005-2010) initiated HIV programming for KPs through the National AIDS Control Council (NACC) and with it brought about the definition of who was considered to be primary KPs in Kenya (National AIDS Control Council, 2005). The reason for initiating this programming was premised on the increasing global recognition of significant increase in HIV related morbidity and mortality among key vulnerable populations namely SW, MSM, IDU, and other people linked to sex trade including SW clients and fishing communities.

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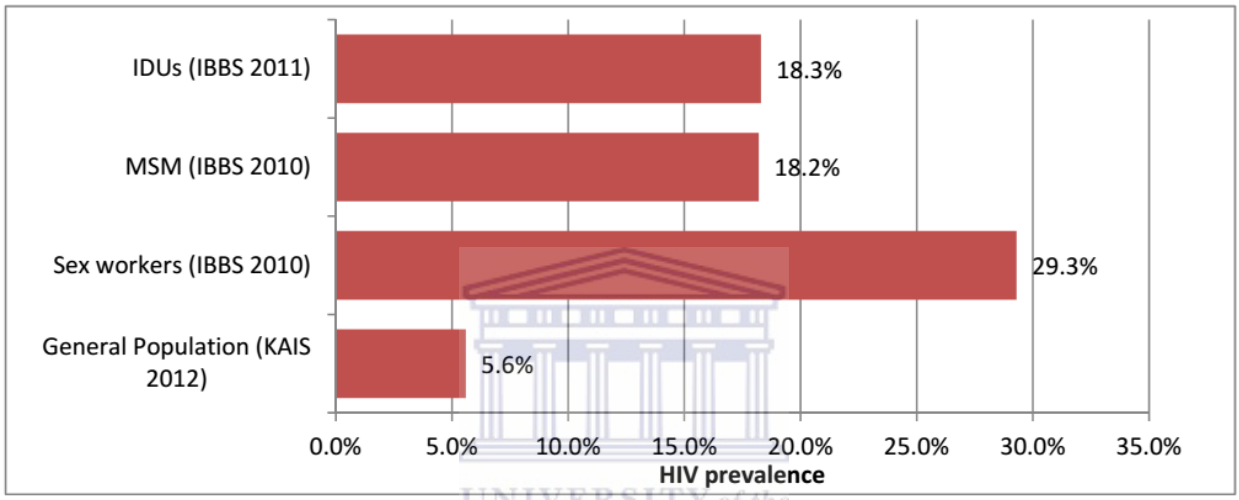
The epidemic in Kenya is both generalised and concentrated with the epidemic being deeply rooted among the general population but with concentrated pockets of high prevalence being seen among people considered to be KPs (National AIDS Control Council, 2014b). The Kenya Modes of Transmission Study of 2009 (National AIDS Control Council, 2009a) showed the concentration of the HIV epidemic among SW, MSM and IDU. It also showed that these populations contribute a disproportionately high number of new HIV infections annually despite their small population size. The study showed that despite the KPs representing less than 2% of the general population, they contributed about one third of all new HIV infections in the country. These results together with the Kenya AIDS Indicator Survey of 2007 (National AIDS and STD

Control Programme, 2009) bolstered the Kenyan government to revise the existing national HIV programming framework and emphasized the importance of KPs in the HIV transmission dynamics and prioritized comprehensive targeted programming for them in the 3rd Kenya National HIV and AIDS Strategic Plan (National AIDS Control Council, 2009b). Figure 1.3.1 below show the prevalence of HIV among KPs in 2010 and 2011 compared to the HIV prevalence from the general population in 2012.

Figure 1.3.1: HIV Prevalence among General and Key Populations



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Some definitions of KPs also include other people linked to the sex trade who have generally been defined as a 'Proxy Population' (UNAIDS and WHO, 2011). The definition of these proxy populations do not necessarily look at social groups but uses socio-demographic characteristics of these groups, such as occupation, or venues these persons are likely to be found. These socio-demographic characteristics are necessarily not the cause of the increased risk for HIV but are seen as an indicator of interaction with a primary KPs group. The most commonly used proxy populations include truck drivers and fisher folk (fishermen, middlemen and fishmongers) (Kissling et al., 2005, Ramjee and Gouws, 2002).

1.4. Environment of HIV Prevention and Treatment Programs in Kenya

Through support from the President's Emergency Plan for AIDS Relief (PEPFAR) initiative, the HIV prevention and treatment programmes in Kenya have evolved since the year 2000. These programmes include Voluntary Counselling and Testing (VCT), prevention of mother to child transmission (PMTCT) services, Evidence Based Behavioural interventions (EBI), HIV

prevention programmes for youth, and tuberculosis (TB) control programs including HIV diagnostic testing and counselling of TB patients. Kenya has also undergone rapid scaling up of antiretroviral treatment (ART). In 2003, there were about 11,000 patients on ART in Kenya, mostly in the private sector (National AIDS and STI Control Programme and Ministry of Health Kenya, 2008). In recent years, ART availability has led to an expansion of care and treatment services across Nyanza Province and the country.

In 2012, an estimated 1.19 million people were HIV-infected nationwide. Of these, 89.3% reported to have enrolled into care with 79.4% of those in care enrolling within 3 months of HIV diagnosis (National AIDS and STI Control Programme, 2014). There are 674,000 eligible for ART based on the Kenya national guidelines and this increases to 888,000 using the 2013 WHO treatment guidelines (National AIDS and STI Control Programme, 2014). Of these, approximately 60.5% are on ART compared to 28.6% in 2007. The national guidelines for ART initiation is based on a CD4 cut off of <350 cells/mm^3 while the WHO guidelines are based on a CD4 cut off of <500 cells/mm^3. ART is provided by the Kenyan Ministry of Health mainly with support from the Global Fund for AIDS, TB and Malaria and PEPFAR. This has seen ART being provided in all government level 3 to 6 facilities as well as most mission and private health facilities (PEPFAR, 2014).

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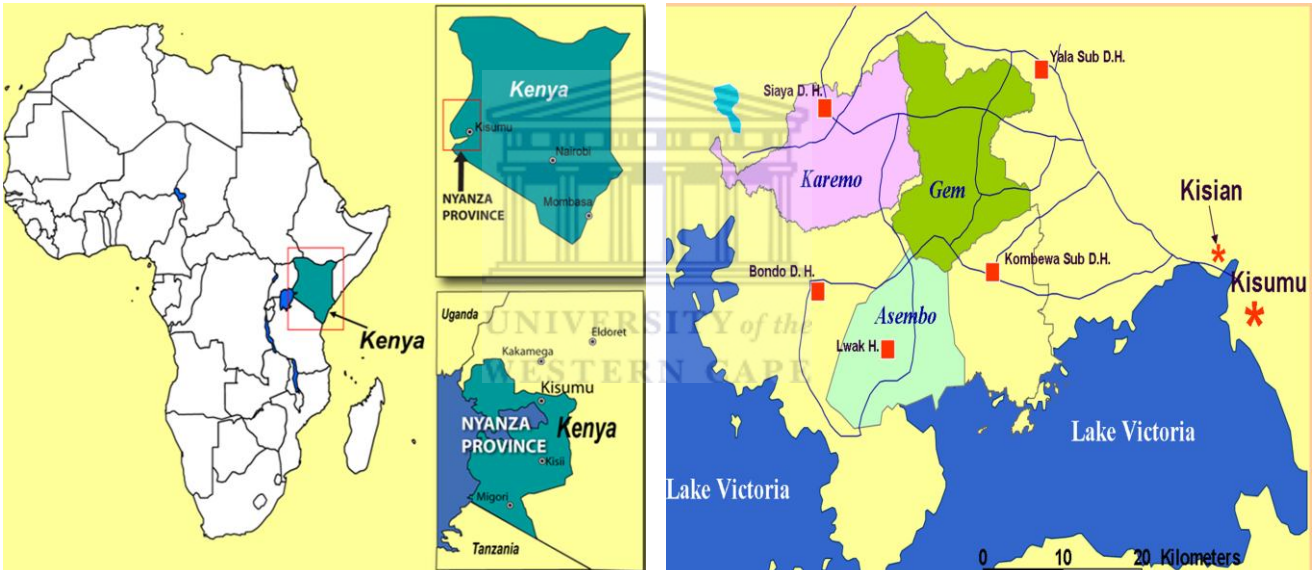
In Kenya majority of IDUs are found in Mombasa and Nairobi. The government of Kenya initiated a programme to prevent HIV infections among IDUs beginning in 2008 in these two regions. The programme is aimed at distributing needles and syringes to IDUs but has not been very successful with the programme distributing about 271,941 needles and syringes to approximately 15% of the estimated number of IDUs (National AIDS Control Council, 2014b).

The growing availability of ART in Kenya represents an important milestone for HIV care and treatment programs. In spite of this, the importance of continued efforts to identify effective interventions to prevent HIV infection remains critical. There is need for continued emphasis on HIV prevention research. The existence of established and growing HIV care and treatment programs, presents an important resource for referral of HIV prevention research study participants who may need to access such services.

1.5. KEMRI/CDC Research and Public Health Collaboration

Since 1979, the KEMRI/CDC Research and Public Health Collaboration has operated a research field station near Kisumu city, western Kenya. This joint KEMRI/CDC collaboration, houses state-of-the art administrative office space and laboratories in 2 locations: the main KEMRI/CDC research field station at Kisian (25 minutes from Kisumu) and the clinical research centre (CRC) located on the grounds of the Nyanza Provincial General Hospital in Kisumu. In addition, the field station operates research sites within the communities of western Kenya. KEMRI/CDC operates a Health and Demographic Surveillance System (HDSS) within Siaya County with an approximate population of 220,000 individuals (Odhiambo et al., 2012, Adazu et al., 2005).

Figure 1.5.1: Map of Nyanza Province, Kisumu and the HDSS



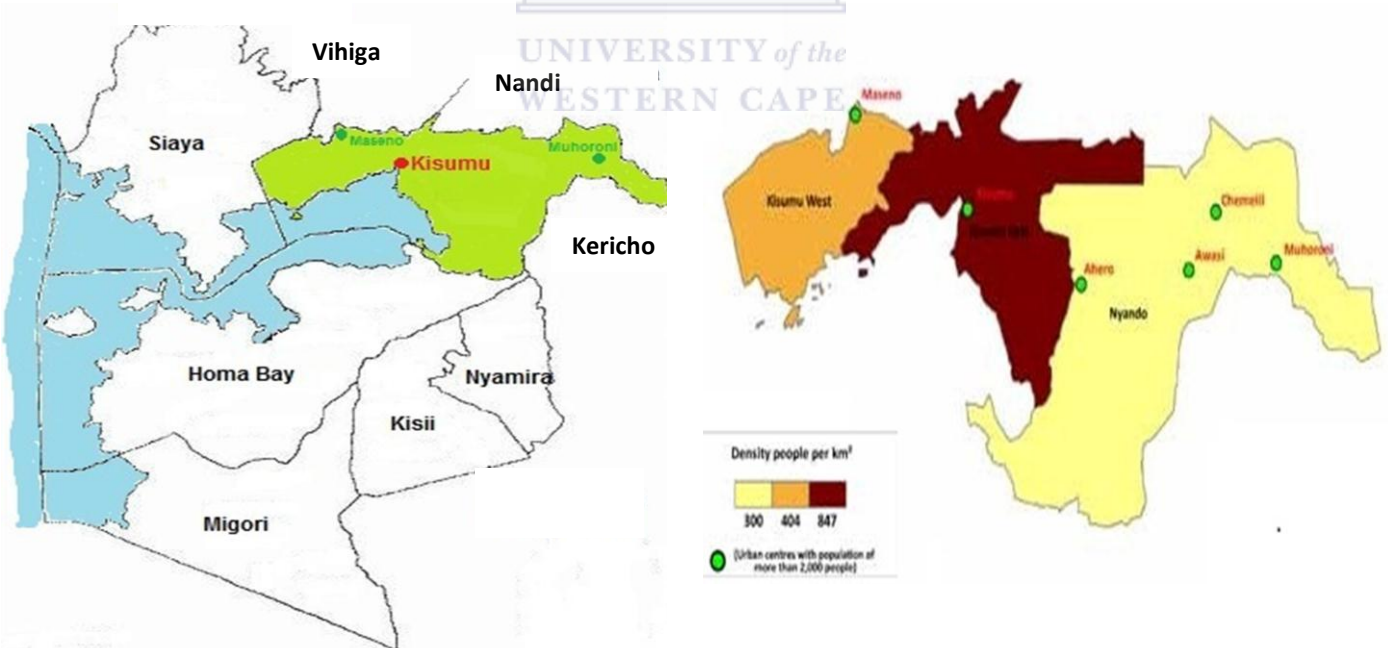
Source: KEMRI/CDC Health And Demographic Surveillance System 2012

Kisumu county is comprised of 3 administrative sub counties (Kisumu East, Kisumu West and Nyando) and covers an area of 2,086.9 km^2 with an estimated total population of 968, 909 (474,760 males and 494,149 females) and a population density of 465 persons per km^2 based on 2009 census data (Commission on Revenue Allocation, 2011, Kenya Open Data, 2014). The county headquarters is located in Kisumu city, in Kisumu East Sub County which has the highest population density (112,977 persons per km^2). A considerable proportion of the population (39.2%) live in the urban area while the remainder live in peri-urban and rural areas. Urban areas

are comprised mostly of housing estates, while villages may be found in the peri-urban and rural areas (Commission on Revenue Allocation, 2011, Kenya Open Data, 2014).

Kisumu city has a catchment area including the whole county and areas in the bordering counties that are in very close in proximity to Kisumu city. These counties include Siaya to the West, Vihiga to the North, Nandi to the North East and Kericho to the East. It also neighbours Nyamira to the South and Homa Bay to the South West. The county has a shoreline on Lake Victoria, occupying northern, western and a part of the southern shores of the Winam Gulf. The predominant ethnic group in these communities is Luo and the main languages spoken are Dholuo, English and Kiswahili (Commission on Revenue Allocation, 2011, Kenya Open Data, 2014).. KEMRI/CDC research activities conducted in Kisumu have included schistosomiasis studies, malaria studies, (including study on impact of malaria on mother to child HIV transmission), prevention of mother to child transmission HIV studies and a cotrimoxazole HIV prophylaxis study.

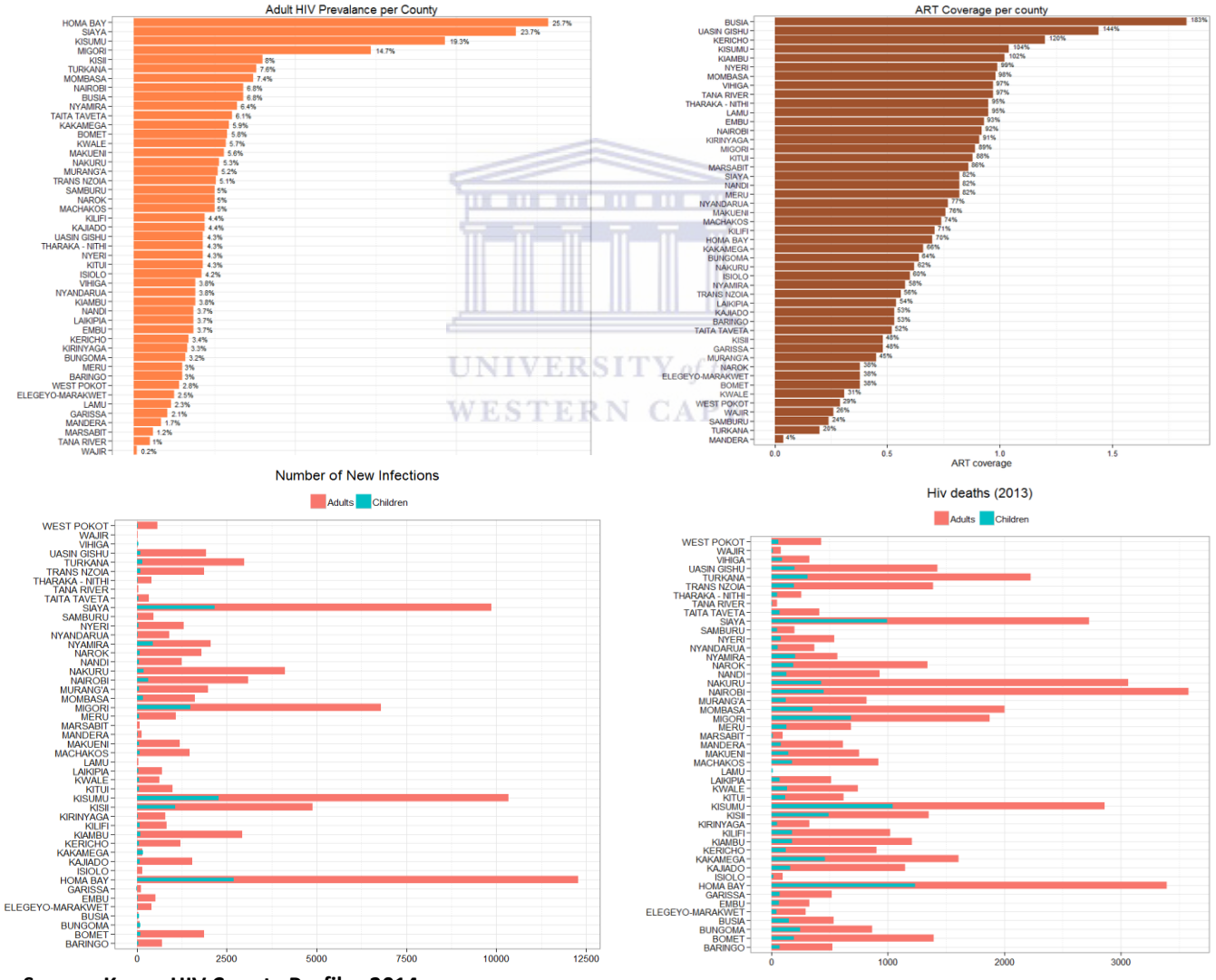
Figure 1.5.2: Map of Kisumu County and Its Neighbouring Counties



Kisumu has the third highest number of PLHIV at 134,826 giving it an HIV prevalence of 19.3% third to Homa Bay and Siaya counties which neighbour it. Its ART coverage is at 104% which is fourth to Busia, Uasin Gishu and Kericho counties. This might be as a result of people from

bordering counties enrolling for treatment in facilities within the county. Kisumu had 10,349 people newly infected with HIV in 2014 making it only second to Homa Bay county. AIDS related mortality was at 2,861 adults and 1,040 children which ranked the county as the fourth highest following Nairobi, Homa Bay and Nakuru counties. Kenya has seen a surge in rates of male circumcision with rates increasing from 85.0% in 2007 to 91.2% in 2012 with the highest increase seen in Nyanza province and Kisumu having a 91% circumcision prevalence (National AIDS Control Council, 2014c).

Figure 1.5.3: Kisumu County HIV/AIDS Indicators



Source: Kenya HIV County Profiles 2014

1.6. Problem Statement

KPs have been identified as the core group(s) and driver(s) for HIV infection in Kenya (Kenya National AIDS Control Council, 2009). This is mostly augmented by the fact that KPs tend to sexually interact with the general population. This is seen with a significant proportion of MSM not being exclusively homosexual, and may even be married. The number of IDUs having heterosexual intercourse is also large with SW also having clients who are married or in the 'not at risk' portion of the general population. There is thus need to not only identify these populations, but also involve them in HIV prevention research to stem the spread of HIV.

1.7. Study Rationale

There is an urgent need to develop and evaluate new biomedical and behavioural interventions to reduce the rates of incident HIV infection. Biomedical prevention methods will require evaluation for their safety and efficacy in human populations living in various environments under a wide-range of social, political, and cultural conditions. Variation in HIV viral sub-types may result in an effective intervention from one location or group of individuals being significantly less effective in another region or group with a different viral subtype. With KPs accounting for one third of all incident HIV infections in Kenya despite only being 2% of the population (Kenya National AIDS Control Council, 2009), there is an urgent need to not only have cost effective and targeted interventions, but also representative surveillance mechanisms to monitor the trends of the epidemic in these populations. This brings with it the need to design methodologies of identifying, accessing and including them into HIV prevention research. This would involve conducting formative research to gain sufficient understanding of the characterisation of KPs, or of the best strategies to recruit and retain them in HIV prevention research studies in Kisumu and use this information to successfully recruit and retain them in an HIV prevention trial in Kisumu.

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2. CHAPTER 2: LITERATURE REVIEW

2.1. Introduction

This chapter reviews the available literature on the subject matter. It starts by investigating the HIV prevention trials landscape by describing what kinds of HIV prevention trials are on-going and what is needed to make those trials successful. It also looks at what kinds of populations are needed for these trials. Secondly the chapter reviews the HIV risk, knowledge and attitudes seen among the KPs. Thirdly it looks at the available literature on how to access KPs and finally conclude by reviewing different strategies that may be used to sample KPs for HIV prevention research participation.

2.2. The HIV Prevention Trials Landscape

HIV prevention methods can generally been classified into behavioural (abstinence, behavioural changes and condom usage) and biomedical methods (drugs, circumcision, and vaccines). Behavioural methods are still the most widely used methodologies with good news coming from some biomedical options. In the recent past the HIV prevention trials field has seen some positive results from different biomedical interventions and with varying effect sizes. These interventions have included treatment as prevention trials, male circumcision trials, HIV vaccine trials, microbicide trials and pre exposure prophylaxis trials (AVAC Report, 2009).

2.2.1. HIV Treatment

In 2008, Granich and his colleagues put together mathematical models to explore the effect of universal voluntary HIV testing with immediate ART as a strategy for elimination of HIV transmission. They used data from South Africa as the test case for a generalised epidemic, and assumed that all HIV transmission was heterosexual and they defined elimination as a reduction of incidence to less than one case per 1000 people per year. The study showed that this strategy could greatly increase the uptake of ART from its current endemic phase to an almost universal coverage in 5 years. It could also reduce HIV incidence and mortality to less than one case per 1000 people per year within 10 years of full implementation of the strategy, and reduce the prevalence of HIV to less than 1% within 50 years (Granich et al., 2009). This study set the ball rolling for the next two population studies that showed great success and changed the HIV prevention and treatment map.

In the HPTN 052 trial done across nine countries 1,763 discordant couples were enrolled, with 54% of the participants being from Africa. HIV infected participants with CD4 counts between 350 and 550 cells/mm^3 were randomly assigned to receive immediate ART or delayed ART when they meet the WHO requirements for ART initiation. The study had 39 HIV transmission events (incidence of 1.2 per 100 person-years) with 28 being virologically linked to the infected partner (incidence of 0.9 per 100 person-years). Of the 28 linked transmissions, only 1 occurred in the immediate ART group (Cohen et al., 2011).

The Partners in Prevention trial analysed data from 3,381 couples of whom 349 initiated ART during the study. The analysis showed that only 1 of 103 genetically-linked HIV-1 transmissions was from an infected participant who had started ART representing a transmission rate of 0.37 per 100 person-years in those on ART and 2.24 per 100 person-years in those not on ART (Donnell et al., 2010). Another observation cohort study in Rakai analysed data from 250 discordant couples who were followed between 2004 and 2009 of whom 32 HIV positive partners initiated ART. The study had 42 HIV transmission events prior to ART initiation giving an incidence of 9.2 per 100 person-years with no transmission event noted in the 32 couples in which the HIV positive partner had started ART (Reynolds et al., 2011).

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These two studies demonstrated that the use of ART in the HIV infected partner reduced the rates of sexual transmission of HIV-1 in discordant couples and formed the basis of Treatment as prevention and pre exposure prophylaxis of HIV. This is mainly because ART suppresses the viral loads of the infected patients to mostly undetectable levels and thus reducing their infectiousness.

2.2.2. Male Circumcision

Three randomised controlled trials of male circumcision have presented compelling evidence that male circumcision reduces the risk of heterosexually acquired HIV infection in men by approximately 60%. These studies bolstered the over 30 observational studies that previously suggested that there was a protective effect of male circumcision on HIV acquisition in heterosexual men. The trial in Orange farm, South Africa enrolled 3,274 uncircumcised men, aged 18-24 years who were randomised to a control or an intervention group with circumcision being offered as the intervention following randomisation. Follow up visits occurred at months 3,

12, and 21. The trial was stopped at the interim analysis, and demonstrated an incidence of 0.85 per 100 person-years in the intervention group and 2.1 per 100 person-years in the control group giving a 60% protective effect (Auvert et al., 2005). The Rakai trial in Uganda had an HIV incidence of 0.66 cases per 100 person-years in the intervention group and 1.33 cases per 100 person-years in the control group, giving an estimated efficacy of intervention of 51% with the as-treated efficacy of 55% (Gray et al., 2007). The third trial in Kisumu Kenya was also stopped after a third interim analysis and gave an HIV incidence of 2.1 per 100 person years in the circumcision group and 4.2 per 100 person years in the control group thus demonstrating a 60% protective effect of circumcision (Bailey et al., 2007).

These studies provide compelling evidence that male circumcision is associated with a reduced risk of HIV infection in sub-Saharan Africa. In vitro studies have shown that HIV-1 has a high affinity to the CD4 receptors in the Langerhans cells that are well supplied in the inner prepuce. So removing the prepuce removes a greater magnitude of these cells thus reducing the entry points for HIV-1 (Szabo and Short, 2000, Soto-Ramirez et al., 1996). Even though these studies were done in different populations and in different epidemic circumstances, the results were pretty similar thus bolstering their conclusions on the protective effect of male circumcision on HIV.

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2.2.3. HIV Vaccines

An effective HIV vaccine has been touted as the magical bullet that would otherwise have the greatest impact on HIV eradication. The disappointing results from the VaxGen's phase III trials in Thailand (Pitisuttithum et al., 2006) as well as by failure of Ad5 based multi country STEP (HVTN 502/Merck 023) and Phambili (HVTN 503) vaccine trials (Buchbinder et al., 2008, Gray et al., 2011), and HVTN 505 trial (Flynn et al., 2005) dampened the spirit of the HIV vaccine world. The VaxGen trial was a randomized, double-blind, placebo-controlled efficacy trial of AIDSVAX B/E trial among IDUs in Bangkok, Thailand. The primary end point was HIV-1 infection and follow up was for 36 months. The study enrolled 2,546 IDUs and an overall HIV-1 incidence of 3.4 infections/100 person-years, and cumulative incidence of 8.4% was found. The study did not show any difference between the vaccine and placebo arms in terms of HIV-1 incidence (Pitisuttithum et al., 2006). Even though this trial was successful and it gave valuable data in enrolment and follow up of subjects in HIV vaccine trials, it failed to demonstrate any

efficacy with and estimated vaccine efficacy of 0.1%.

The STEP trial was a multi country double-blinded, phase II, event driven, test-of-concept study at 34 sites in North America, the Caribbean, South America, and Australia. Three thousand HIV-1-seronegative subjects were randomised to receiving three injections of MRKAd5 HIV-1 gag/pol/nef vaccine or placebo. The primary objective was a reduction in 6 monthly HIV-1 acquisition rates or a decrease in HIV-1 viral-load set point. The study was however stopped early due to futility with 24 (3%) of all vaccine recipients versus 21 (3%) of all placebo recipients in the adenovirus 5 (Ad5) antibody titre 200 or less at baseline becoming HIV-1 infected. The study also found out that irrespective of baseline Ad5 antibody titre, the hazard ratio of HIV-1 infection between vaccine and placebo recipients was higher in Ad5 seropositive men (2.3) and uncircumcised men (3.8), but was not increased in Ad5 seronegative (1.0) or circumcised (1.0) men (Buchbinder et al., 2008).

The HVTN 503/Phambili study though similar to the STEP trial, was conducted in South Africa. This study was also stopped when the STEP trial was stopped. At the time of stoppage, the study had enrolled 801 participants (26·7%) of a planned 3,000 subjects with 216 receiving only one injection, 529 receiving only two injections, and 56 receiving three injections. At the median follow up time of 42 months, 63 vaccine recipients (16%) had HIV-1 infection compared with 37 (9%) placebo recipients. The study however did not find any differences in the risk of HIV-1 infection by the number of vaccinations received, sex, circumcision, or Ad5 serostatus (Gray et al., 2011).

Study vaccinations were stopped in both studies when the STEP trial was stopped for futility. None of the two trials demonstrated a protection from HIV acquisition at stoppage. Even though both trials did not demonstrate a decrease in HIV acquisition nor decreased early plasma viral load in vaccinees compared to placebo recipients, the STEP trial showed a larger number of HIV infections in vaccinated men who were Ad5 seropositive and uncircumcised compared to a comparable placebo group. The Phambili study did not demonstrate this even though most of the men in this study were heterosexual, while most in STEP trial were either homosexual or bisexual.

Results from the RV144 vaccine trial on the other hand demonstrated modest efficacy of 31%

and gave some hope to the HIV vaccine field. The study was a community-based, randomized, multicentre, double-blind, placebo-controlled efficacy trial that enrolled 16,402 healthy men and women between the ages of 18 and 30 years in Thailand. The participants were primarily at heterosexual risk for HIV infection and were monitored for the HIV-1 infection and early HIV-1 viraemia, at the end of the 6-month vaccination series and every 6 months thereafter for 36 months of study participation. The intention-to-treat analysis, which is the result based on the study arm the participant was assigned to regardless of treatment received, showed a vaccine efficacy of 26.4% while the per-protocol analysis, which is based on the actual treatment received regardless of assigned study arm, showed a vaccine efficacy of 26.2% with a modified intention-to-treat analysis of 31.2% excluding 7 participants found to have been HIV infected at baseline (Rerks-Ngarm et al., 2009). Even though this study had a large sample, the yielded vaccine efficacy was non-significant in the intent-to-treat analysis with wider confidence intervals seen in the modified intent-to-treat analysis results. This was probably as a result of the low HIV incidence among this sample of the general population which gave the study limited power.

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2.2.4. HIV Microbicides

Microbicide trials have also been growing with a shift from non-antiretroviral (ARV) based microbicides to ARV based microbicides. The first phase of microbicide development started with nonspecific agents, including surfactants such as nonoxynol-9 (N-9) and other non-specific polyanions in the prevention of HIV. These studies were largely ineffective and suggested that some of these agents may be associated with local vaginal toxicity, including ulcerations and inflammation. The studies also demonstrated that multiple usage of N-9 enhanced HIV-1 transmission probably due to their vaginal toxicity.

The study looking at the efficacy of N-9 contraceptive sponge use in preventing heterosexual acquisition of HIV was conducted among prostitutes in Nairobi, Kenya. The study enrolled 138 HIV-seronegative women of whom 74 were randomised to N-9 sponge use and 64 to placebo use. Participants in the N-9 sponge arm were found to have an increased frequency of genital ulcers (RR, 3.3) and vulvitis (RR, 3.3) and a reduced risk of gonococcal cervicitis (RR, 0.4). There were 45% and 36% HIV infections in the N-9 and placebo arms respectively, presenting a hazard ratio of 1.7 (Kreiss et al., 1992).

Roddy et al., enrolled 1,292 HIV-negative female SW in Cameroon in a double-blinded, placebo-controlled study. the women were randomly assigned use either a film containing 70 mg of N-9 or a placebo film, inserted into the vagina before intercourse. There were 6.7 and 6.6 incident cases per 100 woman years in the N-9 and placebo arms respectively. The rates of genital lesions were 42.2 and 33.5 incident cases per 100 woman years in the N-9 and placebo arms respectively with the rates gonorrhoea being 33.3 and 31.1 cases per 100 woman-years in the N-9 and placebo groups, respectively. Chlamydia infection was comparable across the 2 arms with 20.6 and 22.2 per 100 woman years in the N-9 and placebo arms respectively (Roddy et al., 1998).

Another double-blind placebo controlled trial to determine the effect of an intravaginal gel containing 52.5 mg of N-9 on acquisition of STDs in a cohort of HIV-1-seronegative female SW in Mombasa, Kenya randomised 278 to either N-9 or placebo. The study showed significantly higher incidence of gonorrhoea in the N-9 group than in the placebo group with a lower incidence of vaginal erythema in the N-9 group (Richardson et al., 2001).

Another N-9 study done in Benin, Côte d'Ivoire, South Africa, and Thailand enrolled 892 female SW in a randomised, placebo-controlled, triple-blinded, phase 2/3 trial with COL-1492, a nonoxynol-9 vaginal gel. Of the 765 women who were included in the primary analysis, 16% of those in the N-9 and 12% of those in the placebo arm became HIV-1 infected representing a hazard ratio of 1.5. The risk of HIV-1 infection was considerably higher in women who reported using more than 3.5 applicators per working day with a hazard ratio of 1.8 (Van Damme et al., 2002).

These studies were followed by two other studies looking at another surfactant, SAVVY® (C31G), which demonstrated safety of the product but failed to show any significant efficacy in the prevention of HIV-1 acquisition. This is probably due to the fewer seroconversions than expected seen in each of the studies. The two trials were done in Ghana and Nigeria. The Ghana trial was a phase 3, double-blind, randomized, placebo-controlled trial in Kumasi. The trial enrolled 2,142 HIV-negative women at high risk of HIV infection, and randomized them to SAVVY® or placebo gel. Even though the study did not report any clinically significant differences in the overall frequency of adverse events, abnormal pelvic examination findings, or

abnormal laboratory results between the two arms, 13% of participants in the SAVVY® group reported reproductive tract adverse events than 9.4% in the placebo group. There were 17 HIV seroconversions with 8 in the SAVVY® group and 9 in the placebo group (Peterson et al., 2007a)s. the Nigerian trial, conducted in Lagos and Ibadan, was similar to the Ghana trial and enrolled 2,153 HIV-negative women at high risk of HIV infection. There 33 HIV seroconversions with 21 in the SAVVY® group, 12 in the placebo group. Rates of adverse events, reproductive tract adverse events, abnormal pelvic examination findings, chlamydial infections and vaginal infections were similar in the study arms (Feldblum et al., 2008).

Further studies in this phase included polyanionic sulfated, or sulphonated polymers, that blocked HIV from binding with the cell membrane. Even though these agents showed much promise in vitro, they were largely ineffective in human clinical trials. One such study is the randomized, double-blind, placebo-controlled trial of cellulose sulfate, an HIV-entry inhibitor formulated as a vaginal gel, that was conducted among women at high risk for HIV infection at three African and two Indian sites. The study enrolled 1,398 women with 706 receiving the cellulose sulfate gel and 692 receiving placebo. At the time of premature stoppage, the study had 41 incident HIV infections with 25 in the cellulose sulfate group and 16 in the placebo group giving an estimated hazard ratio for the cellulose sulfate group of 1.61. This study, in addition to being ineffective, also indicated that cellulose sulphate might increase the chances of HIV acquisition (Van Damme et al., 2008). A different cellulose sulphate phase III, double-blind, randomized, placebo-controlled trial was conducted in Lagos and Port Harcourt, Nigeria. The study enrolled 1,644 HIV negative women at high risk of HIV acquisition who were randomised to either cellulose sulphate or placebo and asked to use gel plus a condom for each vaginal sex over one year of follow-up with monthly visits. The trial was stopped prematurely following the results of the trial by Van Damme et al., concluded that cellulose sulfate might be increasing the risk of HIV acquisition. However at the time of stoppage, this study concluded that cellulose sulfate gel appeared to be safe but there was insufficient evidence that it prevented male-to-female vaginal transmission of HIV, gonorrhoea or chlamydial infection (Halpern et al., 2008).

Another randomised, placebo-controlled, double-blind trial was conducted in three South African sites among 6,202 sexually-active, HIV-negative women, aged 16 years and older. The study randomised 3,103 women to Carraguard plus condom and 3,099 to placebo plus condom. Follow

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up occurred for 2 years with quarterly visits. There were 134 HIV seroconversions in the Carraguard arm and 151 in the placebo arm giving an HIV incidence of 3.3 and 3.8 per 100 woman-years in the Carraguard and placebo group respectively. Even though there were high self-reported gel (96.2% Carraguard, 95.9% placebo) and condom use (64.1% in both groups) at last sex act, applicator testing estimated average gel use at only 42.1% (41.1% Carraguard, 43.1% placebo) of sex acts (Skoler-Karpoff et al., 2008).

The Microbicides Development Programme (MDP) 301 was a phase III, randomised, double blind, parallel-group trial, undertaken in South Africa, Tanzania, Uganda, and Zambia. The study randomised 9,385 sexually active HIV uninfected women, aged 18 years or older to 2% PRO2000 (2,591), 0.5% PRO2000 (3,156), or placebo gel (3,112) groups for 52 weeks. Use of 2% PRO2000 gel was discontinued by the data safety and management committee because of low probability of benefit. HIV-1 incidence was similar across the study groups with 4.5 for 0.5% PRO2000, 4.3 for placebo, and at discontinuation 4.7 for 2% PRO2000 gel, 3·9 0.5% PRO2000 gel, and 3.9 for placebo gel. Gel use was also very good with a mean reported gel use at last sex act of 89% (McCormack et al., 2010).

Another 0.5% PRO2000 trial was conducted in Malawi, South Africa, Zambia, Zimbabwe, and the USA. The study was a phase II/IIb, randomized, placebo-controlled trial with three double-blinded gel arms and an open-label no gel arm that had study participants apply study gel up to 1 hour before sex. A total of 3,101 women were enrolled and followed for an average of 20.4 months with 93.6% retention and 81.1% self-reported gel adherence. HIV incidence rates in the 0.5% PRO2000 gel, BufferGel, placebo gel, and no gel arms were 2.70, 4.14, 3.91, and 4.02 per 100 women-years, respectively with the 0.5% PRO2000 gel demonstrating a 30% reduction in HIV acquisition in women. (Abdool Karim et al., 2011). The HPTN 035 was a phase II/IIb study conducted by Guffey et al., to estimate the effectiveness of BufferGel and 0.5% PRO2000 gel fro prevention of non-ulcerative STIs) including Neisseria Gonorrhoeae (NG), Chlamydia Trachomatis (CT) and Trichomonas Vaginalis (TV). The overall incidence rates were 1.6 for NG, 3.9 for CT and 15.3 for TV. The hazard ratios for BufferGel versus placebo gel were 0.99, 1.00 and 0.95 for prevention of NG, CT and TV, respectively while for PRO2000 they were 1.66, 1.16 and 1.18 for prevention of NG, CT and TV, respectively (Guffey et al., 2014).

For as much as these six studies showed the polyanionic sulfated, or sulphonated polymers to be safe when used in humans, they were largely ineffective in the prevention of sexual transmission of HIV and other non ulcerative STIs. Even though the Abdool Karim et al., study demonstrated up to 30% reduction in HIV acquisition, the results were not statistically significant and if looked at together with the MDP 301 trial, these results confirmed that 0.5% PRO2000 gel has little or no protective effect.

Phase two studies involved the assessment of the antiretroviral drugs with tenofovir (TFV), formulated as a vaginal gel, being found to be modestly effective in a Phase IIb trial (CAPRISA-004) when dosed in a coitally-dependent manner. The CAPRISA 004 trial assessed the effectiveness and safety of a 1% TFV vaginal gel in sexually active, HIV uninfected 18 to 40 year old women in South Africa who were followed up monthly for 30 months. Women in this study had to have engaged in vaginal sex at least twice in the 30 days prior to screening, were not pregnant, and were using a non-barrier form of contraceptive. The study showed an HIV incidence of 5.6 per 100 person years in the TFV gel arm compared to 9.1 per 100 person years in the placebo gel arm. (Abdool Karim et al., 2010). This study had a small sample size and a small number of study sites thus broad generalizability of the results is not possible. The study also used the BAT 24 dosing regimen that required women to insert 1 dose before sex and 1 dose after sex and not to exceed 2 doses in 24 hours. This made it difficult to attribute the protective effect to the pre or post coital dose.

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This study was followed by another Phase IIb trial, VOICE (MTN-003), which showed TFV gel to be ineffective when dosed once-daily in a coitally-independent manner. The study compared 3 different once-daily HIV prevention strategies: 1) Truvada® (combination pill of emtricitabine and tenofovir), 2) TFV (Viread®), and 3) TFV 1% vaginal gel among 5,029 women from South Africa, Zimbabwe and Uganda. The oral TFV, the vaginal TFV and the placebo arms of the trial were stopped due to futility. Drug levels were detected on average in 28% of participants taking oral TFV, 29% of participants taking oral Truvada®, and 23% of participants in the 1% TFV gel study arm. This low adherence contributed to none of the study products being effective in reducing HIV acquisition with hazard ratios of 1.49 for oral TFV, 1.04 for oral Truvada® and 0.85 for 1% TFV gel. This ineffectiveness has been largely attributed to non adherence of the regimen (Marrazzo et al., 2013).

The recently concluded FACTS-001 Phase III safety and efficacy trial in South Africa, using the coitally-dependent dosing regimen employed in CAPRISA-004 was not successful. The study demonstrated that pericoital vaginal TFV 1% gel was not effective in preventing HIV acquisition. The study had an overall incidence of 4.0 per 100 women years with an incidence rate ratio of 1.0 (95% CI: 0.7-1.4) (Rees et al., 2015). A new phase of microbicide trials has begun with studies using intravaginal rings being in different stages of planning or implementation (Moss et al., 2012, Smith et al., 2013, Devlin et al., 2013, Abdool Karim and Baxter, 2014)

2.2.5. Pre Exposure Prophylaxis

There have been about a dozen randomized controlled trials (RCTs) of pre-exposure prophylaxis (PrEP) completed or on going to evaluate the effectiveness of PrEP in HIV transmission. These studies have been done in different populations including heterosexuals, MSMs and IDUs. These studies have mostly used TFV, tenofovir disoproxil fumarate (TDF) or TDF and emtricitabine (TDF/FTC) combinations. The PrEP trials as opposed to the microbicide trials have largely been safe and with most of them demonstrating that daily use of TDF or TDF/FTC was protective to HIV acquisition. The studies that did not show this protection mostly had poor adherence to the study regimen.

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The Bangkok Tenofovir study enrolled 2,413 IDUs from drug-treatment clinics in Thailand and used daily oral TFV prophylaxis as the intervention. Participants chose either daily directly observed treatment or monthly visits and could switch at monthly visits. Participants received monthly HIV testing and individualised risk-reduction and adherence counselling. The study demonstrated a 48.9% reduction in HIV incidence 17 HIV infections in the TFV group (incidence of 0.35 per 100 person years) and 33 in the placebo group (incidence of 0.68 per 100 person years) (Choopanya et al., 2013). A phase 2, randomized, double-blind, placebo-controlled trial with daily oral 300 mg TDF as the intervention was conducted in Ghana, Cameroon and Nigeria among 936 sexually active women at high risk of HIV infection. The study had 8 transmission events with 2 in the TDF arm (incidence of 0.86 per 100 person years) and 6 in the placebo arm (incidence of 2.48 per 100 person years). Even though daily oral was not associated with increased clinical or laboratory adverse events, the study could not establish effectiveness

due to the small number of infections observed and the premature closures of the Cameroon and Nigeria study sites (Peterson et al., 2007b).

Several studies have used TDF/FTC combinations with the iPrEx study among MSM in Peru, South Africa, Brazil, Thailand, United States and Ecuador, that enrolled 2,499 participants being one of them. The study randomised 2,499 HIV-seronegative men or transgender women who have sex with men to receive TDF/FTC or a placebo once daily. The study demonstrated a 44% reduction in the incidence of HIV in the TDF/FTC arm. There were 100 HIV infections with 36 in the TDF/FTC group and 64 in the placebo group. The study demonstrated that oral TDF/FTC provided protection against the HIV acquisition among the participants (Grant et al., 2010). Another study using this combination was conducted in Kenya, South Africa and Tanzania among 2,120 women but did not significantly reduce the rate of HIV infection, as compared with the placebo group. HIV infections occurred in 33 women in the TDF/FTC group (incidence of 4.7 per 100 person years) and in 35 in the placebo group (incidence of 5.0 per 100 person years). Rates of drug discontinuation because of hepatic or renal abnormalities were higher in the TDF/FTC group (4.7%) than in the placebo group (3.0%). Less than 40% of the HIV-uninfected women in the TDF/FTC group had evidence of recent pill use at visits matched to the HIV-infection window for seroconverted women. The study was stopped early because of lack of efficacy (Van Damme et al., 2012).

