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Strengthening HIV preventive care services for Transgender Women and Men who have Sex with Men in Coastal Kenya

- Makobu Kimani -

About the Author

Makobu Kimani was born in Nairobi, Kenya in 1978. He grew up in a small town at the foot of the Ngong hills just outside the city of Nairobi. He joined the University of Nairobi in 1999 for a Bachelor of Medicine and Bachelor of Surgery Degree. Upon graduation in 2003, he was posted to work in Western Kenya as a Government Medical officer.

In 2007, he began working as a physician in a research clinic providing services to low social-economic status female sex workers. It was while working here that his interest in research was kindled. He subsequently obtained a Master of Public Health Degree from the University of Nairobi

In 2016 he was accepted for a PhD studentship at the KEMRI-Wellcome Trust research program in Kilifi, Coastal Kenya and registered at the University of Amsterdam. He continued to work with marginalized communities including MSM and TW. He has a keen interest in HIV prevention especially the intersection of biomedical, behavioral and structural intervention.

Outside of work he is married to Salome Chira and they have two children. He is a strong believer in Gender equity in all spheres of life. Additionally, he is a lover of books and fast cars, though he has none. When not writing up research papers Makobu is a dedicated fitness enthusiast.



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Strengthening HIV preventive care services for Transgender Women and Men who have Sex with Men in Coastal Kenya



**Strengthening HIV preventive services for Transgender Women and Men who have Sex with Men
in Coastal Kenya**

"Because learning does not consist only of knowing what we must or we can do, but also of knowing what we could do and perhaps should not do."

The Name of the Rose

— **Umberto Eco, Italian Novelist**

Thesis, University of Amsterdam, The Netherlands

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**Strengthening HIV preventive services for Transgender Women and Men who have Sex with
Men in Coastal Kenya**

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad van doctor
aan de Universiteit van Amsterdam op
gezag van de Rector Magnificus
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ten overstaan van een door het College voor Promoties ingestelde commissie,
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List of abbreviations

AIDS	Acquired Immuno Deficiency Syndrome
ART	Anti-retroviral Therapy
CI	Confidence interval
CBO	Community-based organisation
CMD	Common Mental Disorders
EDCTP	European & Developing Countries Clinical Trials Partnership
FSW	Female sex worker
HCP	Health care provider
HIV	Human immunodeficiency virus
iPrEX	initiative to provide pre-exposure prophylaxis
IR	Incidence rate
KNASP	Kenya National AIDS strategic plan
KP	Key populations
MDI	Malindi Desire Initiative
MSM	Men who have sex with men
MSME	Men who have sex with men exclusively
MSMW	Men who have sex with men and women
NASCOP	National AIDS and STI control program
OLE	Open-label extension
OST	Oral self-Test
PEPFAR	Presidents emergency program for AIDS relief
PHQ-9	Public Health Questionnaire (9-items)
PLWH	People living with HIV
PrEP	Pre-exposure Prophylaxis
PWID	People who inject drugs
SDG	Sustainable Development Goals
sSA	sub-Saharan Africa
TDF	Tenofovir Disoproxil Fumarate
TFV	Tenofovir
TW	Transgender Women
UN	United Nations
VMMC	Voluntary medical male circumcision
WHO	World Health Organisation

Chapter 1

Introduction

Preamble

Globally, the human immunodeficiency virus (HIV) epidemic is currently in its fourth decade. In sub-Saharan Africa (sSA), the HIV epidemic was initially considered to be largely a result of heterosexual transmission [2]. Consequently, for the first three decades of the epidemic, the impact of HIV on men who have sex with men (MSM) was unknown [3, 4]. However, over the last decade, reports confirming high HIV incidence and prevalence among MSM, both in Kenya and the larger sSA region, have been published [5-7]. Supported by this evidence, MSM in Kenya are recognized as a key population (KP) deserving targeted HIV prevention [8, 9]. However, despite this recognition, access to HIV preventive services remains a challenge for MSM in Kenya, as elsewhere in sSA.

Transgender women (TW) are individuals who were assigned male sex at birth but currently identify as women, with or without the use of gender-affirming treatment [10]. Globally, even in settings where HIV prevalence is low in the general population, TW consistently demonstrate higher prevalence [11]. TW face major challenges to societal acceptance, especially in sub-Saharan Africa (sSA) [12]. TW are often categorized as MSM [13]. This is problematic to TW as they neither identify as men [14] nor are their needs met at MSM focused facilities [15]. Frequently TW experience continued denial of their existence and basic human rights [16].

In Kenya, like most of sSA, there are no legal structures to guarantee protection for gender minorities including TW [17]. This legal context can be very challenging for TW to change either names or sex on official documents [18]. Consequently, TW often experience an incongruence between their official and current identities. Furthermore, due to stigma and discrimination from the general community, TW frequently are unable to secure stable housing or engage in formal employment, and consequently many resort to sex work. These facts synergistically create a hostile environment that may increase behavioural risk for HIV infection among TW.

The effectiveness of pre-exposure prophylaxis (PrEP) for HIV prevention has been previously demonstrated [19-22]. Since 2017, Kenya has been providing programmatic PrEP for people at increased risk for HIV infection [23]. However, Kenyan PrEP guidelines do not specifically target either MSM or TW [24]. For example, current PrEP guidelines lack recommendations about assessment and screening based on condomless anal intercourse, specific, and they do not consider factors that might affect PrEP initiation and adherence in these groups such as stigma and mental health. Additionally, TW are not recognized as a KP in Kenya. The lack of guidelines may result in healthcare providers (HCP) being unsure how to serve patients who identify as TW [16]. In addition to HIV prevention, TW desire gender-affirming therapy and may prioritize it over other interventions [25]. In general, healthcare services for TW are severely lacking [14].

The overall objective of this thesis was to assess the challenges to the uptake of HIV prevention services among both TW and MSM in coastal Kenya and propose possible mitigation measures. This thesis addresses the following sub-objectives: (i) assessment of HIV incidence and desire to take up PrEP in MSM and TW; (ii) PrEP adherence and persistence in MSM and TW; (iii) qualitative exploration of perceived and experienced challenges to PrEP provision for MSM and TW; and (iv) assessment of the association between common mental health disorders (CMD) and HIV among in MSM.

HIV in Kenya

It is almost four decades since the first diagnosis of the human immunodeficiency virus (HIV) was made in the United States [26]. Initially, HIV first manifested as a rarely seen skin malignancy, Kaposi's Sarcoma in gay men living in San Francisco, California [27]. Since it was first diagnosed, HIV has spread globally, and by 2019, an estimated 38 million (95% Confidence interval (CI), 31.6-44.5 million) people are living with HIV (PLWH), and 32.7 million (95% CI 24.8-42.2 million) have died of HIV/AIDS. Of this number, a majority, i.e. 20.7 million (95% CI, 18.4 - 23.0 million), live in either Eastern or Southern Africa [28].

Some of the earliest documented reports of HIV infection in Africans involved migrants from the then Republic of Zaire (now the Democratic Republic of Congo) living in Brussels and Paris diagnosed with acquired immunodeficiency syndrome (AIDS) [29], as HIV had as yet not been

identified. Piot et al. then carried out a three-week survey at a large public hospital in Kinshasa, Zaire, and diagnosed AIDS in 38 patients [30]. Subsequently, in 1984, while working in Rwanda, Van de Perre et al. reported on 26 participants from a public hospital in Kigali Rwanda diagnosed with AIDS [31].

Similar to most of sSA, HIV began to be diagnosed in Kenya in the mid-1980s. The earliest documentation of HIV in Kenya was in 1984 [32]. Subsequently, among low social-economic female sex workers (FSW), a high HIV prevalence (66%) was documented among 90 low socioeconomic female sex workers (FSW) [33, 34]. Additionally, a study involving a small number of higher socioeconomic status FSW (n=26), found an HIV prevalence of 31% (8 prevalent infections) [34]. In the same study, Kreiss *et al.* also established an 8% HIV prevalence among men receiving treatment for sexually transmitted infections (STI), including one man that admitted to having sex with both men and women [34]. None of the FSW in the study reported sexual contact with foreigners, thus the study hypothesized that men may have been responsible for HIV introduction from Central Africa and transmission in Kenya [34].

In 1994, an investigation involving 970 long-distance truck drivers demonstrated an HIV prevalence of 27% (n=257) [35]. Of the 257 HIV positive drivers, only 40% reported condom use and 13% reported regular contact with FSW. Only 2% reported either anal or oral sex, but data were not stratified by the sex of the sexual partner [35]. In an earlier study set in Uganda, an HIV prevalence of 35% was documented among 68 long-distance track drivers that regularly began their journey from the port city of Mombasa in Kenya [36]. Initially, the HIV epidemic in Kenya was thought to be transmitted exclusively by heterosexual contact [2, 37]; the existence of anal sex between males was denied and discounted as a possible source of HIV transmission [38, 39]. Consequently, the role of anal sex between males and HIV transmission was rarely assessed or recognized over two decades into the Kenyan epidemic [3].

HIV prevalence peaked in Kenya at 10.5% between 1995-1996 [40]. However, by 2003, a 40% decline in HIV prevalence to 6.5% was recorded. The precipitous decline in prevalence between 1996-2003 is attributed to high mortality in the period before antiretroviral therapy (ART) was available.

Currently in the general Kenyan population, at the end of 2018 HIV prevalence was 4.9% [41]. Kenya, alongside Uganda and Mozambique, are jointly ranked third for nations with the highest number of people living with HIV (PLWH) [42]. According to the 2018 Kenya Population-based HIV Impact Assessment (KENPHIA) report, there are approximately 1.3 million Kenyan PLWH, and an estimated 36,000 new infections occurred in 2018 [41]. The Kenyan population HIV incidence is currently estimated at 0.14 per 100 person-years (95% CI 0.06-0.23) [41]. However, there is variability in both sex distribution and age ranges most affected. There is sex disparity in HIV prevalence, estimated at 6.2% (95% C.I 5.7-6.8) in women, which is over twice that in men (2.7%, 95% C.I 2.4-3.1) [41]. Among youth aged 15-24 years, overall HIV prevalence was 2.0%, and similar to the general population, twice higher in female youth (2.6%) compared to male youth (1.3%) [43]. As of 2018, the coastal Kenya HIV prevalence was highest in Mombasa county at 5.6% and lowest in Tana river county at 1.1%. Kilifi county, the setting for a majority of the studies in this thesis, is a medium burden county, with HIV prevalence at 2.3% [41]. Unfortunately, county HIV data are not disaggregated by risk groups; therefore, the contribution of MSM or TW to county HIV prevalence remains a matter of deduction.

Early Response to the HIV epidemic in Kenya

In the early part of 1985, the Kenyan government issued statements denying the existence of HIV in the country [44]. The denial might have been in an attempt to alleviate public apprehension and protect the tourism industry [45], which was at the time Kenya's largest source of foreign exchange [46]. Later in 1985, only under pressure from the public did the Government finally admit that about 20 Kenyans were HIV infected. These infections were attributed to the interaction between Kenyan FSW and foreign tourists [44]. However, this claim was inaccurate as the findings from the FSW cohort [33] did not document interaction between FSW and foreigners; instead, all their clients were local Kenyan men.

In the early 1990s with an increase in the number of new HIV infections in Kenya, information-based prevention efforts began. However, in the absence of other evidence-based strategies, prevention messaging focused on behaviour change. Messaging was based on the effectiveness of the 'ABC' strategy from Uganda [47]. The 'ABC' strategy championed, in decreasing

preference; abstinence, being faithful to one partner or a reduction in the number of sexual partners, and condom use. Consequently, within Kenyan society, HIV acquired a moral perception; being infected with HIV was equated with promiscuity [48]. In addition, religious leadership contributed to stigma towards HIV infection by portraying prevention as only possible from a social-moral point of view [45, 49]. Media sensationalism [50, 51] and official denialism [44] around HIV may have been partially responsible for the uncontrolled transmission of HIV in the mid-1990s [40].

To better coordinate the Ministry of Health response to HIV/AIDS, the National AIDS and sexually transmitted infections control program (NASCO) was set up in 1987 [52]. Its mandate was the promotion of knowledge on HIV transmission, encouragement of safer sex practices including condom use and the recognition, and prompt treatment for STIs. Unfortunately, within the wider society, stigma towards HIV continued as deeply held social, cultural, and religious norms still regarded HIV from a morality point of view. Prevention messages painted HIV infection as a death sentence. Archived infographics available over the internet from the period the late 1980s to the mid 1990s, often featured pictures of extremely ill individuals as the face of AIDS [50]. Journalists were also ill-prepared to report on HIV and often referred to PLWH as 'AIDS victims' implying an almost hopeless situation [50].

In contrast to Kenya, the Government in neighbouring Uganda had a long-running HIV recognition policy that had been hailed as a success [53]. Partly in response to pressure from donor institutions [45], the Kenyan Government began to accord HIV prevention a more prominent status and in 1992 developed the second medium-term plan (MTP) that acknowledged HIV as a national problem needing intersectoral collaboration [54]. In 1999, on account of statistics that pointed to over half a million AIDS-related deaths, Kenyan president Daniel Arap Moi finally declared HIV to be a national disaster, requiring concerted prevention effort [55]. An HIV prevention policy dubbed the 'ABC' was rolled out. It emphasized the practice of either abstinence, reduced sexual partners, or consistent condom use in descending order of preference [56]. Significantly missing, however, was an appreciation of key populations in the Kenyan HIV epidemic.

ART Success and scale-up

Following the 1999 Kenyan presidential declaration, a more coordinated response to the epidemic was initiated. The first Kenya National AIDS Strategic Plan (KNASP I) was launched. It resulted in the development of multiple policy documents that guided the HIV response, spanning the period from 1999-2004. It was superseded by KNASP II [57]. This marked the period when access to ART began to be scaled up both globally and in Kenya.

At the 13th International AIDS Society conference held in Durban Republic of South Africa in 2000, over 5,000 HIV researchers penned a commentary calling for the availability of safer, more affordable, and easier to use ART drugs [58]. Consequently, in 2002, the United States Government launched PEPFAR, which has been hailed as the world's largest single effort at HIV prevention and treatment (<https://www.hiv.gov/federal-response/pepfar-global-aids/pepfar>) [59]. Its overriding mission was to accelerate progress towards control of the HIV epidemic in 12 sSA target countries, amongst them Kenya. In its 17 years of existence, PEPFAR has supported access to ART for over 15.7 million PLWH. In Kenya, approximately 1.1 million PLWH have accessed life-saving ART through PEPFAR [60]. On their website, PEPFAR estimates that globally about 18 million lives have been saved through the provision of ART. The findings from three large long-running cohorts involving serodiscordant couples show that virally suppressed individuals had minimal likelihood of transmitting HIV to their sexual partners [61-63]. This result informed the 2018 UNAIDS press release coined 'Undetectable=Untransmissible' (or U=U) [64] as a testament to the success of the ART scale-up.

Evolution of HIV epidemic control

According to the 2017 World Health Organization (WHO) Global AIDS Update report, new HIV infections have declined 16% during the past decade [65]. According to the UNAIDS 2020 report, global HIV incidence has reduced by approximately 40% since the peak in 1998 [28]. However, infections continue as evidenced by the approximately 1.7 million (95% CI 1.2-2.2 million) incident HIV infections estimated globally in 2019 [28]. In sSA, overall HIV incidence reduction has been reported in cohort studies conducted in both Southern [66] and Eastern Africa [67, 68]. Between 2012-2018, participants in a South African prospective cohort with

access to ART demonstrated an overall 43% reduction in HIV incidence [66]. However, the reduction was more pronounced in men with a 59% reduction in incidence rate (IR) from 2.49 (95% CI 1.83-1.76) in 2012 to IR 1.01 (0.58-1.76) in 2018. Among women, incidence declined by 37% from IR 4.89 (95% CI, 4.09-5.84) in 2012 to IR 3.06 (95% CI 2.38-3.94) in 2018. That men had a more precipitous decline in HIV incidence was attributed to scale-up of voluntary medical male circumcision (VMMC) five years prior. Additionally, as more women took up PrEP and achieved viral suppression, heterosexual HIV transmission declined further preventing new infection in men. Findings from a prospective cohort study conducted in the Rakai district in Uganda demonstrated an overall HIV incidence decline from 1.17 cases/100 person-years (py) in the year 1999 to 0.66 cases/100py by the year 2016, translating to an adjusted incidence rate (aIR) of 0.46 (95% CI, 0.29-0.73) [67]. Similar to the findings from South Africa, in the Rakai study, there were differences in HIV infections between men and women. Of the 931 incident infections over a 16-year follow-up period, 59% (n= 549) were in women. Finally, in a 2018 study from Western Kenya, HIV incidence in men was reported at 6.4 (95% CI, 5.1-7.8)/1000 py compared to 8.2 (95% CI, 6.7-8.7)/1000py[68] among women. The reduced HIV incidence in western Kenya was partially attributed to increased access to ART and the scale-up of VMMC for HIV management and prevention. In the Rakai study, ART coverage increased from 12% in 1999 to 69% in 2016. Similarly, the uptake of VMMC increased from 15% to 59% in the same period [68]. The combination of ART coverage (in men and women) and increased VMMC uptake is associated with a reduction in HIV incidence in men (aIR 0.46, 95% CI, 0.29-0.73) [67]. In corroboration of the success of these population-level interventions, the UNAIDS fast track 95-95-95 targets to accelerate the elimination of HIV by the year 2030 are informed by successes of ART scale-up in these regions [69].

HIV in Kenyan key populations

The World Health Organization (WHO), describes key populations (KP) as groups that, due to specific higher risk behaviours, are at increased risk of HIV irrespective of the epidemic type or local context. There are typically legal and social issues related to behaviours that increase vulnerability to HIV among KP members [70]. In the Kenyan context, KP encompass multiple diverse groups including FSW, adolescent girls and young women (AGYW), people who inject

drugs (PWID), MSM, truck drivers and fisherfolk. In the context of this thesis, two key population groups will be discussed in more detail – i.e. MSM and TW.

Men who have Sex with men (MSM)

Worldwide, MSM have a higher HIV prevalence compared to the general population. This is confirmed by results of a recent systematic review and metanalysis of HIV prevalence in which males in the general sSA population were compared to MSM in sSA [7]. HIV prevalence in MSM was 17.8% (95% C.I 3.7-33.5) compared to 6.1% (95% C.I 0.5-19.7) in the general male population. Even in West Africa, where HIV incidence in the general population is comparatively lower than in other sSA settings, prevalence was still higher among MSM [7].

While the existence of MSM in Kenya was previously ignored in HIV policy, anecdotal evidence has long indicated the occurrence of male homosexual relationships [71] and a possible link to HIV transmission has been hypothesized [72]. However, the earliest published epidemiological reports on HIV among MSM in Kenya emerged in 2005 through the efforts of researchers from the Population Council, which conducted snowball recruitment to identify 500 MSM in Nairobi [73]. This initial study found that a significant MSM population existed in Nairobi but faced stigma and discrimination and had reduced access to HIV screening. Respondents also reported having multiple sex partners including female partners. A follow-up report by Population Council documented the prevailing homophobic sentiment at the time, which challenged HIV research and programs addressing MSM [74]. To obtain an initial MSM population size estimate, in 2006, a capture-recapture enumeration in Mombasa was conducted, which estimated that 739 (95 % CI, 690-798) MSM were selling sex [75]. Notably, this enumeration study was unable to estimate the number of MSM not engaged in selling sex. That over a thousand MSM had been identified in two of Kenya's largest cities was indicative of a large population underserved by existing HIV prevention policy guidelines. During this time, Sanders *et al* began to enrol individuals who engaged in transactional sex, including some men who reported to have sex with men, in preparation for an HIV vaccine trial involving at-risk individuals [76]. Consequently, a cohort of 285 MSM was set up in the town of Mtwapa, 20

kilometres north of Mombasa. Unlike the previous two studies of MSM [73, 75] that only collected behavioral data, MSM participants in the Mtwapa cohort provided biological samples for HIV and STI testing. From the cohort emerged the first MSM HIV prevalence estimate of 24.5% (95% CI, 19.7-30.7) [76].

Engagement of MSM in Sub-Saharan Africa

In most parts of sub-Saharan Africa, same-sex relationships are both socially stigmatized and legally criminalized. Of the 54 recognized countries and territories in sSA, only 21 do not have specific sections in their penal codes that ascribe punishment for homosexuality [17]. Of the 32 African countries where homosexuality is illegal, 4 (Mauritania, Nigeria, Somalia, and Sudan) have extreme punishment including possible death penalties [17]. However, even in countries where there are no laws criminalizing homosexuality, the protection of gay and lesbian human rights is not guaranteed. Only the Republic of South Africa has a provision in its constitution that recognizes the legality of same-sex marriage [17].

The strong sentiment against homosexuality in this region is perpetuated by a combination of conservative cultures, deeply held religious beliefs on matters of sexuality, and a legal context that offers no protection to the basic rights for lesbian, gay, bisexual and transgender (LGBTI) community members. To a large degree, this situation was borne out of the wholesale adoption of the English common law by most former British colonies in Africa as part of their penal codes. Indeed, so similar was the adoption of British colonial law that the wording of the section about same-sex relations in Kenya, Malawi, Botswana, Zambia, and Zimbabwe's are essentially identical [77]. However, in 2019 Botswana repealed that section of their penal code and decriminalized same-sex relationships [78]. Mozambique, Angola, and Seychelles have also amended their penal codes to decriminalize same-sex relationships [17].

The general societal stigma toward male homosexuality may also be rooted in a perceived aversion to anal sex even among heterosexual partners [79]. However, the occurrence of anal sex has been documented in heterosexual partnerships in Kenyan society [80, 81] as an alternative to vaginal sex during menses [82], for the preservation of virginity [83], and as a form of contraception [82]. Anthropological studies among communities in coastal Kenya have

described the occurrence of same-sex behaviour as a rite of passage into adulthood for boys [84]. The relationship often involved an older male and ended when the younger male married a woman.

Other cultural factors contribute to societal stigma toward homosexuality and MSM behaviour in sSA. For example, there are widely held expectations regarding masculinity, manhood, and the continuation of lineage in sSA families. Men are typically socialized to settle with a female partner and have children [84], and being in a same-sex relationship negates both of these expectations. MSM who are living with HIV face additional forms of stigma. Findings from Cape Town demonstrated that 57% of MSM living with HIV had internalized stigma, which refers to the acceptance and belief in the legitimacy of their marginalized status [85]. In qualitative work with healthcare providers and MSM living with HIV from Coastal Kenya, healthcare providers expressed the sentiment that MSM had deeply internalized stigma and observed that MSM patients were likely to interpret most interpersonal healthcare interactions through the lens of discrimination, thereby further driving a wedge between MSM and society [86]. However, this negative sentiment towards MSM from healthcare providers may not be unfounded. In a study of MSM in three Southern African countries, over 20% had experienced some form of stigma and 5% had been denied services at a health facility on account of their sexual orientation [87].

Challenges among healthcare providers when providing services to MSM

Article 34 Section 1(a) of the Kenyan constitution guarantees the right of all Kenyans to access the highest attainable standard of health including health care services [88]. At face value this might seem an inalienable right; however, the enforcement of this Article is challenging [89]. HCPs hold positions of power and trust, and those seeking health services tend to believe that HCP will exercise responsibility in wielding this power. However, HCP may have personal beliefs about homosexuality that compromise their ability to provide services to MSM. Medical training curricula in Kenya do not prepare HCP for working with different sexual orientations [90] and often HCPs must learn on the job about services for MSM.

Previous research in coastal Kenya involving 74 HCP demonstrated strong levels of homophobic sentiment in this group. The profile of HCP most likely to be intolerant to MSM included those

who were younger, male, and working in a public health facility. A pilot three-month MSM sensitization programme for HCP in coastal Kenya found that, at post-test analysis, HCP participants were more likely to acknowledge the need to respectfully engage with and provide services to MSM as part of HIV transmission prevention efforts, compared with their attitudes assessed at baseline [91, 92]. HCP participants also anticipated possible challenges in providing services to MSM, due to their heavy workloads and pressure from the larger society against sexual minorities [92]. This study concluded that an MSM sensitization programme for HCP was feasible and contributed to positive changes in attitudes toward MSM patients, but also indicated that HCP who choose to provide services to MSM must navigate a complex set of barriers including personal values regarding homosexuality as well as peer pressure and societal expectations to affirm heterosexuality. Notably, this study did not assess HCPs' attitudes and ability to serve TW patients.

Transgender women (TW)

Gender refers to the social construct that confers attributes of either being male or female. While biological sex conferred to an individual at birth based on the newborn's external genitalia [10], an individual's sense of their gender might change over time and might depart from their sex assigned at birth. Gender dysphoria describes an individuals' cognitive discontent with the biological sex assigned to them at birth [93]. Previously, gender dysphoria was known as gender identity disorder [94]. In the 2012 version of the international classification of diseases (ICD-11), the WHO removed gender identity disorder as a mental condition and replaced it with gender dysphoria, which refers to a sexual health condition [95], and thereby challenges the assumption that people with this condition are mentally ill.

Transgender is an umbrella term that includes a broad spectrum of individuals whose gender identity is outside the dichotomy of male or female. An individual assigned male sex at birth but who currently identifies as female is a transgender woman, whereas an individual assigned female sex at birth but who identifies as male is a transgender man [10]. Individuals who do not identify with the traditional gender binary are referred to as non-binary. The content in this thesis is restricted to TW due to the recognition of high HIV risk in this group. By contrast, HIV

prevalence among transgender men (TM) is currently low, and thus this group is not examined in this thesis.

Globally, TW have been previously misclassified as MSM and these two groups have typically not been disaggregated as distinct populations [13]. This is both epidemiologically and socially problematic, as TW neither identify as men nor have the same sexual and lived experiences as MSM [14, 15, 96, 97]. This misclassification can result in a feeling of erasure of TW by society [16]. This feeling of erasure was demonstrated in a recent editorial in which TW researchers challenged the aggregation of TW and MSM as an indication of being ignored in research and called for a need for research to prioritize TW as a distinct population to better prepare healthcare providers for working with this population and to reduce misgendering (i.e., misclassification of people's gender identity) in health service settings [16].

Accurate population estimates for the transgender population are difficult to obtain [98]. TW often hide their identity due to risks to safety and security, endemic stigma, discrimination and violence. Even where societies are more tolerant of transgender populations, there are challenges to harmonizing enumeration methods [99]. Enumeration could either be clinic-based sampling or community-based sampling [98]. Clinic-based sampling faces challenges as it assumes all transgender people will seek gender-affirming therapy at a medical facility, and thus transgender individuals who do not seek therapy are unlikely to be appropriately counted. Indeed, findings from a respondent-driven survey among 314 TW in the United States demonstrated that a majority (68.7%) were on feminizing hormone therapy but almost half (49.1%) self-medicated [100]. The reasons for self-medication included the inability to access a specialist and a desire to transition faster [100]. Community-based sampling faces challenges insofar as transgender people must disclose their gender identity to researchers.

A 2016 survey by the Williams Institute estimated between 0.36% and 0.95% (854,066-2,293,511) of the national population in the United States were transgender [101]. The report did not disaggregate respondents by gender identity subgroup (e.g., TW versus TM versus non-binary). In South-East Asia, TW have historically been known to exist and words to describe them are reflected in local languages. In Pakistan, India, and Bangladesh TW are known as *hijra*,

while in Thailand they are called *kathoey*. Since 2014, the *hijra* in India have been officially recognized as a third gender [102].

HIV burden in TW

Globally, TW have the highest risk of HIV infection. In a 2008 systematic review including 25 studies, Operario et. al demonstrated an HIV prevalence of 27.3% among TW sex workers, compared to 15.1% in cisgender male sex workers and 4.5% in cisgender female sex workers. Differences in HIV prevalence translated to a four-fold increased risk of living with HIV among TW sex workers compared to cisgender female sex workers (RR 4.02, 95% CI 1-6-10.1)[103]. Findings from a review by Herbst et al. of HIV among TW in the United States including 22 studies [104], demonstrated a similar HIV prevalence of 27%, (95% CI 24.8-30.6). Additionally, the Herbst review demonstrated clear racial disparities, with 56.3% of African American TW testing positive compared to 16.7% in Caucasian TW and 16.1% amongst Hispanic TW [104].