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The TDF2 study in Botswana that enrolled 1,219 HIV negative men and women is another study that used this combination. HIV-seronegative men and women were randomised to either TDF/FTC or matching placebo once daily. The study had low retention and had to conclude early participants were followed through an orderly study closure of the study. The study demonstrated an efficacy of 66.2% with 9 infection in the TDF/FTC group and 24 in the placebo group giving incidences of 1.2 and 3.1 infections per 100 person years, respectively. The TDF/FTC group had higher rates of adverse events than the placebo group, but the rates of serious adverse events were similar. The study concluded that daily TDF/FTC prophylaxis was not only safe but also prevented HIV infection in sexually active heterosexual adults (Thigpen et al., 2012). The partners PrEP study on the other hand enrolled 4,747 HIV discordant heterosexual couples in Kenya and Uganda and assigned the HIV-1-seronegative partner in each couple to daily TDF (1,584), TDF/FTC (1,579) or placebo (1,584) and followed up for 36 months. The study demonstrated a relative reduction of 67% in the incidence of HIV with TDF

and of 75% with TDF/FTC with 17 transmission events in the TDF group, 13 in the TDF/FTC group, and 52 in the placebo group (Baeten et al., 2012).

The successes of the test and treat as well as the PrEP studies have brought hope for the use of biomedical interventions in the prevention of HIV acquisition. These successes led to the WHO giving recommendations on the use of ART for prevention as well as PrEP (WHO, 2014, WHO, 2012). Even with these recommendations, different countries are on different pathways on their implementation. This will thus delay the expected effect of these two methodologies. Additionally male circumcision has been shown to work and the rollout is on-going. These interventions though effective, still do not provide us with the much needed magic 'bullet' to effectively stop the continuing incidence of HIV. As it is, they will have to be used in combinations with other behavioural interventions to achieve the much desired effect (UNAIDS, 2013b, WHO, 2013).

The other prevention trials have demonstrated on the urgent need to continue in the development and evaluation of new biomedical and behavioural interventions to reduce the rates of newly acquired HIV infection. This is majorly because of the varying efficacies shown by these studies. As these new interventions to prevent HIV emerge, they require evaluation throughout many regions (Padian et al., 2008, Richardson et al., 2001, McGowan, 2010). In addition, target populations for future HIV prevention trial participation should also be reflective of populations most affected by HIV and/or driving the HIV epidemic. Even though several studies worldwide have been conducted in high-risk populations such as MSMs, IDUs, pregnant women and SW, there is need for continued inclusion of these populations as current evidence are clearly pointing at them as being among the key driving forces of the HIV epidemic (Solomon et al., 2010, AVAC Report, 2009, Johnston and Fauci, 2008, Thomas et al., 2011, Kumta et al., 2010).

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2.3. HIV Risk, Knowledge and Attitudes

Reports have shown that HIV risk has generally been reducing over time with a comparable increase in HIV knowledge and improvement in attitudes in the general population (UNAIDS, 2013b). This is however not true for KPs who have demonstrated increases in prevalence and incidence despite having increase knowledge of HIV risks. For SW, as for MSM and other KPs, programmatic deficits are compounded by legal and social disadvantages that deter individuals from accessing the much needed services (Fay et al., 2011, Global Forum on HIV and MSM,

2012). Data from 4 countries in Eastern and Southern Africa identified insufficient access to condoms and lubricants among the unmet health needs of SW. In this study, trained SW conducted 55 in-depth interviews and 12 focus group discussions with 106 female, 26 male and 4 transgender SW across 6 urban sites in Kenya, Zimbabwe, Uganda and South Africa. Thematic analysis of the data elicited numerous unmet health needs, including diagnosis and treatment for STIs and insufficient access to condoms and lubricants. Denial of treatment for injuries following physical assault or rape and general hostility from public-sector providers was common. Even though many SW reported attending private services, citing higher quality and respect for dignity and confidentiality, this was mostly hampered by lack of adequate resources (Scorgie et al., 2013).

Another survey among MSMs in 165 countries also identified structural, community/ interpersonal and individual factors impacting access to HIV services for MSM. This was the second biennial Global Men's Health and Rights study conducted by the Global Forum on MSM & HIV. It was composed of a global online survey component and focus group discussion component, aimed to A) identify barriers and facilitators that affect access to HIV services for MSM, and B) place access to HIV services in the broader context of sexual health and lived experiences of MSM globally. The global online survey recruited 5,779 MSM from 165 countries. Homophobia, provider stigma, and negative consequences for being open as MSM were significantly associated with reduced access to services while community engagement and comfort with health service provider were each significantly associated with increased access to services.

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A total of 71 MSM PLWHA participated across 5 focus groups in Pretoria, Johannesburg, Nairobi, Lagos, and Abuja. Structural barriers included criminalization of homosexuality, high levels of stigma and discrimination, homophobia in health care systems, and poverty while facilitators included existence of safe spaces to meet other MSM, safe spaces to receive services, access to competent mental health care, and access to comprehensive health care. Interpersonal barriers were reduced trust, reduced communication, reduced learning opportunities, and reduced social support between men and their familial, social, and health networks leading to poor self-worth, depression, and anxiety, undermining health-seeking behaviours. Community engagement, family support, and stable relationships were recognized as facilitators of health and

well-being. At the individual level, limited access to education, work, and sustainable income, contributing to substance abuse and sex work among some participants we recognised as barriers while facilitators were described as stable financial resources, sustainable work, and education (Global Forum on HIV and MSM, 2012).

2.3.1. HIV Risk

HIV continues to profoundly affect female, male and transgender SW with female SW being 13.5 times more likely to be living with HIV than other women globally (Baral et al., 2012). About 10 – 32% of all incident infections in West Africa are attributed to sex work with countries like Swaziland and Zambia attributing approximately 7–11% of their incident infections to sex work too (Gouws and Cuchi, 2012). The prevalence of HIV among male SW on the other hand has been shown to be as high as 14% in 24 countries (UNAIDS, 2013b).

Similar to most of sub-Saharan Africa, HIV transmission in Kenya has been overwhelmingly associated with unprotected heterosexual sex, either casual, with SW, or within long-term relationships. Several factors have an impact on susceptibility to HIV infection, perceptions and knowledge about HIV transmission risk, higher risk behaviour, and therefore the risk of HIV transmission during heterosexual contact (Fraser-Hurt et al., 2011). With a demonstrated high level of HIV awareness through practically the whole country (Kenya National Bureau of Statistics [KNBS] and ICF Macro, 2010), Kenya is expected to understand its epidemic and be able to control it effectively with SW showing the highest level of knowledge. However KPs still face a high level of community stigma and discrimination in the country thus forcing them to continue hiding despite this level of knowledge (Sharma et al., 2008). There is a high prevalence of risky sex involving multiple sexual partners, with more MSM reporting multiple sexual partners and also selling sex (Geibel et al., 2007a). IDUs on the other hand are also accounting for up to 7% of the national HIV incidence with certain areas like Nairobi and Mombasa going as high as 16% and 18% (Ndetei, 2004a, Deveau et al., 2006, Deuchert and Brody, 2006).

The HIV risk in Kenya is still significant despite evidence of some behaviour change. This is majorly due to a number of factors, including high rates of casual sex with low rates of condom use, high rates of sexual and physical violence, and high rates of transactional sex, which can result in riskier sexual practices (Kenya National Bureau of Statistics [KNBS] and ICF Macro,

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2010).

There has been documented behaviour changes that would decrease transmission including increased awareness of modes of transmission, reduction of risky behaviour, increased condom use, delays in sexual debut, reductions in the number of sexual partners and reduction in the prevalence of other STIs not only in the general population but among KPs too. This was seen in the Kenya Analysis of HIV Prevention Responses and Modes of HIV Transmission study conducted from December 2007 to June 2008. The study analysed HIV epidemiological data and incidence modelling data, from the UNAIDS Modes of Transmission Model, together to obtain an epidemiological synthesis of 'know your epidemic' ('KYE synthesis'), while the HIV prevention review and resources data were analysed together to obtain an HIV response synthesis or "know your response" (KYR) synthesis (National AIDS Control Council, 2009a).

Even though SW and truck drivers were initially identified as the core groups and bridge for the infection to spread to the general population, currently there is evidence that MSM, are a most-at-risk population that needs to be recognised in Kenya (National AIDS Control Council, 2009a). The National Incidence Model indicated that MSM including those in prisons accounted for 15.2% of all new infections in 2008, while the model for Nairobi and Coast placed this group's contribution at 16.4% and greater than 20% of all new infections respectively, representing one-fifth of new infections (National AIDS Control Council, 2009a). The same data also indicate that a significant proportion of MSM in Kenya are not exclusively homosexual, and may even be married thus widening the risk of spread of HIV beyond the MSM community. The number of IDUs in the population is low, and they are mainly concentrated in certain areas, specifically Nairobi and coastal areas. However, this is a group with a high potential to transmit the disease, and this is reflected in the extremely high incidence rates in the model seen in table 2.3.1 below.

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Table 2.3.1: National Incidence of HIV and % Incidence by Mode of Exposure for Kenya

	Percent of New infections			
Groups	**National**	**Nyanza**	**Nairobi**	**Coast**
Heterosexual sex within union/ regular partnership	44.1%	38.5%	37.4%	37.9%
Casual heterosexual sex	20.3%	30.5%	23.0%	14.9%
Sex workers and Clients	14.1%	23.1%	14.7%	18.2%
MSM and Prison	15.2%	6.0%	16.4%	20.5%
Injecting Drug Use (IDU)	3.8%		5.8%	6.1%
Health Facility Related	2.5%	1.9%	2.7%	2.3%
Number of New Infections	**76,315**	**25,195**	**10,155**	**6,656**

Source: Kenya Modes of Transmission Study 2008

Even though most casual sex involves the use of condoms, with time this is discarded as the partners become 'regular'. This together with the low uptake of HIV counselling and resting still puts more people at risk (Kenya National AIDS Control Council, 2009, National AIDS and STD Control Programme, 2009, Kenya National Bureau of Statistics [KNBS] and ICF Macro, 2010, National AIDS and STD Control Programme, 2013).

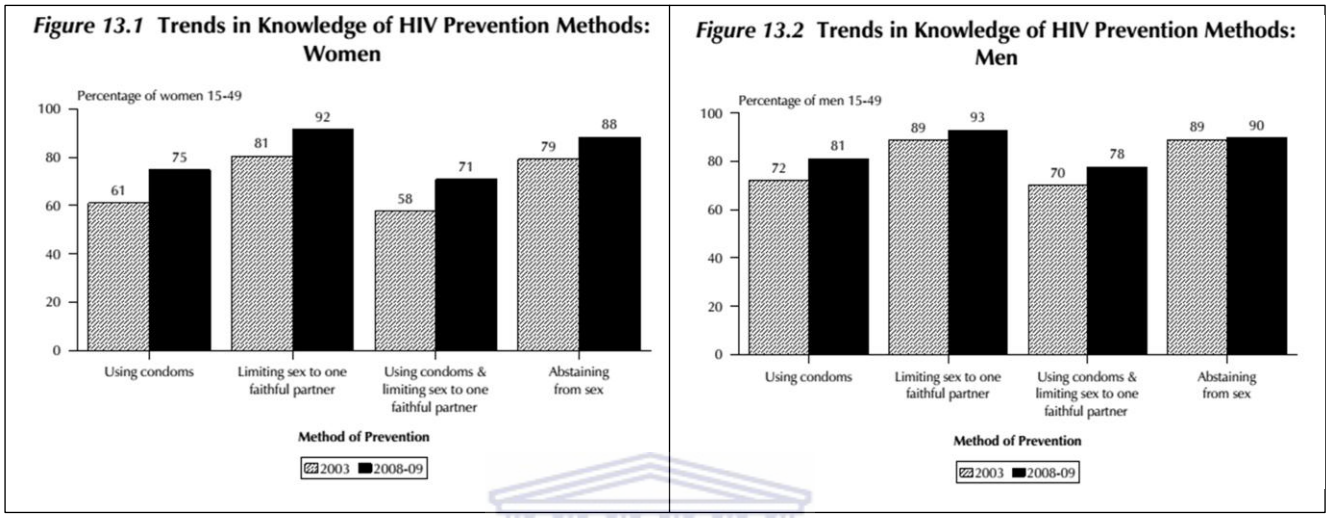
2.3.2. Knowledge and Attitudes of HIV Transmission

Correct knowledge of HIV and perceptions of personal risk for HIV infection are essential for reducing the risk of acquiring and transmitting HIV. Even though there have been spirited campaigns in HIV education in several areas about HIV, how it is acquired, and how to prevent new infections, these have still not resulted in the dissipation of new infections (UNAIDS, 2013b).

Kenya has demonstrated a high level of AIDS awareness as seen in the Behavioural Surveillance Surveys (BSS) of 2002, Kenya Demographic and Health Survey (KDHS) of 2003 and 2008/9 as well as the Kenya AIDS Indicator Surveys (KAIS) of 2007 and 2012. The levels of awareness ranged from an average of 26% in the BSS to a high of 98% in KAIS 2012 (National AIDS and STI Control Programme, 2005, Kenya National Bureau of Statistics [KNBS] and ICF Macro, 2010, National AIDS and STD Control Programme, 2009, National AIDS and STI Control Programme, 2014). In the KDHS 2008/9 while asking a direct question of how would people reduce their risk of transmission of HIV, most of the 8,444 women and 3,465 men aged 15-49 listed use of condoms, having one uninfected faithful sex partner and abstaining from sexual intercourse. The trend show that there have been marked improvements since 2003 (8,195

women and 3,363 men) in knowledge of HIV prevention methods among both women and men age 15-49 as seen in figure 2.3.1 below.

Figure 2.3.1: Trends in Knowledge of HIV Prevention Methods



Source: KDHS 2003 & KDHS 2008/9

Early sexual debut has been linked to an increase in the risk of HIV acquisition. Even though some studies have directly attributed early sexual debut to an increased risk of HIV acquisition (Onsomu et al., 2013, Pettifor et al., 2009), some other studies have demonstrated that the increase in women's HIV infection risk seems to result from women's later engagement in risky sexual behaviours, or other biological factors like genital trauma (Wand and Ramjee, 2012, Stockl et al., 2012). The age of sexual debut in Kenya generally occurs between ages 15 to 19 years, with low condom use experienced in the first sexual encounter. Data from 2007 to 2012 have been showing a reduction in the proportion of people starting sex before age 15 from 25.1% in 2007 to 12.8 in 2012 as shown in figure 2.3.2 below. When this is segregated by gender, males dropped from 33.7% (2007) to 15.4% (2012) and females from 16.4% (2007) to 10.1% (2012) (National AIDS Control Council, 2014a).

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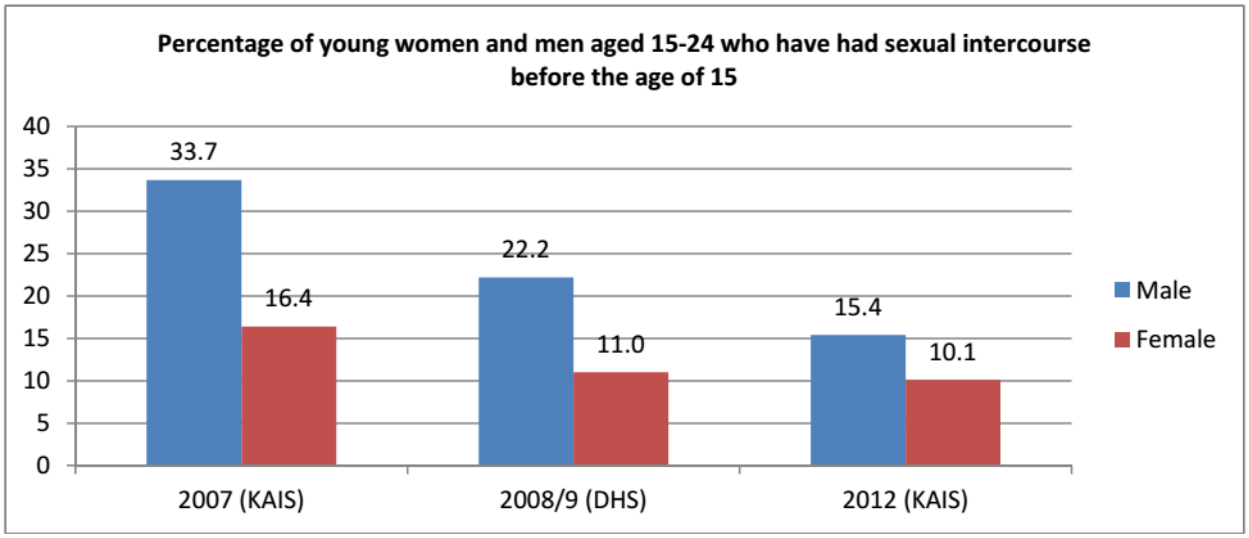
Figure 2.3.2: Percentage of Young Women and Men aged 15-24 who Have Had Sexual Intercourse before age 15



Source: KAIS 2007, KDHS 2008/9 & KAIS 2012

Female SW and their partners generally have an elevated risk of HIV acquisition as a result of frequent and frequently-unprotected sex with multiple casual and concurrent partners, other risky sexual practices, their illegal and stigmatised status, the young age at which they initiate sex work, their reluctance to attend clinics, and the lack of clinics catering to their special needs (National AIDS and STI Control Programme, 2014). Empowerment of SW has been shown to increase their knowledge and attitudes with a resultant protection being passed to their clients and community. In a review article, Bates and Berg describe the journey it has taken Australia to keep its HIV incidence and prevalence low. This was majorly as a result of educating SW with the support of the Australian government mainly through legislative reforms (Bates and Berg, 2014).

Concurrent partnerships have been listed as a key risk factor in the spread of HIV. Reductions of number of partners have also been demonstrated as a driving factor in the reduction of HIV prevalence. Having multiple partners is closely related to condom use as having multiple partners and not using condoms consistently puts someone at a much higher risk of HIV acquisition. (Adimora et al., 2007, Allais and Venter, 2012, Carnegie and Morris, 2012, Eaton et al., 2011, Epstein and Morris, 2011, Goodreau et al., 2012, Gourvenec et al., 2007, Kretzschmar and Carael, 2012, Mah and Shelton, 2011, Tanser et al., 2011, Yamanis et al., 2012) . Recent surveys in several countries in sub-Saharan Africa have detected decreases in condom use and/or an

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increase in the number of sexual partners (UNAIDS, 2013b). Kenya has seen a rise in men and women having concurrent partnerships over the last 10 years. Even though the increase has been highest in males with an increase from 11.6% in 2003 to 14.7% in 2012, women have also had an increase from 1.7% to 2.5% in 2003 to 2012 respectively. Uptake of condoms have also not increased significantly with an increase of 1% seen between 2008 and 2012 (National AIDS Control Council, 2014a).

Even though male circumcision has been shown to be protective against HIV acquisition (Auvert et al., 2005, Bailey et al., 2007, Gray et al., 2007), the uptake of this intervention has not been smooth. A study in Zambia evaluating the acceptability and uptake of neonatal male circumcision enrolled 1,000 mothers who despite having 97% of them saying they definitely or probably planned to have their new born son circumcised, only 11% brought their new born sons for circumcision (Waters et al., 2013). A study in Turkana in Northern Kenya conducted 20 focus group discussions and 69 in-depth interviews with circumcised and uncircumcised men and their partners to elicit their attitudes and perceptions toward male circumcision. The results show that barriers to circumcision include stigma associated with VMMC, the perception of low risk for HIV for older men and their "protection by marriage," cultural norms, and a lack of health infrastructure. Facilitators include stigma against not being circumcised, protection against disease including HIV, and cleanliness. It was also noted that older men should adopt the practice to serve as role models to younger men (Macintyre et al., 2014).

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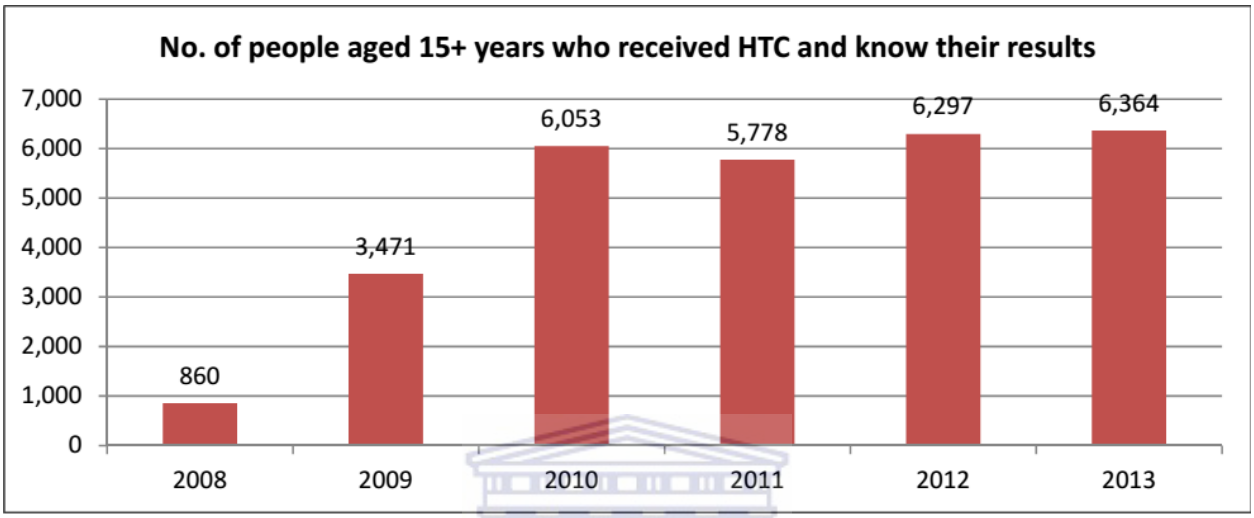
Another population based study in Zimbabwe with 2,350 respondents aged 15–49 using a mixed method study elicited 68% and 53% of female and male respondents, respectively, had heard about voluntary medical male circumcision for HIV prevention, mostly through the radio. Of the males, 11.3% reported being circumcised and 49% reported willingness to be circumcised. The study also reported that promoting male circumcision among women is crucial as they appear to have considerable influence over men's decision to get circumcised (Hatzold et al., 2014) .

The HIV treatment cascade emphasises on the importance of knowing one's status at the beginning of the HIV treatment cascade before anything else can happen in the cascade (WHO, 2013). Even though there has been significant scale up in HIV testing in sub-Saharan Africa, an estimated 36% of people in the region have never been tested for HIV (UNAIDS, 2013b). There

has been a significant increase in the number of people being tested in Kenya from 860,000 in 2008 to 6.4 million in 2012 as seen in figure 2.3.2 below (National AIDS Control Council, 2014a).

Figure 2.3.3: Number of People Tested for HIV in Thousands



Source: Kenya AIDS Response Progress Report 2014

2.4. Accessing KPs

Cost effective and targeted surveillance, prevention, intervention and treatment programs for KPs depend on their accessibility and collection of quality biological and behavioural data (Johnston et al., 2010, Magnani et al., 2005, Johnston and Sabin, 2010). There has been a global increase in monitoring KPs but with most focus being on IDUs, MSM and SW. The biggest challenge on this monitoring has been obtaining a representative sample of the KPs mostly since they do not have a ready sampling frame and because the behaviours they practice are either stigmatised and/or illegal (Mills et al., 1998, Schwartlander et al., 2001, Johnston and Sabin, 2010, Johnston et al., 2010, Heckathorn, 1997, Heckathorn, 2002).

Meaningful surveillance requires devising sampling strategies that are both feasible and capable of producing unbiased estimates for these populations not efficiently captured using conventional surveillance data collection strategies (Magnani et al., 2005). To be unbiased, these sampling strategies should be capable of reaching all members of the population. Use of probability sampling methodology is most preferred in these surveillance as sample elements are randomly chosen such that each element has a non-zero probability of selection that may be calculated

(WHO and UNAIDS, 2010).

2.4.1. Snowball Sampling

In the past 30 years there have been several methods for recruiting hidden populations with the most commonly used being snowball sampling (Heckathorn, 1997, Heckathorn, 2002, Heckathorn et al., 2002, Semaan et al., 2002, Thompson and Collins, 2002, Sharma et al., 2002). Snowball sampling is a non-probability sampling technique that is used to identify potential subjects in studies where subjects are hard to locate. This entails identifying an initial number of individuals from the interest group from whom the desired data are gathered and who then serves as 'seeds', to help identify other interest group members to be included in the sample. The 'seeds' provide information on other group members, and the process continues until either a target sample size is achieved or the sample becomes saturated (Biernacki and Waldorf, 1981, Goodman, 1961, Noy, 2008).

Although 'seeds' are theoretically randomly chosen, its practicality is difficult, with 'seeds' tending to be chosen via convenience sampling. This results in bias with subsequent choices either being influenced by the choice of initial seeds, or being the more cooperative of those approached. There are three types of snowball sampling namely 1) Linear snowball sampling where the first respondent recruits one more person for the survey, who in turn recruits one more person for the survey with the number increasing in a linear manner; 2) Exponential non-discriminative snowball sampling where the first chosen subject refers to multiple subjects, and all of these multiple subjects are chosen as the next subject and subsequently refer other subjects; Exponential discriminative snowball sampling where among the multiple referrals by the primary subjects at each level, only one is chosen as the subject of research.

Because snowball sampling is hardly representative of the larger study population, it is primarily used for exploratory purposes. Its other advantages are that it also allows the researcher to reach populations that are difficult to sample when using other sampling methods; the process is cheap, simple and cost-efficient; and it needs little planning and leaner workforce compared to other sampling techniques. The disadvantages include having little control over the sampling method; the subjects that the researcher can obtain rely mainly on the previous subjects that were observed; representativeness of the sample is not guaranteed and researcher having no idea of the

true distribution of the population and of the sample. Sampling bias is also a fear of researchers when using this sampling technique. Initial subjects tend to nominate people that they know well. Because of this, it is highly possible that the subjects share the same traits and characteristics, thus, it is possible that the sample that the researcher will obtain is only a small subgroup of the entire population (Heckathorn, 1997, Heckathorn, 2002, Heckathorn et al., 2002, Patton, 2002a, Thompson and Collins, 2002).

2.4.2. Targeted Sampling

Targeted sampling tried to overcome the limitations of snowball sampling by extending snowball to include an initial ethnographic assessment aimed at identifying various networks existing in a given setting for use with KPs. The networks serve as sampling strata with quota samples chosen within each stratum using systematic sampling when feasible. The methodology combines aspects of street ethnography, theoretical sampling, stratified survey sampling, quota sampling and snowball sampling. The magnitude of bias in this methodology depends on the thoroughness of the ethnographic assessment. Limitations include; 1)indicator data may not be useful in characterizing target population; 2) sampling may be biased and difficult to replicate; 3) geographic areas may not be sampled in proportion to the number of members in the population of interest; 4) population of interest may not be sampled in proportion to the intensity of risk behaviour and 5) the probability of selecting a member of the population of interest may not be known (Booth et al., 2004, Watters and Biernacki, 1989, Peltzer et al., 2004).

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2.4.3. Venue Based Sampling

Venue based sampling (VBS) is another method of recruiting 'floating populations' such as KPs from venues frequented by them including correctional facilities for IDUs and SW (Thiede et al., 2001, Kassira et al., 2001, Thaisri et al., 2003), drug treatment centres and needle exchange programmes for IDUs (Fauziah et al., 2003, Caiaffa et al., 2003, Bastos et al., 2005, Hacker et al., 2005) and sexually transmitted diseases (STD) clinics for MSM and SW (Ghys et al., 2002, Levine et al., 1998, Gray et al., 1997). It is also known as the Time Location Sampling (TLS) or Time Space Sampling (TSS) methodologies. It is a venue-based sampling that is based on the clusters, and can achieve a high degree of generalizability. The primary sampling unit is defined as the combination of the venue, day and the time (VDT), and the same site may be included in the sampling frame more than once, at different times of the day or a week. For example, a VDT

unit could be a defined period of four hours on a Monday in a specific venue. The fieldwork team identifies a range of time-location units to locate the members of the target population through interviews and key informants, service providers, and members of the target population. Then, the team visits the venues and prepares a list of VDT units which are considered potentially eligible on the basis of checking the number of people present. In addition, interviews are conducted with those in charge of the venue to ascertain affluence on certain days and at certain times. With this information, population size for each VDT unit and the number eligible for each sample are estimated.

The sample is selected in stages. In the first stage of the sampling strategy, a simple or stratified sample of all the time-location units which appear in the sampling frame list (preferably with probability proportional to the total number of members of the population eligible for each time-location unit) is selected. In the second stage, the participants are systematically selected for each time-location unit selected randomly. Using Time-Location Sampling allows the surveying of informal venues, such as private houses, into the sampling frame, to reach the least visible members of the target population, or those who do not typically frequent public places (Muhib et al., 2001, Semaan et al., 2002).

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The advantages of VBS include; all members of a population have a known, non-zero probability of selection in an unbiased selection; It provides a sampling framework that allows calculation of the probability selection of each individual in the sample; It significantly reduces arbitrary selection of venues and individuals and provides a replicable method of sample selection; and it is recommended when all population members can be reached at certain sites at different times and where no comprehensive list (census) of the target population exists. Each of these venues come with certain biases; correctional facilities rely on application of local laws that may or may not allow inclusion of inmates, none of the facilities provides a probability sample and dedicated clinics and centres e.g. needle exchanges, MSM or SW clinics are not present everywhere thus making them unrepresentative. The challenges include non-extrapolation of results to larger target population, non-response and accuracy of statistical assumptions and weights (Johnston et al., 2010, Kendall et al., 2008, MacKellar et al., 2007, Stueve et al., 2001, Magnani et al., 2005).

2.4.4. Conventional Cluster Sampling

In limited circumstances, conventional cluster sampling may be an adequate for KPs. It should be applicable where there is no sampling frame from which KPs would be selected, but instead there is available a good list of locations where KPs are found. This methodology assumes that the distribution of the variable of interest is similar between these clusters and is spread evenly across them. The clusters are randomly selected and data is gathered from the selected clusters. Its main advantage is that it is inexpensive and is not time intensive. It is prone to potentially large non-response bias, rendering it infeasible (Magnani et al., 2005, Shepherd et al., 2005).

2.4.5. Indigenous Field Worker Sampling

The Indigenous field worker sampling (IFS) recruitment method uses a standard chain referral approach. Indigenous field workers are selected from the target community and undergo training covering aims of the study, fieldwork protocols, ethics, informed consent, interview skills and safety procedures. Their selection is based on the fact that they have privileged access to the population being targeted, and would normally be accepted in that community without question. Field workers (FW) identify individuals known to them from the community, recruit; and then interview them in community settings, separate from the rest of the research team, that provides a feeling of safety and trust to the research participants. Eligible participants are given an incentive to take part and also asked to introduce their peers to the FW. The use of multiple site and network recruitment ensures a wide coverage of the population, providing as representative a sample as possible. The technique is believed to reduce masking, volunteer bias and under-reporting of socially undesirable behaviours (Griffiths et al., 1993, Power, 1994, Rhodes et al., 2006, Platt et al., 2006, Power and Harkinson, 1993). There have been questions asked about the extent in which unique ethical problems arise when indigenous FWs participate in field studies. Even though many of the data quality issues that arise with the use of indigenous FWs appear similar to those found in conventional studies, unique problems may arise in terms of risk and protection of confidentiality, especially when FWs occupy dual roles of both data collectors and service providers (Smith, 2008).

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2.4.6. Capture Re-captures Sampling

The capture re-captures sampling method allows the researcher to contact and later re-contact research participants. This method has widely been used in estimating numbers of wild animals

in parks but has also been found to be suitable to determine population size, coverage of census or sampling success rate in epidemiological studies (Chao et al., 2001, Geibel et al., 2007b). The methodology makes an assumption that the study population is stable during the observation period. Two interviewers are usually used to contact the study group and an estimate of the coverage is made. The most basic application of capture-recapture sampling consists of two stages. The first stage involves drawing (or picking) a random sample of participants from the population. The sampled participants are then identified and their information captured, and released back into the population. This can be through collecting biometrics like fingerprints, or dipping fingers in indelible ink. The second stage consists of drawing another random sample of participants from the same population. The second-stage sample must be obtained without dependence on the first-stage sample. Information from the two samples is used to estimate the overall population and thus get a representative sample from it. Since the number of marked participants within the second stage should be proportional to the number of marked participants in the whole population, an estimate of the total population size is obtained by dividing the number of marked participants by the proportion of marked participants in the second sample. The method is most useful when it is not practical to count all the individuals in the population. Some of the most common problems that lead to biased results in the estimation of the size of a population in Capture-Recapture Sampling result from what is known as trap-shy or trap-happy behaviour with some participants avoiding re-contact (trap-shy) while others frequenting places they know they will be re-contacted (trap-happy) (Hook and Regal, 1992, Hook and Regal, 1995, Neugebauer and Wittes, 1994, Sakshaug, 2008).

2.4.7. Respondent Driven Sampling

Respondent driven sampling (RDS) is similar to snowball sampling since it involves chain referral sampling. However, the recruitment process is implemented in a manner that allows for the calculation of selection probabilities, thus allowing it to qualify as a probability sampling method (Heckathorn et al., 2002, Salganik and Heckathorn, 2004, Abramovitz et al., 2009). In addition it has greater external validity since it is not limited to subgroup members accessible at sites, but rather extends the sample to all potential members by accessing them through their social networks. 'Seeds' are enlisted as temporary recruiters who receive an explanation of the study and a limited number of coupons for them to use in recruiting peers who are eligible for the study. The recruits redeem the coupon to enrol in the study and receive their own recruitment

coupons and this continues in from wave to wave to form a recruitment chain. Recruitment ends when the calculated sample size is reached. In addition to the social incentive of peer pressure, RDS often relies on monetary or 'gift' incentives for participating in the survey and for peer recruitment (Heckathorn, 1997).

Limiting the number of respondents recruited by the 'seeds' minimises the influence of initial seeds on the final sample composition. It also encourages long recruitment chains, thus expanding the sample into more hidden pockets of the population. In RDS, the relationship between recruiters and recruits is documented with an avenue of assessing and adjusting recruitment biases in the analysis. Information on the personal network size of each respondent is collected to allow weighted analysis to compensate for the oversampling of respondents with larger social networks. RDS provides more externally valid probability samples compared to other non probability sampling methodologies which limit themselves to sub groups. It also does not require an exhaustive mapping process to construct sampling frames and the dual incentive system of financial reward in combination with peer pressure reduces non-response bias because those who would not participate for financial reasons alone may do so for peer reasons (Heckathorn, 1997, Heckathorn, 2002, Salganik and Heckathorn, 2004, Johnston et al., 2008).

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This chapter has presented a review of the available literature from investigating the HIV prevention trials landscape to accessing KPs. The HIV prevention trial landscape has presented a review of on-going HIV prevention trials and what is needed to make those trials successful. This was followed by a review of HIV risk, knowledge and attitudes seen among the KPs and finally a review of different methodologies that may be used to sample KPs for HIV prevention research participation.

3. CHAPTER 3: PHASE I

3.1. Introduction

Chapter three describes aim and objectives of phase I of the research; followed by a description of the research methodology and finally results of the same phase. Phase I identifies and determines categories of KPs and techniques of locating and motivating them to participate in HIV prevention trials. The research methodology explores the study design, the study population, the sample size, the sampling procedure and data collection procedures followed. Finally there is a description and presentation of results for the phase.

3.2. Study Methods

3.2.1. Study Aims

Phase I of the research study aimed at identifying and determining categories of KPs and techniques of locating and motivating them to participate in HIV prevention trials in Kisumu, western Kenya.

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3.2.2. Study Objectives

To achieve this aim, the study phase had the following specific and distinct objectives:

1. To identify different categories of persons considered to be KPs within Kisumu.
2. To identify different techniques of locating KPs with a view to including them in HIV prevention studies in Kisumu.
3. To determine what would motivate and what would inhibit KPs from participating in HIV prevention studies in Kisumu.

3.2.3. Study Setting

The study was carried out at the KEMRI/CDC Research and Public Health Collaboration Programme's clinical research centre (CRC) in Kisumu.

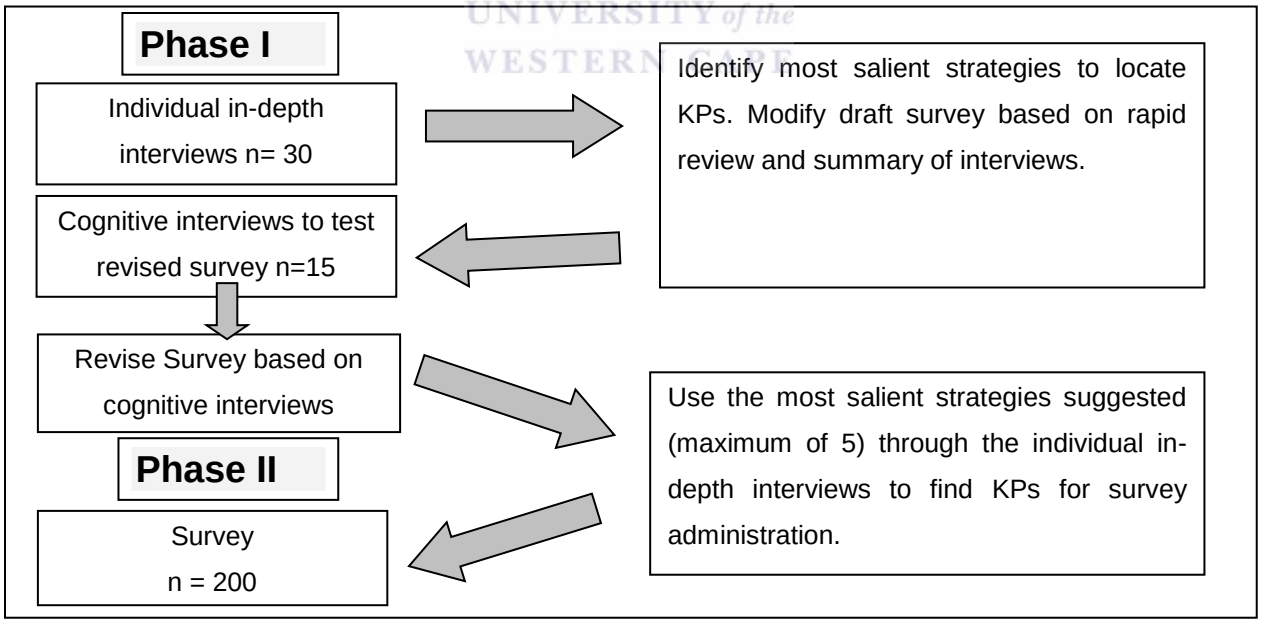
3.3. Study Design

This study provided the framework for engaging and mobilizing KPs "communities" and providing an insight into subcultural dynamics and characteristics that could influence how, where, and when people interact with KPs. There was no collection of biological specimen or testing for HIV or sexually transmitted diseases in this phase of the study. This phase of the

study involved the identification and determination of categories of persons considered to be KPs and techniques of locating and motivating them to participate in HIV prevention trials.

The study employed a mixed methods design. This design combined elements of qualitative and quantitative approaches by using qualitative and quantitative viewpoints, data collection, analysis and inference techniques for the purpose of breadth and depth of understanding and corroboration (Johnson and Onwuegbuzie, 2004, Lopez-Fernandez and Molina-Azorin, 2011). The study used a dominant/less-dominant approach (Tashakkori and Teddlie, 2003, Creswell and Clark, 2011), whereby inclusion of a survey was made consistent with a qualitative evaluation design as opposed to a quantitative one. The methodology was mixed by ordering them sequentially and combining the data within the context of this study. Strategies to recruit KPs were identified through individual In-Depth Interviews (IDIs) followed by think aloud cognitive interviews (CIs) that were used to refine a draft survey that will be used later in phase II. CIs are pre-test methods to explore the conceptual equivalence of survey items (Nápoles-Springer et al., 2006, Collins, 2003). Figure 3.5.1 below provides an overview of the study procedures.

Figure 3.3.1: Overview of Study Procedures



3.3.1. Inclusion and Exclusion Criteria

Individuals included in phase I of this study were:

- 18 to 64 year old male and female residents of the Kisumu catchment area.

- From potential KPs groups (e.g. SW, truck drivers, fishermen, female fishmongers and HIV negative persons in serodiscordant relationships, and others) suggested by study staff in conjunction with others who may be knowledgeable sources of this information.
- Able and willing to provide informed consent and detailed locator information.

Individuals excluded in phases I of this study were:

- Aged less than 18 years or more than 64 years at the time of interview.
- Not belonging to any of the potential KPs groups.
- Not willing or able to provide informed consent.
- Individuals who participated in the IDIs were not eligible to participate in the CIs.

3.3.2. Study Population

The target population included potentially high risk individuals (e.g. SW, truck drivers, fishermen, female fishmongers and HIV negative persons in serodiscordant relationships, and others) living within the Kisumu District (918.5 km^2) suggested by the KEMRI/CDC staff in conjunction with others who may be knowledgeable sources of this information. The study intended to recruit 45 individuals from this population for whom 30 IDIs with 15 CIs were conducted.

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3.3.3. Sampling Procedure

To identify participants for this phase of the study, a snowball sampling methodology was used. Study staff purposively approached individuals that they knew (from personal contact or referral by other stakeholders) belonged to the potential KPs groups and asked them if they wanted to participate in the study. Those who accepted were recruited into the study and these initial recruits were known as the 'seeds'. These individuals, after being recruited into the study, were further asked to refer other individuals sharing the same characteristics as them for recruitment into the study. The subsequent recruits were known as the 'offspring'. This process was continued until the required sample size was achieved.

The study kept track of and matched the seeds to their offspring and each seed was only allowed to recruit a total of three offspring. A rapid analysis of the interview recordings and notes was performed to generate a summary of the strategies to recruit KPs. This analysis was done at the end of each interview and later on collated for all the interviews. This process allowed the

inclusion of additional strategies that might have not been originally identified by study staff for recruitment.

3.4. Data Collection

Data collection occurred between 10th and 21st March 2013. All interviews were conducted in English or the local languages (Dholuo or Swahili). Consent forms, recruitment guides, interview guides and the draft survey were translated into Dholuo and Swahili from English, and back-translations verified. All interviews were done using personal digital assistants (PDA). IDIs were used because of the sensitive nature of the topic and to gain an in-depth understanding of each person's experience. All study activities took place at a private location that was considered safe, appropriate, secluded and agreeable to the participants. Participants were reimbursed for transport expenses (KES 300, equivalent to approximately $4).

Study staff underwent specific training for recruitment of participants into this study and also conducting these specific interviews. In addition, they also conducted mock interviews prior to the actual interviews. In addition they had the following characteristics:

1. Fluency in Swahili, Dholuo, and English;
2. Familiarity and comfort with discussing health topics;
3. Ability to respect dignity and confidentiality of participants;
4. Good listening skills, non-judgmental and non-biased approach;
5. Previous experience with interviews or other qualitative data collection methods.

3.4.1. Individual In-depth Interviews

Interview recruitment was initiated by contacting one person falling into each of the following categories: SW, long distance drivers, fishermen, salon workers, fishmongers, HIV negative persons in serodiscordant relationships and MSM. The individuals were first asked if they were willing to answer two screening questions about their age and residence to see if they are eligible to participate. Following eligibility screening the informed consent form (ICF) (Appendix 1.1) was administered to them. Following the provision of informed consent, an individual demographic questionnaire (Appendix 4.1) was administered. Questions in the individual questionnaire included gender, age, level of education, income in past one month, current marital status, ethnic group, religion and duration of residence in Kisumu county.

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Following the demographic questionnaire, an in-depth interview guide was used to collect further in-depth information from the participant. The in-depth information included, context of work, defining how the participant understood being at high risk of HIV acquisition to be, determining if the respondent is at high risk of HIV infection, how to find people who are at high risk of HIV infection, how to attract people at high risk of HIV infection to HIV research studies and practical issues regarding study participation and retention. The individuals were further asked to identify others with similar characteristics until the target of participants to be recruited was reached.

Interviews were conducted in the vicinity of the workplace or at a venue (e.g. nearby lodging facility) that was agreeable to the participant provided that it was judged to be a safe and conducive environment for conducting the interview (minimal distractions and secure). However in instances where there were difficulties in finding nearby appropriate venues, participants were asked to come to the CRC for the interviews. In this way, study staff ensured that all interviews were conducted in appropriate locations that were safe, secluded and provided sufficient privacy for the interview. Each interview was conducted by an individual staff who not only audio recorded the interview, but also took field notes. The field notes included, mentioned strategies as well as the environment of the interview not limited to the demeanour, body language, time and venue.

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Daily interviewer debriefings were conducted to determine saturation (the point at which no new information or themes are observed in the data). Similarities and differences in question responses were discussed and debriefing notes were taken during these sessions. Information from these debriefing sessions was used to tailor the draft survey which was used in phase II (Appendix 4.2). IDI recordings were transcribed and stored on a personal computer following the interviews. Transcriptions of interviews conducted in Swahili and Dholuo were translated into English. These translations were back translated and verified by a different person to ensure accuracy. Participants were not identified by name in the interview transcripts, rather by participant IDs. The investigator performed a rapid analysis of the interviews to generate a summary of the strategies to recruit KPs. This rapid analysis was further discussed with the staff conducting the interviews during the daily debriefing. The most salient strategies were identified and later used in Phase II. The criteria for identifying a salient strategy was that 1) it was

mentioned by 3 or more individuals; 2) it was feasible in terms of cost and practicality (in the expert opinion of the reviewer); and 3) it was likely to reach KPs (in the expert opinion of the reviewer).

3.4.2. Piloting the Survey Interview Questionnaire (Cognitive Interview)

Purposive sampling was used to recruit 15 individuals meeting the basic demographic characteristics of the IDI population. Participants who had earlier participated in the IDIs were excluded from this part of the study. Following modification of the survey, cognitive think-aloud interviews were conducted with these individuals, 5 in each of the languages of the study (English, Dholuo and Kiswahili). The study interviewer reviewed the revised survey questions by reasoning through with the participants to gauge perceptions and understanding of the questions. Study interviewers administered individual surveys and after each question, they asked the person specific questions, for instance, how difficult it was to answer the question. There was no script for this portion of the study. However, the study employed a set of pre-determined prompts that were used for the questions (Appendix 3.2). These prompts were used together with spontaneous probes to best assess the interpretation of the question so that emerging issues could be probed as the interview proceeded (Willis, 1999). Persons were also asked to provide suggestions for improved clarity for survey modification.

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3.5. Data Management and Analysis

3.5.1. Data Management

The IDI data collection tools were designed electronically using Visual CE, Microsoft Visual Basic and TELEforms. Field data was transported in secure boxes with locks to CRC. Records containing names or other personal identifiers (consent forms) were locked and stored separately from other study records. Records with participant names were de-linked from the main database and stored in separate secure database. Local databases were secured with password-protected limited access systems.

Audio recordings were saved on the PDAs in password protected format. The survey questionnaire was also pre-programmed with the final questions and data saved on the PDAs (password protected). Interview data was transcribed within 24 hours of interview. Data was downloaded to a secure server and all PDA data erased. A back-up copy of the data was made on

DVD-RWs on a daily basis. Digital recordings and any backup copies were deleted from the computers within 6 months of the last interview and all other paper-based data were destroyed after a year.

3.5.2. Data and Statistical Analysis

For the qualitative data, a rapid review process was initiated with 3 to 4 reviewers. The reviewers were experienced study staff in addition to the investigator. Each independently listened to the relevant sections (regarding questions about strategies) of the interviews as well as read through the interview notes and debriefing notes and completed an abstraction form for each interview to facilitate identification of the most salient recruitment strategies. The reviewers independently rated all strategies mentioned by 3 or more interviewees on a 1 (poor) to 4 (very good) scale in terms of its feasibility (including cost and practicality) and its likelihood to reach KPs (based on background knowledge and opinion of reviewer). The reviewers then met to compare and discuss their abstraction form results and provided common identified strategies which were rank ordered and strategies with the highest scores chosen and implemented in Phase II. Full interview transcripts were analysed with in depth analysis to examine what participants said about various topics. As new themes and issues emerge, all of the relevant information was retrieved and examined for further coding designations using Nvivo, a QSR qualitative analysis software.

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3.5.3. Validity/Reliability

All the study staff were trained on good clinical practice and all the study procedures to ensure accuracy and completeness of the data collected. The study standard operating procedures (SOP) brought consistency in carrying out study activities and minimised errors. To ensure data quality, internal checks for consistency and validity were programmed and embedded in the design of questionnaires. Study forms were linked through unique participant study numbers. For the qualitative phase of this study, translations were performed by local persons who have extensive experience in translating local languages to English. To assure correct translation of the interviews, someone other than the translator who is literate in the local languages and English verified the transcript against the digital recording. A total of three people were engaged for this. Quality assurance (QA) of 10% of the interview transcriptions were done by an independent contractor.

3.6. Ethical Considerations

Ethical approval for the study was sought from the ethics committee of the Kenya Medical Research Institute, the US CDC and the University of the Western Cape. This protocol, informed consent forms, questionnaires, participant education and recruitment materials, and other study forms, and any subsequent modifications, was reviewed by the regulatory authorities with respect to ethical and scientific compliance with applicable research and human subjects regulations. Individual informed consent was obtained from each study participant before participation. Participants were informed of the purpose of the study, how confidentiality will be maintained, rights not to participate if they want to. Progress reports were made to the regulatory authorities as required.

3.7. Response Rates

A total of 57 individuals were approached to participate in this phase. Of the 57 individuals, there were 42 (73.7%) males and 15 (26.3%) females. Four (7.0%) individuals did not participate in the study (1 Male and 3 females) with the reasons for non participation being; not resident of Kisumu district (3/4) and aged below 18 years (1/4). This translated to a response rate of 93.0% (53/57).

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3.8. Results

3.8.1. Socio-Demographics

Table 3.8.1: Socio-Demographic Characteristics of Phase I Participants

Characteristic	Males N (%)	Females N (%)	Total N (%)
TOTAL	41 (77.4)	12 (22.6)	53 (100)
Age group (years)			
18-25	24 (58.5)	2 (16.7)	26 (49.1)
26-35	9 (22.0)	6 (50.0)	15 (28.3)
36-45	5 (12.2)	2 (16.7)	7 (13.2)
46-55	1 (2.4)	1 (8.3)	2 (3.8)
56-65	2 (4.9)	1 (8.3)	3 (5.7)

Characteristic	Males N (%)	Females N (%)	Total N (%)
Marital status			
Single/Never married	23 (56.1)	6 (50.0)	39 (73.6)
Married/Living as married	15 (36.6)	5 (41.7)	20 (37.7)
Separated/Divorced/Widowed	3 (7.3)	1 (8.3)	4 (7.5)
Duration of Residence in Kisumu			
Less than 3 Years	8 (19.5)	2 (16.7)	10 (18.9)
3-5 Years	2 (4.9)	0 (0)	2 (3.8)
6-10 Years	10 (24.4)	0 (0)	10 (18.9)
Over 10 Years	21 (51.2)	10 (83.3)	31 (58.5)
Ethnic group or tribe			
Luo	37 (90.3)	10 (83.3)	47 (88.7)
Luhya	2 (4.9)	2 (16.7)	4 (7.5)
Arab	1 (2.4)	0 (0)	1 (1.9)
Kikuyu	1 (2.4)	0 (0)	1 (1.9)
Religion			
Roman Catholic	10 (24.4)	1 (8.3)	11 (20.8)
Protestant or other Christian	27 (65.9)	9 (75.0)	36 (67.9)
Muslim	2 (4.9)	2 (16.7)	4 (7.5)
Nomiya	2 (4.9)	0 (0)	2 (3.8)
Highest education level			
Primary School/Vocational	16 (39.0)	6 (50.0)	22 (41.5)
Secondary School	13 (31.7)	5 (41.7)	18 (34.0)
College	12 (29.3)	1 (8.3)	13 (24.5)
Income			
Below KES 1,000 (USD 11.00)	4 (9.8)	2 (16.7)	6 (11.3)
KES 1,001 - 2,000 (USD 11.00 – 22.00)	3 (7.3)	2 (16.7)	5 (9.4)
KES 2,001 - 5,000 (USD 22.00 – 55.00)	9 (22.0)	3 (25.0)	12 (22.6)
KES 5,001 - 10,000 (USD 55.00 – 110.00)	16 (39.0)	5 (41.7)	21 (39.6)
Above KES 10,000 (USD >110.00)	9 (22.0)	0 (0)	9 (17.0)

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Characteristic	Males N (%)	Females N (%)	Total N (%)
Risk category			
Sex worker	0 (0)	5 (41.7)	5 (9.8)
Men who have sex with men	20 (48.8)	0 (0)	20 (39.2)
Fishermen/Fishmongers	5 (12.2)	0 (0)	5 (9.8)
Transport (drivers)	8 (19.5)	0 (0)	8 (15.7)
HIV neg. member of discordant couple (self-report)	2 (4.9)	3 (25.0)	5 (9.8)
Boda Boda Rider	1 (2.4)	0 (0)	1 (1.9)
Water Vendor	5 (12.2)	0 (0)	5 (9.8)
Hair Salon Worker	0 (0)	4 (33.3)	4 (7.5)

Majority (77.4%) of the respondents were males compared to 22.6% females with most of the respondents being in the age groups of 18-25 (49.1%) and 26-35 (28.3%) years. Respondents in the age categories of 36-45 years were 13.2%, 46-55 years were 3.8% and those in the categories of 56-65 years were 5.7%. More than half (58.5%) of the males were those in the 18-25 years age group. Being single and never married was the most common (73.6%) marital status of the respondents. This was followed by being married or living as married (37.7%) and lastly being separated, divorced or widowed (7.5%). This distribution was also seen in the gender separation with majority of males (50.0%) and females (56.1%) being single and never married.

Of all the respondents, 58.5% had been resident of Kisumu and its environs for over 10 years. This was followed by 18.9% who had been resident for between 6 to 10 years and a similar proportion that had been resident for less than 3 years. The remaining 3.8% had been resident for between 3 to 5 years. More females (83.3%) had been resident of Kisumu and its environs for over 10 years compared to their male (51.2%) counterparts for the same duration. Luos were the predominant ethnic group with 88.7% of all respondents being from that ethnic group. Of all the respondents, 83.3% of all females and 90.3% of all males were Luos. Of all the respondents 67.9% were Protestant or other Christian with 75.0% of all females and 65.9% of all males being in this religious grouping. Roman Catholics were the next common religion with 20.8% (24.4% males and 8.3% females) of all respondents professing that religion.

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Primary school or vocational training colleges were the highest attended institutions with 41.5% of all respondents reporting to have them as their highest level of education. Gender distribution of respondents showed 50.0% of all females and 39.0% of all males to have reported primary or vocational education. The second highest level of education was secondary education with 34.0% of the respondents (41.7% females and 31.7% males) reporting to have reached this level. Those with college education were 24.5% with 8.3% being females and 29.3% being males. About one-third (39.6%) of the respondents earned between KES 5,001 - 10,000 (USD 55.00 – 110.00), with 39.0% and 41.7% of all males and females respectively being in this income category. This was followed by the KES 2,001 - 5,000 (USD 11.00 – 22.00) category that had 22.6% of all respondents and 22.0% of all male and 25.0% of all female respondents.

When asked which risk categories they belonged to, respondents reported to come from 8 self identified risk groups which included some not previously identified during the planning of the study. SW and MSM were the most common risk groups with 41.7% of females and 48.8% of males belonging to the SW and MSM risk groups respectively. Of all the females, 33.3% belonged to the hair salon workers group, while 19.5% of all males belonged to the transport risk group. The hair salon workers group consisted of respondents who reported that they work in hair salons either as stylists, masseuses or manicurists. Those in the transport group were night time taxi drivers. Of the 9.8% of respondents who reported to be in the HIV discordant couples group, majority (25%) were females. Females in this category accounted for 25.0% of all females while males accounted for 4.9% of all male respondents. People in this category were those who self reported being HIV negative while their sexual partner was HIV positive.

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3.8.2. Categories of Persons Considered to be KPs within Kisumu

On being asked if they considered themselves to be at risk of HIV infections, most respondents reported that the groups they belonged to were at risk of HIV infection in addition to other groups of people they also mentioned. The responses ranged from very general groups (e.g. youth, married people, adults, teenagers, rich people, poor people) to more specific groups such as people who frequent bars (e.g. bar workers, drunkards, SW, businessmen), people who work in transportation (e.g. truck drivers, matatu drivers, motorcycle drivers, taxi drivers, bicycle taxi drivers), fishermen/fishmongers, MSM and hair salon workers. Below are a few excerpts from the transcripts:

"Those who are at high risk of getting HIV are, one of them being Female SWs… They are at high risk because they are on job; somebody may force you if, if for him to play you, you will just have to do it without a "CD" and now that probably you are in, you are in need of money, could be, you'll be for the same, at long last you contract a, HIV… Also polygamy can make you get HIV… Some specific behaviours like those built on peer pressure… like alcohol… Yeah, if you take alcohol you may end up, you, you go to bed with somebody probably you are so drunk and you didn't know and now you haven't used "CDs." Drugs also… Yeah, like "Njagaa *[marijuana]*." Some people think if they take njagaa *[marijuana]* they are so high that even just a small kid of two years wants to engage in sex, and if they are infected and the young girl is not infected, "si" he will transmit the same to her and it's one of the behaviours that lead to the high risk of HIV."

26 year old sex worker, college education

"Poverty will make someone be at high risk of HIV because the person is vulnerable, needs money… also if someone is having a carefree attitude and is not taking good care of himself, then he would be at high risk of HIV… Only those two, but also peer influence… Yes; for example, let's say for ladies maybe those parking after their work; maybe they show others how they are rich. They turn others down that they are wasting their time sleeping while these people are making money outside. So with that motivation, they say that "let me go and try for me just to get that money" and for such people in the first day the others will help you searching for a client… Repugnant traditional belief! That is one; modern culture or western culture… You know nowadays the Western culture has movies, pornographic what not; you find a child at [an] early stage, a youth at [an] early stage has watched these movies and has known that there is something like….. playing sex and so on….. you find that in the past there were no such movies at all. You get that the youth were not being exposed like this at early stage. You get that a teenager is already exposed at puberty stage… Another behaviour, but this one more so deals with trade personnel where you have middlemen; like when you go to the beaches you find that women have middlemen who can connect them with where they can get fish very easily… Most of these middlemen there could be a relationship [with the woman]. It's not just a matter of money and mostly it is love affair; not that just a relationship that this one is my customer. That's why you cannot get a middle man

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between a man and a man; it just a woman and a man. ***24 year old man who has sex with men, secondary education***

"Fishermen and 'jaboya' are at risk… 'jaboya' means you are taken when you come here at the lake with basin to get fish… We must build a relationship between us for intimacy for you to have your fish." ***32 year old fisherman, primary education***

"… fellow truck drivers who go the long distance when they stop at Salga, they stop at Nyamasaria, they stop at Luanda or at Salga or at Gilgil or Otonglo. What they have is the possibility that [they will get] girlfriends there or they get women there... and this makes them get HIV. ***24 year old truck driver, secondary education***

"You here we have two groups who are at high risk of getting HIV, there are the rich and the poor. The rich will get it since they have all the money to spend i.e. immorality. They always buy sex when they want it. And the poor will get in that they really want to have the money but they have it the wrong way, they sell their body in exchange for money… Married couple is at risk, because currently there have been cases of divorce… it [is] alarming, yah. What causes divorce to my knowledge is mistrust, yah, when the trust is not there somebody who is well will not stay in [an] unhealthy marriage. Yah." ***27 year old hair stylist, secondary education***

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"The group, I know a bar like ring road, those devours are common, they can place someone at risk of getting HIV virus… I may say groups like people working in trailers, some water venders few of them like sex, others are just there… They could be at high risk because previously they were not good people, they [are] people who become sick and now they are at home. Even my brother, who brought me here, has gone home and he is sickling. Though I do not know what he is suffering from, I suggested to him to be tested for HIV but he refused. It seems as if he had known his status and resort[ed] to drinking alcohol too much. He thinks all his stress should be directed to alcohol… in addition I may add Ngware *[Bicycle]* riders… Apart from the two, drivers like those who drive trailers… They have women in stopping areas like Kisumu, Nairobi, and you may find that these women were got from the bar… Also I may say groups like girls… Girls like prostitutes that go to [a] bar, you may find ladies who stays with their mother and

they do not go to school… Low income, some could not get what to eat in their house so she decides to go to some body and get something. There is a parent we took her child to school for the same issue" ***22 year old water vendor, primary education***

"Those who like leisure, most likely the drunkards because they lose their power to identify what is right or wrong… they like having sex with every one ***47 year old female negative partner in a discordant relationship, secondary education***

"… mmm I think the prostitutes are at high risk. Simply because most of them are not informed about the risk and how to carry their trade… mmm it's because they also just want to earn a living from it, so they would not put much care into the future because what they earn is for today and they don't really budget or plan for what really come in 10 years from now… There is the bicycle group (ngware), like ours for taxi drivers, others where women meet and do things, men can also have a similar one. So I do not know what groups you are asking… What I know about a group that can be at high risk is like these clubs, clubs. That's where people don't protect themselves because once somebody is drunk they don't choose. I always see when we are working. Somebody comes that they are going to look for a lady to go with, and then he picks and goes. So you will not bother how he is going to take it, whether he is going to use a condom or whether he is going take it like that, you don't know. I am saying that these clubs, clubs, these bars, bars, are the ones that are making HIV …they are the ones making AIDS groups to be many." ***27 year old male taxi driver, college education***

3.8.3. Strategies to Find Persons at Risk of HIV Infection

When asked as to which strategies would be best to locate persons at high risk for HIV infection, we asked the following questions to the in-depth study participants: What would be the best way to approach someone at high risk for HIV infection to ask them to be in an HIV research study?; What would make it convenient for someone at high risk for HIV infection to be part of an HIV research study?. In response, we identified four main recruitment strategies from the interviews as listed below with the number of respondents and percentages in brackets:

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1. Use of a person with specific knowledge of a target population, i.e. persons with a history of affiliating with high-risk persons such as those affiliated with HIV advocacy groups or non-governmental organizations (link person mobilization) (40/53 [75.5%]);
2. Use of co-workers or contemporaries (peer mobilization) (27/53 [50.9%]);
3. Use of group or association leaders (leader mobilization) (21/53 [39.6]); and
4. Study staff outreach (staff contact mobilization) (21/53 [39.6]).

There were other strategies reported that were not among the top four and they included campaigns, seminars, working through churches and provincial administration, counselling, displaying posters to announce meetings on a specific day, handing out flyers at pubs and restaurants, door-to-door contact and radio and TV announcements. Below are excerpts from some of the in-depth interviews:

> "I can say seminar maybe if they can come and to receive explanation from the study and teachings… These things are many, we can sit down in a meeting like the way we are 12 girls and discuss them… They can be found every day, because they are always looking for money and money can never be enough. So, everyday, they can be found. They can be found in the pub they are many, they can be found at obambla, fanana, and many other pubs. You know, someone can stay at fanana until midday, then they leave if they don't find a client, then they go to another pub… Even making announcements is ok… What can be of use is seminar, because once one girl learns that there is a seminar where certain girls are wanted, they will inform each other and they will meet there… They will hear the announcement, but they will not come because what time will they go to look for money and at the same time listen to announcements? Seminars are better." ***22 year old female sex worker, primary education***

> "The best way first of all you have to identify that so and so is participating in MSM activity. Then secondly, you have to know the reason he is participating is when you can tell him to participate in the activity. But without knowing the reason, identifying or knowing the reason why he is participating, it's very difficult… Identifying, doing a sort of research; by visiting the place to identify that so and so is participating. It is very easy to know when you visit the place and see the kind of dress… Approaching them it depends,

but the easier way is to use the person who is involved; because you if you go direct maybe you are not a member, they will feel somehow guilty and may not give you the answers you want. Or you can use a worker at the hotel… That one, you know it must take time; it's not just a matter of one day that you can convince them to take part in the study and you must know why they are doing that. So you find groups, some are doing it because of peer (influence), some poverty, and some are doing it for leisure… You must have friendship with them first and to some extent you can even pretend to be one of them, a member for them to trust you. If you just come from nowhere and say 'I'm so and so working with so and so and I am doing research; they say that, more so even in my times I used to say that we've seen many people like that but at the end they are the people who are at high risk. Then you conclude like that as a group and you forgo the message. So you can convince them that you offer the services in some other town and even tell them that in that town, the things were like this and that for you just to create that conducive atmosphere for you." ***31 year old man who has sex with men, college education***

" How they can be found, I saw when KEMRI staff came, they turn up in large numbers, even though mobilizing them is hard, they will ask for something small, they don't care what you teach them, they only ask that since you've called them, will they get something, that is what they ask… Even if you are coming to teach them, they don't care, with them they want what they eat like money... So when you come, you leave the word with the Chairman who will announce before you come." ***40 year old fisherman, primary education***

"These… eeh, now you go to where they park vehicles, you reach the time you reach there you know they normally come late eeh… around seven, eight… and that time probably you are going to ask such a question they may shy away, they'll shy away from you. The best time to find those people you can go to any bar eeh… Management of the bar, eeh then you ask the manager there… if you can have some two, three ladies to ask some questions, but on the streets no… Posters would work for someone who would be, probably it'll work for someone who knows to how to read, but we have many, probably some who doesn't know to read or write. Best way probably if you have some films eeh… like cinemas sometimes you go to such a place in the evening. It shows much

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better than these posters... You put somewhere so many people will come and watch at night around between eight and ten around that time." ***32 year old truck driver, primary education***

"There work places, in colleges, in schools... In bars and restaurants… You can find them where they park their bicycles." ***29 year old salonist, college education***

"How to get them, you know most of them like money so even if you said you want three boda [boda] men who can surrender their time then you pay them something then they will come very fast… as for the ladies working in the bars, you just go to them there at the bar… so if you go around 2:00 pm you will find them making themselves [pretty]… this is making themselves look clean… Water vendors you go to their base, like magadi." ***34 year old male water vendor, primary education***

"As discordant couples, the best time to find them is during their meeting days… The others I don't know how you can find them." ***37 year old female negative partner in a discordant relationship, college education***

3.8.4. Motivators and Inhibitors of Participating in HIV Prevention Trials

We then asked the in-depth participants what would motivate or inhibit persons at high risk for HIV infection from participating in HIV research studies by asking them; For instance, what are reasons a person at risk of HIV might be interested in taking part in a research study?; What would motivate them to participate?; What would inhibit them from participating?; What would make it difficult for them to participate**?**; What are the potential threats if they decided to take part in an HIV research study?. Below are tables showing the reported motivators and inhibitors.

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Table 3.8.2: Motivators for Participating in HIV Prevention Trials

Motivators (N=53)	**N (%)**
Getting HIV education	53 (100.0)
Getting free HIV treatment and care	50 (94.0)
Getting other types of free medical care	46 (86.0)
Helping find a cure for HIV	45 (84.0)
Getting incentives for taking part in the research study	40 (75.0)
Getting free HIV testing and counselling	27 (50.0)
Getting information on how to take care of yourself if you become HIV infected	25 (47.2)
Being part of a social group that gets together to talk periodically	21 (39.0)

Table 3.8.3: Inhibitors for Participating in HIV Prevention Trials

Inhibitors (N=53)	**N (%)**
Fear of testing positive for HIV	49 (92.0)
Sexual partner/spouse refusal	27 (50.0)
Having your personal information made available to others in the community	27 (50.0)
Others in the community thinking you have HIV	27 (50.0)
Having to deal with new medical costs that are not covered by the study	20 (37.0)
Losing your job	17 (32.0)
Taking too much time away from your job	14 (26.0)
Having children at home who need you	12 (22.0)
Moving out of the area	9 (16.0)

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Below are a few excerpts from the in-depth interviews:

1) Motivators

> "Everybody is for his or her own health, even if you hear this is touching you, you may go in and please…probably lend an ear that let me also hear about this even if not for me it may even help my children's health." ***22 year old male water vendor, primary education***

"…information and teachings that they will receive." ***26 year old female negative partner in a discordant relationship, secondary education***

"Once you hear of the benefits and risks [*you will decide to participate*]." ***31 year old hair salon worker, college education***

"…ok I just want to talk on my behalf , somebody like me, we have talked and you have told me disadvantages and advantages of doing this, so if I can get somewhere , may be income generating activity it can keep me buy , seriously I want to leave this kind of work… Yea is what I am telling you I want to leave this kind of work to participate in research, in luring some other girls outside not to get into such activity." ***28 year old female sex worker, secondary education***

"You offer training for learning… Those who don't know their HIV status will come to know as well as knowing how bad the disease is if you offer training." ***34 year old male truck driver, secondary education***

"Like me, someone who is an MSM would want to participate in this study because he wants to know the thing of the HIV and AIDS. Sometimes, he can ask you that I want to participate there because I don't have information about HIV and AIDS, and I'm doing it, but I don't know anything. 'Sa kama unaenda kusikia hiyo mambo' (so *if you are going to listen to that information*) about HIV/AIDS, 'Atakimbia kwa haraka sababu anataka kusikia tu hiyo mafundisho. Kama ameshasikia atajua' (*he will come running because he wants to get the information. After listening he'll be aware*), he will know that when I get a client I can be at risk." ***21 year old man who has sex with men, secondary education***

2) Inhibitors

"Probably, like now that I'm here, I get my name out that *(name withheld)* participated on this and this now she's stopped working, when she hears them and she is a sex worker automatically she will not come." ***28 year old female sex worker, secondary education***

"Lack of confidentiality…" ***22 year old male water vendor, primary education***

"Lack of time, being busy, being at work." ***31 year old hair salon worker, college***

education

"I think they may see it as wasting their time. Also like they are all married, some of them may think that their wives will know their secrets behind their backs…" ***34 year old male truck driver, secondary education***

"How will people take me when they know I am in this research of yours…? I don't think I can be in it." ***26 year old female negative partner in a discordant relationship, secondary education***

"Like me, when you came to me, I can think that, when you came to me I know that 'hiyo kitu haitanifaidi chochote. Nitakuangalia' (*that thing wouldn't help me with anything. I will just look at you*) kwanza vile' you are talking to me, I will look at you. When you are talking, it's like I will assume that you are not talking but like I'm not listening but I'm listening to you what you are saying; But I will tell you that, Yes, yes, so there is no any problem. 'Lakini ka ushaongea na mimi vizuri tuseme *tume' (but, after you've talked to me nicely, lets say we've)* meet Sports ground, I will talk to you everything [pause] everything 'na mimi nimeshakuambia Yes! Yes! nimesikia enda tu, na kesho hautaniona. Umejua kuna wengine watakuambia, (*and I will tell you Yes! Yes! I've heard just go, but tomorrow you wouldn't see me. You know some people will tell you*) Eeeh! that somebody 'ni mbaya anafanya' (*is bad he's carrying out some*) investigations, 'na' (*and*) some, 'kuna wengine watakuambia, "umekuja kuniiba", sa umejua anajilenga na hiyo kuiiba, "umekuja kuniiba?" sitaki hizo mambo yako (*others will exclaim! "You've come to steal from me?" You know they are evading you through that, "You've come to steal?" I don't want to hear anything from you*). Na unajua kama umeenda kwa mtu' (*And do you know that if you go to someone*) in a cool place 'ama anaburudika anaweza kukusikia' (*or when enjoying, he can listen to you).*" ***21 year old man who has sex with men, secondary education***

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4. CHAPTER 4: PHASE II

4.1. Introduction

Chapter four describes aim and objectives of phase II of the research; followed by a description of the research methodology and finally results of the same phase. Phase II design and implements a mRDS methodology in recruiting KPs into HIV prevention trials. The research methodology explores the study design, the study population, the sample size, the sampling procedure and data collection procedures followed. Finally there is a description and presentation of results for the phase.

4.2. Study Methods

4.2.1. Study Aims

Phase II of the research study aimed at designing and implementing a mRDS methodology in recruiting KPs into an HIV prevention trial in Kisumu, western Kenya.

4.2.2. Study Objectives

To achieve this aim, the study had the following specific objectives:

1. To design a mRDS methodology that enhances recruitment of KPs into HIV prevention studies within Kisumu.
2. To implement a mRDS for recruitment of KPs into HIV prevention studies in Kisumu.

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4.2.3. Study Setting

The study was carried out at the KEMRI/CDC Research and Public Health Collaboration Programme's CRC in Kisumu.

4.3. Study Design

The study employed a quantitative survey to be able to develop and validate a mRDS methodology. This phase of the study also did not have collection of biological specimen or testing for HIV or sexually transmitted diseases. Following the refining of the draft survey through think aloud CIs in Phase I (chapter 3), the identified four strategies; 1) Use of personal contact; 2) Use of link persons; 3) Use of peer mobilisation and; 4) use of leaders were used to identify individuals to whom a brief survey was administered. The survey: 1) obtained the information on how to recruit KPs from this larger group of potential KPs and 2) assessed the

usefulness and practicality of the strategies used in identifying KPs.

4.3.1. Inclusion and Exclusion Criteria

Individuals included in phases II of this study were:

- 18 to 64 year old male and female residents of the Kisumu catchment area.
- From potential KPs groups including Female SW, MSM, fishermen, fishmongers, truck drivers, HIV negative persons in serodiscordant relationships, boda boda riders, water vendors and hair salon workers suggested in Phase I of the study.
- Able and willing to provide informed consent and detailed locator information.

Individuals excluded in phases I and II of this study were:

- Aged less than 18 years or more than 64 years at the time of interview.
- Not belonging to any of the potential KPs groups identified in phase I.
- Not willing or able to provide informed consent
- Individuals who participated in Phase I of the study.

4.3.2. Study Population

The study population included individuals from groups identified to be at most risk of HIV acquisition from Phase I of the study. These groups included SW, MSM, fishermen and fishmongers, truck drivers, boda boda riders, water vendors, hair salon workers and HIV negative persons in serodiscordant relationships living within the Kisumu District (918.5 km^2). The study intended to recruit 200 individuals from this population for whom the survey will be administered.

4.3.3. Sampling Procedure

The most salient strategies for recruiting KPs identified from Phase I were used in recruiting KPs for this phase of the study. Salience refers to information that is both mentioned by respondents more frequently and the information they relay first (order of mention) (Borgatti, 1996). To recruit participants for the phase II survey, a purposive quota sampling approach (Patton, 2002b) was used. This approach ensured that the study was able to include a sufficient number of persons for each strategy that was identified in Phase I and was being evaluated in this phase. This is because purposive sampling allows for the predetermination of persons to be included in the research based on their appropriateness for the study. To implement this, individuals were

approached using the salient strategies as they were rank ordered. The first 81 individuals were approached using the most salient strategy that scored 5. This was followed by 72 individuals using the second most salient strategy (scored 4) and the final 61 individuals using the third most salient strategy (scored 3).

Table 4.3.1: Sampling for Phase II

Key Qualitative Findings	# of survey participants per strategy (n=214)
5 strategies salient	81
4 strategies salient	72
3 strategies salient	61

4.4. Data Collection

Data collection occurred between 31st March and 18th April 2013. All interviews were conducted in English or the local languages (Dholuo or Swahili). Consent forms, recruitment guides, interview guides and the draft survey were translated into Dholuo and Swahili from English, and back-translations verified. All interviews were done using personal digital assistants (PDA). All study activities took place at a private location that was considered safe, appropriate, secluded and agreeable to the participants. Participants were reimbursed for transport expenses (KES 300, equivalent to approximately $4.00 USD).

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Study staff underwent specific training for recruitment of participants into this study and also conducting these specific interviews. In addition, they also conducted mock interviews prior to the actual interviews. In addition they had the following characteristics:

1. Fluency in Swahili, Dholuo, and English;
2. Familiarity and comfort with discussing health topics;
3. Ability to respect dignity and confidentiality of participants;
4. Good listening skills, non-judgmental and non-biased approach;
5. Previous experience with interviews or other qualitative data collection methods.

4.4.1. Developing the mRDS Algorithm

The most salient strategies identified from Phase I together with the categories of individuals considered to be most at risk of HIV acquisition and the identified motivators and inhibitors to HIV prevention research participation were used to modify the RDS methodology. The RDS by

itself already laid the framework of using chain referral to identify respondents for this survey. Results from Phase I allowed us to modify the RDS by limiting the referral mechanisms to the top four strategies identified in Phase I. these strategies included; 1) Use of personal contact; 2) Use of link persons; 3) Use of peer mobilisation and; 4) use of leaders. In addition to the strategies, phase I also identified categories of individuals considered to be most at risk for HIV acquisition. These individual groups included people who frequent bars (e.g. bar workers, drunkards, SW, businessmen), people who work in transportation (e.g. truck drivers, matatu drivers, motorcycle drivers, taxi drivers, bicycle taxi drivers), fisherman/fishmonger, MSM and hair salon workers.

The mRDS algorithm included the following procedure:

1. Identifying the categories of people to be recruited
2. Assigning the most salient strategy for each of the identified categories
3. Pre assigning referral coupons for each of the categories and strategies used to recruit respondents in those categories.
4. Linking the 'seed' and 'offspring' coupons via a computer algorithm
5. Identifying the first seeds through the salient strategies from the pre-identified categories.
6. Issuing each seed with five coupons for which they are to give to their peers who are considered to be the offspring of the seed who referred them.
7. Each of the offspring also after recruitment is issued with her/his coupons thus making her/him into a seed in addition to being an offspring.
8. There was no incentive other than transport reimbursement for study participation

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4.4.2. Survey

The purpose of the survey was to help assess which strategies were most appropriate for locating KPs as well as provide additional insights on what motivates them to take part in HIV prevention research. By including a survey, the study was able to evaluate recruitment strategies before formally implementing recruitment of KPs into an HIV prevention trial. Moreover, the survey provided the opportunity to look at whether applying perception-based recruitment strategies were sufficient in reaching target populations. Purposive quota sampling was used to recruit 200 individual meeting eligibility criteria and the survey administered to them in a language of their choice (English, Dholuo or Kiswahili). The draft survey questionnaire was tailored according to

the information collected through the IDIs. The survey questionnaire included questions on socio-demographics, definition and perception of high risk status, how to find people at risk for HIV infection and attracting them to HIV research studies and sexual perception and practices (Appendix 4.2)

Recruitment consisted of face-to face invitations to participate in the survey using the most salient strategies suggested from the IDIs during phase I of the study. The questionnaire was administered by a study staff on a PDA which allowed data to be directly downloaded onto a computer without requiring data entry. The individuals were first asked if they were willing to answer two screening questions about their age and residence to see if they are eligible to participate. Following eligibility screening the informed consent form (ICF) (Appendix 1.1) was administered to them. Following the provision of informed consent, the survey was administered to individuals the vicinity of the workplace or at a venue (e.g. nearby lodging facility) that was agreeable to the participant provided that it is judged to be a safe and conducive environment for conducting the survey interview (minimal distractions and secure). In certain instances where it was difficult to find an appropriate venue, participants were asked to come to CRC for the interview.

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4.5. Data Management and Analysis

4.5.1. Data Management

Data collection tools were designed electronically using various tools like, Visual CE, Microsoft Visual Basic, structured query language (SQL) and TELEforms. Field data was transported in secure boxes with locks to CRC. Records containing names or other personal identifiers were locked and stored separately from other study records. Records with participant names were de-linked from the main database and stored in separate secure database. Local databases were secured with password-protected limited access systems. The survey questionnaire was pre-programmed with the final questions and data saved on the PDAs (password protected). Data was downloaded to a secure server and all PDA data erased. A back-up copy of the data was made on DVD-RWs on a daily basis. Digital recordings and any backup copies were deleted from the computers within 6 months of the last interview and all other paper-based data were destroyed after a year.

4.5.2. Data and Statistical Analysis

For the quantitative data the dependent variables were 1) inconsistent condom use (yes/no)- using condoms during sexual intercourse either never or sometimes during the last 3 months and 2) multiple partners (yes/no)- being involved with more than one sexual partner at the same time during the last three months. For condom use, the variables were 1) Did not have vaginal intercourse; 2) Most of the time used condoms; 3) Never used condoms; 4) Used condoms all the time; and 5) Sometimes used condoms. To come up with the regression analysis presented here we collapsed the variables into 1) Never or sometimes used condoms and 2) always or most of the times used condoms. For concurrent sex partners the variables were 1) yes to having concurrent sex partners; and 2) no to having concurrent sex partners.

To determine which of the 3 to 5 strategies for locating KPs was the most successful; we developed two logistic regression models using each of the dependent variables noted above. The independent variables included the strategy used to locate the individual who responded to the survey as well as covariates that may be associated with the strategy and/or the dependent variable (such as age, ethnic group, marital status). We also evaluated the association between the four strategies used to locate participants and their self perception of risk for acquisition of HIV. In addition we also evaluated the association between these strategies and the motivators and inhibitors of their participation in HIV prevention research.

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4.5.3. Validity/Reliability

All the study staff were trained on good clinical practice and all the study procedures to ensure accuracy and completeness of the data collected. The study standard operating procedures (SOP) brought consistency in carrying out study activities and minimised errors. To ensure data quality, internal checks for consistency and validity were programmed and embedded in the design of survey. All survey data was checked and reviewed for completeness and accuracy. Study forms were linked through unique participant study numbers.

4.6. Ethical Considerations

Ethical approval for the study was sought from the ethics committee of the Kenya Medical Research Institute, the US CDC and the University of the Western Cape. This protocol, informed consent forms, questionnaires, participant education and recruitment materials, and other study

forms, and any subsequent modifications, was reviewed by the regulatory authorities with respect to ethical and scientific compliance with applicable research and human subjects regulations. Individual informed consent was obtained from each study participant before participation. Participants were informed of the purpose of the study, how confidentiality will be maintained, rights not to participate if they want to. Progress reports were made to the regulatory authorities as required.

4.7. Response Rates

Even though the study had intended to recruit a total of 200 respondents, 214 individuals were approached to participate in this phase. Of these individuals, there were 127 (59.3%) males and 87 (40.7%) females. Of the 11 (5.1%) individuals who did not participate in the study (6 Male and 5 females), the reasons for non participation included; not eligible to participate (2/11), eligible but not willing to participate (1/11) given interview date and did not show up (8/11). This translated to a response rate of 94.9% (203/214).

4.8. Results

4.8.1. Socio-Demographics

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Study participants were predominantly male (59.6%) with most of the respondents being in the age groups of 26-35 (47.3%) and 18-25 (40.9%) years. While females were the majority (69.8%) of those in the 36-45 years age group and 86.0% of those in the 46-55 years age group, males were the majority in all the other age groups with 54.5% in the 18-25 year age group, 52.0% in the 26-35 year age group, and 100% in the 56-65 year age groups. Being married or living as married was the most common (75.9%) marital status of the respondents. This was followed by being separated, divorced or widowed (20.2%) and lastly being single or never married (3.9%). This distribution was also seen in the gender separation with majority of males (92.5%) and females (52.4%) being married or living as married.

Almost all the respondents were Luo with 92.1% of all respondents reporting to be from that ethnic group representing 94.2% of all males and 89.0% of all females. Catholicism was the most predominant religious grouping with 68.5% of all respondents and 80.5% of all females and 60.3% of all males being in this religious grouping. Those in other religions including Protestants

and other Christians were the next common religion with 28.6% (38.0% males and 14.6% females) of all respondents professing that religion. Those professing the Muslim faith were 3.0% (1.7% males and 4.9% females).

Secondary schools were the highest attended institutions with 46.3% of all respondents reporting to have them as their highest level of education. Majority of the males had secondary education (54.6%) while majority of the females had primary school or vocational training education (56.1%). Participants having university education were the least with 2.5% of all respondents and 1.7% males and 3.7% females having this level of education. On average, majority of the respondents earned over KES 4,000 (USD 44.00) with about one-third (37.4%) of the respondents earning between KES 4,001 - 6,000 (USD 44.00 – 66.00) (males 31.4% and females 46.3%), one-quarter (26.1%) earning between KES 6,001 – 8,000 (USD 66.00 – 88.00) (males 38.0% and females 15.9%) and one-tenth (10.8%) earning between KES 8,001 – 10,000 (USD 88.00 – 110.00) (males 13.2% and females 7.3%). Even though half (51.2%) of the males reported earning more than KES 6,000 (USD 66.00), only about one-quarter (23.2%) of all females were earning the same amount.

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The study staff encountered the respondents in varied areas. These encounter sites were the venues in which the interviews were carried out. About one-quarter (25.3%) of all the respondents were encountered at a beach with 26.7% and 23.2% of males and females being in this encounter category. The next category was for respondents who even though they came from varied areas, had their interviews conducted at the KEMRI/CDC CRC with 21.3% of all respondents and 22.5% of all males and 19.5% of all females falling in this category. About one-third (33.6%) of all the clients were encountered in a hotel (all 19.3%; males 21.7% and females 19.5%), bar/night club (all 7.9%; males 3.3% and females 14.6%) or lodge (all 6.4%; males 6.7% and females 6.1%). Those encountered in residential areas and bus stops were 7.5% each with residential areas having 2.5% males and 14.6% females while bus stops had 12.5 all males. Of the 2% who were encountered in salons, all were females accounting for 4.9% of the female participants and those found in markets, water points and through other CBOs contributing 1% of the encounters each with CBOs and water points having all males each contributing to 1.7% of the male encounters and markets having 0.8% males and 1.2% females.

Eighty one percent of all responds reported to have ever been tested for HIV with 75.2% and 90.2% of all males and females respectively reporting to have ever been tested for HIV. About two-thirds (67.5%) of all participants reported that they had not participated in any research study prior to this study. Of these, 61.3% were males and 38.7% were females. Of the 32.5% who reported to have participated in a research study prior to this study, 56.1% were males while 43.9% were females. Almost one-quarter of the participants were contacted through each of the strategies that were mentioned with link persons and peer mobilisation yielding 26.6% of the participants while leaders yielded 24.6% of the participants and personal contact yielded 22.2% of the participants.

The respondents came from 4 major occupation groups. Fisher folk (fishermen and fishmongers) were the most common occupation at 25.1% followed by taxi operators (night time taxi drivers, matatu drivers, motorcycle riders as well as bicycle riders) at 24.1%. SW and bar maids were next at 18.2% followed by truck drivers at 1.0%. By gender, being a taxi operator (40.5%) was the most common male occupation followed by being a fisherman (27.3%), while being a SW or barmaid (35.4%) was the most common female occupation followed by being a fishmonger (22.0%). Those in the 'Others' category included salon workers, water vendors.

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Table 4.8.1: Socio-Demographic Characteristics of Phase II Participants

Characteristic	Males N (%)	Females N (%)	Total N (%)
TOTAL	121 (59.6)	82 (40.4)	203 (100)
Age group (years)			
18-25	53 (43.8)	30 (36.6)	83 (40.9)
26-35	59 (48.8)	37 (45.1)	96 (47.3)
36-45	7 (5.8)	11 (13.4)	18 (8.9)
46-55	1 (0.8)	4 (4.9)	5 (2.5)
56-65	1 (0.8)	0 (0.0)	1 (0.5)
Marital status			
Single/Never married	7 (5.8)	1 (1.2)	8 (3.9)
Married/Living as married	111 (92.5)	43 (52.4)	154 (75.9)
Separated/Divorced/Widowed	3 (2.5)	38 (46.3)	41 (20.2)

Characteristic	Males N (%)	Females N (%)	Total N (%)
Ethnic group or tribe			
Luo	114 (94.2)	73 (89.0)	187 (92.1)
Luhya	5 (4.1)	6 (7.3)	11 (5.4)
Kisii	1 (0.8)	2 (2.4)	3 (1.5)
Other	1 (0.8)	1 (1.2)	2 (1.0)
Religion			
Roman Catholic	73 (60.3)	66 (80.5)	139 (68.5)
Muslim	2 (1.7)	4 (4.9)	6 (3.0)
Other	46 (38.0)	12 (14.6)	58 (28.6)
Highest education level			
Primary School/Vocational	46 (38.0)	46 (56.1)	92 (42.9)
Secondary School	66 (54.6)	28 (34.2)	94 (46.3)
College	7 (5.8)	5 (6.1)	12 (5.9)
University	2 (1.7)	3 (3.7)	5 (2.5)
Income			
Below KES 2,000 (USD 22.00)	8 (6.6)	12 (14.6)	20 (9.9)
KES 2,001 - 4,000 (USD 22.00 – 44.00)	13 (10.7)	13 (15.9)	26 (12.8)
KES 4,001 - 6,000 (USD 44.00 – 66.00)	38 (31.4)	34 (46.3)	76 (37.4)
KES 6,001 - 8,000 (USD (66.00 – 88.00)	46 (38.0)	13 (15.9)	59 (26.1)
KES 8,001 - 10,000 (USD 88.00 – 110.00)	16 (13.2)	6 (7.3)	22 (10.8)
Risk category			
Fishermen/Fishmongers	33 (27.3)	18 (22.0)	51 (25.1)
Sex Worker/ Bar Maid	8 (6.6)	29 (35.4)	37 (18.2)
Truck Driver	2 (1.7)	0 (0.0)	2 (1.0)
Taxi Operator (Taxi, Matatu, Bicycle, Motorcycle)	49 (40.5)	0 (0.0)	49 (24.1)
Others	29 (24.0)	35 (42.7)	64 (31.5)
Encounter site			
Beach	32 (26.7)	19 (23.2)	51 (25.3)
CRC	27 (22.5)	16 (19.5)	43 (21.3)

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Characteristic	Males N (%)	Females N (%)	Total N (%)
Lodge	8 (6.7)	5 (6.1)	13 (6.4)
Bar/Night Club	4 (3.3)	12 (14.6)	16 (7.9)
Hotel	26 (21.7)	13 (15.9)	39 (19.3)
Bus Stop	15 (12.5)	0 (0.0)	15 (7.5)
Residential Area	3 (2.5)	12 (14.6)	15 (7.5)
Other CBO	2 (1.7)	0 (0.0)	2 (1.0)
Market	1 (0.8)	1 (1.2)	2 (1.0)
Water Point	2 (1.7)	0 (0.0)	2 (1.0)
Salon	0 (0.0)	4 (4.9)	4 (2.0)
Ever tested for HIV			
Yes	91 (75.2)	74 (90.2)	165 (81.3)
No	30 (24.8)	8 (9.8)	38 (18.7)
Ever participated in research study			
Yes	37 (30.6)	29 (35.4)	66 (32.5)
No	84 (69.4)	53 (64.6)	137 (67.5)
Contact strategy			
Personal Contact	25 (20.7)	20 (24.4)	45 (22.2)
Link Person	36 (29.8)	18 (22.0)	54 (26.6)
Peer Mobilisation	30 (24.8)	24 (29.3)	54 (26.6)
Leaders	30 (24.8)	20 (24.4)	50 (24.6)

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4.8.2. Risk Profiles: Correlates of Inconsistent Condom Use

Since 9 of the participants reported never having sex, only 194 participants are included in this analysis. The overall prevalence of inconsistent condom use defined as using condoms sometime or never using condoms was 67.5% (131 /194) with majority of those inconsistent being males (56.4%). Most inconsistency was seen among the younger age groups 26 -35 years (45.0%) and 18 – 25 years (43.5%), those working (80.2%) and those having other occupation (35.1%). Other

occupation included salon workers, water vendors. Inconsistent condom use was spread evenly among the contact strategies used to recruit respondents, and was more predominant among those with an income of between KES 4,000 to 6,000 (38.2%), those having secondary education (46.2%), those belonging to the Luo ethnic group (62.4%), those professing the Roman Catholic faith (64.1%), those married or living as married (76.3%), those tested for HIV previously (84.0%), those who had not participated in HIV research previously (64.9%) and those who considered themselves at risk of HIV infection (56.5%).