In 2013, a systematic review of the global literature by Baral et. al revealed that TW had an almost 49-fold increased risk for HIV acquisition (OR 48.8, 95% CI 31.2-76.3) compared to the general population. The review also demonstrated HIV infection risk among TW was high in all global regions, with the highest risk in India (OR 208.0, 95% CI 148.0-292.3) and lowest in Thailand (OR 9.9, 95% CI 7.8-12.6) [105]. Reasons for this increased risk for HIV acquisition include unprotected receptive anal sex, multiple sexual partners, unequal power dynamics during sex work, shared needles for either drug use or gender-affirming hormones, homelessness, stigma, marginalization and unmet healthcare needs [104-110].

There are very limited data on TW in East and Southern Africa. Indeed, at the time of the 2013 systematic review by Baral et. al, there were no studies involving TW from the African continent [105]. An opinion piece in 2012 by Jobson et. al concluded that TW remain invisible and ignored in sSA due in part to lack of legal protection, stigma, and discrimination, which contribute to their absence in the empirical literature [111]. It has also been postulated that the lack of recognition of TW in Kenya and most of sSA can be partially attributed to the absence of explicit assessment of gender identity (compared to sex assigned at birth) in survey research conducted in sSA [112].

The existence of TW in sSA and their associated HIV-risk cannot be ignored. Findings from three studies across sSA have demonstrated high HIV incidence among TW. In a study of 22 TW conducted in 2015 at the Sibanye health project in two South African cities, HIV incidence was estimated as 32.0 (95% CI 3.7-111.8)/100 py [113]. In a larger Nigerian cohort of 71 TW, HIV incidence was 23.8 (95% CI 13.6-39.1)/100 py [114]. These two incidence estimates among TW are in the same range as the incidence estimate among TW in coastal Kenya [115] (this thesis). These initial HIV incidence estimates suggest a need for further research to characterize the prevention needs for TW in sSA.

The emergence of transgender populations in Kenya

Anthropological reports from the late 19th century have documented the existence of cross-dressing males in Swahili culture in Mombasa [116]. There are, however, no explicit descriptions of non-conformity in gender identity in Kenya. While peer-reviewed studies involving TW are beginning to emerge, media reports have highlighted harassment of TW in Kenya from as far back as 2010 [117]. Prior to the 2019 study (Chapter 2 of this thesis) [115], the existence of TW in Kenya was largely unknown in HIV research literature. Indeed, TW are not yet recognized as a KP in Kenya’s HIV prevention guidelines. It is conceivable that TW have been conflated alongside MSM.

In the last five years, TW have gradually become more visible in Kenya. There have been increased spaces – community and online – where TW can express themselves. Ms. Audrey Mbugua is an openly living TW in Kenya. She won a lawsuit that compelled the Ministry of Education to remove the male sex mark on her high school certificates [18]. She also heads a community-based organization (CBO), known as the Transgender Education and Advocacy (TEA) that advocates for transgender rights. Her advocacy work helped to bring attention to the existence of TW in Kenya [118].

Over the last five years, with support from the Global Fund, a raft of LGBT-lead community organizations have burgeoned in Kenya. There are both national and regional CBOs, including the East Africa Transgender health and advocacy network (EATHAN), and *Jinsiangu* (Swahili for ‘my gender’). Regional CBOs in coastal Kenya include *Pwani* transgender initiative (PTI) in

Mombasa, *Mwamko Mpya* (Swahili for 'the new beginning') in Kilifi and Lamu counties, and the Malindi Desire Initiative (MDI). An umbrella organization, the Trans*Alliance Kenya, is charged with coordinating the activities of these CBOs. In 2019, at a 2-day workshop in Mombasa attended by leadership and membership of 39 local and national organisations, 6 CBOs (15%) were specifically programming for TW [119]. The existence of these and possibly many other organizations may be indicative of a larger TW population in Kenya than that currently observed by research to date.

A research policy brief released in 2016 by FHI 360 entitled "The nexus of gender and HIV in transgender communities" noted that TW in Kenya were often classified as MSM, which perpetuated their social, legal and political invisibility and contributed to their deprivation from necessary services [119]. Additionally, transgender competent healthcare services including gender affirmation therapy were deemed as missing. Transgender respondents described in this brief expressed that gender affirmation was more important to them than HIV prevention [120]. A key recommendation from the report was that NASCOP should recognize transgender people as a KP for HIV prevention and treatment services. It additionally advocated for competency training to prepare HCP to provide services to transgender people [120].

To better understand and update the epidemiological landscape of KP in Kenya, NASCOP conducted an enumeration exercise of KP in 2018. This exercise aimed to better understand the impact of KP programming since the most recent one conducted in 2012 [121]. The enumeration identified transgender individuals in 34 counties. They estimated 4,305 (range: 2,826-5783) transgenders are living openly in Kenya. About 1,064 (25%) transgender individuals were living in Nairobi, while 341 (8%) were living in Kilifi county [122]. However, a limitation to this enumeration is that data were not segregated according to the respondents' current gender identity. Due to stigma and transphobia from society, some transgender individuals may not have presented themselves for enumeration. It is likely that the enumeration exercise underestimated the transgender population. Future research is necessary to build a stronger foundation for intervention and policy addressing TW. A respondent driven sampling (RDS) survey could possibly give more accurate results compared with enumeration methodology, although RDS is also limited by the assumption that members of targeted communities are

linked within identifiable social networks. Also important is the need for future research to disaggregate data by individuals' current gender identity (TW versus TM versus non-binary) to better plan for interventions.

Legal recognition for TW in Kenya

In 2016, five individuals identified only by their initials and three organizations filed a petition at the high court in Nairobi. Known formally as Petition 234 of 2016, it challenged the legality of Section 162 (a), (c) and Section 165 of the Kenya penal code [123]. The petitioners considered these Sections to be in contravention of the Kenyan constitution because of their discrimination towards the lesbian, gay, bisexual and transgender community (LGBT). Sections 162 and 165 of the penal code criminalize same-sex relationships and prescribe a jail term not exceeding 14 years for anyone convicted under the Unnatural Offense Act [77]. By 2019, the petition had attracted significant public attention and was commonly known as the *#repeal162* petition. On the 24th of May 2019, Justice John Mativo of the Kenyan High Court ruled against the petitioners and the sections of the penal code remained in place [123]. The petitioners plan to appeal the ruling in a higher court. If successful, the petition would be the first crucial step towards the legal recognition to TW in Kenya.

Pre-exposure prophylaxis for HIV prevention in MSM and TW

Introduction to PrEP effectiveness globally

Pre-Exposure prophylaxis (PrEP) is the use of antiretroviral therapy (ART) in HIV negative individuals for prevention [10].

The earliest evidence of daily PrEP effectiveness was from the multi-country PrEP initiative trial (iPrEx) [19]. The overall trial demonstrated that PrEP conferred a 44% protective effect against HIV infection. However, secondary data analysis showed that PrEP was 92% effective for HIV prevention among MSM and TW with detectable drug levels (95% CI 40-99; $P < 0.001$), indicating the importance of adherence and sustained involvement in PrEP counselling and support [11, 19]. Subsequently, PrEP effectiveness has been demonstrated in heterosexual men and women

in Botswana in 2012 [22], in serodiscordant couples in East Africa [21], and Thailand among people who inject drugs (PWID) [124].

Collectively, the body of initial PrEP studies reported varied results, from a high of 75% HIV prevention effectiveness in the partners' PrEP study [21] to a low of 44% in the IPrEx study [19]. In 2012, WHO commissioned a systematic review that included complete or ongoing randomized clinical trials of PrEP efficacy. The pooled findings from 12 studies concluded that Tenofovir (TFV) containing PrEP was protective against HIV acquisition (RR 0.51, 95% CI, 0.30-.86) [125]. Based on this evidence, WHO has since 2015, recommended the use of tenofovir disoproxil fumarate (TFV-DP) containing PrEP medication in individuals at increased risk for HIV acquisition to complement HIV prevention efforts [70].

In 2016, Kenya's NASCOP issued updated HIV prevention and treatment guidelines that included the provision of programmatic PrEP to people at increased risk for HIV acquisition [23]. Kenya became the second country in Africa after the Republic of South Africa to provide PrEP to a wide range of population groups. In 2017, in a highly publicized event, NASCOP launched the national PrEP implementation framework that signalled the official introduction of PrEP services in Kenya [126, 127]. According to PrEPWatch ([www. https://www.prepwatch.org/country/kenya/](https://www.prepwatch.org/country/kenya/)) at the beginning of October 2020, between 72,000-73,000 Kenyan individuals had initiated PrEP [128]. This is a significant achievement and currently, Kenya has the world's largest PrEP program. The data are however not available disaggregated by gender or risk group accessing PrEP, and sustained use of PrEP is not known.

PrEP provision to MSM and TW in Kenya

As described, MSM and TW are at disproportionate risk for HIV infection [4, 11]. However, risk for HIV infection in these groups is not homogenous. A 2013 study among MSM in coastal Kenya demonstrated an overall HIV incidence of 8.6 (95% CI 6.7-11.0)/100 py. Among MSM that also had sex with women (MSMW) HIV incidence was 5.8 (95% CI 4.2-7/9)/100 py compared to 35.2 (95% CI 23.8- 52.1)/100 py among those that exclusively had sex with other men (MSME) [5]. These high incidence estimates from the period preceding programmatic-PrEP were indicative of an unmet yet urgent HIV prevention need.

In a mixed-methods study involving 55 MSM from both Nairobi and Kisumu, 83% expressed willingness to take up PrEP if it was made available [129]. There was heterogeneity in PrEP uptake willingness; exclusively homosexual men (those with the highest risk of HIV-acquisition) expressed lower willingness compared to bisexual men. Similarly, younger MSM (less than 22 years) were more enthusiastic about PrEP uptake. It is possible that younger MSM had more sexual partners and probably engaged in more risky sex, and hence were more cognizant of their HIV acquisition risk. All respondents expressed reservations about uptake if they had to pay for PrEP [129].

The Kenya PrEP guidelines [23] have a set of criteria to assess for HIV infection risk and guide PrEP provision but do not target or address the unique needs of MSM or TW. Current PrEP guidelines include specific language for individuals who: have a serodiscordant sexual partner, engage in transactional sex, have recurrent sexually transmitted infections, have recurrent post-exposure prophylaxis use (PEP), have sex under influence of alcohol, have inconsistent condom use, or share needles for intravenous drug abuse. However, the guidelines fail to mention receptive anal sex and group sex, both of which are predictors of HIV acquisition [5].

The challenge in adherence to PrEP

PrEP effectiveness is proportional to adherence. In the iPrEx open-label extension trial (OLE)[130], overall HIV incidence was 1.8/100 py. However, clear differences were seen in HIV incidence between trial participants who were PrEP adherent compared to those with low adherence. Adherence in this study was determined by an assessment of dried blood spot (DBS) for Tenofovir Disoproxil Fumarate (TDF) drug levels. There were no incident infections in those that had DBS drug levels corresponding to 4 or more pills per week (≥ 700 fmol per punch) [130, 131]. In an exploratory analysis of MSM accessing PrEP at the Mtwapa cohort in coastal Kenya, only 14% had evidence for protective drug levels (≥ 700 fmol per punch) [132]. This low level of adherence among MSM suggests limited likelihood for PrEP effectiveness. Research is needed to understand the experiences of MSM and TW who initiate PrEP, in order to identify strategies to enhance protective effects in these KPs.

Barriers and facilitators to PrEP in MSM

Data on barriers and facilitators to PrEP uptake in MSM in sub-Saharan Africa (SSA) are limited, but include fear of side effects, HIV related stigma, and concerns about drug efficacy [133-135]. In contrast, free drugs and higher self-risk perception have been noted as facilitators to PrEP uptake [136, 137]. Potential PrEP recipients may be willing to receive PrEP, but access to these medications may be an additional hurdle. Challenges to PrEP use are exacerbated when health care providers (HCP) become a barrier to PrEP access. Research conducted in diverse global settings has found that HCP report being hesitant to prescribe PrEP for reasons including fear of future ART resistance [138-140], not being sure who is qualified to receive it [137-140], and personal values and morals [137, 139]. The majority of these data were collected during the period preceding programmatic PrEP availability. To optimize the population level impact of PrEP, additional research is needed to examine the patient-level and provider-level factors that influence uptake and adherence. PrEP research addressing KPs in SSA is especially warranted. While MSM and TW in Kenya and elsewhere in SSA stand to benefit significantly from PrEP, users' personal preferences, health seeking behaviour, and health-system related factors may individually or collectively impact uptake, adherence, and retention.

Mental health and key populations

Mental health and HIV infection risk in MSM: The Syndemics theory

The term syndemic was originally coined by medical anthropologist Merrill Singer to describe the concurrent occurrence and mutual reinforcement of substance use and HIV infection in marginalized communities [141]. Among MSM, syndemic theory has been used to explain the mutual interaction between mental health conditions and increased risk for HIV infection, and the exacerbated effects of a health condition on one another [142, 143]. Another syndemic has been described among MSM, characterized by history of childhood abuse, marginalization, and victimization due to sexual orientation that result in the development of depressive symptoms,

harmful alcohol use, and substance use [140-142]. Consequently, this syndemic process may influence sexual risk-taking behaviour further compounding risk for HIV infection, with mental health being a key health condition contributing to and exacerbating HIV and other behavioural risk factors. In light of the important role of mental health and substance use in determining HIV risk and prevention, this thesis considers these health issues as co-occurring areas of concern for MSM and TW in Kenya.

Introduction to mental health

WHO defines mental health as a 'state of well-being, where an individual both recognizes and realizes their ability to cope with the stress of normal life and can make a meaningful contribution to their community [144]. Target 3.4 of the United Nations (UN) sustainable development goals (SDGs) prioritizes attention to mental health [145]. According to the WHO, approximately 25% of the world's population experience some form of mental health challenge [146]. In 2016, approximately 6.8% of all disability-adjusted life years (DALYs) were lost to mental health conditions [147]. The highest number of DALYs lost to mental health were reported from high-income countries [147], however, this finding may be biased due to under-reporting or limited research on mental health conditions from low and middle-income countries.