In the bivariate analysis, females had twice the odds of having inconsistent condom use (OR 2.08; 95% CI 1.08 - 4.01; p value 0.025) compared to males. Sex worker/barmaid (OR 5.23; 95% CI 1.82 - 14.99) had three times the odds of inconsistent condom use while those having 'other' occupation (OR 3.01; 95% CI; 1.32 - 6.79) had three times the odds of inconsistent condom compared to fishermen/fishmonger respectively. The other variables had no impact on inconsistent condom use as per table 4.8.2 above.

Multivariate analysis was performed on all the variables that had p values of <0.25 from the bivariate analysis. These variables included; gender, occupation, contact strategy, income, level of education, tested for HIV and at risk of HIV Infection. The variable that had significant odds included occupation and income. Taxi drivers (AOR 2.75; 95% CI 1.04 - 7.23) and those having other occupation (AOR; 2.87 95% CI 1.12 - 7.39) had three times the odds of having inconsistent condom use compared to those having a fishermen/fishmonger occupation. The odds of inconsistently using condoms were lower among those with an income of between KES 6,000 to 8,000 (AOR 0.16; 95% CI 0.03 - 0.78) compared to those with an income of less than KES 2,000.

Table 4.8.2: Multiple Regression Analysis: Correlates of Inconsistent Condom Use

	Condom Use (N=194)		Bivariate		Multivariate	
	Never/sometimes use condom (N=131)	Always/most of the time use condom (N=63)	OR		AOR	
	N (%)	N (%)	(95% CI)	p-value	(95% CI)	p-value
Gender				**0.024**		
Male	74 (56.4)	46 (73.0)	ref		ref	
Female	57 (43.5)	17 (27.0)	2.08 (1.08 - 4.01)		1.41 (0.56 - 3.55)	**0.466**
Age Groups				**0.865**		
18 - 25	57 (43.5)	24 (38.1)	ref			
26 - 35	59 (45.0)	32 (50.8)	0.78 (0.41 - 1.48)			
36 - 45	11 (8.4)	5 (7.9)	0.93 (0.29 - 2.95)			
46 - 55	3 (2.3)	2 (3.2)	0.63 (0.10 - 4.02)			
Working				**0.338**		
No	26 (19.9)	9 (85.7)	ref			
Yes	105 (80.2)	54 (85.7)	0.67 (0.29 - 1.54)			
Occupation				**0.005**		
Fishermen/Fishmonger	22 (16.8)	23 (36.5)	ref		ref	
Sex worker/Bar maid	30 (22.9)	6 (9.5)	5.23 (1.82 - 14.99)		3.39 (0.94 - 12.19)	**0.061**
Taxi drivers	31 (23.7)	18 (28.6)	1.80 (0.79 - 4.10)		2.75 (1.04 - 7.23)	**0.041**
Other	46 (35.1)	16 (25.4)	3.01 (1.32 - 6.79)		2.87 (1.12 - 7.39)	**0.028**
Contact Strategy				**0.165**		
Personal contact	29 (22.1)	12 (19.1)	ref		ref	
Link Persons	35 (26.7)	16 (25.4)	0.91 (0.37 - 2.22)		1.04 (0.39 - 2.80)	**0.933**
Peer mobilization	40 (30.5)	13 (20.6)	1.27 (0.51 - 3.19)		1.20 (0.44 - 3.31)	**0.711**
Use of leaders	27 (20.6)	22 (34.9)	0.51 (0.21 - 1.22)		0.47 (0.18 - 1.23)	**0.124**

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	Condom Use (N=194)		Bivariate		Multivariate	
	Never/sometimes use condom (N=131)	Always/most of the time use condom (N=63)	OR		AOR	
	N (%)	N (%)	(95% CI)	p-value	(95% CI)	p-value
Income				**0.22**		
Less than KES 2000 (USD 22)	15 (11.5)	4 (6.4)	ref		ref	
Btw 2000 – 4000 (USD 22 – 44)	17 (13.0)	8 (12.7)	0.57 (0.14 - 2.27)		0.31 (0.57 - 1.64)	**0.167**
Btw 4000 – 6000 (USD 44 – 66)	50 (38.2)	21 (33.3)	0.63 (0.19 - 2.14)		0.28 (0.06 - 1.25)	**0.097**
Btw 6000 – 8000 (USD 66 – 88)	32 (24.4)	25 (39.7)	0.34 (0.10 - 1.15)		0.16 (0.03 - 0.78)	**0.024**
Btw 8000 – 10000 (USD 88 – 110)	17 (13.0)	5 (7.9)	0.90 (0.20 - 4.01)		0.25 (0.04 - 1.57)	**0.138**
Level of education				**0.056**		
Primary/Post Primary/Vocational	57 (43.9)	32 (51.6)	ref		ref	**0.124**
Secondary	60 (46.2)	29 (46.8)	1.16 (0.63 - 2.16)		1.32 (0.62 - 2.77)	**0.471**
College/University	13 (10.0)	1 (1.6)	7.30 (0.91 - 58.39)		6.75 (0.76 - 59.67)	**0.086**
Tribe				**0.54**		
Luo	121 (92.4)	57 (90.5)	ref			
Luhya	6 (4.6)	5 (7.9)	0.57 (0.17 - 1.93)			
Other	4 (3.1)	1 (1.6)	1.88 (0.21 - 17.24)			
Religion				**0.42**		
Roman Catholic	84 (64.1)	46 (73.0)	ref			
Muslim	4 (3.1)	2 (3.2)	1.10 (0.19 - 6.21)			
Other	43 (32.8)	15 (23.8)	1.56 (0.79 - 3.13)			
Marital status				**0.357**		
Single/Never married	4 (3.1)	4 (6.4)	ref			
Married/living as married	100 (76.3)	50 (79.4)	2.00 (0.48 - 8.33)			
Separated/Divorced/Widowed	27 (20.6)	9 (14.3)	3.00 (0.61 - 14.53)			

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	Condom Use (N=194)		Bivariate		Multivariate	
	Never/sometimes use condom (N=131)	Always/most of the time use condom (N=63)	OR		AOR	
	N (%)	N (%)	(95% CI)	p-value	(95% CI)	p-value
Tested for HIV				**0.199**		
No	21 (16.0)	15 (23.8)	ref		ref	
Yes	110 (84.0)	48 (76.2)	1.63 (0.78 - 3.45)		1.41 (0.60 - 3.33)	**0.436**
Participated in Research				**0.36**		
No	85 (64.9)	45 (71.4)	ref			
Yes	46 (35.1)	18 (28.6)	1.35 |(0.70 - 2.60)			
At Risk of HIV Infection				**0.07**		
Agree	74 (56.5)	25 (39.7)	ref		ref	
Disagree	35 (26.7)	21 (33.3)	0.56 (0.28 - 1.14)		0.53 (0.24 - 1.19)	**0.123**
Don't Know	22 (16.8)	17 (27.0)	0.43 (0.20 - 0.95)		0.42 (0.17 - 1.05)	**0.063**

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Notes:

OR – Odds Ratio

AOR – Adjusted OR; adjusted for gender, contact strategy, occupation, income, level of education, tested for HIV and at risk of HIV infection.

ref – Reference group

4.8.3. Risk Profiles: Correlates of Concurrent Sex Partners

The prevalence of having concurrent sex partners was 33.0% (67 /203) with more males having concurrent partners (55.2%) than females (44.8%). Those with higher proportions of concurrent sex partners were; aged 18 -25 years (53.7%), working (80.6%), SW/bar maids (43.3%), those with an income of between KES 4,000 to 6,000 (35.8%), those having primary/post primary/vocational education or secondary education (43.3%) each, Luo ethnic group (89.6%), Roman Catholic (67.2%), married or living as married (59.7%), those tested for HIV previously (85.1%), those who had not participated in HIV research previously (64.9%) and those who considered themselves at risk of HIV infection (59.7%).

In the bivariate analysis, SW/barmaids had 11 times the odds of having concurrent sex partners (OR 10.59; 95% CI 3.88 - 28.93) compared to fishermen/fishmonger. Those with a higher income of between KES 8,000 – 10,000 also had a 5 times odds of having concurrent sex partners (OR 4.72; 95% CI 1.06 - 20.89) compared to those with an income of below KES 2,000. The odds of having concurrent sex partners was otherwise lower in those age 26 – 35 years (OR 0.53; 95% CI 0.29 - 0.99) and those aged 36 – 45 years (OR 0.16; 95% CI 0.04 - 0.76) compared to those aged 18 – 25 years. Also having lower odds of concurrent sex partners were those who did not consider themselves to be at risk of HIV infection (OR 0.45; 95% CI 0.22 - 0.94) compared to those who considered themselves to be at risk.

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Multivariate analysis was performed on all the variables that had p values of <0.25 from the bivariate analysis. These variables included; age group, occupation, income, level of education, religion, marital status, participated in research and at risk of HIV infection. The odds of having concurrent sex partners were lower in those aged 26 – 35 years (AOR 0.41 95% CI 0.18 - 0.92) and those aged 36 – 45 years (AOR 0.09; 95% CI 0.01 - 0.71) compared to those aged 18 – 25 years. Also having lower odds of concurrent sex partners were those who did not consider themselves to be at risk of HIV infection (AOR 0.36; 95% CI 0.14 - 0.90) compared to those who considered themselves to be at risk. SW/barmaids had six times the odds of having concurrent sex partners (AOR 5.54; 95% CI 1.62 - 18.89) compared to fishermen/fishmongers.

Table 4.8.3: Correlates of Concurrent Sexual Partners

	Concurrent partners (N=203)		Bivariate		Multivariate	
	Yes (N=67)	No (N=136)	OR		AOR	
	N (%)	N (%)	(95% CI)	p-value	(95% CI)	p-value
Gender				**0.373**		
Male	37 (55.2)	84 (61.8)	ref			
Female	30 (44.8)	52 (38.2)	1.31 (0.72 - 2.36			
Age Groups				**0.022**		
18 - 25	36 (53.7)	47 (34.6)	ref		ref	
26 - 35	28 (41.8)	68 (50.0)	0.53 (0.29 - 0.99)		0.41 (0.18 - 0.92)	**0.031**
36 - 45	2 (3.0)	16 (11.8)	0.16 (0.04 - 0.76)		0.09 (0.01 - 0.71)	**0.021**
46 - 55	1 (1.5)	4 (2.9)	0.32 (0.04 - 3.05)		0.42 (0.03 - 5.16)	**0.496**
Working				**0.761**		
No	13 (19.4)	24 (17.7)	ref			
Yes	54 (80.6)	112 (82.4)	0.89 (0.42 - 1.88)			
Occupation				**0.000**		
Fishermen/Fishmonger	13 (19.4)	38 (27.9)	ref		ref	
Sex worker/Bar maid	29 (43.3)	8 (5.9)	10.59 (3.88 - 28.93)		5.54 (1.62 - 18.89)	**0.006**
Taxi drivers	13 (19.4)	36 (26.5)	1.05 (0.43 - 2.58)		1.30 (0.44 - 3.85)	**0.632**
Other	10 (14.9)	54 (39.7)	0.54 (0.22 - 1.36)		0.70 (0.24 - 2.05)	**0.513**
Contact Strategy				**0.679**		
Personal contact	14 (20.9)	31 (22.8)	ref			
Link Persons	17 (25.4)	37 (27.2)	1.02 (0.43 - 2.39)			
Peer mobilization	16 (23.9)	38 (27.9)	0.93 (0.39 - 2.20)			
Use of leaders	20 (29.9)	30 (22.1)	1.48 (0.63 - 3.45)			

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	Concurrent partners (N=203)		Bivariate		Multivariate	
	Yes (N=67)	No (N=136)	OR		AOR	
	N (%)	N (%)	(95% CI)	p-value	(95% CI)	p-value
Income				**0.207**		
Less than KES 2000 (USD 22)	3 (4.5)	17 (12.5)	ref		ref	
Btw 2000 – 4000 (USD 22 – 44)	11 (16.4)	15 (11.0)	4.16 (0.97 -17.77)		3.06 (0.57 - 16.50)	**0.191**
Btw 4000 – 6000 (USD 44 – 66)	24 (35.8)	52 (38.2)	2.61 (0.70 - 9.78)		1.69 (0.37 - 7.68)	**0.498**
Btw 6000 – 8000 (USD 66 – 88)	19 (28.4)	40 (29.4)	2.69 (0.70 - 10.31)		2.53 (0.54 - 11.89)	**0.238**
Btw 8000 – 10000 (USD 88 – 110)	10 (14.9)	12 (8.8)	4.72 (1.06 - 20.89)		1.34 (0.19 - 9.51)	**0.768**
Level of education				**0.234**		
Primary/Post Primary/Vocational	29 (43.9)	63 (46.7)	ref		ref	
Secondary	29 (43.9)	65 (48.2)	0.97 (0.52 - 1.80)		1.21 (0.50 - 2.92)	**0.670**
College/University	8 (12.1)	7 (5.2)	2.48 (0.82 - 7.50)		3.92 (0.81 - 18.99)	**0.089**
Tribe				**0.634**		
Luo	60 (89.6)	127 (93.4)	ref			
Luhya	5 (7.5)	6 (4.4)	1.76 (0.52 - 6.01)			
Other	2 (3.0)	3 (2.2)	1.14 (0.23 - 8.67)			
Religion				**0.228**		
Roman Catholic	45 (67.2)	94 (69.1)	ref		ref	
Muslim	4 (6.0)	2 (1.5)	4.17 (0.73 - 23.66)		6.16 (0.49 - 76.67)	
Other	18 (26.9)	40 (29.4)	0.94 (0.49 - 1.81)		0.46 (0.16 - 1.30)	**0.143**
Marital status				**0.001**		
Single/Never married	4 (6.0)	4 (2.9)	ref		ref	
Married/living as married	40 (59.7)	114 (83.8)	0.35 (0.08 - 1.47)		0.27 (0.05 - 1.52)	**0.140**
Separated/Divorced/Widowed	23 (34.3)	18 (13.2)	1.28 (0.28 - 5.82)		0.69 (0.99 - 4.79)	**0.705**

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	Concurrent partners (N=203)		Bivariate		Multivariate	
	Yes (N=67)	No (N=136)	OR		AOR	
	N (%)	N (%)	(95% CI)	p-value	(95% CI)	p-value
Tested for HIV				**0.323**		
No	10 (14.9)	28 (20.6)	ref			
Yes	57 (85.1)	108 (79.4)	1.48 (0.67 - 3.26)			
Participated in Research				**0.182**		
No	41 (61.2)	96 (70.6)	ref		ref	
Yes	26 (38.8)	40 (29.4)	1.52 (0.82 - 2.81)		2.12 (0.95 - 4.72)	**0.066**
At Risk of HIV Infection				**0.082**		
Agree	40 (59.7)	60 (44.1)	ref		ref	
Disagree	14 (20.9)	46 (33.8)	0.45 (0.22 - 0.94)		0.36 (0.14 - 0.90)	**0.028**
Don't Know	13 (19.4)	30 (22.1)	0.65 (0.30 - 1.40)		0.57 (0.21 - 1.56)	**0.274**

Notes:

OR – Odds Ratio

AOR – Adjusted OR; adjusted for age group, occupation, income, level of education, religion, marital status, participated in research and at risk of HIV infection.

ref – Reference group

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4.8.4. Association between Contact Strategies and Study Recruitment Acceptability

Table 4.8.4 below shows the association between contact strategy and study recruitment acceptability. There were no significant differences across the four strategies in relation to five questions chosen for their relevance to study recruitment: self-perception of risk for HIV acquisition (x^2 (6) 1.2656; p-value 0.974); main motivation for participating in the study (x^2 (24) 26.0863; p-value 0.349); main withdrawal reason from the study (x^2 (33) 37.9878; p-value 0.252); difficulty in getting to the clinic (x^2 (6) 4.9719; p-value 0.547); and willingness to be contacted for a future HIV research study (x^2 (6) 8.883; p-value 0.180).

Approximately half (49.26%) of the respondents agreed that they were at risk for HIV acquisition with 46.66%, 48.14% , 48.14% and 54.00% of those contacted through personal contacts, link persons, peer mobilisation and leaders respectively agreeing they were at risk of HIV acquisition. Getting HIV education was the most common (47.78%) main motivating factor for participating in HIV research studies (personal contact 48.88%; link person 46.29%; peer mobilisation 51.85%; and leader 44.00%). Of the main reasons that would make someone withdraw from an HIV prevention trial, having your personal information made available to others in the community was the most common (31.00%) reason (personal contact 37.78%; link person 27.78; peer mobilisation 31.48%;and leader 28.00%). The vast majority of the participants reported they would not have any difficulty in getting to the clinic (93.59%) and would be willing to be contacted for a future HIV research study (92.11%).

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Table 4.8.4: Association between Contact Strategy and Study Recruitment Acceptability

	How did you hear about the study? (N=203)				Test of Association	
	Personal contact (N=45) N (%)	Link Persons (N=54) N (%)	Peer mobilization (N=54) N (%)	Use of Leaders (N=50) N (%)	p-value	x^2
Self Assessment of HIV risk					**0.9735**	**1.2656**
Agree	21 (10.34)	26 (12.81)	26 (12.81)	27 (13.30)		
Disagree	13 (6.40)	18 (8.87)	16 (7.88)	13 (6.40)		
Don't Know	11 (5.42)	10 (4.93)	12 (5.91)	10 (4.93)		
Main motivation for participating in the study					**0.349**	**26.0863**
Getting HIV education	22 (10.00)	25 (12.31)	28 (13.79)	22 (10.00)		
Getting free HIV treatment and care	3 (1.47)	11 (5.42)	3 (1.47)	6 (2.95)		
Getting other types of free medical care	2 (0.98)	1 (0.49)	0 (0.00)	3 (1.47)		
Helping find a cure for HIV	3 (1.47)	7 (3.44)	9 (4.43)	5 (2.46)		
Getting incentives for taking part	1 (0.49)	1 (0.49)	4 (1.97)	0 (0.00)		
HIV testing and counselling	4 (1.97)	3 (1.47)	4 (1.97)	7 (3.44)		
Getting information on how to take care of yourself if you become HIV infected	7 (3.44)	4 (1.97)	5 (2.46)	3 (1.47)		
Being part of a social group that gets together to talk periodically	2 (0.98)	1 (0.49)	1 (0.49)	3 (1.47)		
Other	1 (0.49)	1 (0.49)	0 (0.00)	1 (0.49)		
Main Withdrawal reason from the study					**0.252**	**37.9878**
Fear of testing positive for HIV	9 (4.43)	5 (2.46)	11 (5.42)	10 (4.93)		
Sexual partner/spouse refusal	2 (0.98)	2 (0.98)	4 (1.97)	2 (0.98)		
Having your personal information made available to others in the community	17 (8.37)	15 (7.93)	17 (8.37)	14 (6.90)		
Others in the community thinking you have HIV	0 (0.00)	1 (0.49)	6 (2.96)	5 (2.46)		

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	How did you hear about the study? (N=203)				Test of Association	
	Personal contact (N=45) N (%)	**Link Persons (N=54) N (%)**	**Peer mobilization (N=54) N (%)**	**Use of Leaders (N=50) N (%)**	**p-value**	**x^2**
Having to deal with new medical costs that are not covered by the study	4 (1.97)	7 (3.44)	3 (1.47)	4 (1.97)		
Losing your job	2 (0.98)	4 (1.97)	0 (0.00)	1 (0.49)		
Taking too much time away from your job	2 (0.98)	8 (3.94)	2 (0.98)	3 (1.47)		
Having children at home who need you	0 (0.00)	3 (1.47)	1 (0.49)	0 (0.00)		
Taking too much of your blood	3 (1.47)	3 (1.47)	1 (0.49)	1 (0.49)		
Moving out of the area	3 (1.47)	5 (2.46)	3 (1.47)	5 (2.46)		
Other	3 (1.47)	1 (0.49)	6 (2.95)	5 (2.46)		
Difficulty in getting to the clinic every 3 months					**0.547**	**4.9719**
No	42 (20.69)	49 (24.14)	52 (25.62)	47 (23.15)		
Yes	3 (1.47)	5 (2.46)	2 (0.98)	2 (0.98)		
Not sure	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.49)		
Willing to be contacted In future HIV prevention trials					**0.18**	**8.883**
No	2 (0.98)	2 (0.98)	1 (0.49)	3 (1.47)		
Yes	42 (20.69)	50 (24.63)	53 (26.11)	42 (20.69)		
No/Not sure	1 (0.49)	2 (0.98)	0 (0.00)	5 (2.46)		

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5. CHAPTER 5: PHASE III

5.1. Introduction

Chapter five describes aim and objectives of phase III, followed by a description of the research methodology and finally results of the same phase. Phase III Evaluates the mRDS in recruitment of KPs into an HIV incidence cohort study. The research methodology explores the study design, the study population, the sample size, the sampling procedure and data collection procedures followed. Finally there is a description and presentation of results for the phase.

5.2. Study Methods

5.2.1. Study Aims

Phase III of the research study aimed at evaluating of the mRDS in recruitment of KPs into an HIV incidence cohort study

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5.2.2. Study Objectives

1. To determine the baseline biomedical and behavioural characteristics of persons screened in an HIV prevention study in Kisumu.
2. To evaluate the risk profile of participants enrolled into an HIV prevention study in Kisumu.
3. To compare the number of KPs enrolled into the HIV prevention trial with that of persons screened into the same trial

5.2.3. Study Setting

The study was carried out at the KEMRI/CDC Research and Public Health Collaboration Programme's CRC in Kisumu.

5.3. Study Design

This stage involved the evaluation of the mRDS in recruitment of KPs into an observational, prospective cohort study. This observational, prospective cohort study was conducted among healthy, HIV-negative adolescent and adult KPs in the catchment area of Kisumu, western Kenya. The study design included a 6 month screening and enrolment period (including an initial 1 month pilot period). The pilot period allowed for any necessary streamlining of study procedures, and final data analysis could be performed with or without the data collected during the pilot period. Follow-up visits will then occur at 3, 6, 9, and 12 months after enrolment.

For this study only recruitment and enrolment data was used with the follow up data being omitted. Only information pertaining to this study that includes only the recruitment and enrolment to this cohort is included in this thesis. The overall enrolment target was approximately 625 HIV-negative study participants. The study involved the collection of demographic and behavioural information. Participants also got a medical history and physical examination with collection of blood, urine, and vaginal swab samples in the case of women. Participants also underwent HIV counselling and testing with pre and post-test counselling. Laboratory tests included HIV testing with CD4 and Viral load testing for all positives, pregnancy testing for females and STI testing for gonorrhoea, chlamydia, syphilis and HSV-2.

5.3.1. Inclusion and Exclusion Criteria

To be included in the cohort study, participants had to meet the following inclusion criteria:

- 15 to 64 year old male and female residents of the Kisumu catchment area.
- Sexually active ≥ one time within the past 3 months.
- Meet at least one of the following behavioural criteria in the last 12 months.
  - Had vaginal or anal sex with an anonymous partner who could not be contacted again.
  - Had a sexual partner who was infected with HIV.
  - Had vaginal or anal sex in exchange for money, goods or services.
  - Had vaginal or anal sex with ≥ 2 partners.
  - Had an STI.
- HIV seronegative by licensed rapid HIV testing in parallel.
- Able and willing to provide informed consent and detailed locator information.

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Potential participants were excluded from the cohort study if they were:

- HIV seropositive
- Pregnant if female
- Younger than 15 or older than 64
- Planning to reside outside the Kisumu catchment area for >3 months

5.3.2. Study Population

The study will be conducted among persons who are healthy, HIV seronegative KPs, and residents of the Kisumu catchment area. The objectives of this prospective cohort study do not

require a final study population that is representative of the source population in Kisumu. Instead, the study requires a cohort of individuals who can be recruited, enrolled and followed closely for the duration of the study period, and among whom adequate estimates of incident HIV infections can be made. Therefore the study anticipated to recruit approximately 1,700 KPs from the catchment area using the mRDS from whom 625 will be enrolled into the prospective cohort study.

5.3.3. Sampling Procedure

A non-probability convenience sampling method was used to recruit participants into phase III of the study. Although there were no population-based estimates of HIV incidence for the city of Kisumu, a recent randomized trial to investigate the impact of male circumcision on infection rates among 18-24 year-old males reported a 2 year incidence of 3.1% from both study arms (Bailey et al., 2007). The sample size calculation was based on expected incidence rate for the follow up study that is not included as part of this thesis. Table 3.6.1 below presents the expected number of seroconverters and 95% confidence intervals for a range of expected incidence point estimates (3.0 to 4.0 per 100 person-years), based on a Poisson distribution and the enrolment sample size target of 625 KPs. For example, with an estimated incidence of 3.0%, enrolment and retention of 500 (80%) of 625 enrolled participants, the study expected at least 15 seroconverters. The study also expected reasonable precision (width of 95% confidence intervals) around point estimates within the range of 3.0 to 4.0 per 100 person-years.

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Table 5.3.1: Incidence, expected number of seroconverters, and 95% confidence intervals for enrolled and retained sample sizes ranging from 500 to 563 in the high risk cohort.

Sample Size Enrolled	Sample Size Retained	% Retained	Incidence (%)	Expected Seroconverters	95% CI	Interval Range
625	500	80	3.0	15	1.67 - 4.94	3.27
625	531	85	3.0	16	1.71 - 4.87	3.16
625	563	90	3.0	17	1.74 - 4.81	3.07
625	500	80	3.5	18	2.06 - 5.57	3.51
625	531	85	3.5	19	2.09 - 5.49	3.40
625	563	90	3.5	20	2.13 - 5.42	3.29
625	500	80	4.0	20	2.44 - 6.17	3.73

Sample Size Enrolled	Sample Size Retained	% Retained	Incidence (%)	Expected Seroconverters	95% CI	Interval Range
625	531	85	4.0	22	2.48 - 6.10	3.62
625	563	90	4.0	23	2.52 - 6.03	3.51

*Assumes that participants who are lost to the study are lost prior to the first follow-up, and do not contribute any person-years of observation to the study. This assumption is conservative in that it is likely to underestimate the person-years of follow-up contributed by those who are lost to the study.

5.4. Data Collection

Phase III data collection involved recruitment, registration, pre-screening, consenting, screening and enrolment activities. Data collection tools were administered using laptop computers or TELEform questionnaires. Rapid HIV testing was conducted using UniGold HIV1/2, (Trinity Biotech, Wicklow, Ireland) and Determine HIV1/2 (Abbott Labs, Tokyo, Japan), with the Bioline test (Meridian Life Science® Company, Cincinnati, Ohio) as a tiebreaker. Testing for syphilis was done using BD MicroVue™ RPR (Rapid Plasma Reagin) cardtest with all reactive tests confirmed by Serodia® TPPA Syphilis Test. HSV2 was detected using KALON® HSV2 IgG enzyme linked immunoassay (ELISA) (Kalon Biologicals Ltd., Surrey, UK) and urine pregnancy test was done using First Sign HCG One Step (UNIMED International, Inc., South San Francisco, CA, USA). The details for these activities are further explained in figure 5.4.1 and the prose below it.

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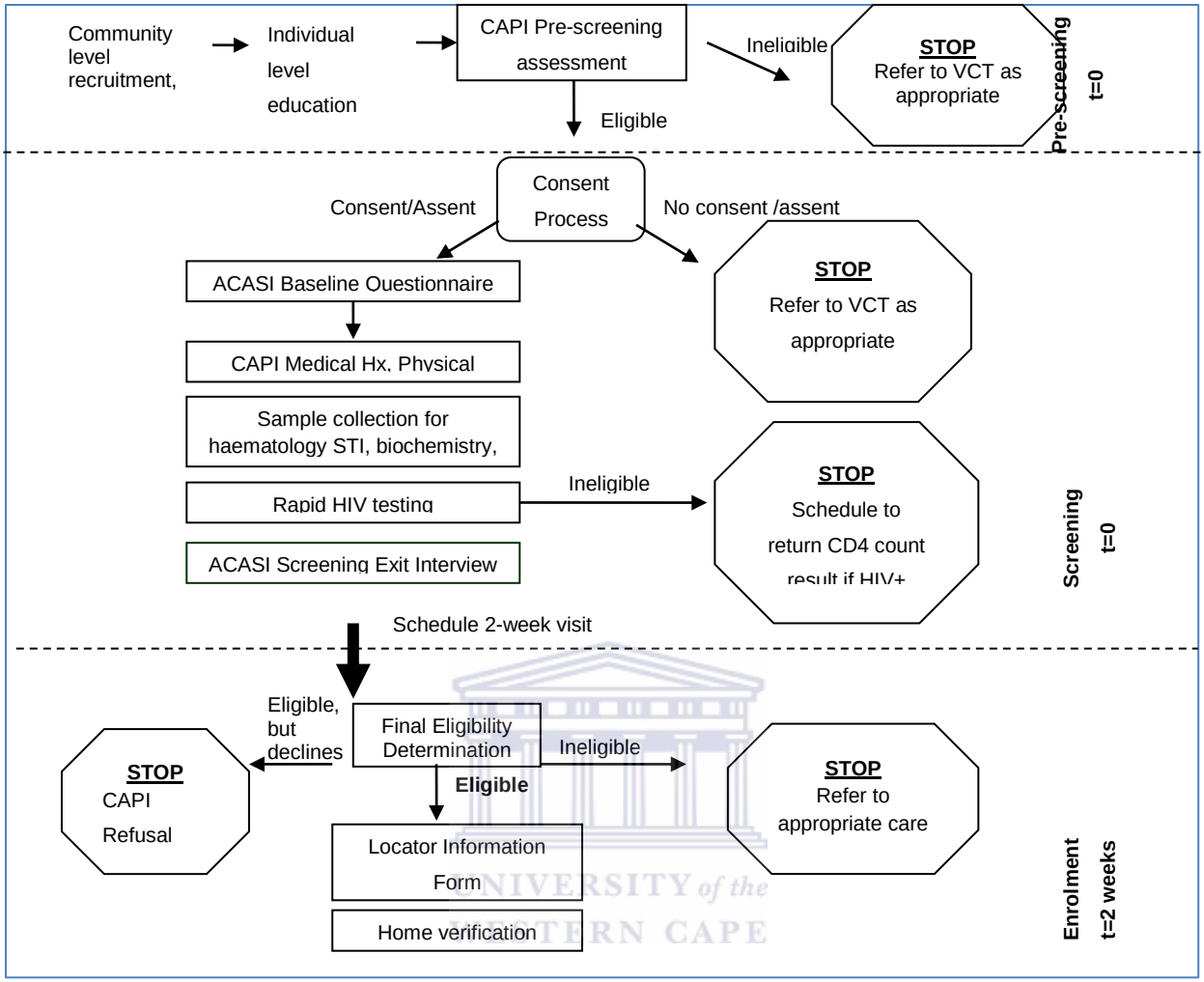
Figure 5.4.1: Overview of Study Procedures for Phase III



5.4.1. Recruitment

Participants were recruited by the use of a mRDS that was designed in phase II of the study. Those accepting to participate in the study were asked to come to the CRC for pre-screening activities. Adult and mature minor volunteers who came for screening underwent a brief pre-screening assessment to determine if they met major eligibility criteria such as age, residence in the study catchment area and risk status (Appendix 4.3). Those meeting these criteria were provided with detailed information about the study and informed consent for participation in the study was requested.

5.4.2. Informed Consent

Informed consent was sought after thorough explanation of study procedures and implications of study participation (risks/benefits) with adequate time for potential study participants to consider information provided about the study and to ask additional questions before deciding to

participate. The informed consent process included information about the study, a description of screening and enrolment procedures, including the sensitive nature of some questions about sexual behaviour and rapid HIV testing with pre- and post- test counselling. The informed consent also included information regarding testing for STIs and pregnancy. In addition, potential study participants were informed about referral for HIV care and treatment services for those found to be HIV positive.

Participants had individual ICFs read to them in English, Dholuo or Kiswahili. Participants signed individual ICFs and functionally illiterate participants were given the option of signing the ICF by marking with a thumbprint on the signature line with an independent witness observing the process and providing a witnessed signature. A copy of the signed ICF was provided to the participant. Persons who required additional time to reach a decision to participate or to discuss their potential participation with others were given time and an option of returning to complete their consent at a later date at which the consent process was repeated to ensure that information was understood regarding the study purpose and procedures. These persons could come back as long as the study was still recruiting. People who declined to participate in the study were asked about their reasons for refusal using a brief refusal questionnaire (Appendix 4.4).

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5.4.3. Screening

Following informed consent/assent, participants completed an audio-computer-assisted structured interview (ACASI) to assess socio-demographics, risk behaviour and motivations for participation. Successful use of ACASI has been demonstrated in a rural population near Kisumu in spite of low literacy rates and limited routine exposure to computers. This is consistent with findings from use of ACASI in other urban and rural settings in Kenya (Waruru et al., 2005). A clinical evaluation was performed including pregnancy testing for women. Individuals underwent blood, urine and vaginal swab sample collection for HIV and HSV-2 antibody testing, biochemistry profile, haematology, urinalysis, and additional STI (chlamydia, gonorrhoea and syphilis) testing. Treatment was provided for all participants testing positive for an STI with their sexual partners. HIV testing was performed with pre- and post- test counselling with results provided immediately.

5.4.4. Enrolment

The enrolment visit was scheduled 2 weeks after completing the screening visit, compilation of all laboratory evaluations, and final determination of study eligibility. At the enrolment visit, persons eligible for study participation received a review of information about the study and the opportunity to ask any questions. Additional HIV testing was not performed at the enrolment visit unless the participant initially tested HIV negative and comes for enrolment more than 4 weeks after screening ("late enrolee"), in which case repeat rapid HIV testing with pre- and post-test counselling was performed using the same algorithm as during screening. Eligibility screening procedures were also repeated, and if found to be ineligible, the "late enrolees" were excluded from participation in the study.

5.5. Data Management and Analysis

5.5.1. Data Management

Data collection tools were designed electronically using various tools like QDS, Visual CE, Microsoft Visual Basic, structured query language (SQL) and TELEforms. Records containing names or other personal identifiers were locked and stored separately from other study records. Records with participant names were de-linked from the main database and stored in separate secure database. Local databases were secured with password-protected limited access systems. Rates of enrolment, follow-up and protocol compliance were monitored closely by the study team. Monthly reports were generated to provide on-going monitoring of critical study variables and included summaries regarding: participant accrual and loss, completeness of data, outlying data, timeliness of locator and follow-up visits, and indicators of participant withdrawal or inability to locate.

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5.5.2. Data and Statistical Analysis

To describe the baseline characteristics of persons screened for eligibility and those enrolled in the study, percentages of participants in various socio-demographic and clinical groups were computed. Percentages of persons enrolled from each of the categories and the strategies used identified from phase II of the study were then computed. These percentages were compared statistically to identify differences between those screened and enrolled and those screened but not enrolled. Statistical tests were conducted using a Chi-square test for categorical variables and a t-test or Wilcoxon test for continuous variables. Percentages of participants who met each of

the exclusion criteria, and the overall percentage of those screened but were not eligible were also reported.

For enrolled participants, analyses were performed for the purpose of describing the clinical and behavioural characteristics of participants, including age, gender, area of residence, marital status, contraceptive use, motivations for participation, attitudes toward HIV testing and test results, past 3 months self-reported STI rates, study-diagnosed STI rates, the number of sexual partners in the past 3 months, rates of unprotected sex with partners by type (spouse vs. others), and the percentage who have had a prior HIV test. Relative risks for factors of interest to quantify the association between various clinical and behavioural characteristics and HIV infection were also computed. These were then adjusted for confounding variables and fit in the multivariate models. Factors of interest included age group, area of residence, marital status, whether the participant reported any unprotected sex during the study follow-up, number of sex partners reported, and STIs among others.

5.5.3. Validity/Reliability

All the study staff were trained on good clinical practice and all the study procedures to ensure accuracy and completeness of the data collected. The study standard operating procedures (SOP) brought consistency in carrying out study activities and minimised errors. To ensure data quality, internal checks for consistency and validity were programmed and embedded in the design of the questionnaires. Study forms were linked through unique participant study numbers. Quality assurance (QA) of 10% of rapid HIV tests was performed at the study laboratory at the CRC using standard enzyme-linked immunoabsorbent assay (ELISA). QA of 20% of STIs was performed at the Nairobi laboratory of the University of Nairobi, Illinois and Manitoba program.

5.6. Ethical Considerations

Ethical approval for the study was sought from the ethics committee of the Kenya Medical Research Institute, the US CDC and the University of the Western Cape. This protocol, informed consent forms, questionnaires, participant education and recruitment materials, and other study forms, and any subsequent modifications, was reviewed by the regulatory authorities with respect to ethical and scientific compliance with applicable research and human subjects regulations. Individual informed consent was obtained from each study participant before

participation. Participants were informed of the purpose of the study, how confidentiality will be maintained, rights not to participate if they want to. Progress reports were made to the regulatory authorities as required.

5.7. Response Rates

Of the 2,205 persons (966 male; 1,239 female) presenting for study consideration, 1,347 (61.1%) met study screening eligibility criteria of whom 1,292 (95.9%) completed the screening procedures. Of the 1,292 (527 male; 765 female) persons completing screening, 643 (49.8%) were enrolled in the study with a gender segregation of 310 (48.2%) males and 333 (51.8%) females. About three quarters (73%) of the females who presented for study consideration were ineligible for reasons such as being HIV positive at baseline, sexual inactivity, pregnancy or not meeting the high risk criteria, reducing the proportion of female enrolees to 51.7%.

5.8. Results

5.8.1. Socio-Demographics of Screened Participants

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Majority (59.2%) of all the respondents were females compared to 40.8% males. The study had more offsprings (59.4%) than seeds (40.6%). This was even seen when disaggregated by sex with offsprings accounting for 51.6% and 70.6% of all females and males respectively. Participants were generally of a younger age group with 51.0% being in the 15-25 year age group and a further 34.8% being in the 26-35 year age group. The median age was 25 years with females being older (median - 27 years) than males (median - 24 years). Being single/never married was the most common marital status with 47.4% of participants having this status followed by those separated/divorced/widowed who were 30.2%. While this was also true for males with 56.3% of them reporting to be single/never married, most of the females on the other hand were separated/divorced/widowed with 44.3% of them reporting this status.

Almost all (97.4%) the respondents reported to be resident of Kisumu district with 98.7% and 96.5% of all males and females being resident of the district. Even though 83.2% of all the respondents were Luo which is the most predominant ethnic group in the district, there were 16.8% in the others category that included Luhyas, Kisiis, Kikuyu and Maasai ethnic groups.

Christianity was the most predominant religion with Roman Catholics accounting for 47.2% of the population while protestant and other Christians accounted for 28.3% of the population.

About half (54.2%) of the respondents had primary or lower education with 33.2% having secondary education and 12.6% having post-secondary education. While majority (60.0%) of females had primary or lower education, their male counterparts were almost equal in having primary or lower education and secondary education with 37.6% and 36.2% respectively. Almost half (49.3%) of the respondents were not employed with self-employment being the next highest occupation (29.7%). While most of the salaried workers were female (6.0%), most of the males who reported to have any form of employment were mostly casual workers (21.3%). The most predominant average monthly income was below KES 2,000 (USD 22) with 72.5% of the respondents being in this category followed by 15.9% being in the KES 2,001 to KES 5,000 (USD 22 – 55) category and 12.1% in the above KES 5,000 (USD 55) category. Males generally reported a higher income.

The three most predominant risk groups were SW at 55.1% (19.0% males and 80.0% females) followed by men who have sex with men at 11.0% and finally the fishermen/fishmonger at 16.5% (34.5% males and 4.1% females). Of the contact strategies used to find the respondents, 44.6% (49.3% males and 41.3% females) were found through their leaders; 40.9% (29.4% males and 28.9% females) were found through personal contacts; 13.2% (18.8% males and 9.3% females) were found through link persons; and 1.3% (2.5% males and 0.5% females) were found through peer mobilisation.

Table 5.8.1: Demographic Characteristics for Participants Screened for Phase III

Characteristic	Males N (%)	Females N (%)	Total N (%)
TOTAL	527 (40.8)	765 (59.2)	1292 (100.0)
Seeds/Offsprings			
Seeds	155 (29.4)	370 (48.4)	525 (40.6)
Offsprings	372 (70.6)	395 (51.6)	767 (59.4)
Age group (years)			
15 - 25	314 (59.6)	345 (45.1)	659 (51.0)
26 - 35	166 (31.5)	283 (37.0)	449 (34.7)
36 - 45	36 (6.8)	93 (12.2)	129 (10.0)
46 - 65	11 (2.1)	44 (5.7)	55 (4.3)
Median Age (range)	24 (24-25)	27 (26- 27)	25 (25 – 26)
Marital status			
Single/Never married	294 (56.3)	313 (41.3)	607 (47.4)
Married/Living as married	178 (34.1)	109 (14.4)	287 (22.4)
Separated/Divorced/Widowed	50 (9.6)	336 (44.3)	386 (30.2)
District of residence			
Kisumu	520 (98.7)	738 (96.5)	1258 (97.4)
Vihiga/Nyando	7 (1.3)	27 (3.5)	34 (2.6)
Ethnic group or tribe			
Luo	448 (85.2)	624 (81.9)	1072 (83.2)
Luhya/Other	78 (14.8)	138 (18.1)	216 (16.8)
Religion			
Roman Catholic	227 (43.2)	381 (49.9)	608 (47.2)
Protestant or other Christian	179 (34.1)	189 (24.8)	368 (28.6)
Muslim/Hindu/Other	98 (18.7)	164 (21.5)	262 (20.3)
No religion	21 (4.0)	29 (3.8)	50 (3.9)

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Characteristic	Males N (%)	Females N (%)	Total N (%)
Highest education level			
Never attended school/Primary school	241 (45.7)	459 (60.0)	700 (54.2)
Secondary school	191 (36.3)	238 (31.1)	429 (33.2)
Post-secondary school	95 (18.0)	68 (8.9)	163 (12.6)
Occupation			
Self Employed (incl. Farmer)	162 (30.7)	222 (29.1)	384 (29.7)
Salaried Worker	26 (4.9)	46 (6.0)	72 (5.6)
Casual Worker	112 (21.3)	87 (11.4)	199 (15.4)
Not Employed (incl. homemaker)	227 (43.1)	409 (53.5)	636 (49.3)
Income			
Below KES 2,000 (USD 22.00)	326 (61.9)	605 (79.1)	931 (72.0)
KES 2,001 - 5,000 (USD 22.00 – 55.00)	96 (18.2)	109 (14.2)	205 (15.9)
Above KES 5,000 (USD 55.00)	105 (19.9)	51 (6.7)	156 (12.1)
Risk category			
Sex worker	100 (19.0)	612 (80.0)	712 (55.1)
Men who have sex with men	142 (26.3)	0 (0.0)	142 (11.0)
Fishermen/Fishmongers	182 (34.5)	31 (4.1)	213 (16.5)
Transport (drivers)	43 (8.2)	20 (2.6)	63 (4.9)
HIV neg. member of discordant couple (self-report)	6 (1.1)	9 (1.2)	15 (1.2)
Widows/Widowers	5 (1.0)	70 (9.2)	75 (5.8)
Street youth	37 (7.0)	0 (0.0)	37 (2.9)
Car washers	18 (3.4)	7 (0.9)	25 (1.9)
Police	6 (1.1)	4 (0.5)	10 (0.8)
Contact strategy			
Personal Contact	155 (29.4)	374 (48.9)	529 (40.9)
Link Person	99 (18.8)	71 (9.3)	170 (13.2)
Peer Mobilisation	13 (2.5)	4 (0.5)	17 (1.3)
Leaders	260 (49.3)	316 (41.3)	576 (44.6)

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5.8.2. Baseline Biomedical and Behavioural Characteristics

Of all the male respondents, 54.5% reported to be uncircumcised. The age of sexual debut was most commonly between the ages of 15 – 19 years (61.6%) with 63.0% of females and 59.5% of males reporting to have started having sex at this age. Age of the first sexual partner of males was generally same as for the participants (65.6%) with females generally having sexual partners who were about 5 or more years older than them (52.3%). Majority (78.6%) of the participants reported having 4 or more sexual partners in their lifetime with more males (82.3%) than females (76.0%) reporting 4 more sexual partners. In the 3 months prior to the interview, 47.6% of all respondents reported having had 4 or more sexual partners. Condom use in the last 3 months was predominantly absent with only 17.0% reporting having protected sex within the past 3 months. Other forms of sexual intercourse were also not widely practiced with only 34.7% reporting having ever had anal sex and 42.1% reporting having ever had oral sex.