Common mental disorders (CMD) is a WHO classification for three conditions highly prevalent in the general population, including depressive symptoms, anxiety disorders and harmful alcohol and substance use [148]. Of the three CMDs, depression is the most prevalent affecting over 300 million people or 4.4% of the world's population [148]. However, depression is generally underdiagnosed and poorly managed, especially in low social-economic settings [149]. When left undiagnosed, modelling studies report that depression cost about 7.3 trillion dollars in lost economic activity between 2010 and 2013 throughout sSA [149], which is comparable to 7.1 trillion dollars lost to cardiovascular diseases. Additionally, depression has been linked to an increase in suicidal ideation. In Uganda, a study amongst PLHIV (n=618) found that the prevalence of lifetime attempted suicide was 3.9%, and that major depressive disorder diagnosis was strongly associated with suicide attempts (aOR 30.3, 95% 14.4-63.6) [150]. CMD

have major social and economic ramifications when untreated. However, CMD are frequently deprioritized in favour of curative health care provision in developing countries. This thesis attempts to bring light to the importance of CMD in MSM and TW, and elucidate potential interconnections between CMD and HIV risk.

Kenyan mental health services

In Kenya, as in most African countries, mental illnesses are frequently viewed from a cultural perspective and sometimes perceived as a form of reprisal for known and unknown religious offences rather than as a medical condition [151]. Consequently, insufficient attention is given to mental health service provision. Indeed according to the WHO, Kenya is one of 28 other member states that do not have a specific budget for mental health service provision [144]. According to a 2015 report, in the African region, there is one mental health care service provider to cover 100,000 people, compared to 50/100,000 in Europe [144].

The Kenyan mental health policy (2015-2030) was developed to align mental health service provision to the constitution [152]. It aims to address systematic challenges to mental health services in Kenya, specifically to increase the number of mental health service providers. There is only one specialized mental health referral facility in Kenya. Additionally, a recent situational analysis reported that there are only 92 psychiatrists in Kenya – a majority of whom are in major cities [153].

While nationally representative data on mental health in Kenya are scarce, there are statistics from regional studies. In 2015, Jenkins et al. documented a 10.8% prevalence of CMD in rural Western Kenya [154]. A 2017 study in the same region disaggregated CMD and demonstrated high population prevalence of depressive disorders (12.6%), anxiety disorders (15.7%) and alcohol/substance use (11.7%) in Western Kenya [155]. A study in coastal Kenya among people living with HIV documented depressive disorder prevalence at 13.8% (95% C.I 10.9-17.3) [156]. Even in the absence of nationally representative data, sentinel surveys point to unmet mental health needs. No known studies have documented CMD among MSM and TW in Kenya. Unfortunately, there exists an acute shortage of both mental health practitioners and specialized mental health institutions that serve the general population; services that are

sensitive to MSM and TW populations are currently absent. Despite having a policy in place, Kenya has not prioritized provision mental health services. Research

Mental health in MSM and TW

There are limited data on mental health among MSM in sSA. Emerging findings depict urgent challenges. Studies of MSM conducted in Swaziland and South Africa find this group to have a higher prevalence of common mental disorders compared to the general population – especially depressive disorders, as well as harmful alcohol use, and substance abuse [157, 158]. CMD among MSM in these settings has been attributed to stigma, lack of legal recognition, discrimination from HCP, lack of social support and abuse. In Tanzania, a study of 200 MSM found that 30% reported physical abuse and almost half (48.5%) reported verbal abuse. The perpetrators of anti-MSM violence included family members, law enforcement officers and even strangers on the street [159].

In Coastal Kenya [160], a study involving 112 MSM estimated prevalence of depression at 16.1% (95% CI 9.8-24.2) based on the PHQ-9 (a well-validated depression screening instrument), while harmful alcohol use prevalence was 45.0% (95% CI 35.2-54.3). In the same study, almost half of MSM respondents had a history of childhood abuse. A recent publication involving 595 MSM and male sex workers in Nairobi demonstrated high prevalence of depression (36.0%), harmful alcohol use at 36.8%, and substance abuse in 39.2% of respondents. Over half of all respondents (50.2%) reported having needed to seek help for a mental health condition. Of those seeking mental health services, 92.0% did so at an MSM-lead community-based organization [161].

To the best of our knowledge, there are currently no data available on mental health studies involving TW in Kenya.

Aim of the thesis

The objective of this thesis was to understand the challenges faced by both MSM and TW to the uptake of HIV prevention services in coastal Kenya, with a focus on PrEP uptake and adherence.

A brief introduction to the study site

Three of the studies in this thesis were carried out at the most at-risk populations (MARPs) office adjacent to the comprehensive care clinic (CCC) at the Malindi sub-County hospital. One study was a secondary data analysis of a multisite study conducted in Kisumu, Nairobi and Mtwapa.

Malindi is the largest urban municipality in Kilifi county. It is about 120 km north of Mombasa. It has good road linkage to Mombasa and is also served by a small airport. Malindi is known for its resorts, popular with tourists, initially from Italy. According to the 2019 Kenya national census, the population of Malindi was about 120,000 people [162]. Data on HIV prevalence at a sub-county level are unavailable. According to the 2018 KenPHIA report HIV prevalence in Kilifi county was 2.3%, (95% CI 0.2-4.5) [41]. There has been previous documentation on the existence of male sex-workers in Malindi [163].

In 2016, through a collaboration with an MSM-lead CBO, known as *AMKENI*, an HIV peer-lead oral self-testing (OST) pilot study reached out to over 300 MSM [164].

At the MARPs office, KP including MSM and TW can access HIV testing, linkage to care, PrEP, and limited STI screening and treatment. While the clinic is integrated into the hospital, KP can discreetly enter through a backdoor, making it a safe space for MSM and TW.

With support from the European & Developing Countries Clinical Trials Partnership (EDCTP) in 2018, a 40-foot shipping container was refurbished into an office and houses a counselling room, a mini-laboratory and a large data room.

In 2019, TW in *AMKENI* established their own organization. Consequently, a new CBO known as Malindi Desire Initiative (MDI) has been allocated space within the MARPs-office to start HIV

prevention work in collaboration with KEMRI-Wellcome researchers. This author continues to lead a capacity-building project to strengthen the leadership of MDI.

Outline of the thesis

This thesis is organized as follows: *Chapter 2* estimates HIV-1 incidence in MSM and TW in Malindi, Kenya, and their interest to take up PrEP. *Chapter 3* assesses PrEP adherence and persistence among MSM and TW who were followed in a one-year cohort study in Malindi. *Chapter 4* explores the barriers to PrEP provision from the perspective of health care providers, community leaders, and PrEP end users. *Chapter 5* assesses mental health and substance use challenges of MSM across 3 locations in Kenya. Finally, *Chapter 6* discusses recommendations for improved HIV preventive care services for TW and MSM, including PrEP services, in coastal Kenya, and reflects on limitations of current KP programming in Kenya. *Chapter 6* also notes the limitations of studies included in this thesis and provides suggestions for further research to improve Kenya's evidence base to guide HIV prevention programming for MSM and TW. This collection of research studies presents a crucial step forward in Kenya's capacity to provide effective, sensitive, and ethical HIV services to Kenyan MSM and TW, who are highly stigmatized in the national context. Although these challenges are rooted in complex histories, public health research can provide a platform to move the needle toward improved inclusion of these groups in HIV prevention, treatment, and policy in Kenya.

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Chapter 2:

PrEP Interest and HIV-1 Incidence among MSM and Transgender Women in coastal Kenya

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Abstract

Background: There is emerging data on HIV-1 incidence among MSM in sub-Saharan Africa (SSA), but no known estimate of HIV-1 incidence among transgender women (TGW) in the region has yet been reported. We assessed HIV-1 incidence and pre-exposure prophylaxis (PrEP) interest in men who have sex with men exclusively (MSME), men who have sex with men and women (MSMW), and TGW in coastal Kenya.

Methods: HIV-1-seronegative individuals who had participated in an HIV testing study in 2016 were traced and retested in 2017 according to Kenyan guidelines. All participants were assigned male sex at birth and had male sex partners; additional data on gender identity and sexual orientation were obtained. We assessed factors associated with HIV-1 acquisition using Poisson regression and calculated HIV-1 incidence in MSME, MSMW, and TGW. PrEP interest was assessed through focus group discussions to characterize sub-categories' perceived PrEP needs.

Results: Of 168 cohort participants, 42 were classified as MSME, 112 as MSMW, and 14 as TGW. Overall, HIV-1 incidence was 5.1 (95% confidence interval [CI]: 2.6-9.8) per 100 person-years (PY): 4.5 [95% CI: 1.1-17.8] per 100 PY among MSME, 3.4 [95% CI: 1.3-9.1] per 100 PY among MSMW, and 20.6 [95% CI: 6.6-63.8] per 100 PY among TGW. HIV-1 acquisition was associated with exclusive receptive anal intercourse (aIRR 13.0, 95% CI 1.9-88.6), history of an STI in preceding 6 months (aIRR 10.3, 95% CI 2.2-49.4), and separated/divorced marital status (aIRR 8.2 (95%: 1.1-62.2). Almost all (98.8%) participants were interested in initiating PrEP. MSME and TGW felt that PrEP would lead to increases in condomless anal or group sex.

Conclusion: TGW had a very high HIV-1 incidence compared to MSME and MSMW. Subcategories of MSM anticipated different PrEP needs and post-PrEP risk behaviour. Further studies should assess if TGW may have been wrongly categorized as MSM in other HIV-1 incidence studies in the region.

Introduction Globally, key populations including men who have sex with men (MSM) are at disproportionate risk for HIV-1 acquisition [5, 165]. However, within populations categorized as MSM, there is important variability that carries implications for HIV prevention interventions, such as pre-exposure prophylaxis. Estimated HIV-1 incidence in coastal Kenya has been as high as 35.2 [95% confidence interval (CI) 23.8–52.1] per 100 person-years (PY) among MSM who exclusively have sex with men (MSME), compared to 5.8 (95% CI: 4.2–7.9) per 100 PY among MSM who have sex with both men and women (MSMW) [5]. However, no HIV-1 incidence has been estimated in transgender women (TGW) in sub-Saharan Africa (SSA).

A systematic review and meta-analysis of studies in developed countries reported that TGW have 49 times the odds of having HIV-1 when compared to the general population[105]. The elevated risk for HIV-1 acquisition in TGW may be due to higher rates of unemployment, drug and alcohol use, transactional sex, homelessness, gender based violence and social stigma [106, 166]. Due to risk for being re-victimized by law enforcement, TGW are less likely to report their assaults or go to hospitals for post-assault care such as post exposure prophylaxis (PEP) [167].

The efficacy of PrEP among high-risk MSM and TGW has been demonstrated in the iPrEx trial [168, 169]. Additional analysis of iPrEX revealed lower PrEP drug concentrations among TGW compared with MSM participants, suggesting problems with adherence among TGW [170].

Since May 2017, Kenya has promoted PrEP use among various at-risk populations [171]. Kenyan PrEP guidelines do not specifically target known risk factors for HIV-1 acquisition among MSM, including condomless anal intercourse, group sex (i.e., sex with more than one partner during a sexual episode), and the biological sex of sexual partners [172]. TGW are not discussed as a population at risk in current Kenyan PrEP guidelines.

As willingness to take PrEP differed among MSMW and MSME in a previous study in Kenya [129], we hypothesised that subgroups of MSM may have different motivations to start PrEP. We further

hypothesized that TGW would have different motivations to start PrEP compared with MSM. The aim of this study was to 1) estimate HIV-1 incidence among different high-risk sub-groups: MSME, MSMW, and TGW; and 2) to assess PrEP interest and barriers and facilitators of PrEP adherence among these high-risk sub-groups.

Methods

Study setting

The study was carried out at the Malindi Sub-County Hospital in coastal Kenya. Since 2008, KEMRI-Wellcome Trust Research Project (KWTRP) has been supporting the hospital to provide HIV-1 testing and counselling to key populations, including MSM, TGW and female sex workers. Engagement with these subgroups was supported by a partnership with *AMKENI*, a community based organisation serving local key populations.

Recruitment

Inclusion criteria for the cohort study included: male gender at birth, report of a male sex partner in the previous 6 months, and participation in a parent study of HIV oral self-testing (OST) conducted between March and June 2016 [173]. *AMKENI* peer educators were asked to trace all 219 MSM who tested HIV-1 seronegative in 2016 for retesting with Determine (Abbott, Laboratories, Abbott Park, Illinois, USA), followed by First Response (Premier Medical Corporation, Nadi Daman, India) according to Kenyan national guidelines [68].

Between May and July 2017, prospective participants were screened by study staff who verified previous participation in the OST study, including participant's name (or nickname), age, and date of confirmatory HIV-1 test in 2016. Individuals whose participation in the OST study could not be verified were excluded. All participants underwent HIV-testing at the enrolment visit. Those who tested HIV-1 positive were offered ART. The estimated date of infection of these seroconverters was calculated as the

mid-point between their last documented HIV-1 negative test and the date of study enrolment and repeat testing.

Social-demographic information including age, education level, marital status, and employment status were collected. In addition, participants were asked their gender identity and sexual orientation. Participants were also asked to report risk behaviour over the previous 6 months, including vaginal intercourse; anal intercourse; role taking during anal intercourse (i.e. insertive, receptive or versatile); receipt of cash, goods, or living expenses in exchange for sex, and if they had symptoms suggestive of a sexual transmitted infection (i.e. penile or rectal discharge). TGW were asked to report hormone therapy. All participants did the PrEP interest survey, a 26-item survey tool capturing knowledge on, and desire to access PrEP, and preferred venue to receive PrEP. For this analysis, MSME was defined when intercourse was reported only with men; MSMW when intercourse was reported with men and women, and TGW when a participant identified as a female.

Focus group discussions

HIV-1 negative individuals were invited to participate in focus group discussions (FGD). Depending on participant's self-reported sexual behaviour and gender identity, participants were invited to one of three FGD groups MSME, MSMW, and TGW. FGD were facilitated by Kenyan study staff who were fluent in both Kiswahili and English. FGD guides addressed the following general topics: PrEP knowledge, interest to take up PrEP, perceived barriers and facilitators to PrEP uptake and adherence, and preferred PrEP dispensing venue. FGD lasted approximately 90 minutes. Most discussions were conducted in Kiswahili, although English was also used based on participants' language preference. All discussions were audio-recorded, transcribed, and those conducted in Kiswahili were translated into English. All participants provided written informed consent for FGD. In total, 11 MSMW, 10 MSME and 7 TGW participated in the FGDs.

Data management and analysis

Quantitative analysis

Data from the OST study were used to compare participants in that study who enrolled or did not enroll in the current study. In the 2017 study, data were entered on an online data base (REDCap™ Research Electronic Data Capture). Data cleaning and analysis was done on Stata 15.0 (StataCorp LLC, College Station, Texas, USA). Descriptive statistics were used to compare baseline sociodemographic and behavioural characteristics of the three subgroups at enrolment. Observation time for each participant was calculated as the time between the HIV-negative test during the OST study and the date of the current study expressed in terms of PY. HIV-1 incidence rates were calculated as the number of HIV-1 incidence cases divided by PY of follow-up, and expressed as incidence per 100 PY.

We assessed potential predictors of HIV-1 acquisition using data collected in 2017. Poisson models with robust standard errors were used to obtain population-averaged incidence rate ratios. Variables significant at $P \leq .2$ in bivariable analysis were included in a multivariable model of potential predictors for HIV-1 acquisition. P values were 2-sided and significance was set at $P \leq 0.05$.

Qualitative analysis

Analyses of qualitative data followed the thematic analysis as described by Braun and Clarke [174], which involved systematic coding to identify and define concepts, map the concepts, create typologies, find associations between concepts, and seek explanations from the data. NVivo 10 was used for managing the data. Data were coded by two independent qualitative researchers to ensure that interpretations of quotes were consistent and that data quality was rigorous and transparent; differences between coding were resolved by group discussion involving other members of the research team. Recurring issues,

concepts and patterns were identified using both inductive and deductive reasoning. Analyses highlighted whether findings differed by participant sub-categories.

Ethics Statement

Study procedures were approved by the KEMRI scientific and Ethical Review Unit (KEMRI/SERU/CGMR-C/0073/3418). All participants provided written informed consent prior to data collection. All participants were informed that PrEP was freely available at Malindi sub-county hospital.

Results

Between May-July 2017, 219 MSM participants in the 2016 OST pilot study were targeted for enrolment and of whom 168 (76.7%) enrolled into the 2017 study. The 51 participants who could not be located were more likely than enrolled participants to be MSMW, Muslim, and married, and reported more frequent vaginal sex and less frequent receptive anal intercourse in the past 6 months (data not shown).

Of the 168 enrolled participants, 112 were MSMW, 42 MSME and 14 TGW (Table 1). They had similar background characteristics except for employment status. Overall, the mean age for all participants was 26.7 years (interquartile range: 25.9-27.5), 68.5% had primary education only, 83.3% were single, and 45.8% were Muslim. Formal employment was higher among TGW compared with MSME and MSMW. Almost all (98.2) had lived in Malindi for two or more years.

Since the OST pilot study in 2016, all participants tested for HIV at least once, with approximately 1 in 4 MSME and TGW taking ≥ 4 or more HIV tests in the year preceding data collection. There were differences in reported sexual behavior in the three groups in the past 6 months: TGW had the highest report of either receptive anal intercourse only, or both receptive and insertive anal intercourse. Two participants (1 MSME and 1 TGW) reported having an STI in the past 6 months.

Approximately one third (32.1%) of all participants reported transactional sex in the past 6 months, with higher reported transactional sex in MSME (42.9%) and TGW (42.9%) compared to MSM (24.1%). One TGW reported hormonal therapy to support gender transition.

A quarter of all participants had ever tried to get post exposure prophylaxis (PEP); 2.4% had ever tried to access PrEP. Interest to take up PrEP was high across all sub-categories. A total of 163 (97%) said that they would take PrEP if it was offered with only 4 MSMW being unsure. Over half of all participants (53.0%) expressed that the preferred venue to access PrEP would be a private health facility, none of the TGW preferred to collect PrEP from a public hospital, and 42.9% of MSME and 72.7% of TGW preferred to obtain PrEP from a LGBT-run community centre.

Nine incident HIV-1 infections occurred: 4 in MSMW, 2 in MSME, and 3 in TGW (Table 2). Overall, the estimated HIV-1 incidence was 5.1 per 100 PY (95% CI: 2.6-9.8). Within the sub-categories of MSM, HIV-1 incidence in MSMW was 3.4 per 100 PY (95% CI: 1.1-18.2), in MSME 4.5 per 100 PY (95% CI: 1.2-9.2), and in TGW 20.6 (95% CI: 6.6-63.8) per 100 PY.

In multivariable analysis, HIV-1 acquisition was strongly associated with exclusive receptive anal intercourse adjusted (incidence rate ratio (aIRR) 13.0, 95% CI 1.9-88.6), history of an STI in preceding 6 months (aIRR 10.3, 95% CI 2.2-49.4), and separated/divorced marital status (aIRR 8.2 (95%: 1.1-62.2), while a self-or unemployed status had a borderline significance (aIRR 3.3 (95%: 0.9-11.6, $p=0.06$) in a model controlling for risk group.

Qualitative findings:

A total of 11 MSMW, 12 MSME and 7 TGW (all HIV-negative) participated in three sub-group distinct FGDs. Four themes regarding PrEP implementation emerged from the qualitative analysis, revealing

some commonalities and distinctions by subgroup regarding their stated interests and concerns related to PrEP (Table 3).

PrEP awareness and potential for risk compensation

Participants in all sub-categories expressed knowledge on PrEP including efficacy and mode of action, as exemplified by a member of the MSME group (Quote A, Table 3) Additionally, the limitations of PrEP were noted across all subgroups, as noted by a member of the MSMW group who acknowledged that *“PrEP will not protect you from STIs.”*

However, we observed subgroup differences regarding acknowledgment about the possibility of increased sexual risk behavior following PrEP uptake (i.e., risk compensation), particularly alluding to erratic condom use. Members of the TGW and MSME group were especially likely to acknowledge the potential reduction in condom use (Quotes B and C, Table 3).

Barriers to PrEP uptake

All sub-categories commented on the possibility for HIV-related stigma due to PrEP, and feared that PrEP medication would be confused by others in their social networks (e.g., family members, partners) with anti-retroviral drugs, as one member of the TGW group noted *“the pill that looks like the medication for HIV-positive patients”*. MSME particularly talked about anticipated enacted stigma in the context of their homophobic social environment, and expressed fear that healthcare providers may not be willing to offer them PrEP (Quote D, Table 3).

Across the subgroups, we observed concerns about the potential need to disclose to partners or family members about the reasons for taking PrEP medications. Participants across subgroups described the dilemma of living a “double life” such that their partners or family members were unaware of their sexuality or gender identity. Participants from both MSM subgroups discussed the likelihood that

“promiscuity would be blamed on them....”. As one TGW remarked: *“What explanation will a Trans like me, who has a wife and family, give?”* Another TGW expressed concern that being witnessed using PrEP would lead others to mistake them as sex workers:

“... but it can be very challenging at times, especially to us who are not sex workers. I’m not a sex worker; I’m in a steady relationship...Yes, PrEP is a new good thing, but convincing your faithful partner that it protects against HIV..... it will raise suspicion. It can be much easier to a sex worker... but it may not be applicable to a Trans who has a faithful partner.....(TGW)

In addition, participants commented on PrEP adherence challenges. Daily dosing was expressed as a barrier to PrEP, especially noted by those in the MSMW group (Quote E, Table 3). Other barriers to PrEP adherence were noted by TGW participants, including the likelihood for missed doses due to alcohol or drugs, perceived risk for interactions between PrEP and hormones, and potential side effects.

Motivations to initiate PrEP

PrEP availability was described in all subgroups as a welcome “relief” and PrEP information helped them in getting answers to their questions.

MSME and TGW in particular described that receptive condomless sex for them was common and often a consequence of alcohol and or drug use. As such, members of these groups felt that *“PrEP could be an alternative, or extra ‘layer’ of protection”*. TGW also noted that PrEP could help to protect against inadvertent disclosure of their “double life”. As a TGW remarked on the potential for PrEP to protect female partners from HIV transmission: *“Yes, I’m married to a lady, but at the same time, I identify myself as a lady. Therefore, I secretly have a sexual relationship with a man, because I feel I’m a woman... (With PrEP) I will be able to protect my wife and family, while at the same time fulfilling my sexual desires by going out as a lady”*.

Preferred PrEP dispensing location

Across groups, participants preferred PrEP to be dispensed either at LGBT operated clinics or private health facilities (Quote F, Table 3). Despite the government's endorsement of PrEP availability, participants in all three subcategories felt PrEP is still a controversial and divisive issue among health staff in general health clinics Kenya, hence they did not "*perceive them as suitable to dispense PrEP to MSM*".

Discussion

This study characterizes potential differences in HIV risk and PrEP interest between subgroups that are typically categorized as MSM in Kenya - MSME, MSMW, and TGW. Through disaggregating subgroups, we found a very high HIV-1 incidence in TGW, in comparison with incidence estimates for MSMW and MSME. It is possible that an earlier HIV-1 incidence estimate in MSME of 35.2 per 100 PY in coastal Kenya may have included TGW [5]. In the present study, TGW and MSME reported transactional sex more frequently than MSMW, and TGW had the highest reports of receptive anal course. While our study had few seroconverters, participants who reported only taking the receptive role during anal sex, who were separated or divorced, who had a history of a sexually transmitted infection, or who were unemployed or self-employed had an increased risk of HIV-1 acquisition. The high incidence in TGW is likely indicative of unmet prevention needs [105].

Globally, TGW have been underserved and have shown to have an exceptionally high HIV-1 burden [105, 111, 175]. Because TGW identify as female, they may prefer not to be identified alongside MSM[14]. The recent formation of a Kenyan community-based organization exclusively for transgender individuals may attest to the preference for specific services for TGW.

In this study, interest to PrEP was high in all three groups studied, suggesting that participants were sensitized about PrEP by peer educators before study start. In contrast to findings from a

systematic review that indicated that less than a third of MSM in low and middle income countries were unaware of PrEP [176].

Motivations to start PrEP varied by subgroup. While PrEP's effectiveness in conjunction with condoms was mentioned, MSME and TGW expressed particularly strong interests in PrEP in comparison with MSMW. Relatively little is known about risk compensation after PrEP initiation outside of trial settings [177]. MSME and TGW participants commented that they may increase their risk taking behavior, and that they were also unsure about taking PrEP daily, whereas these comments were not raised by MSMW participants [137]. Although community concerns about possible interactions between PrEP and feminizing hormones have been noted in previous research [25], participants in this study did not note such a concern.

Participants in all subgroups expressed strong disapproval of government hospitals as the venues for dispensing PrEP. This sentiment may reflect the limited skills training among healthcare to work effectively with MSM and TGW patients [92], and also suggests that national prevention programmes in Kenya do not yet note specific considerations for PrEP implementation with MSM or TGW populations [172].

There are limitations to this research. First, the sample of TGW was small, as recruitment depended on participants' willingness to disclose their gender identity. Second, the data were obtained from a convenience sample recruited through an LGBT community based organization. Third, because participants had not actually used PrEP, discussions reflected hypothetical concerns. Lastly, the study was conducted around the time of national PrEP roll-out, which may have influenced participants' PrEP interest and -knowledge.

Conclusion

There is variability within the population categorized as MSM that has implications for HIV incidence estimates and HIV prevention interventions, including PrEP. TGW in the Kenyan coast represents a previously unresearched group, and has not yet been targeted in HIV prevention programming in Kenya. As TGW have among the highest HIV-1- acquisition risks empirically documented in Kenya, they would benefit from specific PrEP adherence support. Further research on PrEP and other HIV prevention strategies with MSME, MSMW, and in particular with TGW is needed to identify specific public health promotion models that maximally respond to the specific needs of these unique vulnerable at-risk populations.

Author Contributions: ES, EvdE and MK conceived and designed the study, while the parent study of oral self-testing had been done by EvdE. MK coordinated the study. WK and SM consented participants and did the HIV-1 testing and counselling. OC provided logistical support for study activities. CO managed the database for the quantitative data. MK transcribed the audio recordings. EW supported MK with quantitative data analysis. EvdE independently reviewed the coding of the transcripts. ES provided overall oversight for fieldwork and supervision. TRdW, SG and DO supported the manuscript writing and provided oversight. All authors critically reviewed and approved of the write-up.