Thirty nine percent of the respondents reported having ever been forced to have sex against their will with half (49.3%) of the females and quarter (24.0%) of the males acknowledging having ever been forced into sex. Fifty one percent of the participants reported having used a form of family planning with 63.1% of the females and 34.5% of the males having used a method. A fifth (21.1%) of the participants reported having had sex with a partner with suspected or known HIV positive status while 48.9% reported having sex with a partner with unknown HIV status. Half of the participants reported having had sex in exchange for money with 63.0% of the females reporting sex in exchange for money compared to 30.7% of males. Sex with multiple partners was also prevalent with 52.5% of all respondents and 54.7% of females and 49.3% of all males reporting having had multiple sex partners.

Two hundred and ninety two participants reported to having been previously treated for STIs with 32.2% of them reporting being treated within the past 3 months. Previous STI treatment was more predominant in males with 55.1% (161/292) of all those reporting previous STI treatment being males. Use of drugs in the last 3 months was reported by 32.6% (41.7% males; 26.3% females) while alcohol use in the last 3 months was reported by 69.4% (71.9% males; 67.7% females). About two thirds of the males (60.7%) and females (69.3%) reported having had sex with a partner other than main spouse in the last 3 months with 50.0% of the males and 65.7% of

the females who reported sex with other partner reporting using condoms at that sexual intercourse. Almost half (48.8%) of all respondents reported having sex during special occasions like panting, weeding etc., while only 18.8% of all the respondents reported using condoms at all or most of their sexual intercourse. Of the 662 (55.6%) respondents who reported to have given/received money to have sexual intercourse, 80.1% (530) were females. On the other hand 42.6% of the respondents (26.3% males; 54.3% females) reported giving/receiving gifts to have sexual intercourse.

Table 5.8.2: Behavioural Characteristics for Participants Screened for Phase III

Behaviour	**Males N (%)**	**Females N (%)**	**Total**
Circumcision Status			
No	287 (54.5)		287 (54.5)
Yes	240 (45.5)		240 (45.5)
Age of Sexual Debut			
Less than 15 Years old	161 (31.5)	190 (25.8)	351 (28.2)
Btw 15 - 19 years old	304 (59.5)	463 (63.0)	767 (61.6)
Above 20 years old	46 (9.0)	82 (11.2)	128 (10.2)
Age of first sexual partner			
About your age	343 (65.6)	274 (35.9)	617 (47.9)
5 or more years younger	87 (16.6)	90 (11.8)	177 (13.8)
5 or more years older	93 (17.8)	400 (52.3)	493 (38.3)
Lifetime number of sexual partners			
0 - 1 partners	18 (3.7)	26 (3.7)	44 (3.7)
2 - 3 partners	68 (14.0)	142 (20.3)	210 (17.7)
≥ 4 partners	401 (82.3)	532 (76.0)	933 (78.6)
Number of sexual partners in the last 3 mos.			
0 - 1 partner	88 (18.3)	104 (15.7)	192 (16.8)
2 - 3 partners	216 (44.8)	191 (28.9)	407 (35.6)
≥ 4 partners	178 (36.9)	367 (55.4)	545 (47.6)

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Behaviour	Males N (%)	Females N (%)	Total
Protected sex in last 3 months			
No	452 (86.1))	616 (81.0)	1068 (83.0)
Yes	73 (13.9)	145 (19.0)	218 (17.0)
Ever had anal sex			
No	357 (68.1)	483 (63.3)	840 (65.3)
Yes	167 (31.9)	280 (36.7)	447 (34.7)
Ever had oral sex			
No	319 (61.1)	423 (55.7)	742 (57.9)
Yes	203 (38.9)	337 (44.3)	540 (42.1)
Ever been forced into sex			
No	398 (76.0)	386 (50.7)	784 (61.0)
Yes	126 (24.0)	375 (49.3)	501 (39.0)
Used family planning			
No	324 (65.5)	281 (36.9)	605 (48.2)
Yes	171 (34.5)	480 (63.1)	651 (51.8)
Sex with known/suspected HIV infected partner			
No	365 (83.1	471 (75.9)	836 (78.9)
Yes	73 (16.9)	150 (24.1)	223 (21.1)
Sex with partner of unknown HIV status			
No	263 (53.9)	337 (49.1)	600 (51.1)
Yes	225 (46.1)	350 (50.9)	575 (48.9)
Sex in exchange for money			
No	338 (69.3)	255 (37.0)	593 (50.4)
Yes	150 (30.7)	434 (63.0)	584 (49.6)
Sex with multiple partners			
No	247 (50.7)	313 (45.3)	560 (47.5)
Yes	240 (49.3)	378 (54.7)	618 (52.5)

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Behaviour	Males N (%)	Females N (%)	Total
STI History			
Never had STI treatment	361 (69.2)	631 (82.8)	992 (77.3)
STI treatment, not recent	110 (21.0)	88 (11.6)	198 (15.4)
Recent STI treatment (last 3 months)	51 (9.8)	43 (5.6)	94 (7.3)
Used drugs in the last 3 mos.			
No	306 (58.3)	564 (73.7)	870 (67.4)
Yes	219 (41.7)	201 (26.3)	420 (32.6)
Drank alcohol in the last 3 mos.			
No	148 (28.1)	246 (32.3)	394 (30.6)
Yes	378 (71.9)	516 (67.7)	894 (69.4)
Sex with someone other than spouse/main partner in the last 3 mos.			
No	193 (39.3)	212 (30.7)	405 (34.3)
Yes	298 (60.7)	479 (69.3)	777 (65.7)
Used condoms for sex with someone other than spouse/main partner in the last 3 mos.			
No	149 (50.0)	164 (34.3)	313 (40.3)
Yes	149 (50.0)	314 (65.7)	463 (59.7)
Sex during special occasions in the last 3 mos.			
No	240 (48.6)	367 (53.1)	607 (51.2)
Yes	254 (51.4)	324 (46.9)	578 (48.8)
Frequency of condom use in the last 3 mos.			
Never/Sometimes	424 (80.8)	623 (81.5)	1047 (81.2)
Always/Most of the time	101 (19.2)	141 (18.5)	242 (18.8)
Given/received money to have sex in the last 3 mos.			
No	362 (73.3)	166 (23.8)	528 (44.4)
Yes	132 (26.7)	530 (76.2)	662 (55.6)

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Behaviour	Males N (%)	Females N (%)	Total
Given/received gifts/other favours to have sex in the last 3 mos.			
No	364 (73.7)	317 (45.7)	681 (57.4)
Yes	130 (26.3)	376 (54.3)	506 (42.6)

Of all the females in the study, only 3.3% were pregnant. The prevalence of Chlamydia was 2.9% with 2.1% in males and 3.5% in females. Gonorrhoea had a prevalence of 5.0% with male prevalence being 1.9% and female prevalence being 7.1% while the prevalence of syphilis was 0.4% with male and female prevalence being 0.2% and 0.5% respectively. HSV-2 seropositivity was 46.0% with 60.9% of females and 24.3% of males being seropositive. An additional 13% (12.5% males and 13.3% females) had indeterminate results. Those who tested positive for HIV were 26.2% with 12.5% males and 35.6% females testing positive for HIV. Of those who tested HIV positive, CD4 count testing was done for 94.4% (319/338) with majority (42.3%) of the seropositive participants having CD4 counts between 250 – 500 cells/ml.

Table 5.8.3: Biomedical Characteristics for Participants Screened for Phase III

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Characteristic	Males N (%) [95% CI]	Females N (%) [95% CI]	Total N (%) [95% CI]
Pregnant (as confirmed by lab test)			
Positive		25 (3.3) [2.2-4.7]	25 (3.3) [2.2-4.7]
Negative		740 (96.7) [95.2-97.7]	740 (96.7) [95.2-97.7]
Chlamydia Results			
Positive	11 (2.1) [1.6-3.7]	27 (3.5) [2.4-5.1]	38 (2.9) [2.1-4.0]
Negative	516 (97.9) [96.3-98.8]	738 (96.5) [94.9-97.6]	1254 (97.1) [96.0-97.9]
Gonorrhoea Results			
Positive	10 (1.9) [1.0-3.5]	54 (7.1) [5.4-9.1]	64 (5.0) [3.9-6.3]
Negative	517 (98.1) [96.5-99.0]	711 (92.9) [90.9-94.6]	1228 (95.0) [93.7-96.1]

Characteristic	Males N (%) [95% CI]	Females N (%) [95% CI]	Total N (%) [95% CI]
Syphilis Results			
Positive	1 (0.2) [0.0-1.3]	4 (0.5) [0.2-1.4]	5 (0.4) [0.2-0.9]
Negative	526 (99.8) [98.6-99.9]	761 (99.5) [98.6-99.8]	1287 (99.6) [99.1-99.8]
HSV-2 Results			
Positive	128 (24.3) [20.8-28.1]	466 (60.9) [57.4-64.3]	594 (46.0) [43.2-48.7]
Negative	333 (63.2) [59.0-67.2]	197 (25.8) [22.8-29.0]	530 (41.0) [38.4-43.7]
Indeterminate	66 (12.5) [10.0-15.6]	102 (13.3) [11.1-15.9]	168 (13.0) [11.3-15.0]
HIV Results			
Positive	66 (12.5) [10.0-15.6]	272 (35.6) [32.2-39.0]	338 (26.2) [23.8-28.6]
Negative	461 (87.5) [84.4-90.0]	493 (64.4) [61.0-67.8]	954 (73.8) [71.4-76.2]
Viral Load			
< 1000 copies/ml	0 (0.0)	7 (36.8) [17.4-61.7]	7 (31.8) [15.0-55.3]
1000 - 10,000 copies/ml	0 (0.0)	6 (31.6) [13.9-41.8]	6 (27.3) [11.9-51.0]
10,000 - 100,000 copies/ml	1 (33.3) [21.6-918]	3 (15.8) [4.7-41.8]	4 (18.2) [6.4-41.9]
>100,000 copies/ml	2 (66.7) [8.1-97.8]	3 (15.8) [4.7-41.8]	5 (22.7) [9.1-46.5]
CD4 count			
< 250 cells/ml	8 (12.7) [6.4-23.6]	45 (17.6) [13.4-22.7]	53 (16.6) [12.9-21.1]
250 - 500 cells/ml	33 (52.4) [40.0-64.5]	102 (39.8) [34.0-46.0]	135 (42.3) [37.0-47.8]
500 - 1000 cells/ml	21 (33.3) [22.7-45.9]	99 (38.7) [32.9-44.8]	120 (37.6) [32.4-43.0]
>1000 cells/ml	1 (1.6) [0.2-10.6]	10 (3.9) [2.1-7.1]	11 (3.5) [1.9-6.1]

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5.8.3. Risk Profiles for Phase III Participants

Since the HIV prevalence and the HSV-2 prevalence was high in the screened population, we evaluated demographic, behavioural and biomedical correlates of HIV infection in these participants to be able to describe the risk level of phase III participants.

With the HIV prevalence was 26.2% only the 338 participants who tested HIV positive are included in this part of the analysis. Females had a higher (35.6%) prevalence compared to the males (12.5%) with the HIV prevalence among seeds and recruits being comparable at 29.9% (seeds) and 23.6% (offspring). The prevalence was higher in the older age groups with 36 – 45 years having 39.5% while the others had 34.7% (26 – 35 years), 30.9% (46 – 65 years) and 17.3% (15 – 25 years). HIV prevalence was higher among HIV negative partners of discordant couples/widowers (37.3%) and SW (33.2%). This was followed by fishermen/fishmongers (18.8%), transport workers (15.9%), street youth/car washers/police (12.5%) and finally MSM (10.6%). Separated, divorced or widowed participants had a higher HIV prevalence (43.8%) compared to those who were married/living as married (20.0%) or single/never married (18.0%). HIV prevalence was also higher in those having primary or lower education (31.0%) in contrast to those with secondary (20.3%) or post secondary (20.9%) education. HIV prevalence was generally similar across the occupation stratum ranging from 20.8% among students to 29.2% among self employed or casual workers.

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Those who used any method of family planning had a higher prevalence of 28.3% with prevalence being comparable across different ages of sexual debut at between 22.7% among those who had debuted at above 20 years old and 26.9% among those who debuted at between 15 and 19 years old. Those who had a first partner who was 5 years or more older than them had a higher prevalence of 27.6% while those who reported 4 or more partners in their lifetime or past 3 months also had 27.6% and 28.4% respectively. Those who reported protected sex in last 3 months or not having had anal sex in last 3 months had a HIV prevalence of about 27% each while there was no difference in prevalence among those who reported having had oral sex and those who reported not having oral sex (26.9% vs. 25.5%). HIV prevalence was also higher amongst those who reported having been forced into sex (30.5%) or having had sex with known/suspected HIV infected (28.3%). There was no difference in the prevalence of HIV in those who had sex with partner of unknown HIV status (25.6% vs. 26.7%) or those who had sex

in exchange for money (26.5% vs. 26.0%). Those not having multiple sex partners had a higher prevalence (29.6%) while the HIV prevalence was not different in those who did not have or those who had history of previous STI treatment.

Participants who reported they did not use drugs in the past three months had an almost double prevalence (30.1%) compared those who used while there was no difference in those who used or did not used alcohol in the past three months and those who had or did not have sex with someone other than spouse/main partner in the last 3 months. HIV prevalence was higher among those who; used condoms at last sex with someone other than spouse/main partner in the last 3 months (29.2%), did not have sex during special occasions in the last 3 months (28.2%). Those reporting use of condoms all the time or not had a comparable prevalence while those who had given or received money or gifts/other favours for sex had higher prevalences of 30.7% and 29.1% respectively. While HIV prevalence was higher among those who tested positive for HSV-2 (40.7%), gonorrhoea (35.9%) and syphilis (60.0%), it was higher among those who tested negative for chlamydia (26.3%).

In the bivariate analysis, females had almost four times the odds of being HIV seropositive (OR 3.85; 95% CI 2.86 – 5.19) compared to males. Offsprings had a one and half times odds of HIV seronegativity (OR 0.72; 95% CI 0.56 - 0.93) compared to seeds. The odds of HIV seropositivity were 2.5 times higher among 26 - 35 years (OR 2.54; 95% CI 1.92 - 3.37), 3 times higher among 36 - 45 years (OR 3.13 95% CI 2.08 - 4.69) and 2 times higher among 46 - 65 years (OR 2.14; 95% CI 1.16 - 3.92) compared to those aged 15 – 25 years. Compared to SW, MSM had a 4 times odds (OR 0.24; 95% CI 0.14 - 0.42) while fishermen/fishmongers (OR 0.47; 95% CI 0.32 - 0.68), Transport workers (OR 0.38 95% CI 0.19 - 0.76) and Street youth/Car Washer/Police (OR 0.29; 95% CI 0.14 - 0.59) had two times, two and half times and three and half times the odds of HIV seronegativity respectively. Being separated, widowed or divorced gave someone four times the odds of HIV seropositivity (OR 3.56; 95% CI 2.67 - 4.75) compared to being single/never married. Those having secondary (OR 0.57; 95% CI 0.43 - 0.75) or post secondary education (OR 0.59; 95% CI 0.39 - 0.88) had about two times the odds of HIV seronegativity compared to those having primary education.

Having had a first sexual partner who was 5 or more years older than the respondent gave the

responded a one and half times the odds of HIV seropositivity (OR 1.58; 95% CI 1.21 - 2.06) compared to those who had age mates. Participants who reported protected sex in the last 3 months had an almost twice the odds of HIV seronegativity (OR 0.59; 95% CI 0.41 - 0.85) compared to those not reporting protective sex. Ever been forced into sex gave participants a one and half times the odds of HIV seropositivity (OR 1.45; 95% CI 1.13 - 1.87) compared to those who had not while those reporting sex with multiple partners (OR 0.69; 95% CI 0.53 - 0.89) or using drugs in the last 3 months (OR 0.51; 95% CI 0.38 - 0.68) had one and half to two times the odds of HIV seronegativity respectively. Participants who used condoms for sex with someone other than spouse/main partner in the last 3 months had a one and half times odds for HIV seropositivity (OR 1.51; 95% CI 1.08 - 2.12) while those who reported having been given or received money (OR 1.74; 95% CI 1.33 - 2.28) or gifts/other favours (OR 1.32; 95% CI 1.02 - 1.72) to have sex with someone in the last 3 months had odds of 1.7 and 1.3 respectively. Being HSV-2 negative predisposed participants to having nine times the odds of HIV seronegativity (OR 0.11; 95% CI 0.08 - 0.16).

Multivariate analysis was performed on all the variables that had p values of <0.25 from the bivariate analysis. These variables included gender, seeds/offsprings, age group, risk category, marital status, highest education level, age of sexual debut, age of first sexual partner, lifetime number of sexual partners, number of sexual partners in the last 3 months, protected sex in last 3 months, ever had anal sex, ever had oral sex, ever been forced into sex, sex with multiple partners, used drugs in the last 3 months, used condoms for sex with someone other than spouse/main partner in the last 3 months, given/received money to have sex with someone in the last 3 months, HSV-2 results, gonorrhoea results and syphilis results. The variable that had significant odds included age group, sex with multiple partners, used drugs in the past 3 months and HSV-2 results. Being aged between 26 – 35 years gave a participant about two times the odds of HIV seropositivity (AOR1.88; 95% CI 1.15 - 3.06) compared to being aged between 15 - 25 years. On the other hand the odds of HIV seropositivity were lower amongst those who; reported sex with multiple partners (AOR 0.61; 95% CI 0.38 - 0.97), reported using drugs in the last 3 months (AOR 0.49; 95% CI 0.30 - 0.80) and those who tested HSV-2 negative (AOR 0.19 95% CI 0.10 - 0.34).

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Table 5.8.4: Correlates of Prevalent HIV Infection among Participants Screened in Phase III

Characteristic	HIV Prevalence at Screening N (%)	Bivariate Analysis		Multivariate Analysis	
		OR [95% CI]	p-value	OR [95% CI]	p-value
Gender	**338 (26.2)**		**< 0.0001**		
Male	66 (12.5)	*ref.*		*ref.*	
Female	272 (35.6)	3.85 [2.86 - 5.19]		2.14 [0.97 - 4.76]	**0.061**
Seeds/Offsprings			**0.011**		
Seeds	157 (29.9)	*ref.*		*ref.*	
Offsprings	181 (23.6)	0.72 [0.56 - 0.93]		0.77 [0.49 - 1.20]	**0.250**
Age group (years)			**< 0.0001**		
15 - 25	114 (17.3)	*ref.*		*ref.*	
26 - 35	156 (34.7)	2.54 [1.92 - 3.37]	**< 0.0001**	1.88 [1.15 - 3.06]	**0.011**
36 - 45	51 (39.5)	3.13 [2.08 - 4.69]	**< 0.0001**	1.53 [0.75 - 2.97]	**0.223**
46 - 65	17 (30.9)	2.14 [1.16 - 3.92]	**0.014**	0.73 [0.26 - 2.03]	**0.559**
Risk category			**< 0.0001**		
sex worker	236 (33.2)	*ref.*		*ref.*	
Men who have sex with men	15 (10.6)	0.24 [0.14 - 0.42]	**< 0.0001**	0.97 [0.34 - 2.76]	**0.947**
Fishermen/Fishmongers	40 (18.8)	0.47 [0.32 - 0.68]	**< 0.0001**	1.20 [0.53 - 2.71]	**0.659**
Transport (drivers)	10 (15.9)	0.38 [0.19 - 0.76]	**0.006**	0.63 [0.18 - 2.17]	**0.469**
Discordant Couples/Widow(ers)	28 (37.3)	0.91 [0.57 - 1.46]	**0.699**	1.01 [0.24 - 4.36]	**0.971**
Street youth/Car Washer/Police	9 (12.5)	0.29 [0.14 - 0.59]	**0.001**	0.96 [0.22 - 4.19]	**0.980**

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Characteristic	HIV Prevalence at Screening N (%)	Bivariate Analysis		Multivariate Analysis	
		OR [95% CI]	p-value	OR [95% CI]	p-value
Marital status			**< 0.0001**	*ref.*	
Single/Never married	109 (18.0)	*ref.*			
Married/Living as married	57 (20.0)	1.13 [0.79 - 1.62]	**0.495**	0.82 [0.41 - 1.62]	**0.584**
Separated/Divorced/Widowed	169 (43.8)	3.56 [2.67 - 4.75]	**< 0.0001**	1.60 [0.95 - 2.67]	**0.072**
Highest education level			**0.0001**		
Never attended school/Primary school	217 (31.0)	*ref.*		*ref.*	
Secondary school	87 (20.3)	0.57 [0.43 - 0.75]	**< 0.0001**	0.79 [0.49 - 1.29]	**0.351**
Post-secondary school	34 (20.9)	0.59 [0.39 - 0.88]	**0.011**	1.65 [0.85 - 3.21]	**0.137**
Occupation			**0.240**		
Self employed/casual worker	112 (29.2)	*ref.*			
Students, not otherwise employed	15 (20.8)	0.64 [0.35 - 1.18]	**0.150**		
Other (incl. salaried worker & farmer)	45 (22.6)	0.71 [0.48 - 1.06]	**0.092**		
Not employed (incl. homemaker)	116 (26.1)	0.86 [0.65 - 1.14]	**0.287**		
Used family planning			**0.127**		
No	148 (24.5)	*ref.*			
Yes	184 (28.3)	1.22 [0.95 - 1.57]			

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Characteristic	HIV Prevalence at Screening N (%)	Bivariate Analysis		Multivariate Analysis	
		OR [95% CI]	p-value	OR [95% CI]	p-value
Age of Sexual Debut			**0.052**		
Less than 15 Years old	88 (25.1)	*ref.*		*ref.*	
Btw 15 - 19 years old	206 (26.9)	1.09 [0.82 - 1.46]	**0.529**	1.32 [0.82 - 2.10]	**0.245**
Above 20 years old	29 (22.7)	0.88 [0.54 - 1.41]	**0.586**	0.60 [0.25 - 1.37]	**0.227**
Age of first sexual partner			**0.003**		
About your age	139 (22.5)	*ref.*		*ref.*	
5 or more years younger	43 (24.3)	1.10 [0.75 - 1.63]	**0.622**	0.65 [0.33 - 1.28]	**0.212**
5 or more years older	155 (31.4)	1.58 [1.21 - 2.06]	**0.001**	0.10 [0.62 - 1.59]	**0.982**
Lifetime number of sexual partners			**0.081**		
0 - 1 partners	8 (18.2)	*ref.*		*ref.*	
2 - 3 partners	48 (21.4)	1.23 [0.53 - 2.82]	**0.630**	1.07 [0.22 - 5.05]	**0.931**
≥ 4 partners	257 (27.6)	1.71 [0.78 - 3.72]	**0.177**	1.46 [0.34 - 6.38]	**0.609**
Number of sexual partners in the last 3 mos.			**0.045**		
0 - 1 partner	49 (25.5)	*ref.*		*ref.*	
2 - 3 partners	87 (21.4)	0.79 [0.53 - 1.19]	**0.259**	0.77 [0.32 - 1.82]	**0.594**
≥ 4 partners	155 (28.4)	1.16 [0.80 - 1.69]	**0.437**	0.93 [0.39 - 2.23]	**0.875**
Protected sex in last 3 months			**0.003**		
No	296 (27.7)	*ref.*		*ref.*	
Yes	40 (18.4)	0.59 [0.41 - 0.85]		0.84 [0.43 - 1.60]	**0.590**

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Characteristic	HIV Prevalence at Screening N (%)	Bivariate Analysis		Multivariate Analysis	
		OR [95% CI]	p-value	OR [95% CI]	p-value
Ever had anal sex			**0.165**		
No	231 (27.5)	*ref.*		*ref.*	
Yes	107 (23.9)	0.83 [0.64 - 1.08]		1.08 [0.68 - 1.73]	**0.737**
Ever had oral sex			**0.579**		
No	189 (25.5)	*ref.*			
Yes	145 (26.9)	1.08 [0.83 - 1.38]			
Ever been forced into sex			**0.003**		
No	182 (23.2)	*ref.*		*ref.*	
Yes	153 (30.5)	1.45 [1.13 - 1.87]		1.14 [0.74 - 1.76]	**0.544**
Sex with known/suspected HIV infected partner			**0.637**		
No	213 (25.5)	*ref.*			
Yes	63 (28.3)	1.15 [0.83 - 1.60]			
Sex with partner of unknown HIV status			**0.667**		
No	160 (26.7)	*ref.*			
Yes	147 (25.6)	0.94 [0.73 - 1.23]			
Sex in exchange for money			**0.823**		
No	154 (26.0)	*ref.*			
Yes	155 (26.5)	1.03 [0.79 - 1.34]			

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Characteristic	HIV Prevalence at Screening N (%)	Bivariate Analysis		Multivariate Analysis	
		OR [95% CI]	p-value	OR [95% CI]	p-value
Sex with multiple partners			**0.005**		
No	166 (29.6)	*ref.*		*ref.*	
Yes	139 (22.5)	0.69 [0.53 - 0.89]		0.61 [0.38 - 0.97]	**0.036**
STI History			**0.989**		
Never had STI treatment	260 (26.2)	*ref.*			
STI treatment, not recent	52 (26.3)	1.00 [0.71 - 1.42]	**0.988**		
Recent STI treatment (last 3 months)	24 (25.5)	0.97 [0.59 -1.57]	**0.886**		
Used drugs in the last 3 mos.			**< 0.0001**		
No	262 (30.1)	*ref.*		*ref.*	
Yes	76 (18.1)	0.51 [0.38 - 0.68]		0.49 [0.30 - 0.80]	
Drank alcohol in the last 3 mos.			**0.881**		
No	102 (25.9)	*ref.*			
Yes	235 (26.3)	1.02 [0.78 - 1.34]			
Sex with someone other than spouse/main partner in the last 3 mos.			**0.948**		
No	106 (26.2)	*ref.*			
Yes	202 (26.0)	0.99 [0.75 - 1.30]			

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Characteristic	HIV Prevalence at Screening N (%)	Bivariate Analysis		Multivariate Analysis	
		OR [95% CI]	p-value	OR [95% CI]	p-value
Used condoms for sex with someone other than spouse/main partner in the last 3 mos.			**0.015**		
No	67 (21.4)	*ref.*		*ref.*	
Yes	135 (29.2)	1.51 [1.08 - 2.12]		1.32 [0.85 - 2.04]	
Sex during special occasions in the last 3 mos.			**0.774**		
No	171 (28.2)	*ref.*			
Yes	136 (23.5)	1.01 [0.96 - 1.06]			
Frequency of condom use in the last 3 mos.			**0.291**		
Sometimes/Never	281 (26.8)	*ref.*			
All the time/Most of the time	57 (23.5)	0.84 (0.61 - 1.16)			
Given/received money to have sex with someone in the last 3 mos.			**< 0.0001**		
No	107 (20.3)	*ref.*		*ref.*	
Yes	203 (30.7)	1.74 [1.33 - 2.28]		1.05 [0.58 - 1.87]	
Given/received gifts/other favours to have sex with someone in the last 3 mos.			**0.327**		
No	161 (23.6)	*ref.*			
Yes	147 (29.1)	1.32 [1.02 - 1.72]			

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Characteristic	HIV Prevalence at Screening N (%)	Bivariate Analysis		Multivariate Analysis	
		OR [95% CI]	p-value	OR [95% CI]	p-value
HSV-2 Results			**< 0.0001**		
Positive	242 (40.7)	*ref.*		*ref.*	
Negative	37 (7.0)	0.11 [0.08 - 0.16]	**< 0.0001**	0.19 [0.10 - 0.34]	**< 0.0001**
Indeterminate	59 (35.1)	0.79 [0.55 - 1.12]	**0.189**	0.79 [0.45 - 1.40]	**0.462**
Chlamydia Results			**0.457**		
Positive	8 (21.1)	*ref.*			
Negative	330 (26.3)	1.34 [0.61 - 2.95]			
Gonorrhoea Results			**0.077**		
Positive	23 (35.9)	*ref.*		*ref.*	
Negative	315 (25.7)	0.62 [0.36 - 1.04]		1.95 [0.78 - 4.84]	**0.151**
Syphilis Results			**0.111**		
Positive	3 (60.0)	*ref.*		*ref.*	
Negative	335 (26.0)	0.23 [0.04 - 1.41]		0.29 [0.02 - 3.32]	**0.318**

Notes:

OR – Odds Ratio

AOR – Adjusted OR; adjusted for gender, seeds/offsprings, age group, risk category, marital status, highest education level, age of sexual debut, age of first sexual partner, lifetime number of sexual partners, number of sexual partners in the last 3 months, protected sex in last 3 months, ever had anal sex, ever had oral sex, ever been forced into sex, sex with multiple partners, used drugs in the last 3 months, used condoms for sex with someone other than spouse/main partner in the last 3 months, given/received money to have sex with someone in the last 3 months, HSV-2 results, gonorrhoea results and syphilis results.

ref – Reference group

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5.8.4. Comparison of KPs Screened and those Enrolled in Phase III

Of the 1,292 individuals who were screened for enrolment into Phase III, only 49% (643) were eventually enrolled into the study. The gender segregation was similar in screened vs. enrolled population with most of the participants being female in both instances (59.2% screened; 51.8% enrolled). The offspring were also the majority in both instances with 59.4% and 58.8% of those screened and enrolled respectively being offspring. Age categorisation was also similar with more than 50% of the participants being aged between 15 and 25 years in both screened (51.0%) and enrolled (59.3%) populations with the median age being 25 (25 - 26) for those screened and 24 (24 - 25) for those enrolled. The similarity was also seen in marital status with most participants being single/never married (47.4% vs. 56.2%) in both categories and in religion and highest education level where most of the participants were Roman Catholics (47.2% vs. 43.2%) and had primary or no education (54.2% vs. 45.9%).

The three most predominant risk categories among those screened and enrolled were SW (55.1% vs. 50.9%), MSM (11.0% vs. 15.9%) and fishermen/fishmongers (16.5% vs. 15.9%). Use of leaders was the most successful contact strategy for screening (44.6%) and enrolment (43.7%). Age of sexual debut was between 15 and 19 years old in most of those screened (61.6%) and those enrolled (59.9%) while almost half of the participants reported having at least 4 sexual partners in both instances. Proportions of participants reporting the other risk behaviours of having sex with known/suspected HIV infected (21.1% vs. 25.3%), having sex with multiple partners (52.5% vs. 68.8%) and using condoms all or most of the time in the last 3 months (18.8% vs. 22.8%) was also similar while there were some differences in those reporting sex with partner of unknown HIV status (48.9% vs. 63.1%) and sex in exchange for money (49.6% vs. 61.8%). STI prevalence was also comparable across those screened and those enrolled with screening and enrolment prevalence being comparable for Chlamydia (2.9% vs. 3.4%), Gonorrhoea (5.0% vs. 4.4%), Syphilis (0.4% vs. 0.3%) and HSV-2 (46.0% vs. 37.8%).

Table 5.8.5: Selected Socio-Demographic and Biomedical Characteristics of KPs Screened and those enrolled into Phase III

Characteristic	Screened N (%)	Enrolled N (%)
TOTAL	1292	643
Males	527 (40.8)	310 (48.2)
Females	765 (59.2)	333 (51.8)
Seeds/Offsprings		
Seeds	525 (40.6)	265 (41.2)
Offsprings	767 (59.4)	378 (58.8)
Age group (years)		
15 - 25	659 (51.0)	381 (59.3)
26 - 35	449 (34.7)	194 (30.2)
36 - 45	129 (10.0)	44 (6.8)
46 - 65	55 (4.3)	24 (3.7)
median	25 (25 - 26)	24 (24 - 25)
Marital status*		
Single/Never married	607 (47.4)	359 (56.2)
Married/Living as married	287 (22.4)	138 (21.6)
Separated/Divorced/Widowed	386 (30.2)	142 (22.2)
Religion*		
Roman Catholic	608 (47.2)	278 (43.2)
Protestant or other Christian	368 (28.6)	213 (33.2)
Muslim/Hindu/Other	262 (20.3)	132 (20.6)
No religion	50 (3.9)	18 (2.8)
Highest education level		
Never attended school/Primary school	700 (54.2)	295 (45.9)
Secondary school	429 (33.2)	250 (38.9)
Post-secondary school	163 (12.6)	98 (15.2)

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Characteristic	Screened N (%)	Enrolled N (%)
Risk category		
Sex worker	712 (55.1)	327 (50.9)
Men who have sex with men	142 (11.0)	102 (15.9)
Fishermen/Fishmongers	213 (16.5)	102 (15.9)
Transport (drivers)	63 (4.9)	34 (5.3)
HIV neg. member of discordant couple (self-report)	15 (1.2)	11 (1.7)
Widows/Widowers	75 (5.8)	28 (4.4)
Street youth	37 (2.9)	23 (3.6)
Car washers	25 (1.9)	9 (1.4)
Police	10 (0.8)	7 (1.1)
Contact strategy		
Personal Contact	529 (40.9)	251 (39.0)
Link Person	170 (13.2)	103 (16.0)
Peer Mobilisation	17 (1.3)	8 (1.3)
Leaders	576 (44.6)	281 (43.7)
Age of Sexual Debut*		
Less than 15 Years old	351 (28.2)	194 (30.8)
Btw 15 - 19 years old	767 (61.6)	377 (59.9)
Above 20 years old	128 (10.2)	58 (9.2)
Number of sexual partners in the last 3 months*		
0 - 1 partner	192 (16.8)	71 (11.5)
2 - 3 partners	407 (35.6)	227 (36.6)
≥ 4 partners	545 (47.6)	322 (51.9)
Sex with known/suspected HIV infected partner*		
No	836 (78.9)	413 (74.7)
Yes	223 (21.1)	140 (25.3)
Sex with partner of unknown HIV status*		
No	600 (51.1)	232 (36.9)
Yes	575 (48.9)	396 (63.1)

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Characteristic	Screened N (%)	Enrolled N (%)
Sex in exchange for money*		
No	593 (50.4)	240 (38.2)
Yes	584 (49.6)	389 (61.8)
Sex with multiple partners*		
No	560 (47.5)	191 (30.2)
Yes	618 (52.5)	441 (68.8)
Frequency of condom use in the last 3 months*		
Never/Sometimes	1047 (81.2)	495 (77.2)
Always/Most of the time	242 (18.8)	146 (22.8)
Chlamydia Results		
Positive	38 (2.9)	22 (3.4)
Negative	1254 (97.1)	621 (96.6)
Gonorrhoea Results		
Positive	64 (5.0)	28 (4.4)
Negative	1228 (95.0)	615 (95.6)
Syphilis Results		
Positive	5 (0.4)	2 (0.3)
Negative	1287 (99.6)	641 (99.7)
HSV-2 Results		
Positive	594 (46.0)	243 (37.8)
Negative	530 (41.0)	330 (51.3)
Indeterminate	168 (13.0)	70 (10.9)

*Not all numbers add up to 1292 in screening and 643 in enrolment as some questions were skipped

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6. CHAPTER 6: DISCUSSION

6.1. Introduction

This chapter provides a detailed discussion of the results of the study that investigated the use of modified respondent driven sampling methodology to enhance identification and recruitment of most at risk persons into an HIV prevention trial in Kisumu, western Kenya. In addition, the chapter also provides the limitations under which the study was conducted and finally provides conclusions and recommendations from the results of the study. The discussion in this chapter is structured along the aims of each of the phases of the study.

6.2. Phase I: Identification and determination of categories of KPs and techniques of locating and motivating them to participate in HIV prevention trials.

Overall the study was able to identify different categories of people considered to be at high risk of HIV acquisition. The groups identified included people who frequent bars (e.g. bar workers, drunkards, SW, businessmen), people who work in transportation (e.g. truck drivers, matatu drivers, motorcycle drivers, taxi drivers, bicycle taxi drivers), fishermen/fishmongers, MSM and hair salon workers. Most definitions of KPs are based on either their behavioural risk factors or their HIV prevalence and incidence or a combination of both. Several definitions have agreed SW, MSM, IDU and truck drivers are the Key KPs (International HIV/AIDS Alliance, 2010, National AIDS Control Council, 2009a, UNFPA, 2008, Dutta and Maiga, 2011, National AIDS Control Council, 2005). However there are additional groups of people who have been identified as KPs due to their linkage to sex trade including SW clients and fishing communities (UNAIDS and WHO, 2011, Kissling et al., 2005, Ramjee and Gouws, 2002, Ogendo et al., 2012).

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With the mainstream definitions of SW, MSM, IDU and truck drivers being KPs based on their HIV prevalence and incidence that have been shown to be about three times that of the average population, other studies have looked at the perception of persons on their risk levels. For as much as other people frequenting bars are not being identified as KPs in the mainstream definitions, several studies have demonstrated them to be at high risk of HIV acquisition mostly due to their relationship with SW, the effect of alcohol on their sexual behaviours and a probable confusion between bar workers and SW. In a study conducted among bar workers in northern Tanzania, HIV prevalence was found to be as high as 26.3% with reports of multiple sexual partnerships and inconsistent condom use of which were similar to this phase of the study despite not having HIV prevalence data at this point (Kapiga

et al., 2002). Another study in Mbeya, Tanzania looking at baseline prevalence of STI and other reproductive tract infections and their association with HIV as well as sociodemographic and behavioural characteristics in a newly recruited cohort of female bar workers also found high HIV prevalence of 68% with a high burden of STIs (syphilis 9%; HSV-2 87%; chlamydia, 12%; gonorrhoea, 22%; trichomoniasis, 24%; and bacterial vaginosis, 40%) among female bar workers (Riedner et al., 2003).

In a study looking at background characteristics, sexual relationships, condom use and risk perception of bar workers in Magu district, north-west Tanzania, Mgalla and Pool, even though not equating bar workers to prostitutes, found that they were involved in risk sexual behaviours like multiple sex partnerships, as well as inconsistent condom use. The bar workers also reported to consider themselves at high risk of HIV acquisition (Mgalla and Pool, 1997). In a review paper on alcohol use and sexual risk behaviour in southern Africa, Kalichman and his colleagues found a consistent association between alcohol use and sexual risks for HIV infection with the greater quantities of alcohol consumption predicting greater sexual risks than frequency of drinking (Kalichman et al., 2007).

Consistent with this study, fisherfolk have also been documented to be at a higher risk of HIV acquisition especially along the shores of Lake Victoria in Kenya, Tanzania and Uganda. In a paper analysing the phenomenon of fish-for-sex in small-scale fisheries and its links to HIV/AIDS and transactional sex practices, Béné and Merten reveals that fish-for-sex is a practice increasingly reported in many different developing countries, with the largest number of cases observed in Sub-Saharan African inland fisheries (Béné and Merten, 2008). An 18 month cohort study among 1,000 HIV uninfected at risk volunteers from 5 fishing communities along the shores of Lake Victoria in Uganda reported an incidence rate of 4.9 per 100 person years. The study concluded that the fishing communities experienced high HIV infection mainly as a result of their high risk behaviour including alcohol and drug use and STI infection (Seeley et al., 2012).

In a qualitative study describing the nature, context and implications of a unique form of transactional sexual relationships in the fishing communities along Lake Victoria in Kisumu County, Kenya, Kwena et al found that women engaged in sex to secure rights to purchase fish caught by specific fishermen. The sex is usually hurried and conducted in contexts that compromise their ability to practice safer sex (Kwena et al., 2012). A cross sectional survey of 46 fishing communities in Uganda found an overall HIV prevalence of 22% with age,

religion, ever condom use and number of lifetime sexual partners being the risk factors associated with HIV infection (Opio et al., 2013). These different studies have confirmed that the different categories of persons mentioned to be KPs in this phase of the study have behaviours putting them at higher risk of HIV acquisition, including the ones not mentioned in mainstream international definitions.

With the importance ascribed to KPs in driving the HIV epidemic (National AIDS Control Council, 2014b, National AIDS Control Council, 2009a, National AIDS and STD Control Programme, 2009) and an understanding of the importance in including them into mainstream HIV prevention research (National AIDS Control Council, 2009b, Kenya National AIDS Control Council, 2009) is needed. It has been documented that there need to devise sampling strategies that are both feasible and capable of producing unbiased estimates of KPs (Magnani et al., 2005, WHO and UNAIDS, 2010, Ogendo et al., 2012). The identification of using personal contact, link persons, peer mobilisers and leaders as a means of identifying and locating KPs, even though not expressly mentioned in literature, are part of the different strategies that have been used in identifying and locating KPs. The key denominator amongst these four key strategies identified was that they all involved trust in one way or another. Personal contact would be from someone known to the KPs and most likely whom they trust to know them. The same would be said for link person as these persons act as a link between the KPs and the general community. Peers and leaders come from the KPs groups themselves thus are trustable members of the communities they come from.

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In a qualitative study among 18- to 29-year-old African American MSM in Chicago and Atlanta, use of leaders was identified as a way of bringing MSM together and create opportunities for dialogue between MSM and African American community groups (Kraft et al., 2000). This strategy was also mentioned in this study in the context of a trusting relationship between the KPs and the persons being mentioned. All the other modes of identifying and locating KPs that have been mentioned in literature also highly depend on the development and maintenance of a trusting relationship amongst the KPs and recruiters.

Snowball sampling which is the most widely used method for recruiting hidden populations primarily depends on a trusting a seed who was used to recruit other members of the same population (Heckathorn, 1997, Heckathorn, 2002, Heckathorn et al., 2002, Semaan et al., 2002, Thompson and Collins, 2002, Sharma et al., 2002). The other different variants of

snowball sampling which include targeted sampling (Booth et al., 2004, Watters and Biernacki, 1989, Peltzer et al., 2004) and RDS (Heckathorn et al., 2002, Salganik and Heckathorn, 2004, Abramovitz et al., 2009), also depend on the same tenet as snowball sampling which ends up being a hybrid between using personal contact and peer mobilisation as you identify the seeds based on personal contact and use the seeds as peer mobilisers to identify the offspring.

Venue based sampling also involves the use of key informants, service providers, and members of the target population to identify a range of time-location units to locate the members of the target population (Johnston et al., 2010, Kendall et al., 2008, MacKellar et al., 2007, Stueve et al., 2001, Magnani et al., 2005). The same is applicable to IFS recruitment method which uses a standard chain referral approach after the identification of indigenous field workers who are selected based on the fact that they have privileged access to the population being targeted and would normally be accepted in that community without question (Griffiths et al., 1993, Power, 1994, Rhodes et al., 2006, Platt et al., 2006, Power and Harkinson, 1993, Smith, 2008).