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Table 1. Socio-demographic and risk perception and PrEP interests of 168 MSM and TGW in Malindi, Kenya, 2016 to 2017

Characteristics	Total (N = 168) n (%)	MSMW (N = 112) n (%)	MSME (N = 42) n (%)	TGW (N = 14) n (%)	p value
Age group (years)					
18 to 24	63 (37.5)	38 (33.9)	19 (45.2)	6 (42.9)	0.695
25 to 34	87 (51.8)	62 (55.4)	19 (45.2)	6 (42.9)	
>35	18 (10.7)	12 (10.7)	4 (9.5)	2 (14.3)	
Education					
Primary	115 (68.5)	79 (70.5)	27 (64.3)	9 (64.3)	0.751
Secondary	41 (24.4)	24 (21.4)	13 (31.0)	4 (28.6)	
Higher	12 (7.1)	9 (8.0)	2 (4.8)	1 (7.1)	
Marital status					
Single	140 (83.3)	93 (83.0)	36 (85.7)	11 (78.6)	0.072
Married	14 (8.3)	13 (11.6)	0 (0.0)	1 (7.1)	
Separated/divorced	14 (8.3)	6 (5.4)	6 (14.3)	2 (14.3)	
Religion					
Muslim	77 (45.8)	50 (44.6)	20 (47.6)	7 (50.0)	0.197
Christian	56 (33.3)	33 (29.5)	18 (42.9)	5 (35.7)	
None/other	35 (20.8)	29 (25.9)	4 (9.5)	2 (14.3)	
Employment status					
Employed	29 (17.3)	14 (12.5)	10 (23.8)	5 (35.7)	0.041*
Self/un-employed	139 (82.7)	98 (87.5)	32 (76.2)	9 (64.3)	
Time lived in Malindi					
<2 years	3 (1.8)	1 (0.9)	2 (4.8)	0 (0.0)	0.236
≥2 years	165 (98.2)	111 (99.1)	40 (95.2)	14 (100.0)	
HIV testing frequency last 12 months ^a					
<4 times	128 (76.2)	89 (79.5)	30 (71.4)	9 (64.3)	0.326
≥4 times	28 (16.7)	14 (12.5)	10 (23.8)	4 (28.6)	
Vaginal sex last six months					
Yes	110 (65.5)	107 (95.5)	0 (0.0)	3 (21.4)	<0.001* **
Anal sex practice last six months					
IAI only	90 (53.6)	76 (67.9)	12 (28.6)	2 (14.3)	<0.001* *
RAI only	11 (6.5)	0 (0.0)	4 (9.5)	7 (50.0)	
RAI and IAI	67 (39.9)	36 (32.1)	26 (61.9)	5 (35.7)	
Sexually transmitted infection symptoms in last six months					
Yes	2 (1.2)	0 (0.0)	1 (2.4)	1 (7.1)	0.048* *
Transactional sex last six months					
Yes	51 (30.4)	27 (24.1)	18 (42.9)	6 (42.9)	0.042* *
Ever tried getting PEP					
Yes	43 (25.6)	24 (21.4)	14 (33.3)	5 (35.7)	0.213
Ever taken PEP					
Yes	36 (21.4)	19 (17.6)	12 (28.6)	5 (45.5)	0.354
Completed PEP					

Yes	17 (10.1)	11 (10.2)	3 (7.1)	3 (27.3)	0.232
Ever tried getting PrEP					
Yes	4 (2.4)	1 (0.9)	2 (4.8)	1 (9.1)	0.181
Likelihood of using PrEP if offered ^b					
Likely	163 (97.0)	107 (99.1)	42 (100.0)	14 (100.0)	0.631
Not sure	4 (2.4)	4 (3.7)	0 (0.0)	0 (0.0)	
Preferred venue for PrEP access ^b					
Public hospital	28 (16.7)	24 (22.2)	4 (9.5)	0 (0.0)	0.007
Private facility	89 (53.0)	64 (59.3)	19 (45.2)	6 (54.5)	
LGBT run community centre	42 (25.0)	20 (18.5)	18 (42.9)	8 (72.7)	
Pharmacy	5 (3.0)	4 (3.7)	1 (2.4)	0 (0.0)	

IAI, insertive anal intercourse; MSME, men having sex with men exclusively; MSMW, men having sex with men and women; RAI, receptive anal intercourse; TGW, transgender women. ^aMissing 12 values for "HIV testing frequency last 12 Months;" ^bmissing one value for "Likelihood of using PrEP if offered," "Ever tried to get PrEP" and "Ever tried to get PEP." *to denote significance of finding not strong; **indicating stronger significance of the difference; ***Very strong significance in the difference seen. Bolded P values indicate that differences between groups were statistically significant (p < 0.05).

Table 2. Factors associated with HIV-1 acquisition among 168 MSM and TGW in Malindi, Kenya, 2017

Characteristics value	Incidence/100 PY (95% CI)	Bivariable analysis		Multivariable analysis	
		IRR (95% CI)	p value	aIRR (95% CI)	p
All men	5.1 (2.6 to 9.8)				
Subgroup					
MSMW	3.4 (1.3 to 9.1)	Reference		Reference	
MSME	4.5 (1.1 to 17.8)	1.3 (0.3 to 7.0)	0.735	0.8 (0.2 to 3.7)	0.798
TGW	20.6 (6.6 to 63.9)	6.0 (1.5 to 24.2)	0.012	1.5 (0.2 to 10.7)	0.663
Age group (years)					
18 to 24	6.0 (2.2 to 15.9)	Reference		-	-
25 to 34	3.3 (1.1 to 10.1)	0.5 (0.1 to 2.4)	0.414		
>35	11.1 (2.8 to 44.4)	1.8 (0.3 to 8.8)	0.498		
Education					
Primary	5.8 (2.7 to 12.1)	Reference		-	-
Secondary	4.6 (1.2 to 18.5)	0.8 (0.2 to 3.7)	0.777		
Other	0	-	-		
Marital status ^a					
Single	3.4 (1.4 to 8.1)	Reference		Reference	
Married (Heterosexual)	7.2 (1.0 to 51.4)	2.1 (0.2 to 16.0)	0.514	3.9 (0.4 to 38.4)	0.238
Separated/divorced	20.0 (6.5 to 62.1)	4.1 (1.6 to 22.6)	0.008	8.2 (1.1 to 62.2)	0.042
Religion					
Muslim	5.0 (1.6 to 15.6)	Reference		-	-
Christian	7.3 (3.3 to 16.2)	1.5 (0.4 to 5.6)	0.586		
None/Other	0	-	-		
Employment status ^a					
Formal employment	9.9 (3.2 to 30.7)	Reference		Reference	
Self/un-employed	4.1 (1.8 to 9.1)	2.4 (0.6 to 9.1)	0.198	3.3 (0.9 to 11.6)	0.061
Time lived in Malindi					
<2 years	0				
≥2 years	5.2 (2.7 to 10.0)	-	-		
HIV testing frequency last 12 months					
<4 times	6.0 (3.0 to 12.0)	Reference		-	-
≥4 times	3.2 (0.5 to 23.0)	0.6 (0.1 to 4.4)	0.592		
Vaginal sex last six months					
No	6.4 (2.4 to 17.0)	Reference		-	-
Yes	4.4 (1.8 to 10.5)	0.7 (0.2 to 2.4)	0.523		
Anal sex practice last six months					
IAI only	4.4 (1.6 to 11.6)	Reference		Reference	
RAI only	17.1 (4.3 to 68.5)	4.1 (0.8 to 19.9)	0.081	13.0 (1.9 to 88.6)	0.009
RAI and IAI	4.1 (1.3 to 12.6)	1.0 (0.2 to 4.4)	0.992	1.4 (0.4 to 5.2)	0.611
Transactional sex last six months					
No	4.1 (1.3 to 9.8)	Reference		-	-
Yes	7.3 (2.7 to 19.5)	1.8 (0.5 to 6.6)	0.351		
History of having a sexually transmitted infection in last six months ^a					
No	4.6 (2.3 to 9.1)	Reference	0.158	Reference	
Yes	53.4 (7.5 to 379.1)	10.4 (2.2 to 48.7)	0.003	10.3 (2.2 to 49.4)	0.003

aIRR, adjusted incidence rate ratio; CI, confidence interval; IAI, insertive anal intercourse; IRR, incidence rate ratio; MSME, men having sex with men exclusively; MSMW, men having sex with men and women; RAI, receptive anal intercourse; TGW, transgender women. ^aOnly factors significant at $p < 0.2$ in the bivariable model were retained in the multivariable model.

Table 3: Summary themes identified from the FGDs with MSME¹, MSMW², TGW³

Major themes	Sub-themes	Representative Quote
PrEP awareness, regardless of sexual orientation		
1	Information and PrEP literacy	PrEP efficacy knowledge <i>PrEP will not protect you from STIs, but I think it is about 99% protective for HIV. I think it is just about the same as Trust (condoms) which are 100% protective (MSMW)</i>
		Awareness of PrEP procedures “Quote A”: <i>For seven days, you take it (PrEP) like at 7 in the morning. After seven days when the drug is concentrated enough, you can have sex probably with an infected person and you will be protected, after that you’ll continue to take (PrEP) because that is how you will be fully protected (MSME)</i>
		Requesting information before starting PrEP <i>....I would first prefer to get proper information about its side effects. You know...maybe the PrEP drugs require that I take it in on a full stomach, yet I’m a hustler (of low economic status) (TGW)</i>
2	Consultation about PrEP	Self-consultation <i>.... the first person to consult should be your own self, your inner self, you must ask yourself, do I really need to use this drug?... (MSMW)</i>
		Peer consultation <i>One should consult his peers, whom they identify with. I think consulting them would bring more sense than consulting a person who has no clue about your sexual orientation... (TGW)</i>
3	Awareness of risk compensation	“Quote B”: <i>The fact is, most of us... Trans, will stop to use condoms, upon starting PrEP (TGW)</i> “Quote C”: <i>Group sex will increase, people will have the mentality that we will not get HIV so people will be rough and they will not use protection ... (MSME)</i>
Barriers to PrEP uptake considered specific to MSM sub-categories		
1	HIV related stigma	Anticipatory stigma <i>The problems can arise if the drugs (PrEP) are seen in public...because someone I know might be at that place (where the drugs are seen) and then they will go tell people that I have AIDS. How can I even explain to them that these are not ARVs? (MSMW)</i>
		Homophobic context “Quote D”: <i>You see, we will be branded sinners ... at the hospitals... the kind of people we are... (MSME)</i>
2	Daily dosing regimen	Uncertainty of daily adherence “Quote E”: <i>What is boring about this (PrEP), is the daily ... like there is a friend of mine who was very excited when he heard about it, but when he realized one has to take it daily, he said: “If this is the case then I will never use it” (MSMW)</i>

3	Fear for side effects		<i>The fact that one has to take it (PrEP) daily my feeling was that it may destroy the kidneys, rather I would have HIV. So, how to protect myself from HIV without getting kidney failure? (MSMW)</i>
4	Concomitant drug use	Forgetfulness/interruption	<i>Sure, alcohol can make one to forget taking his pills (MSMW)</i>
Motivations to embark on PrEP			
1	Sense of relief	Peace of mind	<i>When I heard about PrEP, I was very pleased by it [ilinipunga] because I want to live well without any worries. (MSME)</i>
		Opportunity for increased income	<i>Individuals like us who do sex work, can benefit most. This is because some of us don't use condoms. Therefore, PrEP can guarantee an individual of maximum protection against HIV during an unprotected sexual encounter with an HIV infected person (TWG)</i>
		More pleasurable (condomless) sex	<i>I also fear condom breaks, but I also do not like using condoms during sex. I like having unprotected sex. This is what is more pleasurable. Condoms reduce the pleasure. If I had a choice, yes, I would rather not use condoms (MSMW)</i>
		Ascribing significance to PrEP being a Trans	<i>Those playing top (inserters) have no issues because they have a choice to put on a condom and protect themselves, of which is not the case with us. When I go out, I become a strict bottom. So, it's up to me, to take precautionary measure (TGW)</i>
Preferred PrEP dispensing location			
1	Public run vs. MSM community run healthcare facilities	MSM specific section	"Quote F": <i>At the Government hospital, GBMSM are not free to be themselves. Sometimes there is discrimination. But if there was a special place, like XX that is only for GBMSM that would be best (MSMW)</i>
MSME ¹ Men who have sex with men exclusively, MSMW ² Men who have sex with men and women, TGW ³ Transgender women			

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Chapter 3

Pre-exposure prophylaxis adherence and persistence in TW and MSM in coastal Kenya

“I wish to remain HIV negative”: Pre-Exposure prophylaxis adherence and persistence in Transgender women and Men who have Sex with Men in Coastal Kenya

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Abstract

Background

Transgender women (TGW) and men who have sex with men (MSM) in sub-Saharan Africa have high HIV acquisition risks and can benefit from daily pre-exposure prophylaxis (PrEP). We assessed PrEP adherence by measuring tenofovir-diphosphate (TFV-DP) levels and explore motives for PrEP persistence in TGW and MSM.

Methods

Participants were enrolled in a one-year PrEP programme and made quarterly visits irrespective of whether they were still using PrEP. At their month 6 visit, participants provided a dried blood spot to test for TFV-DP levels; protective levels were defined as those compatible with ≥ 4 pills per week (700-1249 fmol/punch). Before TFV-DP levels were available, a sub-set of these participants were invited for an in-depth interview (IDI). Semi-structured IDI topic guides were used to explore motives to uptake, adhere to, and discontinue PrEP. IDI data were analyzed thematically.

Results

Fifty-three participants (42 MSM and 11 TGW) were enrolled. At month 6, 11 (20.7%) participants (8 MSM and 3 TGW) were lost to follow up or stopped taking PrEP. Any TFV-DP was detected in 62.5% (5/8) of TGW vs. 14.7% of MSM (5/34, $p=0.01$). Protective levels were detected in 37.5% of TGW (3/8), but not in any MSM. Nineteen IDI were conducted with 7 TGW and 9 MSM on PrEP, and 1 TGW and 2 MSM off PrEP. Unplanned or frequent risky sexual risk behaviour were the main motives for PrEP uptake. Among participants on PrEP, TGW had a more complete understanding of the benefits of PrEP. Inconsistent PrEP use was attributed to situational factors. Motives to discontinue PrEP included negative reactions from partners and stigmatizing healthcare services.

Conclusion

While MSM evinced greater adherence challenges in this PrEP programme, almost 40% of TGW were protected by PrEP. Given high HIV incidences in TGW these findings hold promise for TGW PrEP programming in the region.

Key words: PrEP, Adherence, persistence, Transgender women, MSM, Kenya

Introduction

The World Health Organization (WHO) recommends pre-exposure prophylaxis (PrEP) to be offered to all populations at increased risk for HIV acquisition. Since May 2017, Kenya has been providing PrEP (daily pill; Tenofovir and Emtricitabine) through existing antiretroviral care programmes, family planning and partner notification services targeting adults meeting a wide range of risk criteria (1). PrEP eligible participants include mostly young women in HIV high-burden locations (2), and HIV-negative partners from newly diagnosed index participants (3). While men who have sex with men (MSM) are targeted for PrEP initiation in Kenya, PrEP uptake is limited. An assessment of missed opportunities for PrEP delivery among over 47533 MSM and 40338 young women in Kenya showed that MSM had substantially more (75% vs. 8%) missed opportunities to initiate PrEP than young women (4).

While PrEP efficacy has been proven also in sub-Saharan Africa (SSA) (5), it is unknown what motivates the uptake and adherence to PrEP among MSM and transgender women (TGW) in Kenya. In a study in South Africa in 2015, among 167 MSM and TGW, approximately half of the participants started PrEP, but this study did not collect adherence data or laboratory markers of protection (6). In a recent study in coastal Kenya among 170 MSM eligible for PrEP, 140 (82%) started it and 64 (58%) reported PrEP use at the end of study (7). Among 76 MSM who reported PrEP use and had Tenofovir Diphosphate (TFV-DP) determined 6-12 months after PrEP initiation, only 11 (14.5%) had protective TFV-DP concentrations in blood plasma corresponding with ≥ 4 tablets a week (7). To our knowledge, this is the only study that has reported PrEP protective levels in MSM in SSA, and no study has reported PrEP protective levels among TGW in SSA.

The low protective tenofovir concentrations in MSM in coastal Kenya contrast with results from a large demonstration study among MSM and TGW in the US that reported high PrEP protective levels (80% - 82%) at follow-up visits over a similar duration (8). These high protective tenofovir concentrations were attributed to favourable community perception and awareness of PrEP effectiveness (8).

Globally, TGW have a very high HIV-1 prevalence (9) compared to other at-risk groups, and have been largely overlooked in the HIV epidemic response in SSA (10). Our recent work in Kenya demonstrated a high HIV-1 incidence (20.6 per 100 person years) among few TGW, indicative of an unmet PrEP need (11). While both MSM and TGW were interested in starting PrEP, TGW expressed reservation to access PrEP at a public health facility, and indicated that they would prefer to collect PrEP from a community-

based lesbian, gay, bisexual and transgender (LGBT) organization (11). Earlier, we showed that PrEP adherence among MSM was impacted by a range of behavioural and psychosocial factors, including alcohol intake, travel, forgetfulness, and environmental barriers such as stigma and unfriendly healthcare providers (12).

We set out to assess PrEP adherence among a sample of MSM and TGW who participated in a PrEP program in coastal Kenya. We measured protective TFV-DP levels in blood samples and qualitatively explored motives for PrEP use and persistence in a sub-set of participants. Findings can inform development of a comprehensive and synergistic approach to improving PrEP adherence for MSM and TGW.

Materials and Methods

Site

The study took place in a large Government hospital in coastal Kenya where PrEP services were provided along with HIV care services. Participants received PrEP services at a specialized office site for members of key populations, located adjacent to the general HIV care clinic. Site operations have been described previously (11). In brief, MSM and TGW were offered free HIV counselling and testing; those testing HIV-1 positive were linked to care and offered ART. Participants testing HIV negative were offered PrEP provided free of charge by the Ministry of Health. Through a partnership with the community-based organization *AMKENI* supporting MSM and TGW members, participants were contacted to enroll in the PrEP cohort (11).

PrEP-cohort

Between January and March 2018, HIV-negative MSM and TGW who had previously participated in a HIV incidence and PrEP interest study (completed mid 2017) were invited to enroll in the one-year PrEP cohort (11). Participants were 18 years or older, and their HIV-negative status was confirmed at enrolment using a nationally recommended HIV testing algorithm (13). Participants received 350 KSh (3.5 US\$) to cover participation costs for each scheduled visit. PrEP initiation and maintenance followed national guidelines, including a one-month PrEP-supply (irrespective of creatinine result); a two-month supply for the next two months, and a quarterly supply thereafter. Participants were reminded of their upcoming clinic visit 24 hours before the visit date. Physical tracing was done for those who did not attend their assigned visit or who were unreachable on phone. At each visit, participants were provided

with standardized PrEP adherence counselling, supporting participants to take PrEP at a regular moment in the day and discussing possible adherence challenges. Participants who had stopped taking PrEP were encouraged to re-start.

PrEP-adherence

At scheduled visits participants were asked about their PrEP use, if they had missed pills, and how they would rate their adherence (form in supplemental material).

As most participants stated that their adherence was either good or excellent, we categorized participants as consistently adherent or inconsistently adherent if they reported that they had taken their last PrEP within 2 days or more than 2 days ago from their month 6 clinic visit.

Dried Blood Spot sample collection and TFV-DP levels

At the 6-month visit, a Dried Blood Spot (DBS) sample to measure TFV-DP was collected from PrEP-taking participants, stored frozen (in minus 20°Cs), and shipped to a laboratory in Colorado, USA (14). The concentration of TFV-DP in DBS was evaluated in fmol/punch and corresponded to the following weekly PrEP doses: below lower limit of quantification (LLOQ), LLOQ to 350 fmol/punch (< 2 tablets per week), 350 to 699 fmol/punch (2 to 3 tablets per week), and 700 to 1249 fmol/punch (4 to 6 tablets per week). Protective levels of TFV-DP were defined as ≥ 700 fmol/punch consistent with having taken ≥ 4 tablets a week (15, 16).

In-depth interviews

Based on the 6-month visit, a purposefully selected sub-set of participants with consistent or inconsistent PrEP adherence (defined above), or who had stopped taking PrEP, was invited for an IDI. Participants received Ksh 500 (5 US\$) to compensate for the IDI. IDI were conducted by the lead author (MK) who had previously conducted the PrEP interest and HIV-1 incidence assessment among MSM and TGW in the same community (11). Summary notes of each interview were written shortly after the interview and discussed with a senior qualitative researcher (EvDE). All TGW in follow up and a convenient sample of MSM participants were interviewed. Details on consolidated criteria for reporting qualitative studies (COREQ) and the IDI topic guide for TGW are provided as supplemental material.

Data collection and analysis

Data cleaning, recoding and quantitative analysis was done using Stata 15.0 (Stata Corp LLC, College Station, Texas, USA). Descriptive statistics were used to compare baseline socio-demographic and behavioural characteristics of MSM and TGW. Associations between binary or categorical variables were investigated using Chi-square or Fisher's exact tests.

IDIs focused on PrEP use and factors that influenced adherence. Interviews were semi-structured, and topics included PrEP knowledge, motivation for uptake, barriers and facilitators to adherence, and support needs. Specific prompts were included if the interviewee disclosed PrEP discontinuation or identified as TGW. Additional topics explored gender identity, HIV risk-taking perception, experience with public health services, and use of feminizing hormones (semi-structured interview guide in supplementary material). IDIs were conducted in Kiswahili and audio-taped. IDIs were facilitated by a member of the research team (MK) and lasted approximately 45 minutes to 1 hour each.

Recordings were translated into English and transcribed verbatim. Data were managed using NVivo (version 11.4.1). Two qualitative researchers independently coded the transcripts and agreed on the final codebook used for the analysis. Braun and Clarke (17) thematic analysis was applied. A social ecological model, developed by Poundstone et al. (18), was used to organize factors (e.g., social and structural, environmental, individual practices) related to PrEP use. We triangulated quantitative findings on PrEP adherence and TFV-DP levels with qualitative perspectives on PrEP motives, experiences, and discontinuation.

This study was approved by the KEMRI scientific and ethical review unit (KEMRI/SERU/CGMR-C/0073/3418). All participants provided written informed consent prior to all study procedures.

Results

In total, 53 participants (42 MSM and 11 TGW) were enrolled. MSM and TGW participants had similar age distributions with most (52.8%) between 25-34 years old. Two thirds (62.3%) reported only primary level education, the majority (83.0%) were single, and over half (52.8%) reported active sex work. Inconsistent condom use levels were similar in MSM and TGW. All TGW vs. 28.6% of MSM reported the receptive or versatile role during anal sex (Table 1).

TFV-DP levels

At month 6, 11 (20.7%) participants (8 MSM and 3 TGW) had stopped taking PrEP or were lost to follow up. Of the 42 participants still taking PrEP, any TFV-DP was detected in 62.5% (5/8) of TGW vs. 14.7% (5/34, $p=0.01$) of MSM (Table 1). Overall, 3 TGW and no MSM had protective TFV-DP drug levels as per DBS analysis. Among the 53 individuals who initiated PrEP, only 6% (3/53) remained in PrEP care and had protective levels of adherence at 6 months.

Qualitative findings

A total of 19 IDIs were conducted, including 11 MSM (2 consistently adherent; 7 inconsistently adherent; 2 stopped use) and 8 TGW (6 consistently adherent; 1 inconsistently adherent; 1 stopped use; see Table 2). IDI-participants with consistent PrEP use had a higher proportion of any TFV-DP than participants with inconsistent PrEP use (75.0% vs. 14.2%, $p<0.02$; data on days PrEP missed, days in a row missed and TFV-DP level in supplemental table). We identified four main domains: two key facilitators and two barriers to PrEP use and adherence. Table 3 outlines these main domains and presents sub-themes and representative quotes.

PrEP initiation motives: The most important driver of PrEP uptake was self-perceived high risk for HIV infection. For example, one TGW participant stated, “I wish to remain HIV negative. I know that being a trans is putting me at risk for HIV. So, when I heard that PrEP was available here [hospital], I was among the first to ask for it”. (TGW, 30 years, consistently adherent, IDI 004). Additional motives for PrEP uptake included the ability to exercise sexual freedom and protection in the context of sex work.

PrEP adherence facilitators: A key facilitator to PrEP adherence was access to an MSM- and TGW-friendly PrEP service site, staffed by competent providers. Participants appreciated that providers offered counseling to support use of PrEP and assistance in disclosure to partners and family members. TGW participants noted that being on PrEP had a positive effect on their overall outlook of life. For example, one stated:

“...PrEP has been very useful to me. It has made me feel more alive and happier about my life. I even have better appetite and have more drive and purpose in my life...” (TGW, 24 years, consistently adherent, IDI 002).

Taking feminizing hormone therapy (FHT) together with PrEP was not reported but appeared to be an issue for some TGW participants, one stated:

“ I do not have knowledge of [FHT] where to start. I would really need help in that area. I especially would like to get help in getting breasts. Sometimes you are with a client and he wants you to be more female. I would want help in that area. I do not have any worry about PrEP interacting with hormones. I would be OK....” (TGW, 24 years, consistently adherent, IDI 002)

Inconsistent PrEP use: Struggling with daily dosing was mentioned as a challenge to PrEP adherence. Participants felt that daily PrEP was a nuisance and expressed desire to have long-acting formulations. Related to this was concomitant drug usage. One MSM narrated how taking alcohol and recreational drug use resulted in him having to temporarily stop taking PrEP:

... I went out drinking and used some drugs [Khat]. The drugs [combination of PrEP and khat] made me get confused, I got very bad diarrhoea and stopped PrEP for a while... (MSM, 24 years, inconsistently adherent, IDI 002).

When asked how participants could improve the PrEP program when given the opportunity, one TGW remarked:

I would create a PrEP that lasts longer. I would want a pill that can be taken like once a month or even better make an injection. This takes away all the stigma of need to carry pills around (TGW, 22 years, consistently adherent, IDI 014).

Another TGW participant who was among the three participants who had evidence of consistent PrEP use stated:

If it was possible I would like to have an injectable PrEP. Sometimes we have nowhere to keep our medications and an injection would be perfect. It is much easier to use and it is impossible to forget it (TGW, 20 years, consistently adherent, IDI 013)

Of note, these views on long-acting PrEP or injectable PrEP were spontaneously revealed by participants.

One of the main reasons for poor adherence noted amongst TGW was non-disclosure of PrEP use. The need to hide medication and the lack of an opportune moment to take it in the presence of others impacted adherence.

...I have hidden them [PrEP pills], so no one knows about them, so if I forget to take them, there won't be anyone to remind me... (TGW, 28 years, inconsistently adherent, IDI 011).

Motives to discontinue PrEP: A key motive for PrEP discontinuation was concern about the government-affiliated nature of the PrEP clinic, as one MSM participant summarized “*It should not be under Government. You know the problems we have with the Government.*” Others noted discomfort with government-employed health providers, revealed by a TGW participant who commented “*...the staff there are too curious. They just ask questions for the sake of getting things to talk about, not because it is related to our needs... No, I don’t think TGW would want to get services at the Government facility.*” PrEP discontinuation also emerged out of pressure from intimate partners who demanded that participants stop using PrEP. A TGW in a heterosexual union narrated:

...my partner found out about my using [PrEP] medications every day. I tried to explain to her... However, she does not know about me being with men, so she could not understand.... And demanded me to stop taking the [PrEP] drugs... (TGW, 39 years, stopped, IDI 018).

Discussion

This study provides quantitative and qualitative insights into PrEP adherence among MSM and TGW in coastal Kenya. Of the 42 participants who remained on PrEP 6 months post-initiation, 10 (23.8%) had any detectable drug levels, and only 3 participants (37.5%, or 3 of 8 TGW) had evidenced protective drug concentrations in dried blood spot samples. Among the 53 individuals who initiated PrEP, only 6% (3/53) remained in PrEP care and had protective levels of adherence at 6 months. There are limited data on PrEP uptake, adherence, and HIV-1 incidence reduction following programmatic PrEP uptake by any key population in sub-Saharan Africa, and no data on PrEP adherence among African TGW to our knowledge.

In a recent study in Mtwapa, Kenya, in which 14.5% of MSM participants had protective TFV-DP concentrations in dried blood spot samples corresponding with ≥ 4 tablets a week, HIV-1 incidence (3.6 per 100 person years) estimated among PrEP taking MSM was not different from the HIV-incidence (3.5 per 100 person years) among non-PrEP taking MSM (7). In the latter study, four out of five MSM who acquired HIV-1 while reporting PrEP use had not taken it (7). In another Kenyan study, among 347 18-24 year old women who were monitored for PrEP adherence at 6 months post PrEP initiation, only 15% took an average of 5 pills a week, suggesting limited prevention-effective adherence (19). Findings from the current study are therefore consistent with previous research reporting poor adherence to daily PrEP among Kenyan populations.

Our findings contrast with a demonstration study of daily PrEP in the US showing high (>80%) PrEP protective levels among MSM and TGW participants (8), and an on-demand PrEP study in Europe showing that 71% of participants had tenofovir detected suggestive of last drug intake during the previous week (20). The two Kenyan studies to date reveal that overall PrEP persistence was very low in MSM. In the present study, few MSM and TGW participants (5/53, or 9.4%) had detectable TFV-DP levels, indicating less than 4 pills taken during the week of assessment.

All study participants in this study were advised to use PrEP daily, conforming to Kenya guidelines. Our study was completed before event-driven PrEP use has been recommended for MSM by the World Health Organization in 2019 (21). During IDI we did not explore if participants were using non-daily or event-driven approaches to PrEP use. Given the low PrEP persistence in two Kenyan studies, further studies might explore if an event-driven PrEP regimen is attractive to Kenyan MSM (7).

In a PrEP demonstration study among 376 participants in Amsterdam, event-driven PrEP was preferred by 27% of participants, who reported a lower number of sexual partners, total sex acts, and condomless sex acts with casual partners than participants taking daily PrEP (22). In a recent educational intervention study providing “2-1-1” dosing information to over 3000 MSM in San Francisco, 23% opted for event-driven PrEP (23), and event-driven PrEP reduced medication use three-fold while preserving high rates of effective use (23). Research on preferences, motivations, and user characteristics related to event-driven PrEP among MSM in Kenya is needed to inform HIV prevention programming.