Identifying motivators and barriers of KPs participation in HIV prevention research has been shown to be important in their inclusion in research studies. This study identified 8 key motivators and 9 key inhibitors to KPs participating in HIV prevention trials. Acquiring HIV education was mentioned as the main motivating factor for participating in HIV research studies having your personal information made available to others in the community was the most common to make someone withdraw from HIV research studies which translated to breach of confidentiality. These results were similar to those seen in several studies looking at either hypothetical or actual factors influencing study participation by KPs (Buchbinder et al., 1996, Koblin et al., 1997, Halpern et al., 2001, Buchbinder et al., 2004). Even though most of these studies looked at individual KPs groups e.g. SW, MSM and IDU, (DiClemente et al., 2010, Sobieszczyk et al., 2009, Otwombe et al., 2011, Barroso et al., 2009) others reviewed general participation in HIV research (Ross et al., 1999, Koblin et al., 1998, Newman et al., 2006, Djomand et al., 2008).

In general these studies reported results consistent with what was found in this study with some of the studies going further to recommend interventions to address the barriers. In a study of Female SW from Andhra Pradesh, India, Reed and colleagues found that aspects of the consent process, staff gender and demeanour, study environment, survey content, time

requirements for study participation, and perceived SW community support for research were key factors influencing whether SW perceived their confidentiality and privacy had been maintained, and whether they felt the study was conducted respectfully. The study further suggested that partnership with community-based organizations and investigation of participant's experiences in HIV prevention research could provide critical information to best inform research ethics protocols (Reed et al., 2014).

A pilot study to evaluate methods and barriers to recruit high-risk SW in Rio de Janeiro, Brazil found that despite the capacity to contact large numbers of SW, enrolment rate was extremely low with the main barrier to enrolment being social and/or cultural factors associated with high risk for acquiring HIV infection including fear of being tested for HIV, lack of understanding why a trial is necessary to develop a vaccine, illiteracy or functional illiteracy, trial visits limited to the morning period, and lack of money for transportation (Barroso et al., 2009). In an analysis of data to assess willingness to participate in efficacy trials from Project ACHIEVE in New York City, factors influencing willingness to participate in HIV vaccine trials included media reports, safety of the vaccine, fear or mistrust of research or government, and social risks (Koblin et al., 1997). The motivators and barriers to participation identified in this study were evenly spread amongst the participants recruited using the four different strategies of personal contact, use of peers, use of leaders and use of link persons.

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6.3. Phase II: Design and Implementation of a mRDS methodology in recruiting KPs into HIV prevention trials.

The mRDS was successful in recruiting participants considering that it was used to recruit 214 individuals in 14 days giving a yield of 15 persons per working day. Fisher folk (fishermen and fishmongers), taxi operators (night time taxi drivers, matatu drivers, motorcycle riders as well as bicycle riders), SW and bar maids and truck drivers were the most common occupation of persons recruited through the mRDS. The survey was thus able to validate the perceived KP groups identified and mentioned in phase I of this study.

In addition to the risk groups, we also evaluated their risk status based on the variables of inconsistent condom use and multiple sexual partnerships were used. The overall prevalence of inconsistent condom use was 67.5% with most inconsistent users being males (56.4%), from younger age groups 26 -35 years (45.0%) and 18 – 25 years (43.5%), those working (80.2%) and those having other occupation (35.1%). This is consistent with other studies that

also demonstrated inconsistencies among young males and young adults with recent STI cases as follows. In a study examining how condom use and its correlates differed between high-risk young adults and adults, Wallace and colleagues reported that proportional condom use was greater in young adults than adults, while young adults with a recent STI reported less condom use, whereas for older adults, a distant STI was associated with less condom use, compared to others in their age groups. They also found out that negative condom attitudes were more strongly linked to unprotected vaginal sex acts for younger versus older adults (Wallace et al., 2015).

The results from a prospective cohort of sexually active, condom-using women in the Contraceptive CHOICE Project were also similar to those of Wallace and colleagues. Inconsistent and incorrect condom use was found to be common among sexually active women. Greater number of unprotected sex acts was mostly associated with reporting 10 or more sex acts in the past 30 days, younger age at first intercourse, less perceived partner willingness to use condoms, and lower condom use self-efficacy (Shih et al., 2011).

The next variable to be evaluated was concurrent sexual partnerships in which we had 33.0% of all our participants reporting multiple partners with 55.2% of those reporting concurrent partnerships being males consistent with a study carried out among 18 to 39 year olds in the United States (Manhart et al., 2002). Younger age group was also associated with concurrency which was similar to the age groups seen among black men in the United States (Taylor et al., 2011).

Also consistent with other studies investigating correlates of concurrency, sex work was also associated with having concurrent sexual partnerships (Grieb et al., 2012, Mah, 2010, Manhart et al., 2002). This is mostly as a result of the fact that sex work requires multiple sex partners to be able to increase business volumes. Being married or living as married was also associated with having concurrent sexual partnerships (Grieb et al., 2012, Manhart et al., 2002). These might be due to either individual or cultural factors like unmet sexual desire, intra-spousal suspicions of infidelity, male dominance, informal unions and domestic violence among others (Kwena et al., 2014, Fox, 2014). Considering yourself to be at a higher risk of HIV acquisition was also associated with sexual concurrency. This has also been seen in other studies that associated having a current or previous STI, testing HIV positive or using drugs to sexual concurrency (Grieb et al., 2012, Mah, 2010, Manhart et al., 2002).

Based on the risk evaluation of phase II participants using the modelling of inconsistent condom use and multiple sex partnerships, the study demonstrated that the mRDS was effective in recruiting KPs for the survey. The risks evaluated for phase II participants are consistent with those seen in similar studies using standard RDS for different categories of KPs. These included use of RDS in recruiting heterosexual men with multiple partners as seen in an RDS study that examined differences in HIV prevalence and risk behaviours between the two time points. In both surveys, the target population had little difficulty in recruiting others from their social networks that were able to sustain the chain-referral process. With the use of homophily indices that are used to predict whether variables are able to come together or not, Key variables reached equilibrium within one to six recruitment waves and homophily indices showed neither tendencies to in-group nor out-group preferences. The study also showed significant differences in condom use with main sexual partners; numbers of sexual partners; and alcohol consumption (Townsend et al., 2010).

Studies among IDUs also showed consistent results with Malekinejad and colleagues as well as Heckathorn and colleagues presenting consistent findings as follows. In a cross sectional behavioural survey of IDU using RDS in San Francisco, Malekinejad and colleagues were able to use peer referral chains to cross-recruit IDU by diverse demographic characteristics, drug use related behaviours, program access and use, and other factors relevant to reaching and conducting prevention research on this population (Malekinejad et al., 2011). Even though Heckathorn and his colleagues introduced "steering incentives," supplemental rewards for referral of IDUs aged 18-25, their study was able to recruit IDUs effectively. About half of the IDUs were interviewed before introduction of the steering incentives, and another half interviewed afterwards. The study found that steering incentives increased the percentage of younger IDUs sampled by 70% with steering incentives helping to increase recruitment of younger IDUs (Heckathorn et al., 2002).

In three studies tracking trends in HIV prevalence and risk behaviour among MSM between 2004, 2005 and 2006 an application of RDS showed a high prevalence of multiple sex partners, and low consistent condom use. In addition the studies showed that having MSM-friendly HIV testing, STD services, and health provider education contributed greatly to recruitment of MSM in the studies (Ma et al., 2007). Another study using RDS to conduct a behavioural survey among SW and MSM in two urban centres in Papua New Guinea showed that the use of RDS was well accepted and took a short time while minimizing costs and maximising security for staff and respondents (Yeka et al., 2006).

In addition when asked for their self perception of risk, about half of the respondents agreed that they were at risk for HIV acquisition with the spread being similar among those contacted through personal contacts, link persons, peer mobilisation and leaders respectively agreeing they were at risk of HIV acquisition. Self perception of risk has been linked to actual risk as has been seen in SW studies (Coma Auli et al., 2015, Mulieri et al., 2014) as well as adult male and adolescent studies in sub Saharan Africa (Cederbaum et al., 2014, Tenkorang, 2014, Leblanc and Andes, 2015, Khawcharoenporn et al., 2014)

6.4. Phase III: Evaluation of the mRDS in recruitment of KPs into an HIV incidence cohort study

Participants recruited into the study were generally of a younger age below 25 years old. They were also mostly unmarried which might be related to their generally young age. However females were generally separated, divorced or widowed which is consistent with a SW study carried out in the same area in 2007 that proposed that most of the SW were widowed as a result of their husbands having died of AIDS (Vandenhoudt et al., 2013). This might be also be due to the fact that females being generally a bit older than the males in this population (median age of 27 vs. 24 years). Since the study was done in Kisumu town and its catchment area, it was expected that most of the participants to be from the immediate area and belonging to the most dominant tribe of the Luo, and this was true for the study.

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The study reported high unemployment rates that are probably related to the lower education level in the study with about half the respondents being unemployed and an almost similar proportion having primary or lower education. The high rates of unemployment and low education level could also be the cause of the low average monthly income of below KES 2,000 (USD 22) in which almost three quarters of the respondents fell in. The predominant risk groups the participants reported to belong to of SWs, MSM and fisherfolk is consistent with what has been reported in most literature (International HIV/AIDS Alliance, 2010, National AIDS Control Council, 2009a, UNFPA, 2008, Dutta and Maiga, 2011, National AIDS Control Council, 2005, National AIDS Control Council, 2014b, National AIDS and STD Control Programme, 2009, National AIDS Control Council, 2009b, UNAIDS and WHO, 2011, Kissling et al., 2005, Ramjee and Gouws, 2002).

The four different contact strategies used in the study had different yields with use of leaders and personal contacts being the most yielding while link persons and peer mobilisation were the lowest yielding. This is probably due to the trust the respondents place on their leaders

and persons known to them (personal contacts). Even though link persons and peers could also be categorised into people known to the respondents, their yields were the lowest at 13.2% for link persons and 1.3% for peer mobilisation. This was in clear contrast to the results in phase II where link person and peer mobilisation had the highest yields at 26.6% each with use of leader and personal contact yielding 24.6% and 22.2% respectively.

The risk profile for the participants was generally high with evaluation of their behavioural and biomedical characteristics being consistent with the profiles seen in other studies in the region (Gray et al., 2007, Mmbaga et al., 2007a, Mermin et al., 2008, Amornkul et al., 2009, Landman et al., 2008, Morris and Kretzschmar, 1997, Halperin and Epstein, 2007, Meekers et al., 2003, Hearst and Chen, 2004, Vandenhoudt et al., 2013). Male circumcision was generally low among males with more than half not being circumcised which was consistent with the male circumcision trial (Bailey et al., 2007) as well as the general community HIV incidence cohort (Chege et al., 2012) that were done in the same area. Sexual debut was generally at a younger age group with most females engaging in sex with older men while men engaged in sex with females of the same age. Studies done in this region have generally concurred with this including the cross sectional survey of 2003 to 2005 (Amornkul et al., 2004), the HIV incidence cohort of 2007 (Chege et al., 2012), showing that women tended to generally have sex with older men while men tended to have sex with women in the same age groups.

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The high number of multiple sex partnerships seen in this study was further compounded by the low condom use seen in the study. Even though low condom use was predominant amongst stable partnerships, the same partnerships experiencing a high number of multiple partnerships. This negates the perceived 'safety' of these partnerships as the notion of being in a safe relationship that gets extended to the multiple partners who are not necessarily 'safe'. Some of these partnerships involved having unprotected sex with partners of known HIV positive status which could probably be ascribed to those in discordant relationships, or having unprotected sex with persons of unknown HIV status that could just be anyone from the risk categories.

While the 2.9% prevalence of chlamydia was comparable to two other studies done with fisherfolk with a prevalence of 3.2% (Kwena et al., 2010) and SW with a prevalence of 3.4% (Vandenhoudt et al., 2013) and another in the general population with a prevalence of 2.8% (Otieno et al., 2015) in the area, the prevalence of gonorrhoea of 5.0% on the other hand was

higher than the fisherfolk at 1.2% and general population cohort at 2.4% but similar to the SW study at 5.9%. The prevalence of syphilis at 0.4% was lower than any reported in the four studies that had 9.5% (Kwena et al., 2010), 6.4% (Njoroge et al., 2011), 3.4% (Vandenhoudt et al., 2013) and 1.6% (Otieno et al., 2015). The similarities with the SW and the fisherfolk studies done in the same area are probably as a result of enrolments coming from the same population or the reflection of the general sub population prevalence of these infections.

HSV-2 seropositivity was 46.0% which was lower than that seen in the fisherfolk studies at 91.2% (Njoroge et al., 2011) and 58% (Kwena et al., 2010) and the SW study at 83.8% (Vandenhoudt et al., 2013). It was also higher than that seen in KAIS 2012 at 35.1% and the general population cohort at 29.1% (National AIDS and STI Control Programme, 2014, Otieno et al., 2015). The HIV prevalence of 26.2% in this study was higher that that seen in the general population of 5.6% in KAIS 2012 (National AIDS and STI Control Programme, 2014) and 14.8% in a general population cohort in Kisumu (Otieno et al., 2015). It was however comparable to the two fisherfolk studies in the area which reported HIV prevalences of 26% (Kwena et al., 2010) and 28% (Njoroge et al., 2011) and lower than the SW study in the same area at 56.5% (Vandenhoudt et al., 2013). This is probably because the SW study only had females and the female prevalence in the country has always been higher than the male prevalence as seen in KAIS 2012 with female prevalence being 6.9% and male prevalence being 4.4% (National AIDS and STI Control Programme, 2014). The females in this study also had a higher (35.6%) prevalence compared to the males (12.5%) with the HIV prevalence among seeds and recruits being comparable at 29.9% (seeds) and 23.6% (offspring).

The HIV prevalence was higher in older participants probably as a result of having been infected earlier and also higher in HIV negative partners of serodiscordant couples and widowers and SWs which could be a result of the high risk sex they are involved in with HIV positive or individuals of unknown HIV status. Those having lower education also had a higher HIV prevalence which is consistent with what has been reported in literature (Hargreaves and Glynn, 2002, de Walque et al., 2005, Michelo et al., 2006, Mmbaga et al., 2007b, Hargreaves et al., 2008, Amornkul et al., 2009, Birdthistle et al., 2009).

The risk factors associated with HIV acquisition in this study were age group, sex with multiple partners, used drugs in the past 3 months and HSV-2 results. This was seen with

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younger ages, those not reporting sex with multiple partners, not using drugs in the past three months and HSV-2 seropositivity having higher odds of HIV acquisition. This goes against the grain as people reporting multiple sex partners and/or those reporting recreational drug use are generally expected to have higher odds of HIV acquisition (Eicher et al., 2000) (Ndetei, 2004b, Bastos et al., 2005, Amornkul et al., 2009, Apondi et al., 2011, Blower and Boe, 1993, Carnegie and Morris, 2012, Martin et al., 2011). Most of the studies of drug use are centred on IDUs and probably the use of injecting drugs in this study was not that much. Since the bivariate analysis gave the odds of HIV acquisition to be lower among those who used condoms consistently and higher amongst SW and those reporting sex in exchange for money or gifts, these might be the confounders to the multiple sex partners variable.

6.5. Limitations and Bias

Our study has several potential limitations and bias. For phase I, the study staff came up with the initial list of perceived KPs which might have excluded several other KPs such as IDUs. These individuals were further asked to refer people whom they shared similar characteristics with and thus this might have further limited the reach of the study into other KP groups and contributed to selection bias. We also had information bias as we did not collect demographic information for those who did not participate which might have given us an insight into the characteristics of persons refusing to participate. Finally, some participants engaged in behaviour that is deemed criminal by the government and are stigmatised by the public, and this might have affected their responses and introduced some social desirability bias.

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For phase II, we used two behavioural variables as risk indicators. Even though lack of condom use and concurrent partners have consistently been documented as contributing factors to HIV infection, these questions were self reported and the responses might have also been affected by social desirability bias. The groups chosen in this phase were stemming from those who were initially picked by staff in phase I and thus the study could suffer from self selection bias just like in phase I. Some of the participants in this phase were also engaged in behaviour that is deemed criminal by the government and are stigmatised by the public, and this might affected their responses and introduced some social desirability bias. Since specific strategies suggested by the phase I participants were used to contact the participants for phase II, the sample was not probabilistic and the participants cannot be presumed to be representative of the KPs in Kisumu. The referral mechanisms were also limited to the top four strategies while the categories of individuals to be contacted were

limited to those identified in phase I with the monetary incentive also being omitted. This might have also introduced some self selection bias.

For phase III, the study recruited participants using a mRDS which involved respondent referral, there is a probability of participants referring persons who are not actually from similar risk groups as themselves, either for their own benefit or for the benefit of the 'offspring' participants. The study also depended on self report for the behavioural indicators whose validity has been questioned and has the potential of introducing information bias (Peterson et al., 2007b). Finally, it may be that participants in this study who were willing to participate in a one-time interview or survey that required no biological specimen collection and testing may be different than those who would participate in a longitudinal cohort study with biological specimen collection and testing thus comparison of the risk groups in the phases might be misleading.

6.6. Conclusion and Recommendations

The mRDS was successful in recruiting KPs in an HIV prevention trial. This was seen by the high speed of recruitment as well as the risk profiles of those who were recruited. All the 57 phase I participants were recruited in 11 days and they reported to belong 8 different self identified risk groups. Phase II recruited 214 individuals in 2 and half weeks and the individuals came from 4 major occupation groups. Majority of the participants reported inconsistent condom use and having multiple sex partners. The mRDS recruited 2,205 participants into phase III in 6 months and the HIV prevalence was 26.2%. In addition to MSM, SW and transport industry workers, fisherfolk, discordant couples, widowers, street youth, car washers and police also form part of KPs groups. The HIV prevalence was higher amongst these groups compared to general population with discordant couples having the highest HIV prevalence.

The study recommends that mRDS should be used to identify and recruit KPs as it not only allows for faster recruitment of KPs, it also reduces the expense and complexity associated with coupon management in the standard RDS.

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8. APPENDICES

8.1. Appendix 1: Consent Forms

8.1.1. Appendix 1.1: Participant Information Sheet for Qualitative Interviews

Project Title: Use of Modified Respondent Driven Sampling Methodology to Enhance Identification and Recruitment of Most at Risk Persons into an HIV prevention trial in Kisumu, western Kenya.

What is this study about?

This is a research project being conducted by Fredrick Odhiambo Otieno at the University of the Western Cape. We are inviting you to participate in this research project because you belong to a category of persons being considered to be most at risk of HIV acquisition. The purpose of this research project is to identify how to reach most at risk people to take part in HIV prevention research studies and ways to make it easier for them to take part in these studies. These future studies will focus on individuals at high risk for getting HIV and on finding better ways of reducing the chances of people getting HIV.

What will I be asked to do if I agree to participate?

You will be asked to participate in an interview. We will ask you questions about, for instance, your work, your sexual activity, and your opinion about finding people at risk for HIV.

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During the interview you are free to answer or not to answer any question. You can also stop taking part in the interview at any time. If you agree to take part in this study, the information collected from your interview and from interviewing others will be used together to help develop a system of recruiting people into an HIV prevention study. Two people will be helping with this interview. I will be asking you questions and recording your responses. My colleague will be taking notes. We would like you to ask us any questions you have. We also would like you to tell us when you do not understand something. You may take whatever time you need to make your choice. It is important that you fully understand what we are asking.

Would my participation in this study be kept confidential?

We will do our best to keep your personal information confidential. To help protect your confidentiality, we will keep all the recordings and notes of what you say on a locked computer and in a locked cabinet. Only study staff will have access. We will listen to a

recording of your answers and type out what you say. Within approximately 6 months after the last interview in the study, we will destroy the recording. No names will be associated with notes or recordings from the interviews. If we write a report or article about this research project, your identity will be protected to the maximum extent possible.

What are the risks of this research?

There may be some risks from participating in this research study. You may find the questions difficult and some about sexual behaviour may be embarrassing to answer.

What are the benefits of this research?

This research is not designed to help you personally, but the results may help the investigator learn more about how to identify how to reach most at risk people to take part in HIV prevention research studies and ways to make it easier for them to take part in these studies. We hope that, in the future, other people might benefit from this study through improved understanding of how to include persons most at risk of HIV acquisition in HIV prevention studies.

Do I have to be in this research and may I stop participating at any time?

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

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Is any assistance available if I am negatively affected by participating in this study?

If you are negatively affected by participating in this study, study staff will offer you counselling services and if needed, refer you for specialised services.

What if I have questions?

This research is being conducted by Fredrick Odhiambo Otieno, of the School of Public health at the University of the Western Cape. If you have any questions about the research study itself, please contact Fredrick Otieno at the KEMRI/CDC CRC located at the Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), (P.O. Box 1578, Kisumu) on Tel: 0733 981781, or through 057-2022902/59/83

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please

contact:

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This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

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8.1.2. Appendix 1.2: In-depth Interview and Survey Confidentiality Binding Form

Title of Research Project: Use of Modified Respondent Driven Sampling Methodology to Enhance Identification and Recruitment of Most at Risk Persons into an HIV prevention trial in Kisumu, western Kenya.

The study has been described to me in language that I understand and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way. I agree to be audio-taped during my participation in the study.

I also agree not to disclose any information that was discussed during the group discussion.

Participant's name……..

Participant's signature……..

Witness's name……..

Witness's signature……..

Date……

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8.1.3. Appendix 1.3: Participant Information Sheet for Cohort Study

Project Title: Use of Modified Respondent Driven Sampling Methodology to Enhance Identification and Recruitment of Most at Risk Persons into an HIV prevention trial in Kisumu, western Kenya.

What is this study about?

This is a research project being conducted by Fredrick O. Otieno at the University of the Western Cape. We are inviting you to participate in this research project because you may be at a higher risk of HIV acquisition. The purpose of this research project is to help us know what may put people in Kisumu at risk of getting the HIV virus. This study does not focus on people who are already infected with HIV. Instead, it looks at healthy, uninfected men and women.

What will I be asked to do if I agree to participate?

You will be asked to have one study visit today. This visit will take about 5 hours to complete. We will ask you to answer questions about yourself. We will also ask you basic questions about your sexual partners. Most of these questions will be asked on a computer. This will help keep your information private. You will be shown how to use the computer to answer questions. You can ask a staff person for help at any time. We will also ask you to have a medical examination. The examination requires some medical tests. These medical tests include tests for HIV and other sexually transmitted infections (STIs). You will be asked to give blood and urine for these tests. Your blood and urine will not be sold or used for transfusions. It will only be used for research purposes. Women will be asked to use a vaginal swab for STI testing and urine for pregnancy testing. You will also get an HIV test with pre- and post-test counselling. A clinical staff member will explain how this needs to be done. Clinical staff members will ask you questions about any illnesses you have or medicines you are taking. They will use the computer to record your answers. Again, this will help to keep your information private.

Would my participation in this study be kept confidential?

We will do our best to keep your personal information confidential. To help protect your confidentiality, all information you give will be kept private by the study staff. No one else will be told your answers to questions or results of medical tests. Findings from this study will use information from everyone who took part. It will not focus just on your answers and medical test results. You will be given a special study number. This number will be

used on all your study records. Your name will not be on any of these records. Your name and personal information will only be used to reach you. It will not be included in any reports. Overall findings from this study will be shared with the Kisumu community. Nothing about you specifically will be included in these findings. If we write a report or article about this research project, your identity will be protected to the maximum extent possible.

What are the risks of this research?

There may be some risks from participating in this research study. You may not feel that this study is directly helpful to you. You may feel pain when blood is taken from your arm. You may bruise, feel dizzy, or get light-headed. There is a small chance of an infection where the blood is taken from. Clinical staff will use proper procedures to lessen this risk. You may find it hard to answer questions. Some may make you feel embarrassed or uncomfortable. You may be afraid to get your HIV test results. You may be embarrassed that others will find out that you have been tested. You may worry that your HIV test results will be made known to other people. People in your community, including your family, may learn that you are taking part in this study. They may not be pleased that you are doing so.

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What are the benefits of this research?

The benefits to you include this study helping show if you do not have HIV or other STIs. It can get you treatment for some illnesses. It will tell you about what causes HIV and how to prevent spreading it. It may help you to change behaviours that may put you at risk for HIV infection. Your community may learn more about HIV because you have taken part in this study. There is no cost to you for being in the study.

Do I have to be in this research and may I stop participating at any time?

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

Is any assistance available if I am negatively affected by participating in this study?

If you are negatively affected by the study, the study staff will provide you with counselling, management of common ailments and referral for care as appropriate.

What if I have questions?

This research is being conducted by Fredrick Odhiambo Otieno, of the School of Public health at the University of the Western Cape. If you have any questions about the research study itself, please contact Fredrick Otieno at the KEMRI/CDC CRC located at the Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), (P.O. Box 1578, Kisumu) on Tel: 0733 981781, or through 057-2022902/59/83

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

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This research has been approved by the University of the Western Cape's Senate Research Committee and Ethics Committee.

8.1.4. Appendix 1.4: Participant Consent Form to Participate in Cohort Study

Title of Research Project: Use of Modified Respondent Driven Sampling Methodology to Enhance Identification and Recruitment of Most at Risk Persons into an HIV prevention trial in Kisumu, western Kenya.

The study has been described to me in language that I understand and I freely and voluntarily agree to participate.

My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.

Participant's name……..

Participant's signature…….

Witness……

Date……

8.2. Appendix 2: Recruitment Guides

8.2.1. Appendix 2.1: Recruitment Guide for Individual In-Depth Interviews

Hello, my name is _____. I would like to talk to you about how to reach people to take part in HIV prevention research studies. This research involves asking you questions about you, what you think makes someone at high risk for HIV infection, how to find people at high risk for HIV infection, what might motivate people to be part of an HIV research study, and what you know about how much people who might be at high risk for HIV infection move from place to place. To help us know if you might be able to take part in this interview, we will first ask you a couple of questions. If the information you give us shows that you may take part, we will ask for your permission for us to ask you to answer some questions that will last about 60 minutes. At the end of the interview, you will be reimbursed 300 KSH to cover your time and transport expenses.

Verbal consent: Are you willing to first answer two questions about yourself? ☐Yes ☐No

Q1. How old were you on your last birthday? ____ years

Q2. Where do you currently live? _____

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Instruction to interviewer: To be eligible, the person must be between 18-64 years of age <u>and</u> live in Kisumu District.

☐Eligible ☐Not eligible

Do you have any questions? *Instruction to interviewer: Answer any questions.*

Instruction to interviewer: If they are eligible for the interview, proceed to interview .If not, thank them for their time.

Thank you very much for your time.

8.2.2. Appendix 2.2: Recruitment Guide for Cognitive Interviews

Hello, my name is _____. We are conducting a study to find out how to reach people to take part in HIV prevention research studies. I would like to ask you to help us in forming the questions for the study. This research would involve asking you questions about what you think about the questions we already have and the question responses. The questions you would be helping us with involve what makes someone at high risk for HIV infection, how to find people at high risk for HIV infection, what might motivate people to be part of an HIV research study, and what you know about how much people who might be at high risk for HIV infection move from place to place. To help us know if you might be able to take part in this interview, we will first ask you a few questions. If the information you give us shows that you may take part, we will ask for your permission for us to ask you to answer several other questions that will last about 45 minutes. You will be reimbursed 300 KSH to cover your time and transport expenses.

Do you have any questions*? Instruction to interviewer: Answer any questions.*

Did you take part in an interview with KEMRI/CDC staff for an HIV research study in the last 2 months? ☐ Yes ☐ No

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Instruction to interviewer: If "yes", end and thank individual for their time. If "no", proceed to verbal consent.

Verbal consent: Are you willing to first answer two questions about your age and where you live? ☐Yes ☐No

Q1. How old were you on your last birthday? ____ years

Q2. Where do you currently live? _____

Instruction to interviewer : To be eligible, the person must be between 18-64 years of age, live in the Kisumu District and not have taken part in an interview with KEMRI/CDC staff for an HIV research study in the last 2 months.

☐Eligible ☐Not eligible

Do you have any questions*? Instruction to interviewer: Answer any questions.*

Instruction to interviewer: If they are eligible for the cognitive interview, go to Appendix A2. If not, thank them for their time.

Thank you very much for your time.

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8.2.3. Appendix 2.3: Recruitment Guide for Survey Administration

Hello, my name is _____. I would like to talk to you about how to reach people to take part in HIV prevention research studies. This research involves asking you questions about what makes someone at high risk for HIV infection, how to find people at high risk for HIV infection, what might motivate people to be part of an HIV research study, and what you know about how much people who might be at high risk for HIV infection move from place to place. To help us know if you might be able to take part in this interview, we will first ask you a few questions. If the information you give us shows that you may take part, we will ask for your permission for us to ask you to answer other questions that will last about 20 minutes. You will be reimbursed 300 KSH to cover your time and transport expenses.

Do you have any questions*? Instruction to interviewer: Answer any questions.*

Did you take part in an interview with KEMRI/CDC staff for an HIV research study in the last 2 months? ☐ Yes

☐ No

Instruction to interviewer: If "yes", end and thank individual for their time. If "no", proceed to verbal consent.

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Verbal consent: Are you willing to first answer two questions about your age and where you live? ☐Yes

☐No

Q1. How old were you on your last birthday? ____ years

Q2. Where do you currently live?

_____

Instruction to interviewer: To be eligible, the person must be between 18-64 years of age, live in the Kisumu District and not have taken part in an interview with KEMRI/CDC staff for an HIV research study in the last 2 months.

☐Eligible ☐Not eligible

Do you have any questions*? Instruction to interviewer: Answer any questions.*

Instruction to interviewer: If they are eligible for the survey interview, go to Appendix A3. If not, thank them for their time.

Thank you very much for your time.

Note: The strategy used to recruit the participant is noted in the survey.

8.3. Appendix 3: Interview Guides

8.3.1. Appendix 3.1: In-Depth Interview Guide

Thank you for agreeing to take part in this interview. This interview is not a test of your knowledge on the subject. There are no right or wrong answers, but rather differing points of view. Your name will not be connected with anything you say here today. The information collected from you will be used together with information from interview with other people to help us to develop a survey to be given to a larger group of people.

Your responses to the questions I ask will be recorded on this recorder ***[show person the digital recorder and let them hold it for a moment if they wish to].*** Please remember some questions may be sensitive. They may make you feel uncomfortable. You do not have to answer them if you are not willing

[Interviewer should remember the rules of in-depth interviewing; show interest, curiosity, empathy and encouragement. Be flexible, probes need not be asked in the order shown, or at all if the discussion moves that way naturally. This should feel, to the extent possible, like a natural conversation, state your questions in conversational breaks]

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Opening Question (Ice Breaker):

What did you have for lunch? (or similar question)

Demographic questions:

How long have you lived in Kisumu? How do you earn money?

Context of work: (these are general questions that will be tailored to the occupation of the person interviewed e.g. sex workers, long distance drivers, fishermen, saloon workers, fishmongers, others)

How did you come to have your job? [if they have a job]

How long have you been involved in your work?

How are the people in your line of work organized?

Where can they be found?

What do you get in exchange for your work (services)?

How do you find people to purchase your goods/services?

Where do you travel for your work?

Where do you go for health services?

What gets in the way of getting these services?

[For sex workers only]-What rules do you give your clients?

What determines the price of sex acts?

Who are your clients?

Where do they come from?

What other types of sexual partners do you have? (regular partner, concurrent partners, casual partners, others)

Defining what "high risk for HIV infection" means

What do you think makes someone at high risk for getting HIV?

What specific behaviours do you believe put people at high risk for getting HIV? ***[probe: How do you think people get infected with HIV? How do you think people who are infected with HIV transmit the disease to others?]***

Is the respondent at high risk for HIV infection?

Now I would like to ask you some questions about sexual activity:

Are you sexually active? How many partners have you had sex with in the last month?

The last time you had sex, did you or your partner wear a condom?

How often do you or your partner use a condom during sex? ***[probe for at least last 3 sex partners]***

Under what conditions do you/your partner not wear a condom when having sex? ***[probe for at least last 3 sex partners]***

Have you ever been involved with two or more sexual partners during the same period of

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time? ***[probe for concurrency of sexual partnerships by asking first and last time participant had sexual intercourse with each partner, and if they plan to have sexual intercourse again with each partner]***

How do you arrange to have sex when you want to?

Have you had an HIV test? ***[probe: If yes, where did you get tested? How many times have you been tested in total? How did you feel about how you were treated the last time you were tested? Did you reveal to the health care provider that you have sex with men? If no, why not? If yes, in what way and how did the health care provider respond? How did you feel about revealing this information? How did you feel you were treated? What HIV prevention information were you provided? What information or education would have been helpful? Did you receive your test results? If yes, how did learning your test result influence your future sexual behaviour?]***

Do you know someone with HIV? How do you know them?

Finding people at high risk for HIV infection

In your opinion, what group(s) of people do you think are at high risk for HIV infection?

What would be the best way to find them to ask them about being in an HIV research study? ***[probe: Time of day? Days of the week? Venues? How to communicate? Advertisements?]***

Attracting people at high risk for HIV infection to an HIV research study

What would be the best way to approach someone at high risk for HIV infection to ask them to be in an HIV research study?

What would make it convenient for someone at high risk for HIV infection to be part of an HIV research study?

For instance, what are reasons a ***[fill in with the risk group the respondent is most associated with e.g. sex worker, fisherman, trucker, negative partner in a discordant couple]*** might be interested in taking part in a research study?

What would motivate them to participate?

What would inhibit them from participating?

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What would make it difficult for them to participate***? [probe: What would make it inconvenient or not worthwhile?]***

What are the potential threats if they decided to take part in an HIV research study?

Do you think that being in such a study could help them? ***[probe: How?; Do you think that being in such a study could help you? How?]***

Do you think that being in such a study would help your community? ***[probe: How?]***

If you were interested in participating in an HIV research study, would you be willing to spend 1 hour at the clinic every 3 months? ***[probe: 2 hours? 3 hours? 4 hours? 5 or more hours?]***

Practical issues regarding study participation and retention

Do most ***[risk group the respondent is most associated with - sex workers, fisherman, truckers, etc.]*** in Kisumu live here for a long time or do they move?

How long do most of these people stay in Kisumu before moving?

Do you see new people coming here regularly?

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Have you lived in Kisumu for the last three years?

If you were in an HIV research study in Kisumu, would it be difficult for you to get to a study clinic at the New Nyanza Provincial Hospital for visits every 3 months? ***[If yes, probe with "what would make it less difficult? Would it be easier to conduct some study procedures outside of the clinic?]***

If you were in an HIV research study in Kisumu, how would you like to be reminded of your visits? ***[if no response, probe with telephone, home visit, other]***

Would you or your partner be willing to use family planning methods for 2 years if a research study you were interested in required it?

Conclusion

Is there anything else you would like to add at this time that you feel is important?

I do appreciate the time that you took to help us today. The information that you provided

will be used to help us improve a survey to better understand how to recruit persons at high risk for HIV infection to potentially take part in HIV prevention studies. It will also help us know how to best plan to use fingerprinting for identification in future HIV studies. Do you have any questions about the interview or study that we have not answered? [Answer any questions] We will be surveying others in the community in a second stage of the study. If you are approached to complete the survey, it is important that you let the study staff know you have participated in this interview. Thank you very much for your time!

[Present reimbursement]

[Present card with study contact information]

8.3.2. Appendix 3.2: Cognitive Interview Guide

Testing of questions will be carried out to assess if participants will understand the questions and if the responses are culturally appropriate. The interviewer will use the cognitive techniques of "think aloud interviewing" and "probing". The following table modified from Collins (2003) gives some examples of probes that interviewers may use based on the specific question they are testing.

Text: We are interested in your understanding of the questions and if the responses make sense to you, not your responses to the questions. I will read you questions one at a time. I would like for you to tell me how you felt about the question. Next, I will read the response to the question. I would like for you to tell me if you think the choices are appropriate; if not, I would like for you to tell me what the problem is and what suggestions you have for improvement.

Think-aloud general	How did you go about answering that question? Tell me what you are thinking. I noticed you hesitated before you answered—what are you thinking about? How easy or difficult did you find this question to answer? Why do you say that?
Response	How did you feel about answering this question? Did the response options make sense to you? If not, how could they be improved?

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8.4. Appendix 4: Questionnaires

8.4.1. Appendix 4.1: In-Depth Demographic Questionnaire

1. ***Instruction to interviewer:*** Observe whether participant is male or female and check box that applies.

   ☐Male

   ☐Female

   ☐Other (Specify) _____

2. In what day, month and year were you born?
   Day____ Month_____ Year _____

   ☐Other (Specify) _____

3. What is the highest level of school that you attended?
   ☐ Primary

   ☐ Post-primary/vocational

   ☐ Secondary

   ☐ College (Middle level)

   ☐ University

   ☐Other (Specify) _____

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4. How many shillings (KES) did you earn in the last 30 days?
   ☐Less than KES 1000

   ☐1000-2000 KES

   ☐2000-5000 KES

   ☐5000-10, 000 KES

   ☐Over 10, 000 KES

   ☐Other (Specify) _____

5. What is your current marital status?
   ☐Not married but living as married

   ☐Single/Never Married

   ☐Married

   ☐Separated/Divorced

   ☐Widowed

   ☐Inherited

   ☐Other (Specify) _____

6. What is your ethnic group/tribe?
   □ Kikuyu
   □ Masai
   □ Luo
   □ Luhya
   □ Kisii
   □ Luo
   □ Luhya

6a. □ Other (Specify)_____

7. What is your religion?
   □ Roman Catholic
   □ Protestant/Other Christian
   □ Muslim
   □ Hindu
   □ Nomiya
   □ No religion

7a. □ Other (Specify) _____

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8. How long have you lived in Kisumu? _____ months _____ years
   ☐Other (Specify) _____

8.4.2. Appendix 4.2: Survey Questionnaire

Identifying Recruitment Strategies for HIV Research Study

Survey Questionnaire

Date (dd/MMM/yy) ☐☐ ☐☐☐ ☐☐

Study ID: ☐☐☐☐☐☐☐

Encounter site location: □ Beach □ Night-club □ Lodge □ Bar □ Hotel □ Bus stop □ other

Q 1. How did you hear about this study/ how were you contacted for this study? [This question will identify the one or more strategies that served to access this person for the study] (Check all that apply)

☐Strategy 1 ☐Strategy 2 ☐ Strategy 3

(There may be more than 3; Strategies will be more appropriately named)

Q 2. Was this approach of contacting you acceptable?

☐ Yes, it was acceptable for me ☐ No, it was not acceptable for me ☐ **Other (Specify) _____**

If no, is there another approach of contacting you that you would have preferred? _____

Q 3. Age: ☐☐ years

Q 4. Sex:

☐ Male

☐ Female

Q 5. Including yourself, how many people live in your household? _____

☐ Other (Specify)

Q 6. Are you currently working?

☐ Yes

☐ No

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☐ Other (Specify) _____

Q 6. a. What do you do most of the time _____

Q 7. How many shillings (KES) did you earn in the last 30 days? _____ KES earned

Q 8. Have you ever attended school?

☐ Yes

☐ No ***Skip to Q 10***

☐ Other (Specify) _____

Q 9. What is the highest level of school that you have reached?

☐ Primary

☐ Post-primary/vocational

☐ Secondary

☐ College (Middle level)

☐ University

☐ Other (Specify) _____

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Q 10. What is your ethnic group/tribe?

☐ Kikuyu

☐ Maasai

☐ Luo

☐ Luhya

☐ Kisii

☐ Other (Specify)_____

Q 11. What is your religion?

☐ Roman Catholic

☐ Protestant/Other Christian

☐ Muslim

☐ Hindu

☐ Nomiya

☐ No religion

☐ Other (Specify) _____

Q 12. What is your current marital status?

- ☐ Not married but living as married
- ☐ Single/Never Married
- ☐ Married
- ☐ Separated/Divorced
- ☐ Widowed
- ☐ Inherited
- ☐ Other (Specify) _____

Q 13. Have you ever participated in a research study?

- ☐ Yes
- ☐ No
- ☐ Don't know

Q 14. Have you ever been tested for HIV?

- ☐ Yes
- ☐ No
- ☐ Don't know

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Q 14. a. If yes, how many times?_____

Q 14. b. Did you receive the result from your last test?

- ☐ Yes
- ☐ No
- ☐ Don't know

DEFINING WHAT "HIGH RISK FOR HIV INFECTION" MEANS

Q 15. What factors contribute to being at high risk for HIV infection in Kisumu? ***(read all and choose all that apply)***

- ☐ Alcohol use
- ☐ Drug use
- ☐ Widow inheritance
- ☐ Polygamy
- ☐ Not wearing a condom during vaginal sex
- ☐ Not wearing a condom during anal sex
- ☐ Not using lubricants during anal sex
- ☐ Sex work

- ☐ Multiple sex partners
- ☐ Lack of knowledge about HIV
- ☐ Recent sexually transmitted infection
- ☐ Poverty
- ☐ Peer influence to engage in risky behaviours (alcohol/drug use, no condoms)
- ☐ Being involved with two or more sexual partners during a given period of time

IS THE PERSON AT HIGH RISK FOR HIV INFECTION (SELF PERCEPTION AND BEHAVIOUR)

	Agree	Disagree	Don't know
Q 16. My sexual experiences do not put me at risk for HIV/AIDS	☐	☐	☐
Q 17. I may have had sex with someone who was at risk for HIV/AIDS	☐	☐	☐
Q 18. I am at risk for HIV/AIDS	☐	☐	☐
Q 19. There is a possibility that I have HIV/AIDS	☐	☐	☐
Q 19. b. If disagree, how do you prevent/ protect yourself from getting infected? Explain_____	☐	☐	☐
Q 20. There is a possibility that I have an STI	☐	☐	☐
Q 20. b. If disagree, how do you prevent/ protect yourself from getting infected? Explain_____	☐	☐	☐
Q 21. I am comfortable going to a health care provider for health problems	☐	☐	☐
Q 22. I feel like people are staring at me when I go to the health clinic	☐	☐	☐

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Q 23. How many partners have you had sexual intercourse with in the last 3 months?

_____

By sexual intercourse, we mean when a penis is inside a vagina or anus.

Q 24. How long have you been with your current sexual partner only? ___Years ___Months

Q 25. The last time you had sex, did you or your partner wear a condom?

- ☐ Yes
- ☐ No
- ☐ Never had sex

Q 26. Thinking back over the last 3 months, which best describes your use of condoms for sexual intercourse with all of your partners?

- ☐ Did not have vaginal intercourse
- ☐ Most of the time used condoms
- ☐ Never used condoms
- ☐ Used condoms all of the time
- ☐ Sometimes used condoms

Q 27. How often do you use lubricant during anal sex?

- ☐ Most of the time use lubricants
- ☐ Sometimes use lubricants
- ☐ Use lubricants all the time
- ☐ Never use lubricants

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Q 28. Have you been involved with more than one sex partner at the same time during the last 3 months?

- ☐ Yes
- ☐ No

Q 29. Have you ever exchanged sex for money or gifts?

- ☐ Yes
- ☐ No

Q 30. As far as you know, have you ever had sex with a person infected with HIV?

- ☐ Yes
- ☐ No *Skip to Q 31*
- ☐ Don't know

Q 30. a. If yes, how did you learn they had HIV?

☐ Partner told me

☐ Learned from another person

☐ We were tested together

☐ Other

_____

FINDING PEOPLE AT RISK FOR HIV INFECTION

Q 31. Where have you met sexual partners in the last month? (Choose all that apply)

☐ Night club/Disco

☐ Bus stage

☐ Beach

☐ Hotel

☐ Lodging

☐ Bar

☐ Other _____

ATTRACTING PEOPLE AT HIGH RISK FOR HIV INFECTION TO AN HIV RESEARCH STUDY

Q 32. What are reasons that would motivate you to take part in an HIV research study?

[In the first box, check all that apply and in the second box column, check one single box]

All	Main	
☐	☐	Getting HIV education could help you prevent HIV
☐	☐	Getting free HIV treatment and care
☐	☐	Getting other types of free medical care
☐	☐	Helping find a cure for HIV
☐	☐	Getting incentives for taking part
☐	☐	HIV testing and counselling
☐	☐	Getting information on how to take care of yourself if you become HIV infected
☐	☐	Having friends enrol
☐	☐	Being a part of a social group that gets together to talk periodically
☐		Nothing
☐	☐	Other _____

[Of all the above reasons given, which one is the single main reason that would motivate

you to take part in a HIV research study?

Q 33. What are the reasons that would STOP you from taking part in an HIV research study?

[In the first box, check all that apply and in the second box column, check one single box]

All	Main	
☐	☐	Fear of testing positive for HIV
☐	☐	Sexual partner/spouse refusal
☐	☐	Having your personal information made available to others in the community
☐	☐	Others in the community thinking you have HIV
☐	☐	Having to deal with new medical costs that are not covered by the study
☐	☐	Losing your job
☐	☐	Taking too much time away from your job
☐	☐	Having children at home who need you
☐	☐	Taking too much of your blood
☐	☐	Moving out of the area
☐	Nothing	
☐	☐	Other _____

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HEALTH SEEKING BEHAVIORS

Q 34. How comfortable are you seeking health services in the following places?

	Very	Somewhat	Not at all	Do not seek services
Private clinic	☐	☐	☐	☐
Public Hospital	☐	☐	☐	☐
Private Hospital	☐	☐	☐	☐
Pharmacy	☐	☐	☐	☐
Other	☐	☐	☐	☐

Q 34. a. Specify_____

Q 35. Do you receive useful health information from any of the places you receive health services?

☐Yes

☐No

Q 35. a. If Yes, which ones?

☐ Private clinic

☐ Public Hospital

☐ Private Hospital

☐ Pharmacy

☐ Other,

Q 35. b. Specify_____

Q 35. c. If No, where else do you get health information?

Specify_____

SEXUAL IDENTITY

Q 36. How would you describe yourself?

☐ Homosexual

☐ Bisexual

☐ Heterosexual

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Q 37. Do you identify more as a woman or a man?

☐ Woman

☐ Man

Q 38. Do you consider yourself transgender/transsexual?

☐Yes

☐No

Q 39. Would you like to change your body through hormones or surgery?

☐Yes

☐No

Q 40. Do you belong to any group supporting your sexual identity?

☐Yes

☐No

Q 40. a. If Yes, specify_____

Q 41. Do you know of any men who have sex with men who are hesitant to disclose this information to friends?

☐Yes

☐No

Q 41. a. If yes, explain why that is so_____

Q 42. Do you know of any other people who identify themselves as MSM, yet you think they are not?

☐Yes

☐No

Q 42. a. If yes, explain why is that so?_____

SEXUAL PRACTICES

Q 43. What sexual practice do you engage in most frequently? (Choose 1)

- ☐ Insertive/penetrative anal sex
- ☐ Receptive anal sex
- ☐ Both Insertive/penetrative and receptive anal sex equally
- ☐ Frottage (Rubbing body or genitals with partner)
- ☐ Oral sex
- ☐ All of the above
- ☐ Other

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Q 43. a. Specify _____

PRACTICAL ISSUES REGARDING STUDY PARTICIPATION AND RETENTION

Q 44. Have you lived in Kisumu for the last three consecutive years?

- ☐ Yes
- ☐ No

Q 45. If you were in an HIV research study in Kisumu, would it be difficult for you to get to the New Nyanza Provincial Hospital for visits every 3 months?

- ☐ Yes
- ☐ No ***Skip to Q 46***
- ☐ Not sure

Q 45. a. If Yes, what might make it less difficult?

_____

Q 46. If you were in an HIV research study in Kisumu, how would you like to be reminded of your visits?

- ☐ In-person home visit
- ☐ Telephone call
- ☐ Other _____

Q 47. Would you or your partner be willing to use family planning methods (e.g. oral contraceptive) for 2 years if a research study you were interested in required it?

- ☐ Yes
- ☐ No
- ☐ Not sure

Q 48. Would you be willing to be contacted to participate in a future HIV research study?

- ☐ Yes
- ☐ No
- ☐ Not sure

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Q 49. What is the maximum amount of time you would be willing to spend at the clinic for one visit?

- ☐ Less than 1 hour
- ☐ 1 hour
- ☐ 2 hours
- ☐ 3 hours
- ☐ 4 hours
- ☐ 5 hours
- ☐ 6 hours

Q 50. How much money would it cost you for transport to get from your home to the clinic? _____ KSH

END

8.4.3. Appendix 4.3: Pre Screening for Basic Eligibility Questionnaire

CAPI PRE-SCREENING FOR BASIC ELIGIBILITY

READ: Hello, my name is [insert name]. Thank you for your interest in this study. Before we begin, we would like to explain that there are many reasons why a person may not be included in the study. Not everyone who wishes to get into the study will do so. To help us figure out if you might be included, we will need you to answer some basic questions. If the information you give us shows that you might be suitable for the study, we will ask you more questions, get a medical history from you, and run some medical tests. If your answers to our questions show that you should be included and your medical tests show that you are healthy, you will then be invited to take part.

I will ask you questions and put your answers into the computer. This will help keep your information private.

Do you have any questions before we start?

SBE1. [Instruction to the Interviewer] Please enter the computer name. __ __ __ __ __ __

SBE2. *[Instruction to the Interviewer]* Please enter the participant ID. __ __ __ __ __ __

SBE3. *[Instruction to the Interviewer]* Please re-enter the participant ID. __ __ __ __ __ __

SBE4. *[Instruction to the interviewer]* Please enter the interview language. (Choose one)

1 English

2 Swahili

3 Luo

SBE5. *[Instruction to the interviewer]* Please enter the gender of the participant

1 Male

2 Female

SBE6. *[Instruction to the Interviewer]* Please enter your staff ID. __ __ __

SBE7. On what day, month and year were you born?

__ __ / __ __ / __ __ __ __ mm / dd / yyyy

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SBE8. How old were you at your last birthday? __ __

SBE9. Among the following districts, which district do you currently reside? *[Please read all responses and then choose one]* (Choose one)

1 Kisumu District
2 Nandi District
3 Vihiga District
4 Nyando District
5 Other district

If SBE9 is not equal to 5, then skip to instruction before SBE11.

SBE10. What district do you currently reside in? __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ –

SBE11. Within the past two years, have you ever moved out of [Response to SBE9]?

1 Yes
0 No ***Skip to SBE18***

SBE12. Did you move out of [Response to SBE9] for at least 3 consecutive months?

1 Yes
0 No ***Skip to SBE18***

SBE13. What are the reasons you moved out of [Response to SBE9]? *(Check all that apply)*

__ Not enough land
__ Build a new home
__ Attend boarding school
__ Look for a job
__ Start your household elsewhere
__ Join your spouse's/partner's family
__ Join your spouse/partner
__ Further your education
__ Asked to leave
__ Personal or community conflict
__ Committed a crime or harmed someone

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__ Some other reason

If SBE13L is equal to 0, then skip to SBE15.

SBE14. What was the other reason why you moved out of [Response to SBE9]?

__ __

__ __

__ __ __ __ __ __

SBE15. Of the reasons you mentioned, which one is the main reason for leaving [Response to SBE9]? (Choose one)

01 Not enough land
02 Build a new home
03 Attend boarding school
04 Look for a job
05 Start your household elsewhere
06 Join your spouse's/partner's family
07 Join your spouse/partner
08 Further your education
09 Asked to leave
10 Personal or community conflict
11 Committed a crime or harmed someone
12 Some other reason

SBE16. When you moved out of the [Response to SBE9], where did you move to? ***[Please read all responses and then choose one]***

1 Another District in Nyanza Province
2 Another District in Kenya outside of Nyanza Province
3 Outside Kenya

If SBE16 is equal to 3, then skip to SBE18.

SBE17. Please specify [Response to SBE16]. __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

__ __ __

SBE18. If you are found to be suitable to take part in the study, are you willing to come

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in for study visits every 3 months for one year?

1 Yes

0 No

SBE19. If you are found to be suitable to take part in the study, are you willing to give study staff detailed information about how they can reach you?

1 Yes

0 No

SBE20. During the past 3 months, have you had sexual intercourse one or more times? By sexual intercourse, we mean times that a penis is inside the vagina or anus.

1 Yes

0 No

SBE21. Are you willing to get an HIV test as part of being in this study?

1 Yes

0 No

SBE22. If you got tested for HIV, would you be willing to get the results of your test?

1 Yes

0 No

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SBE23. Do you plan to move away from Kisumu within the next 12 months?

1 Yes

0 No ***Skip to SBE25***

SBE24. Will you be gone for 3 consecutive months or longer?

1 Yes

0 No

9 Not Applicable

SBE25. Are you currently taking part in an HIV study where you are receiving any biomedical intervention to reduce risk of HIV infection?

1 Yes

0 No

SBE26. Have you ever been told by a doctor, nurse, or VCT counsellor that your blood test results show that you are infected with HIV?

1 Yes

0 No

If SBE5 is equal to 1, then skip to instruction before SBE35.

SBE27. (Ask of Women Only) Are you currently pregnant?

1 Yes ***Skip to instruction before SBE35***

0 No

7 Don't Know

8 Refuse to Answer

9 Not Applicable

SBE28. (Ask of Women Only) Do you intend to become pregnant within the next 12 months?

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

9 Not Applicable

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High Risk Determination

Thank you for the information you have given us. Please remember that to help us find out what your sexual practices are, we need to ask very personal questions. Remember, that your name is not linked to the answers you give us and that what you enter into the computer will not be shared with anyone.

SBE 30. Did you have a sexual partner who is infected with HIV in the last 12 months?

01 Yes

00 No

SBE 31. Did you have vaginal or anal sexual intercourse with an anonymous partner who could not be contacted again in the last 12 months?

01 Yes

00 No

SBE 32. Did you have vaginal or anal sex in exchange for money, goods or services in the last 12 months?

01 Yes

00 No

SBE 33. Did you have vaginal or anal sex with 2 or more partners in the last 12 months?

01 Yes

00 No

SBE 34. Did you have a sexually transmitted infection (STI) in the last 12 months?

01 Yes

00 No

Thank you very much for taking time to answer these questions. Based on your responses, you [STATUSE]

Do you have any questions for me?

8.4.4. Appendix 4.4: Refusal Questionnaire

CAPI REFUSAL QUESTIONNAIRE

Q1. *[Instruction to the Interviewer]* Please enter the computer name. __ __ __ __ __ __

Q2. *[Instruction to the Interviewer]* Please enter the participant ID. __ __ __ __ __ __

Q3. *[Instruction to the Interviewer]* Please re-enter the participant ID. __ __ __ __ __ __

Q4. *[Instruction to the Interviewer]* Please enter the interview language. (Choose one)

1 English

2 Swahili

3 Luo

Q5. *[Instruction to the Interviewer]* Please enter the gender of the participant.

1 Male

2 Female

Q6. *[Instruction to the Interviewer]* Please enter your staff ID. __ __ __

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READ: Thank you for your interest in this study today, we understand that you do not wish to continue with this study.

Q7. Is this correct?

1 Yes

0 No

8 Refuse to Answer

If Q7 is equal to 0 or Q7 is equal to 8, then skip to instruction before Q21.

READ: We would like to better understand the reasons why people may not want to be in this study, in order to assist in designing future studies better.

Q8. Would you be willing to answer questions about your decision not to take part in this study?

1 Yes

0 No

8 Refuse to Answer

If Q8 is equal to 0 or Q8 is equal to 8, then skip to instruction before Q21.

Q9. Did you decide not to take part because you did not want to get tested for HIV?

1 Yes

0 No

8 Refuse to Answer

Q10. Did you decide not to take part because you did not want to know your HIV status?

1 Yes

0 No

8 Refuse to Answer

Q11. Did you decide not to take part because you are afraid of what people will think if they see you coming here?

1 Yes

0 No

8 Refuse to Answer

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Q12. Did you decide not to take part because if you learnt that you were HIV infected, you would not be given AIDS drugs (ARVs)?

1 Yes

0 No

8 Refuse to Answer

Q13. Did you decide not to take part because you do not want your blood to be taken by study staff?

1 Yes

0 No

8 Refuse to Answer

Q14. Did you decide not to take part because you are concerned that your blood would be sold or used for other purposes?

1 Yes

0 No

8 Refuse to Answer

Q15. Did you decide not to take part because you are concerned about the volume of blood that may be taken?

1 Yes

0 No

8 Refuse to Answer

Q16. Did you decide not to take part because you do not believe that HIV/AIDS exists?

1 Yes

0 No

8 Refuse to Answer

Q17. Did you decide not to take part because you would prefer to wait and see what happens with the study before you agree to take part?

1 Yes

0 No

8 Refuse to Answer

Q18. Did you decide not to take part because you must travel a distance, so coming for study visits is too difficult for you?

1 Yes

0 No

8 Refuse to Answer

Q19. Did you decide not to take part because of any other reasons?

1 Yes

0 No

8 Refuse to Answer

Q20. What is the main reason why you decided not to be in the study? (Choose one)

01 You do not want to get tested for HIV

02 You do not want to know your HIV status

03 You are afraid of what people will think if they see you coming here

04 If you learn you are HIV infected, you will not be given AIDS drugs (ARVs)

05 You do not want your blood to be taken by KEMRI/CDC

06 You are concerned that your blood would be sold or used for other purposes

07 You are concerned about the volume of blood that may be taken

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08 You do not believe that HIV/AIDS exists

09 You would prefer to wait and see what happens with study before you agree to take part

10 You must travel a long distance, so coming for study visits is too difficult for you

11 You do not want to take part because of another reason

98 Refuse to Answer

READ: You have reached the end of this interview. We greatly appreciate your interest in this study and the feedback you have given us. Thank you!

If you have any questions you may ask the study staff.

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8.4.5. Appendix 4.5: Cohort Main Study Questionnaire

ACASI STUDY QUESTIONNAIRE

Q1. ***[Instruction to the Interviewer]*** **Please enter the computer name.__ __ __ __ __ __**

Q2. ***[Instruction to the Interviewer]*** **Please enter the participant ID. __ __ __ __ __ __**

Q3. ***[Instruction to the Interviewer]*** **Please re-enter the participant ID. __ __ __ __ __ __**

Q4. [Instruction to the Interviewer] Please enter the interview language. (Choose one)

1 English
2 Swahili
3 Luo

Q5. [Instruction to the Interviewer] Please enter the gender of the participant.

1 Male
2 Female

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Q6. ***[Instruction to the Interviewer]*** **Please enter your staff ID. __ __ __**

Welcome to the Kisumu Incidence Cohort Study! As you have been told earlier, the interview will be done using this computer. No one will view your answers during the interview. Your answers will be stored securely and your name will not appear anywhere on this interview. Your answers will be kept privately and will not be shared with unauthorized people. Please answer all the questions truthfully. No one will judge you based on your answers. Your answers will help us better understand risk factors for new HIV infections among people in Kisumu and surrounding areas. This will also help us prepare well for future studies looking at ways to prevent HIV infections.

PLEASE "PRESS NEXT QUESTION BUTTON" TO START

We will be asking you questions about your experiences and behaviours. This is not a test. No one will judge you based on your answers. Your answers will not be shared with anyone outside of the study. We would like to begin by asking you questions about yourself.

Demographics Section

DEM1. What is your ethnic group or tribe? (Choose one)

1 Luo
2 Luhya
3 Kisii
4 Kikuyu
5 Maasai
6 Other
8 Refuse to Answer

DEM2. What is your religion? (Choose one)

1 Roman Catholic
2 Protestant or other Christian
3 Muslim
4 Hindu
5 Nomiya
6 No religion
7 Other
8 Refuse to Answer

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DEM3. Are you currently a student?

1 Yes
0 No
8 Refuse to Answer

If DEM3 is equal to 1, then skip to DEM5.

DEM4. Have you ever attended school?

1 Yes
0 No
8 Refuse to Answer

If DEM4 is equal to 0 or DEM4 is equal to 8, then skip to DEM11.

DEM5. What is the highest level of schooling you are attending or have ever attended? (Choose one)

1 Primary

2 Secondary

3 Technical training

4 College

5 University

8 Refuse to Answer

If DEM5 is not equal to 1, then skip to instruction before DEM7.

DEM6. What is the highest standard you completed? __ __

98 Refuse to Answer

If DEM5 is not equal to 2, then skip to instruction before DEM8.

DEM7. What is the highest form you completed at that level? __

8 Refuse to Answer

If DEM5 is not equal to 3, then skip to instruction before DEM9.

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DEM8. What is the highest year you completed at that level? __

8 Refuse to Answer

If DEM5 is not equal to 4, then skip to instruction before DEM10.

DEM9. What is the highest year you completed at that level? __

8 Refuse to Answer

If DEM5 is not equal to 5, then skip to DEM11.

DEM10. What is the highest year that you have completed at that level? __ __

98 Refuse to Answer

DEM11. Are you currently working? This includes if you work in your own home.

1 Yes

0 No

8 Refuse to Answer

If DEM11 is equal to 0 or DEM11 is equal to 8, then skip to MG1.

DEM12. What type of work do you do most of the time? (Choose one)

1 Farmer
2 Salaried worker (e.g. teacher, nurse)
3 Casual worker
4 Self-employed
5 Homemaker
6 Other
8 Refuse to Answer

DEM13. How many Kenya shillings did you earn in the last 30 days?

— — — — — — — — —
999999998 Refuse to Answer

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MG1. In the last 3 months, how many nights did you spend away from your village or home? (Choose one)

1 None
2 One night
3 Two nights
4 3 or more nights
8 Refuse to Answer

If MG1 is equal to 1 or MG1 is equal to 8, then skip to instruction before MG3.

MG2. In the last 3 months, what is the longest time that you have been away from your home? (Choose one)

1 Less than one week
2 Between one week and one month
3 More than one month
8 Refuse to Answer

Now, we would like to ask you questions about your household.

MG3. Are you the head of the household?

1 Yes

0 No

8 Refuse to Answer

MG4. Including yourself, how many people live in your house? __ __

98 Refuse to Answer

MG5. What is the main source of drinking water for members of your household? (Choose one)

1 Water that is piped into the compound

2 Water from a well on your land

3 Water from a public tap or well

4 Water from a river, stream, lake or pond

5 Rainwater

8 Refuse to Answer

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MG6. What kind of toilet facility does your household have? (Choose one)

1 Own flush toilet

2 Shared flush toilet

3 Traditional pit/latrine

4 Ventilated improved pit/latrine (VIP)

5 Bush or field

6 Other

8 Refuse to Answer

DEM17. Do you or any member of your household own a bicycle?

1 Yes

0 No

8 Refuse to Answer

DEM18. Do you or any member of your household own a motorcycle?

1 Yes

0 No

8 Refuse to Answer

DEM19. Do you or any member of your household own a car?

1 Yes

0 No

8 Refuse to Answer

DEM20. Does your household have electricity?

1 Yes

0 No

8 Refuse to Answer

DEM21. Does your household have a radio?

1 Yes

0 No

8 Refuse to Answer

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DEM22. Does your household have a television?

1 Yes

0 No

8 Refuse to Answer

DEM23. Does your household have a telephone or a mobile phone?

1 Yes

0 No

8 Refuse to Answer

DEM24. Does your household have a refrigerator?

1 Yes

0 No

8 Refuse to Answer

DEM25. What is the main material of the floor of your house? (Choose one)

1 Mud or murram, dung or sand

2 Wood planks

3 Polished wood, vinyl or tiles

4 Cement

8 Refuse to Answer

DEM26. What is the main material of the roof of your house? (Choose one)

1 Grass or thatch

2 Corrugated iron

3 Tiles

8 Refuse to Answer

Parenthood

Now, we would like to ask you questions about your family.

If Q5 is equal to 1, then skip to PH8.

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PH1. Have you ever given birth to any children who are currently living?

1 Yes

0 No

8 Refuse to Answer

If PH1 is equal to 0 or PH1 is equal to 8, then skip to instruction before PH6.

PH2. Think only about children that you have given birth to and that are currently living. How many of these children are sons? __ __

98 Refuse to Answer

If PH2 is equal to 0 or PH2 is equal to 98, then skip to PH4.

PH3. How many of these sons live with you? __ __

98 Refuse to Answer

PH4. Think only about children that you have given birth to and that are currently living. How many of these children are daughters? __ __

98 Refuse to Answer

If PH4 is equal to 0 or PH4 is equal to 98, then skip to instruction before PH6.

PH5. How many of these daughters live with you? __ __

98 Refuse to Answer

Sometimes it happens that children die. It may be painful to talk about this and we are sorry to ask you about painful memories, but it is important to get correct information.

PH6. Have you ever given birth to a son or daughter who was born alive but later died?

1 Yes

0 No

8 Refuse to Answer

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If PH6 is equal to 0 or PH6 is equal to 8, then skip to instruction before PM1.

PH7. How many of your children were born alive but later died? __ __

98 Refuse to Answer

If Q5 is equal to 2, then skip to instruction before PM1.

PH8. Have you ever fathered any children that are currently living?

1 Yes

0 No

8 Refuse to Answer

If PH8 is equal to 0 or PH8 is equal to 8, then skip to instruction before PH13.

PH9. Think only about children that you have fathered and that are currently living. How many of these children are sons? __ __

98 Refuse to Answer

If PH9 is equal to 0 or PH9 is equal to 98, then skip to PH11.

PH10. How many of these sons live with you? __ __

98 Refuse to Answer

PH11. Think only about children that you have fathered and that are currently living. How many of these children are daughters? __ __

98 Refuse to Answer

If PH11 is equal to 0 or PH11 is equal to 98, then skip to instruction before PH13.

PH12. How many of these daughters live with you? __ __

98 Refuse to Answer

Sometimes it happens that children die. It may be painful to talk about this and we are sorry to ask you about painful memories, but it is important to get correct information.

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PH13. Have you ever fathered a son or daughter who was born alive but later died?

1 Yes

0 No

8 Refuse to Answer

If PH13 is equal to 0 or PH13 is equal to 8, then skip to instruction before PM1.

PH14. How many of your children were born alive but later died? __ __

98 Refuse to Answer

Partnerships/Marriage

Now, we will ask you questions about sexual partnerships and marriage. By marriage we mean a legal, religious or customary agreement. It can also mean a man and woman living together as married.

PM1. What is your current marital status? (Choose one)

1 Single/Never married

2 Not married, but living as married

3 Married

4 Separated/Divorced

5 Widowed

8 Refuse to Answer

If Q5 is equal to 2 and PM1 is equal to 1 or Q5 is equal to 2 and PM1 is equal to 8, then skip to OTH1.

If Q5 is equal to 1 and PM1 is equal to 1 or Q5 is equal to 1 and PM1 is equal to 8, then skip to instruction before PM9.

If PM1 is equal to 2, then skip to instruction before PM7.

If Q5 is equal to 1 and PM1 is equal to 3, then skip to PM4.

If Q5 is equal to 2 and PM1 is equal to 3, then skip to instruction before PM2.

If PM1 is equal to 4 or PM1 is equal to 5, then skip to instruction before PM8.

If Q5 is equal to 1 and PM1 is not equal to 3, then skip to PM4.

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PM2. Does your husband have other wives?

1 Yes

0 No

8 Refuse to Answer

If PM2 is equal to 0 or PM2 is equal to 8, then skip to instruction before PM6.

PM3. (Ask of Women Only) Including yourself, how many total wives does your husband have right now? __ __

98 Refuse to Answer

If Q5 is equal to 2, then skip to instruction before PM6.

PM4. Do you have more than one wife?

1 Yes

0 No

8 Refuse to Answer

If PM4 is equal to 0 or PM4 is equal to 8, then skip to instruction before PM6.

PM5. (Ask of Men Only) How many total wives do you have right now? __ __

98 Refuse to Answer

If PM1 is equal to 2, then skip to instruction before PM7.

PM6. Before you married one another, had your spouse ever been married or lived as married with someone else?

1 Yes

0 No

8 Refuse to Answer

If PM1 is equal to 3, then skip to instruction before PM8.

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PM7. Before you started living together, had your partner ever been married or lived as married with someone else?

1 Yes

0 No

8 Refuse to Answer

If Q5 is equal to 1, then skip to instruction before PM9.
If Q5 is equal to 2 and PM1 is equal to 1, then skip to instruction before MTV1.

PM8. In the last 3 months, were you inherited?

1 Yes

0 No

8 Refuse to Answer

If Q5 is equal to 2, then skip to instruction before MTV1.

PM9. In the last 3 months, did you inherit a wife?

1 Yes

0 No

8 Refuse to Answer

Other Partner

OTH1. Is there currently someone with whom you have sexual intercourse on a regular or on-going basis?

1 Yes

0 No

8 Refuse to Answer

OTH2. Is there currently someone with whom you only have sexual intercourse with every now and then?

1 Yes

0 No

8 Refuse to Answer

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OTH3. Is there currently someone with whom you have had sexual intercourse with only once?

1 Yes

0 No

8 Refuse to Answer

OTH4. Is there currently a person who gives you or you give money or other gifts for sex?

1 Yes

0 No

8 Refuse to Answer

Motivation for Participation

We are interested in what influenced you to take part in this study. It is important that you know that none of these next set of questions have right or wrong answers. We want to learn what is important to you.

MTV1. Did you want to take part in the study because you would get free counselling

and HIV testing?

1 Yes

0 No

8 Refuse to Answer

MTV2. Did you want to take part in the study because you would get care for sexually transmitted infections and common illnesses?

1 Yes

0 No

8 Refuse to Answer

MTV3. Did you want to take part in the study because you would be able to share with others in your community what you learned about HIV?

1 Yes

0 No

8 Refuse to Answer

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MTV4. Did you want to take part in the study because you would get incentives?

1 Yes

0 No

8 Refuse to Answer

MTV5. Did you want to take part in the study because you would learn more about what causes HIV?

1 Yes

0 No

8 Refuse to Answer

MTV6. Did you want to take part in the study because you will find out what behaviours to avoid so that you do not get HIV?

1 Yes

0 No

8 Refuse to Answer

MTV7. Did you want to take part in the study because you would be able to help control the spread of HIV/AIDS in your community?

1 Yes

0 No

8 Refuse to Answer

MTV8. Did you want to take part in the study because of other reasons?

1 Yes

0 No

8 Refuse to Answer

MTV9. Of the following reasons listed, which best fits your reason for wanting to be part of this study? (Choose one)

01 Get free counselling and HIV testing

02 Get other free medical tests and care for sexually transmitted infections and common illnesses

03 Learn about HIV and share with others in your community

04 Get incentives

05 Learn more about what causes HIV

06 Find out what behaviours to avoid so that you do not get HIV

07 Help control the spread of HIV/AIDS in your community

08 Other reasons

98 Refuse to Answer

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Alcohol Use

The next set of questions is about alcohol use. We will ask you about drinking beer, wine, spirits, and other types of alcohol like busaa or chang'aa. Please remember that your answers are very important to us. All the information you share with us will be kept private.

AL1. In the last 3 months, did you have any types of alcoholic drinks?

1 Yes

0 No

8 Refuse to Answer

If AL1 is equal to 0 or AL1 is equal to 8, then skip to instruction before DRG1.

AL2. In the last 3 months, did you drink beer?

1 Yes

0 No

8 Refuse to Answer

If AL2 is equal to 0 or AL2 is equal to 8, then skip to AL4.

AL3. In the last 3 months, how often did you drink beer? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

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AL4. In the last 3 months, did you drink busaa?

1 Yes

0 No

8 Refuse to Answer

If AL4 is equal to 0 or AL4 is equal to 8, then skip to AL6.

AL5. In the last 3 months, how often did you drink busaa? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

AL6. In the last 3 months, did you drink wine?

1 Yes

0 No

8 Refuse to Answer

If AL6 is equal to 0 or AL6 is equal to 8, then skip to AL8.

AL7. In the last 3 months, how often did you drink wine? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

AL8. In the last 3 months, did you drink spirits?

1 Yes

0 No

8 Refuse to Answer

If AL8 is equal to 0 or AL8 is equal to 8, then skip to AL10.

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AL9. In the last 3 months, how often did you drink spirits? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

AL10. In the last 3 months, did you drink chang'aa?

1 Yes

0 No

8 Refuse to Answer

If AL10 is equal to 0 or AL10 is equal to 8, then skip to AL12.

AL11. In the last 3 months, how often did you drink chang'aa? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

AL12. In the last 3 months, did you drink any other alcoholic drink?

1 Yes

0 No

8 Refuse to Answer

If AL12 is equal to 0 or AL12 is equal to 8, then skip to instruction before DRG1.

AL13. In the last 3 months, how often did you drink other alcoholic drinks? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

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Drug Use

We would now like to ask you about drug use. Here, we are only interested in drugs that you may have used to help you relax, increase your energy, or to have a good time. These include drugs like mandrax, bhang, miraa, heroin, cocaine, valium, glue and kuber. These questions are not about drugs that you have used to help treat an illness or disease.

DRG1. In the last 3 months, did you use any drugs?

1 Yes

0 No

8 Refuse to Answer

If DRG1 is equal to 0 or DRG1 is equal to 8, then skip to instruction before SH1.

DRG2. In the last 3 months, did you use bhang?

1 Yes

0 No

8 Refuse to Answer

If DRG2 is equal to 0 or DRG2 is equal to 8, then skip to DRG4.

DRG3. In the last 3 months, how often did you use bhang? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

DRG4. In the last 3 months, did you use mandrax?

1 Yes

0 No

8 Refuse to Answer

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If DRG4 is equal to 0 or DRG4 is equal to 8, then skip to DRG6.

DRG5. In the last 3 months, how often did you use mandrax? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

DRG6. In the last 3 months, did you use valium?

1 Yes

0 No

8 Refuse to Answer

If DRG6 is equal to 0 or DRG6 is equal to 8, then skip to DRG8.

DRG7. In the last 3 months, how often did you use valium? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

DRG8. In the last 3 months, did you use glue?

1 Yes

0 No

8 Refuse to Answer

If DRG8 is equal to 0 or DRG8 is equal to 8, then skip to DRG10.

DRG9. In the last 3 months, how often did you use glue? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

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DRG10. In the last 3 months, did you use miraa?

1 Yes

0 No

8 Refuse to Answer

If DRG10 is equal to 0 or DRG10 is equal to 8, then skip to DRG12.

DRG11. In the last 3 months, how often did you use miraa? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

DRG12. In the last 3 months, did you use kuber?

1 Yes

0 No

8 Refuse to Answer

If DRG12 is equal to 0 or DRG12 is equal to 8, then skip to DRG14.

DRG13. In the last 3 months, how often did you use kuber? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

DRG14. In the last 3 months, did you use cocaine?

1 Yes

0 No

8 Refuse to Answer

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If DRG14 is equal to 0 or DRG14 is equal to 8, then skip to DRG16.

DRG15. In the last 3 months, how often did you use cocaine? (Choose one)

1 Once in three months

2 1 to 3 times a month

3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

DRG16. In the last 3 months, did you use heroin?

1 Yes

0 No

8 Refuse to Answer

If DRG16 is equal to 0 or DRG16 is equal to 8, then skip to DRG18.

DRG17. In the last 3 months, how often did you use heroin? (Choose one)

1 Once in three months
2 1 to 3 times a month
3 1 to 3 times a week
4 Every day or nearly every day
8 Refuse to Answer

DRG18. In the last 3 months, did you use any other drug?

1 Yes
0 No
8 Refuse to Answer

If DRG18 is equal to 0 or DRG18 is equal to 8, then skip to DRG20.

DRG19. In the last 3 months, how often did you use other drugs? (Choose one)

1 Once in three months
2 1 to 3 times a month
3 1 to 3 times a week
4 Every day or nearly every day
8 Refuse to Answer

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DRG20. Not including drugs that are used to treat illnesses or diseases, did you inject any drugs in the last 3 months?

1 Yes
0 No
8 Refuse to Answer

If DRG20 is equal to 0 or DRG20 is equal to 8, then skip to instruction before SH1.

DRG21. In the last 3 months, how often did you inject drugs? (Choose one)

1 Once in three months
2 1 to 3 times a month
3 1 to 3 times a week

4 Every day or nearly every day

8 Refuse to Answer

Sexual History

The next set of questions focus on sexual intercourse. By sexual intercourse, we mean times that a penis is inside the vagina or anus. We would like for you to think about all the people that you have had sexual intercourse with. This includes times that you did want to have sexual intercourse and times that you did not want to have sexual intercourse.

Your answers are very important to us. We would like for you to be honest and truthful. It may make you feel uncomfortable to answer these questions. Please remember that no one will know your answers.

For the next set of questions please think about the first time you had sexual intercourse, even if it was with someone who had sex with you only once, including sexual intercourse during special occasions, or sex with someone that you did not want to have sex with.

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SH1. How old were you the first time that you had sexual intercourse? __ __

98 Refuse to Answer

SH2. The first time you had sexual intercourse, was any type of alcohol involved?

1 Yes

0 No

8 Refuse to Answer

SH3. The first time you had sexual intercourse, were any drugs involved?

1 Yes

0 No

8 Refuse to Answer

SH4. Was the person that you had sexual intercourse with for the first time male or female?

1 Male

2 Female

8 Refuse to Answer

SH5. What was the age of the person with whom you first had sexual intercourse? (Choose one)

1 About your age

2 5 or less years younger

3 5 or more years older

8 Refuse to Answer

SH6. When you had sex for the first time, how long had you known each other before you had sexual intercourse? (Choose one)

1 Hours

2 Days

3 Weeks

4 Months

5 Years

8 Refuse to Answer

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SH7. What best describes the first time you had sex? (Choose one)

1 You wanted to have sexual intercourse

2 You did not plan on having sexual intercourse, but it happened anyway

3 You wanted to delay sexual intercourse but felt pressured

4 You did not want to have sexual intercourse, but you were physically forced

5 You did not want to have sexual intercourse, but you were tricked into doing so

8 Refuse to Answer

SH8. Did you have sexual intercourse with this person again?

1 Yes

0 No

8 Refuse to Answer

SH9. What was this person's relationship to you? (Choose one)

01 Spouse

02 Boyfriend/girlfriend

03 Some other type of friend

04 Brother/sister in-law

05 A relative, living in the same house

06 A relative, not living in the same house

07 A neighbour

08 Somebody with authority in the community

09 Non-relative, but a person that you know

10 Non-relative and a person you never met before

98 Refuse to Answer

SH10. Did this person give you something like money, gifts, or other favours for having sexual intercourse with him or her?

1 Yes

0 No

8 Refuse to Answer

If SH10 is equal to 0 or SH10 is equal to 8, then skip to SH18.

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SH11. Did you receive food or non-alcoholic drink for having sexual intercourse with this person?

1 Yes

0 No

8 Refuse to Answer

SH12. Did you receive alcohol for having sexual intercourse with this person?

1 Yes

0 No

8 Refuse to Answer

SH13. Did you receive clothing for having sexual intercourse with this person?

1 Yes

0 No

8 Refuse to Answer

SH14. Did you receive school items for having sexual intercourse with this person?

1 Yes

0 No

8 Refuse to Answer

SH15. Did you receive money for having sexual intercourse with this person?

1 Yes

0 No

8 Refuse to Answer

SH16. Did you receive soap, lotion, hair products or beauty products for having sexual intercourse with this person?

1 Yes

0 No

8 Refuse to Answer

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SH17. Did you receive any other gift for having sexual intercourse with this person?

1 Yes

0 No

8 Refuse to Answer

SH18. The very first time you had sexual intercourse, was a condom used?

1 Yes

0 No

8 Refuse to Answer

If SH18 is equal to 1 or SH18 is equal to 8, then skip to instruction before SH20.

SH19. What was the main reason why you did not use a condom? (Choose one)

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted your partner

04 Partner refused to use a condom

05 Wanted to have a child

06 Fear using condom

07 Reduces sexual pleasure

08 Other

98 Refuse to Answer

Thank you for the information you have given us about your sexual history. Please remember that to help find out what puts people at greater risk for HIV infection, we need to ask very personal questions. Remember, that your name is not linked to the answers you give us and that what you enter into the computer will not be shared with anyone.

For the next questions, please think of <u>all</u> the persons that you have had sexual intercourse with.

SH20. Since the very first time you had sexual intercourse, with how many different people have you had sexual intercourse? __ __ __

998 Refuse to Answer

SH21. Please think of all the times that you have had sexual intercourse. Have you ever had sexual intercourse where the penis was put in the anus?

1 Yes

0 No

8 Refuse to Answer

SH22. Please think of all the times that you have had sexual intercourse. Have you ever had sexual intercourse where the penis is put in the mouth or the tongue is put in the vagina?

1 Yes

0 No

8 Refuse to Answer

SH23. Please think of all the times that you have had sexual intercourse. Have you ever had sexual intercourse while you are menstruating or with a female who is menstruating?

1 Yes

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0 No

8 Refuse to Answer

We will now ask you questions about a sexual experience that you might have had against your will. Remember that your name is not written on this questionnaire and the answers you give will not be shared with anyone.

SH24. Think about all of the times you have had sexual intercourse <u>after</u> the very first time. Did anyone ever physically force you to have sexual intercourse against your will?

1 Yes

0 No

8 Refuse to Answer

If SH24 is equal to 0 or SH24 is equal to 8, then skip to instruction before RSB1.

SH25. How old were you when this happened? Again, think only about the times you had sex <u>after</u> your first very first time. ___

98 Refuse to Answer

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SH26. What was the age of the person or persons who forced you? (Choose one)

1 About your age

2 5 or less years younger

3 5 or more years older

8 Refuse to Answer

SH27. What is the sex of the person or persons who forced you? (Choose one)

1 Man/men only

2 Woman/women only

3 Both man/men and woman/women

8 Refuse to Answer

SH28. How was this person or persons related to you? Choose all that apply. (Check all that apply)

__ Relative living in the same house

__ Relative not living in the same house

__ Neighbour

__ Friend

__ Teacher

__ Somebody else known to you

__ Stranger

__ Refuse to Answer

If SH28A is equal to 0 and SH28B is equal to 0 and SH28C is equal to 0 and SH28D is equal to 0 and SH28E is equal to 0 and SH28F is equal to 0 and SH28G is equal to 0 then Please answer this question before proceeding. and skip to SH28.

Recent Sexual Behaviour

Thank you for the information you have given us about your sexual history. The next set of questions will ask you about your sexual behaviour in the last 3 months.

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RSB1. When was the last time you had sexual intercourse? (Choose one)

1 Within the last 3 months

2 Four to six months ago

3 More than six months ago

4 Never

8 Refuse to Answer

If RSB1 is equal to 1, then skip to instruction before RSB3.

RSB2. In the last three months, have you had at least one sexual partner?

1 Yes

0 No

8 Refuse to Answer

If RSB2 is equal to 0 or RSB2 is equal to 8, then skip to instruction before PSH1.

RSB3. In the last 3 months, with how many men or boys have you had sexual

intercourse?

__ __ __

998 Refuse to Answer

RSB4. In the last 3 months, with how many women or girls have you had sexual intercourse?

__ __ __

998 Refuse to Answer

HIV Positive Partners

RSB5. Of all the different persons you mentioned you had sexual intercourse with in the last 3 months, how many do you know or think might have HIV? __ __ __

998 Refuse to Answer

If RSB5 is equal to 0 or RSB5 is equal to 998, then skip to instruction before RSB9.

RSB6. How did you find out that this person or these persons were HIV infected? ***(Check all that apply)***

__ They told you on their own

__ You asked and they told you

__ You guessed and they confirmed it

__ Someone else told you

__ They looked sick to you

__ You got tested together

__ You went with them to get their test results

__ Someone from the testing site came looking for them

__ Because of another reason

__ Refuse to Answer

If RSB6A is equal to 0 and RSB6B is equal to 0 and RSB6C is equal to 0 and RSB6D is equal to 0 and RSB6E is equal to 0 and RSB6F is equal to 0 and RSB6G is equal to 0 and RSB6H is equal to 0 and RSB6I is equal to 0 then Please answer this question before proceeding. and skip to RSB6.

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RSB7. In the last 3 months, when you had sexual intercourse with this person or these persons you know or think might have HIV, how often did you use a condom? (Choose one)

1 All of the time
2 Most of the time
3 Sometimes
4 Never
8 Refuse to Answer

If RSB7 is equal to 1 or RSB7 is equal to 8, then skip to instruction before RSB9.

RSB8. What was the main reason why you did not use a condom all the time? (Choose one)

01 Did not know how to use a condom
02 Did not have a condom available
03 Trusted your partner
04 Partner refused to use a condom
05 Wanted to have a child
06 Fear using condom
07 Reduces sexual pleasure
08 Other
98 Refuse to Answer

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HIV Negative Partners

If RSB3 + RSB4 is equal to RSB5, then skip to instruction before RSB16.

RSB9. Of the remaining persons you mentioned you had sexual intercourse with in the last 3 months, how many do you know for sure <u>do not</u> have HIV? __ __ __

998 Refuse to Answer

If RSB9 is equal to 0 or RSB9 is equal to 998, then skip to instruction before RSB13.

RSB10. How did you find out that this person or these persons do not have HIV? (Check all that apply)

__ They told you on their own
__ You asked and they told you
__ You guessed and they confirmed it
__ Someone else told you
__ They looked healthy to you
__ You got tested together
__ You went with them to get their test results
__ Someone from the testing site came looking for them
__ Because of another reason
__ Refuse to Answer

If RSB10A is equal to 0 and RSB10B is equal to 0 and RSB10C is equal to 0 and RSB10D is equal to 0 and RSB10E is equal to 0 and RSB10F is equal to 0 and RSB10G is equal to 0 and RSB10H is equal to 0 and RSB10I is equal to 0 then Please answer this question before proceeding. and skip to RSB10.

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RSB11. In the last 3 months, when you had sexual intercourse with this person or these persons you know do not have HIV, how often did you use a condom? (Choose one)

1 All of the time
2 Most of the time
3 Sometimes
4 Never
8 Refuse to Answer

If RSB11 is equal to 1 or RSB11 is equal to 8, then skip to instruction before RSB13.

RSB12. What was the main reason why you did not use a condom? (Choose one)

01 Did not know how to use a condom
02 Did not have a condom available
03 Trusted your partner
04 Partner refused to use a condom
05 Wanted to have a child
06 Fear using condom

07 Reduces sexual pleasure

08 Other

98 Refuse to Answer

If RSB3 + RSB4 is equal to RSB5 or RSB3 + RSB4 is equal to RSB5 + RSB9, then skip to instruction before RSB16.

RSB13. Of all the different persons you mentioned you had sexual intercourse with in the last 3 months, how many do you not know of their HIV status? __ __ __

Refuse to Answer

If RSB13 is equal to 0 or RSB13 is equal to 998, then skip to instruction before RSB16.

RSB14. In the last 3 months, when you had sexual intercourse with this person or these persons whose status you do not know, how often did you use a condom? (Choose one)

1 All of the time

2 Most of the time

3 Sometimes

4 Never

8 Refuse to Answer

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If RSB14 is equal to 1 or RSB14 is equal to 8, then skip to instruction before RSB16.

RSB15. What was the main reason why you did not use a condom? (Choose one)

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted your partner

04 Partner refused to use a condom

05 Wanted to have a child

06 Fear using condom

07 Reduces sexual pleasure

08 Other

98 Refuse to Answer

The next set of questions will ask you about sexual intercourse during special occasions like funerals, planting, weeding, wedding or preparing the field.

RSB16. In the last 3 months, did you ever have sexual intercourse during a special occasion, such as preparing the field, planting, weeding, wedding, or funeral?

1 Yes
0 No
8 Refuse to Answer

If RSB16 is equal to 0 or RSB16 is equal to 8, then skip to instruction before RSB27.

RSB17. Was the special occasion during which you had sexual intercourse preparing the field?

1 Yes
0 No
8 Refuse to Answer

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RSB18. Was the special occasion during which you had sexual intercourse planting?

1 Yes
0 No
8 Refuse to Answer

RSB19. Was the special occasion during which you had sexual intercourse weeding?

1 Yes
0 No
8 Refuse to Answer

RSB20. Was the special occasion during which you had sexual intercourse harvesting?

1 Yes
0 No

8 Refuse to Answer

RSB21. Was the special occasion during which you had sexual intercourse a wedding?

1 Yes

0 No

8 Refuse to Answer

RSB22. Was the special occasion during which you had sexual intercourse paying of dowry?

1 Yes

0 No

8 Refuse to Answer

RSB23. Was the special occasion during which you had sexual intercourse a funeral?

1 Yes

0 No

8 Refuse to Answer

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RSB24. Was there any other special occasion during which you had sexual intercourse?

1 Yes

0 No

8 Refuse to Answer

RSB25. During these occasions, how often was a condom used? (Choose one)

1 All of the time

2 Most of the time

3 Sometimes

4 Never

8 Refuse to Answer

If RSB25 is equal to 1 or RSB25 is equal to 8, then skip to instruction before RSB27.

RSB26. What was the main reason why you did not use a condom? (Choose one)

01 Did not know how to use a condom
02 Did not have a condom available
03 Trusted your partner
04 Partner refused to use a condom
05 Wanted to have a child
06 Fear using condom
07 Reduces sexual pleasure
08 Other
98 Refuse to Answer

The next set of questions will ask you about your sexual encounters in the last three months where you were either pressured or given favours to have sexual intercourse.

RSB27. In the last 3 months were you ever tricked into having sexual intercourse when you did not want to?

1 Yes
0 No
8 Refuse to Answer

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RSB28. In the last 3 months were you ever physically forced into having sexual intercourse when you did not want to?

1 Yes
0 No
8 Refuse to Answer

RSB29. In the last 3 months were you ever pressured into having sexual intercourse when you did not want to?

1 Yes
0 No
8 Refuse to Answer

If (RSB27 is equal to 0 or RSB27 is equal to 8) and (RSB28 is equal to 0 or RSB28 is equal to 8) and (RSB29 is equal to 0 or RSB29 is equal to 8), then skip to RSB32.

RSB30. How many times in the last 3 months were you tricked, physically forced or pressured into having sexual intercourse with someone? __ __

98 Refuse to Answer

RSB31. How many of the persons that you had sexual intercourse with in the last 3 months, tricked, physically forced or pressured you into having sexual intercourse with them? __ __

98 Refuse to Answer

RSB32. In the last 3 months were you ever given a place to sleep or live to have sexual intercourse with someone?

1 Yes

0 No

8 Refuse to Answer

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RSB33. In the last 3 months were you ever given food to have sexual intercourse with someone?

1 Yes

0 No

8 Refuse to Answer

RSB34. In the last 3 months were you ever given money to have sexual intercourse with someone?

1 Yes

0 No

8 Refuse to Answer

RSB35. In the last 3 months were you ever given gifts or other favours to have sexual intercourse with someone?

1 Yes

0 No

8 Refuse to Answer

If (RSB32 is equal to 0 or RSB32 is equal to 8) and (RSB33 is equal to 0 or RSB33 is equal to

8) and (RSB34 is equal to 0 or RSB34 is equal to 8) and (RSB35 is equal to 0 or RSB35 is equal to 8), then skip to instruction before SPP1.

RSB36. How many times in the last 3 months were you given a place to sleep and live, food, money, gifts, or other favours for having sexual intercourse with someone?

__ __

98 Refuse to Answer

RSB37. How many of the persons that you had sexual intercourse with in the last 3 months, gave you a place to sleep and live, food, money, gifts, or other favours for having sexual intercourse with them? __ __

98 Refuse to Answer

Sexual Concurrence

We will now ask you questions about your concurrent sex partners or partners you have had sex with during the same time period. By concurrency we mean having sexual relationships with multiple partners in the specified time period. Please think about all the people you have had sexual intercourse with in the last one year when answering these questions. Some of these questions may make you uncomfortable. Remember that your answers will not be shared with anyone outside the study.

SC1. About how many different sexual partners have you had vaginal or anal sex with in the past 12 months (baseline) /3 months (follow up)? ___

If SC1 is equal to 1, then skip to instruction before SPP1.

If SC1 is equal to 3, then skip to next instruction.

In this section, we want you to think back 12 months (baseline) /3 months (follow up). Think about the 2 partners you most recently had vaginal or anal sex with, even if it was only once. To help us talk about each partner, we'll give them numbers. Let's start with the last partner that you had sex with. Think of this partner as partner number 1 and the first one as partner number 2.

If SC1 is more than 3, then skip to next instruction.

In this section, we want you to think back 12 months (baseline) /3 months (follow up).

Think about the 3 partners you most recently had vaginal or anal sex with, even if it was only once. To help us talk about each partner, we'll give them numbers. Let's start with the last partner you had sex with. Think of this partner as partner number 1. Also think of the second last person as partner number 2 and the first person as partner number 3.

If SC1 is more than 3.

In this section, we want you to think back 12 months (baseline) /3 months (follow up). Even though you reported having sexual intercourse with X, think about the 3 partners you most recently had vaginal or anal sex with, even if it was only once. To help us talk about each partner, we'll give them numbers. Let's start with the last partner you had sex with. Think of this partner as partner number 1. Also think of the second last person as partner number 2 and the first person as partner number 3.

Now we will start with asking you questions regarding partner number 1. Remember partner number 1 is the last partner you reported to have had sexual intercourse with.

SC2. When did you start having sex with partner number 1?

Year YYYY

Month MM

Date DD

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SC3. What was your relationship with partner number 1?

1 Your husband or wife

2 A friend

3 Someone you have sex with off and on

4 Your boyfriend/girlfriend or fiancé

5 Your ex-husband/wife or ex-boyfriend/girlfriend

6 Someone you just met and hooked up with one time

8 Refuse to Answer

SC4. What was the gender of partner number 1?

1 Male

2 Female

8 Refuse to Answer

SC5. Did you receive gifts, goods or services or a place to stay from partner number 1?

1 Yes

0 No

8 Refuse to Answer

SC6. Did you or partner number 1 ever use drugs or alcohol within 2 hours of sexual intercourse?

1 Yes

0 No

8 Refuse to Answer

SC7. Did you use a condom every time you had sexual intercourse with partner number 1?

1 Yes

0 No

8 Refuse to Answer

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If SC7 is equal to 1 or SC7 is equal to 8, then skip to SC9.

SC8. What was the main reason why you did not use a condom with this partner? (Choose one)

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted this partner

04 This partner refused to use a condom

05 Wanted to have a child with this partner

06 Fear using condoms

07 Reduces sexual pleasure

08 Knew you would get gifts if you did not use condoms

09 Other

98 Refuse to Answer

SC9. When did you last have sexual intercourse with partner number 1?

Year YYYY

Month MM

Date DD

SC10. What was the HIV status of partner number 1?

1 I am certain she/he was HIV Positive

2 I am certain she/he was HIV Negative

3 I am uncertain of her/his HIV status

8 Refuse to Answer

SC11. Is your relationship with partner number 1 still continuing?

1 Yes

0 No

8 Refuse to Answer

SC12. How many other partners other than you did partner number 1 have by the time you were having sexual intercourse with her/him? __ __

88 Don't Know

98 Refuse to Answer

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If SC1 is equal to or more than 3, then skip to SC15

SC13. During the time period that you were having sexual relations with partner number 1, did you have vaginal or anal sex with anyone else besides partner number 2?

1 Yes

0 No

8 Refuse to Answer

If SC13 is equal to 0 or SC13 is equal to 8, then skip to instruction before SC17.

SC14. How many other partners did you have sexual intercourse with other than partner number 2? ___

Skip to instruction before SC17.

SC15. During the time period that you were having sexual relations with partner number 1, did you have vaginal or anal sex with anyone else besides partner number 2 or partner number 3?

1 Yes

0 No

8 Refuse to Answer

If SC14 is equal to 0 or SC14 is equal to 8, then skip to instruction before SC17.

SC16. How many other partners did you have sexual intercourse with other than partner number 2 or 3? ___

If SC1 is more than 2 skip to next instruction.

Now we will start with asking you questions regarding partner number 2. Remember partner number 2 is the first partner you reported to have had sexual intercourse with out of the two.

Now we will start with asking you questions regarding partner number 2. Remember partner number 2 is the second last partner you reported to have had sexual intercourse with out of the last three.

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SC17. When did you start having sex with partner number 2?

Year YYYY

Month MM

Date DD

SC18. What was your relationship with partner number 2?

1 Your husband or wife

2 A friend

3 Someone you have sex with off and on

4 Your boyfriend/girlfriend or fiancé

5 Your ex-husband/wife or ex-boyfriend/girlfriend

6 Someone you just met and hooked up with one time

8 Refuse to Answer

SC19. What was the gender of partner number 2?

1 Male

2 Female

8 Refuse to Answer

SC20. Did you receive gifts, goods or services or a place to stay from partner number 2?

1 Yes

0 No

8 Refuse to Answer

SC21. Did you or partner number 2 ever use drugs or alcohol within 2 hours of sexual intercourse?

1 Yes

0 No

8 Refuse to Answer

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SC22. Did you use a condom every time you had sexual intercourse with partner number 2?

1 Yes

0 No

8 Refuse to Answer

If SC22 is equal to 1 or SC22 is equal to 8, then skip to SC24.

SC23. What was the main reason why you did not use a condom with this partner? (Choose one)

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted this partner

04 This partner refused to use a condom

05 Wanted to have a child with this partner

06 Fear using condoms

07 Reduces sexual pleasure

08 Knew you would get gifts if you did not use condoms

09 Other

98 Refuse to Answer

SC24. When did you last have sexual intercourse with partner number 2?

Year YYYY

Month MM

Date DD

SC25. What was the HIV status of partner number 2?

1 I am certain she/he was HIV Positive

2 I am certain she/he was HIV Negative

3 I am uncertain of her/his HIV status

8 Refuse to Answer

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SC26. Is your relationship with partner number 2 still continuing?

1 Yes

0 No

8 Refuse to Answer

SC27. How many other partners other than you did partner number 2 have by the time you were having sexual intercourse with her/him? __ __

88 Don't Know

98 Refuse to Answer

If SC1 is equal to 2, then skip to Instruction before SPP1

SC28. During the time period that you were having sexual relations with partner number 2, did you have vaginal or anal sex with anyone else besides partner number 1 or partner number 3?

1 Yes

0 No

8 Refuse to Answer

If SC28 is equal to 0 or SC28 is equal to 8, then skip to instruction before SC30.

SC29. How many other partners did you have sexual intercourse with other than partner number 1 or 3? ___

If SC1 is equal to 2, then skip to Instruction before SPP1

Now we will start with asking you questions regarding partner number 3. Remember partner number 3 is the first partner you reported to have had sexual intercourse with out of the last three.

SC30. When did you start having sex with partner number 3?

Year YYYY

Month MM

Date DD

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SC31. What was your relationship with partner number 3?

1 Your husband or wife

2 A friend

3 Someone you have sex with off and on

4 Your boyfriend/girlfriend or fiancé

5 Your ex-husband/wife or ex-boyfriend/girlfriend

6 Someone you just met and hooked up with one time

8 Refuse to Answer

SC32. What was the gender of partner number 3?

1 Male

2 Female

8 Refuse to Answer

SC33. Did you receive gifts, goods or services or a place to stay from partner number 3?

1 Yes

0 No

8 Refuse to Answer

SC34. Did you or partner number 3 ever use drugs or alcohol within 2 hours of sexual intercourse?

1 Yes

0 No

8 Refuse to Answer

SC35. Did you use a condom every time you had sexual intercourse with partner number 3?

1 Yes

0 No

8 Refuse to Answer

If SC35 is equal to 1 or SC35 is equal to 8, then skip to SC37.

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SC36. What was the main reason why you did not use a condom with this partner? (Choose one)

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted this partner

04 This partner refused to use a condom

05 Wanted to have a child with this partner

06 Fear using condoms

07 Reduces sexual pleasure

08 Knew you would get gifts if you did not use condoms

09 Other

98 Refuse to Answer

SC37. When did you last have sexual intercourse with partner number 3?

Year YYYY

Month MM

Date DD

SC38. What was the HIV status of partner number 3?

1 I am certain she/he was HIV Positive

2 I am certain she/he was HIV Negative

3 I am uncertain of her/his HIV status

8 Refuse to Answer

SC39. Is your relationship with partner number 3 still continuing?

1 Yes

0 No

8 Refuse to Answer

SC40. How many other partners other than you did partner number 3 have by the time you were having sexual intercourse with her/him? __ __

88 Don't Know

98 Refuse to Answer

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SC41. During the time period that you were having sexual relations with partner number 3, did you have vaginal or anal sex with anyone else besides partner number 1 or partner number 2?

1 Yes

0 No

8 Refuse to Answer

If SC41 is equal to 0 or SC41 is equal to 8, then skip to instruction before SPP1.

SC42. How many other partners did you have sexual intercourse with other than partner number 1 or 3? ___

Sexual Behaviour with Spouses/Primary Partners

We will now ask you questions about your sex partners. Some of these questions may make you uncomfortable. Remember that your answers will not be shared with anyone outside the study.

If you are married, please think about your spouse when answering these questions. If you are living as married, have never been married, separated, divorced, or widowed, please think about a main or primary sex partner when answering these questions.

SPP1. In the last 3 months, did you have sexual intercourse with a spouse or a main sex partner?

1 Yes
0 No
8 Refuse to Answer

If SPP1 is equal to 0 or SPP1 is equal to 8, then skip to SPP13.

SPP2. When was the last time that you had sexual intercourse with your spouse or main partner? (Choose one)

1 Hours ago
2 Days ago
3 Weeks ago
4 Months ago
8 Refuse to Answer

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If SPP2 is equal to 8, then skip to SPP7.
If SPP2 is not equal to 1, then skip to instruction before SPP4.

SPP3. How many hours ago? __ __

98 Refuse to Answer

If SPP2 is not equal to 2, then skip to instruction before SPP5.

SPP4. How many days ago? __ __

98 Refuse to Answer

If SPP2 is not equal to 3, then skip to instruction before SPP6.

SPP5. How many weeks ago? __ __

98 Refuse to Answer

If SPP2 is not equal to 4, then skip to SPP7.

SPP6. How many months ago? __ __

98 Refuse to Answer

SPP7. Was a condom used the last time that you had sexual intercourse with your spouse or main partner?

1 Yes

0 No

8 Refuse to Answer

If SPP7 is equal to 1 or SPP7 is equal to 8, then skip to SPP11.

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SPP8. What was the main reason why you did not use a condom? (Choose one)

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted your partner

04 Partner refused to use a condom

05 Wanted to have a child

06 Fear using condom

07 Reduces sexual pleasure

08 Other

98 Refuse to Answer

SPP9. In the last 3 months, when you had sexual intercourse with your spouse or main partner, how often did you use a condom? (Choose one)

1 All of the time

2 Most of the time

3 Sometimes

4 Never

8 Refuse to Answer

If SPP9 is equal to 1 or SPP9 is equal to 8, then skip to SPP11.

SPP10. What was the main reason why you did not use a condom? (Choose one)

01 Did not know how to use a condom
02 Did not have a condom available
03 Trusted your partner
04 Partner refused to use a condom
05 Wanted to have a child
06 Fear using condom
07 Reduces sexual pleasure
08 Other
98 Refuse to Answer

SPP11. In the last 3 months, when having sexual intercourse with your spouse/main partner, how often were alcoholic drinks used immediately before, during, or after sexual activity occurred? This includes when either both of you or only one of you was drinking. (Choose one)

1 All of the time
2 Some of the time
3 Never
8 Refuse to Answer

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SPP12. In the last three months, when having sexual intercourse with your spouse or main partner, how often were drugs used immediately before, during or after sexual activity occurred? This includes times when either both of you or only one of you was using drugs. (Choose one)

1 All of the time
2 Some of the time
3 Never
8 Refuse to Answer

SPP13. In the last 3 months, did you have sexual intercourse with someone other than your spouse or main partner?

1 Yes

0 No

8 Refuse to Answer

If SPP13 is equal to 0 or SPP13 is equal to 8, then skip to SPP28.

SPP14. When was the last time that you had sexual intercourse with someone other than your spouse or main partner? (Choose one)

1 Hours ago

2 Days ago

3 Weeks ago

4 Months ago

8 Refuse to Answer

If SPP14 is equal to 8, then skip to SPP19.

If SPP14 is not equal to 1, then skip to instruction before SPP16.

SPP15. How many hours ago? __ __

98 Refuse to Answer

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If SPP14 is not equal to 2, then skip to instruction before SPP17.

SPP16. How many days ago? __ __

98 Refuse to Answer

If SPP14 is not equal to 3, then skip to instruction before SPP18.

SPP17. How many weeks ago? __ __

98 Refuse to Answer

If SPP14 is not equal to 4, then skip to SPP19.

SPP18. How many months ago? __ __

98 Refuse to Answer

SPP19. Was a condom used the last time you had sexual intercourse with someone other than your spouse or main partner?

1 Yes

0 No

8 Refuse to Answer

If SPP19 is equal to 1 or SPP19 is equal to 8, then skip to SPP21.

SPP20. What was the main reason why you did not use a condom? (Choose one)

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted your partner

04 Partner refused to use a condom

05 Wanted to have a child

06 Fear using condom

07 Reduces sexual pleasure

08 Other

98 Refuse to Answer

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SPP21. In the last 3 months was there ever a special occasion (such as preparing the field, planting, wedding, funeral, etc.), when you had sexual intercourse with a person who was not your spouse or main partner?

1 Yes

0 No

8 Refuse to Answer

If SPP21 is equal to 0 or SPP21 is equal to 8, then skip to SPP25.

SPP22. What was the last special occasion during which you had sexual intercourse with a person who was not your spouse or main partner? (Choose one)

01 Preparing the field

02 Planting

03 Weeding

04 Harvesting

05 Wedding

06 Paying of dowry

07 Funeral

08 Other

98 Refuse to Answer

SPP23. Did you use a condom when you had sex on that occasion?

1 Yes

0 No

8 Refuse to Answer

If SPP23 is equal to 1 or SPP23 is equal to 8, then skip to SPP25.

SPP24. What was the main reason why you did not use a condom? (Choose one)

01 Did not know how to use a condom

02 Did not have a condom available

03 Trusted your partner

04 Partner refused to use a condom

05 Wanted to have a child

06 Fear using condom

07 Reduces sexual pleasure

08 Other

98 Refuse to Answer

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SPP25. When having sexual intercourse with someone other than your spouse or main partner, did you give or receive money or other gifts?

1 Yes

0 No

8 Refuse to Answer

SPP26. In the last 3 months, when having sexual intercourse with someone other than your spouse/main partner, how often were alcoholic drink used immediately before, during, or after sexual activity occurred? This includes when either both of you or one of you was drinking. (Choose one)

1 All of the time

2 Some of the time

3 Never

8 Refuse to Answer

SPP27. In the last 3 months, when having sexual intercourse with someone other than your spouse or main partner, how often were drugs used immediately before, during, or after sexual activity occurred? This includes when either both of you or one of you was using drugs. (Choose one)

1 All of the time

2 Some of the time

3 Never

8 Refuse to Answer

SPP28. In the last 3 months, do you think that your spouse or main partner has had sexual intercourse with other partners?

1 Yes

0 No

8 Refuse to Answer

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If SPP28 is equal to 0 or SPP28 is equal to 8, then skip to instruction before PSH1.

SPP29. In the last 3 months, do you think that your spouse or main partner has had sexual intercourse with another spouse or main partner?

1 Yes

0 No

8 Refuse to Answer

SPP30. In the last 3 months, do you think that your spouse or main partner has had sexual intercourse with an occasional sex partner?

1 Yes

0 No

8 Refuse to Answer

SPP31. In the last 3 months, do you think that your spouse or main partner has had sexual intercourse with one-time sex partners?

1 Yes
0 No
8 Refuse to Answer

SPP32. In the last 3 months, do you think that your spouse or main partner had sexual intercourse with men only, women only or both men and women? (Choose one)

1 Man/men only
2 Woman/women only
3 Both man/men and woman/women
8 Refuse to Answer

Physical and Sexual health

We would now like to ask you questions about your physical and sexual health.

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PSH1. In the last 3 months, have you used any method to delay or avoid pregnancy?

1 Yes
0 No
8 Refuse to Answer

If Q5 is equal to 1 and PSH1 is equal to 0, then skip to PSH24.
If Q5 is equal to 2 and PSH1 is equal to 0, then skip to PSH24.
If PSH1 is equal to 8, then skip to PSH25.
If Q5 is equal to 1, then skip to PSH13.

PSH2. Did you use birth control pills to delay or avoid pregnancy?

1 Yes
0 No
8 Refuse to Answer

PSH3. Were you post-partum or did you use breastfeeding to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH4. Did you use injections to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH5. Did you use condoms to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH6. Did you use sterilization to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

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PSH7. Did you use withdrawal to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH8. Did you use natural, safe days or rhythm method to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH9. Did you use traditional herbs to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH10. Did you use abstinence to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH11. Did you use IUD to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH12. Did you use other methods to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

If Q5 is equal to 2 and PSH1 is equal to 1, then skip to PSH25.

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PSH13. Did your spouse or partner use birth control pills to delay or avoid pregnancy?

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

PSH14. Was your spouse or partner post-partum or did she use breastfeeding to delay or avoid pregnancy?

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

PSH15. Did your spouse or partner use injections to delay or avoid pregnancy?

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

PSH16. Did you use condoms to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH17. Did you use sterilization to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH18. Did you use withdrawal to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

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PSH19. Did you use natural, safe days or rhythm method to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH20. Did you use traditional herbs to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH21. Did you use abstinence to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

PSH22. Did your spouse or partner use IUD to delay or avoid pregnancy?

1 Yes

0 No

7 Don't Know

8 Refuse to Answer

PSH23. Did you use other methods to delay or avoid pregnancy?

1 Yes

0 No

8 Refuse to Answer

If Q5 is equal to 1 and PSH1 is equal to 1, then skip to PSH25.

PSH24. (Ask of Women Only) What is the main reason you did not use a method to delay or avoid pregnancy? (Choose one)

01 Infrequent sex

02 Want more children

03 Because you oppose

04 Because your partner opposed

05 Religious

06 Do not know of any method

07 No access

08 Cost too much

09 Inconvenient to use

10 Side effects and health concerns

11 Pregnant now

12 Cannot get pregnant

13 Postpartum breast feeding

98 Refuse to Answer

PSH24. (Ask of Men Only) What is the main reason you did not use a method to delay or avoid pregnancy? (Choose one)

01 Infrequent sex

02 Want more children

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03 Because you oppose
04 Because your partner opposed
05 Religious
06 Do not know of any method
07 No access
08 Cost too much
09 Inconvenient to use
10 Side effects and health concerns
11 Spouse/Partner pregnant now
12 Spouse/Partner cannot get pregnant
13 Spouse/Partner breastfeeding post partum
98 Refuse to Answer

PSH25. Have you ever had a blood transfusion?

1 Yes
0 No
8 Refuse to Answer

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If PSH25 is equal to 0 or PSH25 is equal to 8, then skip to PSH31.

PSH26. When was the last time that you had a blood transfusion? (Choose one)

1 Days ago
2 Weeks ago
3 Months ago
4 Years ago
8 Refuse to Answer

If PSH26 is not equal to 1, then skip to instruction before PSH28.

PSH27. How many days ago? __ __

98 Refuse to Answer

If PSH26 is not equal to 2, then skip to instruction before PSH29.

PSH28. **How many weeks ago?** __ __

98 Refuse to Answer

If PSH26 is not equal to 3, then skip to instruction before PSH30.

PSH29. **How many months ago?** __ __

98 Refuse to Answer

If PSH26 is not equal to 4, then skip to PSH31.

PSH30. **How many years ago?** __ __

98 Refuse to Answer

PSH31. **In the last 3 months, have you had an injection?**

1 Yes

0 No

8 Refuse to Answer

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If PSH31 is equal to 0 or PSH31 is equal to 8, then skip to PSH33.

PSH32. **Who gave you an injection? Choose all that apply. (Check all that apply)**

__ Doctor

__ Pharmacist

__ Nurse or Clinical officer

__ Injectionist

__ Self

__ Traditional healer

__ Community health worker

__ Refuse to Answer

If PSH32A is equal to 0 and PSH32B is equal to 0 and PSH32C is equal to 0 and PSH32D is equal to 0 and PSH32E is equal to 0 and PSH32F is equal to 0 and PSH32G is equal to 0 then Please answer this question before proceeding. and skip to PSH32.

PSH33. **Have you ever had scarification (saro) involving blood?**

1 Yes

0 No

8 Refuse to Answer

PSH34. Have you ever had any situation where your blood came into contact with someone else's blood?

1 Yes

0 No

8 Refuse to Answer

PSH35. Have you ever been circumcised?

1 Yes

0 No

8 Refuse to Answer

If PSH35 is equal to 0 or PSH35 is equal to 8, then skip to instruction before PSH37.

PSH36. How old were you when you were circumcised? __ __

98 Refuse to Answer

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If Q5 is equal to 2 or Q5 is equal to 1 and PSH35 is equal to 1, then skip to PSH38.
If Q5 is equal to 1 and PSH35 is equal to 1, then skip to PSH38.

PSH37. Would you be interested in getting circumcised?

1 Yes

0 No

8 Refuse to Answer

PSH38. Have you ever been treated for a sexually transmitted infection?

1 Yes

0 No

8 Refuse to Answer

PSH39. In the last 3 months, have you been treated for a sexually transmitted

infection?

1 Yes

0 No

8 Refuse to Answer

If Q5 is equal to 1, then skip to PSH43.

If Q5 is equal to 2, then skip to instruction before PSH40.

If Q5 is equal to 1 and PSH38 is equal to 0 or PSH38 is equal to 8, then skip to PSH43.

PSH40. Do you currently have ulcers anywhere on your vagina and/or labia?

1 Yes

0 No

8 Refuse to Answer

PSH41. Do you currently have any abnormal or smelly discharge from your vagina?

1 Yes

0 No

8 Refuse to Answer

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PSH42. Do you currently have pain during sexual intercourse?

1 Yes

0 No

8 Refuse to Answer

If Q5 is equal to 2, then skip to instruction before AWK1.

PSH43. Do you currently have ulcers anywhere on your penis and/or scrotum?

1 Yes

0 No

8 Refuse to Answer

PSH44. Do you currently have any pus dripping from your penis and/or a burning pain when passing urine?

1 Yes

0 No

8 Refuse to Answer

PSH45. Do you currently have pain in your scrotum?

1 Yes

0 No

8 Refuse to Answer

HIV Awareness and Knowledge

We would now like to ask you questions about your awareness and knowledge of HIV.

AWK1. Can people reduce their chances of getting HIV by having only one uninfected sex partner who has no other partners?

1 Yes

0 No

8 Refuse to Answer

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AWK2. Can people get HIV from mosquito bites?

1 Yes

0 No

8 Refuse to Answer

AWK3. Can people reduce their chances of getting HIV by using a condom every time they have sex?

1 Yes

0 No

8 Refuse to Answer

AWK4. Can people get HIV by sharing food with someone who is infected with the virus?

1 Yes

0 No

8 Refuse to Answer

AWK5. Can people reduce their chances of getting HIV by completely abstaining from sexual intercourse?

1 Yes

0 No

8 Refuse to Answer

AWK6. Can people get HIV because of witchcraft, a curse, or other supernatural means?

1 Yes

0 No

8 Refuse to Answer

AWK7. Is it possible for a healthy-looking person to have HIV?

1 Yes

0 No

8 Refuse to Answer

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AWK8. Are there any special drugs that people infected with HIV can get from a doctor to help them live longer?

1 Yes

0 No

8 Refuse to Answer

HIV Testing History and Attitudes

Thank you for answering our questions thus far. Now we would like to ask you about times that you may have been tested for HIV.

TST1. Before today, have you ever had an HIV test?

1 Yes

0 No

8 Refuse to Answer

If TST1 is equal to 1, then skip to instruction before TST15.

If TST1 is equal to 8, then skip to instruction before TST46.

What would you say are the main reasons you have never tested for HIV?

TST2. You have never been tested because HIV testing services are too far away?

1 Yes

0 No

8 Refuse to Answer

TST3. You have never been tested because you cannot pay for HIV test?

1 Yes

0 No

8 Refuse to Answer

TST4. You have never been tested because you do not know where to go for HIV test?

1 Yes

0 No

8 Refuse to Answer

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TST5. You have never been tested because you are afraid of knowing your HIV result?

1 Yes

0 No

8 Refuse to Answer

TST6. You have never been tested because you are afraid you will get sick or die more quickly?

1 Yes

0 No

8 Refuse to Answer

TST7. You have never been tested because you are afraid that others would reject you?

1 Yes

0 No

8 Refuse to Answer

TST8. You have never been tested because you are embarrassed to ask for the test?

1 Yes

0 No

8 Refuse to Answer

TST9. You have never been tested because you are not at risk of HIV?

1 Yes

0 No

8 Refuse to Answer

TST10. You have never been tested because you are too young to get tested?

1 Yes

0 No

8 Refuse to Answer

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TST11. You have never been tested because you cannot do anything about it if you were HIV infected?

1 Yes

0 No

8 Refuse to Answer

TST12. You have never been tested because you are not sexually active until recently?

1 Yes

0 No

8 Refuse to Answer

TST13. You have never been tested because of other reasons?

1 Yes

0 No

8 Refuse to Answer

TST14. From the previous responses you have given, what would you say is the

one main reason you have never had an HIV test? (Choose one)

01 HIV testing services too far away
02 Cannot pay for HIV test
03 Do not know where to go for HIV test
04 Afraid of knowing your HIV result
05 Afraid will get sick /die more quickly
06 Afraid that others would reject you
07 Embarrassed to ask for test
08 Not at risk of HIV/AIDS
09 Too young to get tested
10 Can not do anything about it if you were HIV infected
11 Not sexually active until recently
12 Other reason
98 Refuse to Answer

If TST1 is equal to 0, then skip to instruction before TST34.

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Why did you decide to get tested?

TST15. You decided to get tested because you wanted to know your HIV status?

1 Yes
0 No
8 Refuse to Answer

TST16. You were tested during an evaluation by a doctor for illness?

1 Yes
0 No
8 Refuse to Answer

TST17. You decided to get tested because you wanted medical care if you were positive?

1 Yes
0 No
8 Refuse to Answer

If Q5 is equal to 1, then skip to TST19.

If Q5 is equal to 2, then skip to TST18.

TST18. You decided to get tested because you were pregnant or wanted to have a child?

1 Yes

0 No

8 Refuse to Answer

If Q5 is equal to 2, then skip to TST20.

TST19. You decided to get tested because it was recommended when spouse or partner was pregnant or wanted to have a child?

1 Yes

0 No

8 Refuse to Answer

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TST20. You decided to get tested as part of sexually transmitted infection or routine check-up?

1 Yes

0 No

8 Refuse to Answer

TST21. You decided to get tested because your spouse, partner, or child has HIV?

1 Yes

0 No

8 Refuse to Answer

TST22. You decided to get tested because your child was sick or died?

1 Yes

0 No

8 Refuse to Answer

TST23. You decided to get tested because you had past risky behaviour?

1 Yes

0 No

8 Refuse to Answer

TST24. You decided to get tested because of your sex partner's risky behaviour?

1 Yes

0 No

8 Refuse to Answer

TST25. You decided to get tested because you were getting married?

1 Yes

0 No

8 Refuse to Answer

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TST26. You were tested as part of employment physical exam?

1 Yes

0 No

8 Refuse to Answer

TST27. You decided to get tested to donate blood?

1 Yes

0 No

8 Refuse to Answer

TST28. You decided to get tested because you took part in a study?

1 Yes

0 No

8 Refuse to Answer

TST29. You decided to get tested because of other reasons?

1 Yes

0 No

8 Refuse to Answer

TST30. **How many times have you been tested for HIV in your life?** __ __

98 Refuse to Answer

TST31. **Do you know the result of your most recent test?**

1 Yes

0 No

8 Refuse to Answer

If TST31 is equal to 0 or TST31 is equal to 8, then skip to instruction before TST46.

TST32. **Have you told anyone about your results?**

1 Yes

0 No

8 Refuse to Answer

If TST32 is equal to 0 or TST32 is equal to 8, then skip to instruction before TST46.

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TST33. **With whom did you share your HIV test results? Choose all that apply. (Check all that apply)**

__ Spouse

__ Other sex partners

__ Parents

__ Spouse's parents

__ Siblings

__ Children

__ Other relatives

__ Friends

__ Employer

__ Health provider

__ Community support group

__ Other

__ Refuse to Answer

If TST1 is equal to 1, then skip to instruction before TST46.

What would encourage you to go for an HIV test?

TST34. If you wanted to know your HIV status?

1 Yes

0 No

8 Refuse to Answer

TST35. If you thought you might have been infected?

1 Yes

0 No

8 Refuse to Answer

TST36. If you were positive and wanted medical care?

1 Yes

0 No

8 Refuse to Answer

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TST37. (Ask of Women Only) If you were pregnant or wanted to have a child?

1 Yes

0 No

8 Refuse to Answer

TST37. (Ask of Men Only) If your spouse or partner was pregnant or you wanted to have a child?

1 Yes

0 No

8 Refuse to Answer

TST38. If it was given as part of sexually transmitted infection or routine check-up?

1 Yes

0 No

8 Refuse to Answer

TST39. If your sex partner told you that he/she was HIV-positive?

1 Yes

0 No

8 Refuse to Answer

TST40. If your doctor suggested that you get tested?

1 Yes

0 No

8 Refuse to Answer

TST41. If your partner suggested that you get tested?

1 Yes

0 No

8 Refuse to Answer

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TST42. If other people would not think that you were HIV-infected just because you were tested?

1 Yes

0 No

8 Refuse to Answer

TST43. If you were sure that the testing and results would not be shared with others?

1 Yes

0 No

8 Refuse to Answer

TST44. If you knew your family would support and take care of you if you were HIV-infected?

1 Yes

0 No

8 Refuse to Answer

TST45. If you had access to medical care if you were HIV-infected?

1 Yes

0 No

8 Refuse to Answer

We have come to the end of our interview. Thank you very much for your cooperation. We greatly appreciate your help in responding to the questions. The information you have given us will help us better understand risk factors for new HIV infections among people in Kisumu and surrounding areas. This will also help us prepare well for future studies looking at ways to prevent HIV infections.

Please call the study staff for assistance to end this interview. If you have any questions you may ask the study staff.

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THANK YOU

TST46. *[Instruction to the interviewer]* Please enter your staff ID to end the Main Question for participant ID [Response to Q2]

— — —

8.4.6. Appendix 4.6: Screening Medical History and Physical Examination

CAPI SCREENING MEDICAL HISTORY AND PHYSICAL EXAMINATION

Participant ID: |__|__|__|__|__|__|__| Date: |__|__|/|__|__|/|__|__|__|__
dd / mm / yyyy

Q 1. Language:
01 English
02 Swahili
03 Luo

Q 2. Residence ID
01 Rural
02 Urban

Q 3. Gender (Dem_1):
01 Male
02 Female

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Staff ID: |__|__|__|

Vital signs:

Q 4. Height ☐☐☐.☐ cm

Q 5. Weight ☐☐☐.☐ kg

Q 6. Axillary Temperature ☐☐.☐ ^{o}C

Q 7. Respiratory Rate ☐☐ breaths / minute

Q 8. Radial Pulse ☐☐☐ beats / minute

Q 9. Blood Pressure ☐☐☐ / ☐☐☐ mmHg
Systolic Diastolic

Q 10. Females only: Last menstrual period
☐☐ ☐☐ ☐☐☐☐
dd mm yyyy

Q 11. Females only: Visibly Pregnant

01 Yes (go to Q13)

00 No

Q 12. Females only: Pregnancy Test

01 Positive

00 Negative

Q 13. Do you have any allergies to any medicine?

01 Yes

00 No

Q13a. [If Q13 = 01] Describe

_____

_____

_____

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Q 14. Are you currently taking any medicines?

01 Yes

00 No

[If Q14 = 01) Specify:

Code	Medication	Date Started dd/mm/yyyy	Reason for medication
☐☐☐☐			
☐☐☐☐			
☐☐☐☐			
☐☐☐☐			
☐☐☐☐			

Systemic review

General

Q 15. Do you currently have cancer?

01 Yes

00 No

Q 16. [If Q15 = 01] Which cancer do you currently have? Specify

_____

_____

__

Q 17. [If Q15 = 01] Have you been on cancer treatment in the last 3 months?

01 Yes

00 No

Cardiac

Q 18. Have you had or do you have heart disease?

01 Yes

00 No

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Q 19. [If Q18 = 01] Do you have any problem with waking up at night with shortness of breath right now?

01 Yes

00 No

Q 20. [If Q18 = 01] Do you have any problem with shortness of breath walking around the house right now?

01 Yes

00 No

Q 21. [If Q18 = 01] Do you have any problems with swelling in the legs right now?

01 Yes

00 No

Q 22. Have you ever had or do you have any problems with your lungs?

01 Yes

00 No

Q 23. Have you ever had or do you have a persistent cough?

01 Yes

00 No

Q 24. Do you have a cough that has been going on for over 3 weeks?

01 Yes

00 No

Q 25. [If Q24 = 01] Do you cough up sputum?

01 Yes

00 No

Q 26. [If Q24 = 01] Is the sputum blood stained?

01 Yes

00 No

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Q 27. Do you sweat a lot at night?

01 Yes

00 No

Q 28. Have you lost weight in the last 1 month?

01 Yes

00 No

Q 29. Have you ever been diagnosed with TB in the past?

01 Yes

00 No

Q 30. [If Q29 = 01] Were you treated for TB?

01 Yes

00 No

Q 31. [If Q29 = 01] Did you complete the treatment?

01 Yes

00 No

Gastrointestinal

Q 32. Have you had diarrhoea in the last one month?

01 Yes

00 No

Q 33. Have you ever had or do you have any stomach problems?

01 Yes

00 No

Q 34. [If Q33 = 01] Do you have stomach ulcers right now?

01 Yes

00 No

Q 35. [If Q33 = 01] Are you taking medicine for ulcers right now? *List medication in table for Q13.*

01 Yes

00 No

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Q 36. Do you have heartburn right now?

01 Yes

00 No

Q 37. [If Q36 = 01]Are you taking medicine for heartburn right now? *List medication in table for Q13.*

01 Yes

00 No

Hepatic

Q 38. Have you ever had yellow eyes?

01 Yes

00 No

Q 39. Have you ever had or do you have any problems with your liver?

01 Yes

00 No

Renal

Q 40. Do you have kidney failure right now?

01 Yes

00 No

Neurology

Q 41. Have you ever or do you have problems with convulsions or "fits"?

01 Yes

00 No

Haematology

Q 42. Do you have sickle cell disease?

01 Yes

00 No

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Endocrine

Q 43. Do you have diabetes?

01 Yes

00 No

Q 44. [If Q43 = 01]How many times have you been hospitalised in the last 12 months because of diabetes?

_____ Times

Psychiatric

Q 45. Have you been admitted to the hospital for mental problems within the last 12 months?

01 Yes

00 No

Q 46. [If Q45 = 01]How many times have you been hospitalised for mental problems within the last 12 months?

_____ Times

Hospitalisations

Q 47. Have you been hospitalised for any reason over the last 3 months?

01 Yes

00 No

[If Q46 = 01] Please list the hospitals.

Hospital	From (mm/yy)	To (mm/yy)	Reason for stay

Following physical evaluation of the participant, indicate YES if participant has any abnormality in the conditions listed below that may make him or her ineligible for the study.

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Q 48. skin

01 Normal

02 Abnormal

03 Healed dermatitis

Head, eyes, ears, nose, and throat

Q 49. Oral candidiasis

01 Yes

00 No

Q 50. Tooth or gum disease

01 Yes

00 No

Q 51. Pale conjunctiva

01 Yes

00 No

Q 52. Jaundiced conjunctiva

01 Yes

00 No

Q 53. Visible mass

01 Yes

00 No

Q 54. Cyanosis

01 Yes

00 No

Q 55. Lymphadenopathy

01 Yes

00 No

Q 56. Others

01 Yes (specify:_____)

00 No

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Chest and Lungs

Q 57. Dullness to percussion

01 Yes

00 No

Q 58. Rales

01 Yes

00 No

Q 59. Rhonchi

01 Yes

00 No

Q 60. Wheezes

01 Yes

00 No

Q 61. Others

01 Yes (specify _____)

00 No

Heart

Q 62. Irregular rhythm

01 Yes

00 No

Q 63. Tachycardia (>120)

01 Yes

00 No

Q 64. Murmur

01 Yes (specify _____)

00 No

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Q 65. Others

01 Yes (specify _____)

00 No

Abdomen

Q 66. Abdominal tenderness

01 Yes

00 No

Q 67. Hepatomegaly

01 Yes

00 No

Q 68. Spleenomegaly

01 Yes

00 No

Q 69. Ascites

01 Yes

00 No

Q 70. Other masses

01 Yes (specify _____)

00 No

Q 71. Others

01 Yes (specify _____)

00 No

Extremities

Q 72. Peripheral oedema

01 Yes

00 No

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Q 73. Limited range of motion

01 Yes

00 No

Q 74. Others

01 Yes (specify _____)

00 No

Nervous system

Q 75. Mental status problem

01 Yes

00 No

Q 76. Peripheral neuropathy

01 Yes

00 No

Q 77. Sensory problem

01 Yes

00 No

Q 78. Motor problem
01 Yes
00 No

Q 79. Reflexes problem
01 Yes
00 No

Q 80. Other problem
01 Yes (specify _____)
00 No

Clinicians Notes

Diagnosis

Diagnosis	Code

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Treatment

Code	Medication	Date Started dd/mm/yyyy	Expiry Date Mm/yy

☐☐☐☐			
☐☐☐☐			

Referrals.

Referred to	Reason for referral

If the participant has any clinically significant illness that would compromise the ability of the person to enrol into the study and / or to complete the study, the message INELIGIBLE will display.

If person is eligible for study enrolment, the message ELIGIBLE will display. To be eligible, NO must be answered to Q81-Q45.

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Q 81. Cardiac (choose all that apply).

01 Yes

Yes, signs and symptoms of cardiac failure (SOB, orthopnea, PND, extremity oedema, hepatomegaly)

Yes, blood pressure: systolic > 160 mmHg or diastolic > 110 mmHg

Yes, other (specify: _____)

00 No

Q 82. Respiratory

01 Yes

Yes, signs and symptoms of respiratory compromise with SOB at rest

Yes, suspicion of tuberculosis

Yes, other (specify: _____)

00 No

Q 83. Hepatic

01 Yes

Yes, signs and symptoms of liver failure

Yes, signs and symptoms of hepatitis

Yes, hepatocellular carcinoma

Yes, other (specify: _____)

00 No

Q 84. Neurological (choose all that apply).

01 Yes

Yes, seizure disorder

Yes, other (specify: _____)

00 No

Q 85. Endocrine (choose all that apply).

01 Yes

Yes, evidence of uncontrolled diabetes, hospitalized in the last 12 months

Yes, other (specify: _____)

00 No

Q 86. Psychiatric (choose all that apply).

01 Yes

Yes, evidence of poorly controlled psychiatric illness, hospitalized in the last 12 months

Yes, other (specify: _____)

00 No

Q 87. Genitourinary

01 Yes

Yes, signs and symptoms of renal failure

Other (specify: _____)

00 No

Q 88. Pregnancy (*Only in females)*

01 Yes

00 No

98 Other

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Q 89. Cancer

01 Yes

00 No

Q 90. Other (specify: _____)

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8.5. Appendix 5: Abstraction Form for Rapid Review of Interviews

Interview # _____

Describe and rate the strategies mentioned in the individual in-depth interview. Use a 1-4 scale with 1 being poor, 2 - fair, 3 - good, and 4 - very good.

Strategy description	**Feasibility**	**Likelihood to reach persons at high risk for HIV infection**	**Notes**
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

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Feasibility - practicality of staff implementing strategy, considering cost and logistics.

Likelihood to reach persons at high risk for HIV infection - based on experience of interview staff.

8.6. Appendix 6: Computer Generated Final Eligibility Report

COMPUTER-GENERATED FINAL ELIGIBILITY REPORT

Participant ID: |__|__|__|__|__|__|__|__| Date: |__|__|/|__|__|/|__|__|__|__
dd / mm / yyyy

Gender (Dem_1):

01 Male

02 Female

Staff ID: |__|__|__|

To be eligible for study participation, all questions must be answered YES. The final eligibility determination is computer generated from the screening data collected.

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Q 1. Consented to take part in the study?

01 Yes

00 No

Q 2. Meets minimal age requirements?

01 Yes

00 No

Q 3. Currently a resident of Kisumu catchment area?

01 Yes

00 No

Q 4. Plans to remain in the Kisumu catchment area for the next 12 months?

01 Yes

00 No

Q 5. Has had sexual intercourse at least once within the last 3 months?

01 Yes

00 No

Q 6. Willing to be tested for HIV?

01 Yes

00 No

Q 7. Willing to participate in a study involving follow-up visits every 3 months.

01 Yes

00 No

Q 8. Willing to provide detailed locator information?

01 Yes

00 No

Q 9. For females: Not currently pregnant?

01 Yes

00 No

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Q 10. Both rapid HIV tests indicate that the person is negative.

01 Yes

00 No

Q 11. Serum creatinine < 1.5mg/dl?

01 Yes

00 No

Q 12. Haemoglobin ≥9.0.g/dl?

01 Yes

00 No

Q 13. Platelets >50,000/ml?

01 Yes

00 No

Q 14. ALT <2.5 times the upper limit of normal?

01 Yes

00 No

Q 15. Is healthy (i.e., no clinical significant cardiac, respiratory, hepatic, gastrointestinal, endocrine, hematologic, psychiatric, neurologic, or allergic disease detected)?

01 Yes

00 No

This participant is:

01 Eligible for Cohort study

02 Not eligible for the cohort study based on **NO** response to one or more items

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