HIV-1 incidence among TGW in sub-Saharan Africa is probably several fold higher than among MSM. Our initial estimate of 20.6 per 100 person years in a small cohort study of TGW in coastal Kenya (11) is now supported by incidence estimates among TGW in Nigeria (23.8 per 100 person years) (24) and in South Africa (31.0 per 100 person years)(6). As protective drug concentrations among TGW taking PrEP were significantly higher than among MSM taking PrEP participants, our findings hold promise for PrEP programmes targeting TGW in the region.

Through qualitative interviews, we found that adherence was stronger among participants who described clear motivations for self-preservation and protection against HIV based on their acknowledgment of personal risk. In particular, TGW expressed strong desires to remain HIV negative and had better adherence indicators compared to MSM. MSM participants seemed to be less cognizant of their risk for HIV acquisition, corresponding with previous research on low perceived personal HIV risk as a reason for lowered PrEP adherence (25). The reasons for stronger PrEP motives among TGW in this

sample are unclear, but this may be due to stronger connections in the local TGW community and the presence of public health messaging linking HIV risk with receptive anal sex and TGW populations globally. In contrast to MSM, TGW associated the use of PrEP with a general better quality of life, and some TGW expressed interest to learn about PrEP and FHT. FHT could help to affirm their female gender identity, a finding corresponding with previous research on the synergistic benefits of PrEP and gender-affirming health services for TGW (26, 27).

Most respondents, irrespective of adherence level, expressed negative sentiments about accessing PrEP from a government-affiliated public health facility. Health care providers at government facilities were thought to be less prepared and competent to serve MSM and TGW, compared with trained staff at the research clinic. This corresponds with previous studies that documented some providers' unease delivering PrEP to MSM and TGW patients (28) and other at-risk individuals due to personal beliefs (29). By contrast, research has also shown transgender-sensitive and competent health care providers can increase TGW patients' empowerment and desires to seek healthcare services (27). In addition, alternative PrEP dispensing venues in Kenya including the use of community pharmacies can potentially expand the reach of PrEP to individuals and communities with discomfort seeking services at government-run facilities. PrEP-taking individuals may also benefit from a peer support model which has recently been shown to improve ART adherence among MSM in a pilot study in coastal Kenya (30, 31).

Participants voiced strong support for long-acting PrEP as a possible improvement for adherence. This view emerged spontaneously when opinions for improvement of the PrEP program were solicited. TGW stated that HIV-related stigma attached to the daily route of PrEP use was a barrier to adherence. HIV-related stigma has been previously described in studies with MSM who described conflicts between the protective effects of PrEP coupled with moral judgements about PrEP use from colleagues and general society (32). Long-acting PrEP formulations may be a solution around this dilemma, as the HPTN 083 trial showed that long acting injectable PrEP among MSM and TGW was safe and reduced the estimated HIV incidence by 66% when compared to daily PrEP (33).

Our findings suggest a possible relationship between initial motives for PrEP uptake and actual adherence. Consequently, future PrEP programs may consider assessing PrEP motives during initial screening and intake in order to incorporate user-specific motives into personalized adherence counseling and interventions to support PrEP persistence. This information may also help identify users at risk for PrEP discontinuation – for example, individuals who express discomfort with clinic facilities or providers or concerns about partner or family disclosure.

Limitations to this research must be acknowledged. First, participants were enrolled in a clinic that specifically provides services to key populations, which might have influenced participants' responses which favoured targeted services for key populations. This type of clinic is also relatively unique in the context of sub-Saharan Africa, thereby limiting generalizability. Second, the drug level outcomes as reported here were not available at the time of conducting the IDIs, and as a result could not be incorporated into interview protocols. Participants were informed of study findings in a generalized dissemination meeting, but not of individual drug level results. Third, while drug level assessments by DBS were informative, they were only able to reveal whether drugs were taken in the preceding 3-7 days and may not indicate PrEP adherence during longer periods (34). Finally, due to the small sample size, findings might have limited generalizability.

Conclusions

In summary, this paper provides evidence concerning the challenges to PrEP adherence and insights into the motives related to PrEP uptake and persistence among Kenyan MSM and TGW. The observed overall low levels of biologically protective PrEP concentrations in blood plasma in this sample were particularly alarming. However, relatively higher protective levels among TGW participants relative to MSM hold promise for PrEP programming for TGW in the region. Qualitative assessments suggested potential links between PrEP uptake motivation and actual adherence and call for PrEP services that are sensitive and supportive of MSM and TGW needs, concerns, and motivations.

Data sharing statement

All relevant data are within the paper and its supporting Information files. A curated copy of the underlying data and analysis code has also been deposited in the Harvard Dataverse repository (<https://doi.org/10.7910/DVN/OEJ3R7>) and may be requested from the KEMRI-Wellcome programme. To access the dataset itself there are instructions on the webpage. They include filling a data request form (that can be located on the webpage) and sending that email to dgc@kemri-wellcome.org

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Table legends

Table 1: Characteristic of MSM and TGW PrEP cohort participants at enrolment, follow up status and PrEP use at month 6, coastal Kenya, 2018.

Table 2: Characteristics of in-depth interview MSM and TGW participants, PrEP adherence and dried blood spot Tenofovir levels, coastal Kenya.

Table 3: Summary of themes, sub-themes, and representative quotes identified from in-depth interviews among MSM and TGW participants, coastal Kenya.

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Table 1: Characteristic of MSM and TGW PrEP cohort participants at enrolment, follow up status and PrEP use at month 6, coastal Kenya, 2018.

Characteristic	MSM n=42	%	TGW n=11	%	Total n=53	%	p-value
Age group							0.60
18-24	12	28.6	3	27.3	15	28.3	
25-34	21	50.0	7	63.6	28	52.8	
>34	9	21.4	1	9.1	10	21.4	
Education							0.35
Primary	28	66.7	5	45.4	33	62.3	
Secondary	11	26.2	4	36.4	15	28.3	
Higher	3	7.1	2	18.2	5	9.4	
Marital status							0.98
Single	35	83.3	9	81.8	44	83.0	
Married	4	9.5	1	9.1	5	9.4	
Separated/ Divorced	3	7.1	1	9.1	4	7.6	
Religion							0.73
None	8	19.1	1	9.0	9	16.0	
Christian	16	38.1	5	45.0	21	39.6	
Muslim	18	42.8	5	45.0	23	43.0	
Sex work							0.42
Yes	21	50.0	7	63.6	28	52.8	
No	21	50.0	4	34.4	25	47.2	
Anal sex role*							<0.01
Insertive	28	66.7	0	0.0	28	52.8	
Receptive	1	2.4	7	63.6	8	15.1	
Both	11	26.2	4	36.4	15	28.3	
Condom use in past 3 months*							0.55
Always	13	31.0	4	36.4	17	32.1	
sometimes	22	52.4	7	63.6	29	54.7	
Never	5	11.9	0	0.0	5	9.4	
Follow up status at month 6							0.55
In follow up and on PrEP							
Yes	34	81.0	8	72.7	42	79.3	
No	8	19.1	3	27.3	11	20.7	
Adherence at Month 6							0.20
Consistent [^]	17	50.0	6	75.0	23	54.8	

based on self-report	Inconsistent [^]	17	50.0	2	25.0	19	45.2
TFV-DP level							<0.01
	Detectable	5	14.7	5	62.5	10	23.8
	Undetectable	29	81.3	3	37.5	32	76.2
Corresponds to pills/week							<0.01
	4-6 pills	0	0.0	3	37.5	3	7.1
	2-3 pills	1	2.9	1	12.5	2	4.8
	<2 pills	4	11.8	1	12.5	5	11.9
	No pills	29	85.3	3	37.5	32	76.2

*Two MSM did not provide a response.

[^] Defined as consistently and inconsistently adherent if days between the last date PrEP was taken and the month 6 clinic visit date was < 3 days or ≥ 3 days, respectively.

TFV-DP-Tenofovir-diphosphate.

Table 2: Characteristics of in-depth interview MSM and TGW participants, PrEP adherence dried blood spot Tenofovir levels, coastal Kenya

Characteristic	MSM n=11	%	TGW n=8	%	Total n=19	%	p-value
In follow up and on PrEP							1.00
Yes	9	81.8	7	87.5	16	84.2	
No	2	18.2	1	12.5	3	15.8	
Adherence at Month 6 based on self-report							0.04
Consistent [^]	2	22.2	6	85.7	8	50.0	
Inconsistent [^]	7	77.8	1	14.3	8	50.0	
TFV-DP level							0.13
~							
Detectable	2	22.2	5	71.4	7	43.8	
Undetectable	7	77.8	2	28.6	9	56.3	
Approximate pills/week							0.07
4-6 pills	0	0	3	42.8	3	18.8	
2-3 pills	0	0	1	14.3	1	6.3	
<2 pills	2	22.2	1	14.3	3	18.8	
No pills	7	77.8	2	28.6	9	56.3	

~ TFV-DP -Tenofovir-diphosphate not known at the time of conducting interviews.

[^] Defined as consistently and inconsistently adherent if days between the last date PrEP was taken and the month 6 clinic visit date was < 3 days or ≥ 3 days, respectively.

Table 3: Summary of themes, sub-themes, and representative quotes identified from in-depth interviews among MSM and TGW participants, coastal Kenya

Major themes	Sub-Themes	Representative quote
Motives to start PrEP		
1	High HIV infection risk	<p>Unplanned/frequent risky sexual behaviour</p> <p><i>Since I started taking up PrEP I feel a lot safer. I have the same number of partners but I have much more sex, I feel more energetic (TGW 27 years, consistently adherent*)- IDI 011</i></p> <p><i>I would say it [who should take PrEP] depends on the sex role. If they are bottoms, they should get it just like Trans. You know the anal region is weak and is not used to rough action so anyone that is getting anal sex should be considered. It's not about MSM or Trans. It's the risk (TGW, 20 years, consistently adherent*)- IDI 013</i></p>
	Multiple sexual partners of unknown HIV status	<p><i>Sometimes I may not be able to convince all my partners to use a condom. (MSM, 24 years, consistently adherent*)- IDI 001</i></p>
2	Gaining more sexual freedom	<p>Risk compensation</p> <p><i>... before I knew about PrEP I had two partners. When I started using PrEP, I added two more [partners] as I felt protected [by PrEP]. Now I have four partners. (MSM, 31 years, inconsistently adherent*)- IDI 012</i></p>
	Being in difficult situations	<p><i>Sometimes I may not be able to convince all my partners to use a condom. Sometimes someone also gets bored of condoms but is still afraid of infections that is where PrEP comes in to help. (TGW, 39 years, stopped PrEP)- IDI 017</i></p>
3	To convenience condomless sex	<p>Monetary gain</p> <p><i>... the other problem is that if you insist on condom use then the money they [clients] are giving you becomes less... (TGW, 24 years, inconsistently adherent*)-IDI 002</i></p>
PrEP adherence facilitators		

1	Integrated healthcare services	Assisted disclosure on PrEP use	<i>We had to come to the clinic together [with partner], and the counsellor explained to both of us what PrEP was and then finally he [my partner] understood (TGW, 27 years, consistently adherent*)- IDI 010</i>
		Disclosure of PrEP use	<i>My immediate family know, ...I live at home and we really can't have any secrets. So, they have seen my [PrEP] pills... ..they also remind me when it is time to take my pills. (TGW, 21 years, consistently adherent*) -IDI 013</i>
		Hope for future improved PrEP delivery models	<i>...PrEP that lasts longer... I would want a pill that can be taken like once a month, or even better, make an injection. This takes away all the stigma, carrying [PrEP] pills around. (TGW, 22 years, consistently adherent*)-IDI 014</i>
Reasons for inconsistent PrEP use			
1	Current PrEP formulation	Struggle with daily dosing	<i>... I think it is a nuisance when it comes to the daily dosing. Having to remember when to take PrEP, having to interrupt my fun just to take a drug. That is the nuisance... (TGW, 28 years, inconsistently adherent*)- IDI 005</i>
2	External influence and circumstances	HIV related stigma	<i>...there is one person who saw me with them [PrEP pills] and asked me whom they belonged to. I told him that they were mine and he told me that I am a gone case... ARVs look just like this... He went spreading the news. (MSM, 21 years, stopped using PrEP)-IDI 018</i>
		Concomitant drug use	<i>...later that same evening I went out drinking with my friends, and I used some drugs [Khat?]. The drugs [combination of PrEP and khat] made me get confused, I used another pill. I got very bad diarrhea and stopped PrEP for a while... (TGM, 22 years, consistently adherent*)-IDI 014</i>
3	Uncertainty about PrEP use	Fear of using drugs close to expiry	<i>I travelled and left them (PrEP pills) here, when I came back I found they were almost expiring. When I see that something is one month to</i>

			<i>expiry, I am afraid. (MSM, 23 years, stopped PrEP)- IDI 018</i>
		Uncertainty about refill date	<i>...time moves so fast. Like now, I was called and told that I was late for my appointment. I was very surprised since I still had a lot of drugs. I thought that drugs are supposed to end that I come to the clinic. ... (TGW, 30 years, consistently adherent*)-IDI 004</i>
Motives to discontinue PrEP			
1	Undesirable dispensing venue	Move away from Government facility	<i>It [PrEP] should be private and specifically for us (MSM). ...it should not be under Government. You know the problems we have with the Government... (MSM, 31 years, inconsistently adherent*)-IDI 003</i>
2	Perceived stigma	Discrimination by healthcare providers	<i>We [TGW] may not be very comfortable at the Government facility as the staff there are too curious. They just ask questions for the sake of getting things to talk about not because it is related to our needs... No, I don't think TGW would want to get services at the Government facility. (TGW, 27 years, consistently adherent*)- IDI 002</i>

*Interviews done before PrEP drug levels were known. Defined as consistently and inconsistently adherent if days between the last date PrEP was taken and the month 6 clinic visit date was < 3 days or ≥ 3 days, respectively.

Supplemental Table: Summary of self-reported PrEP adherence among 16 MSM and TGW participants, coastal Kenya

IDI No	Participant	In-depth interview	Days since last PrEP	Days missed taking PrEP	Days in a row missed PrEP	Visual analogue scale	In general, how do you take your PrEP	Pills remaining	TFV levels
1	MSM	Inconsistent	9	6	6	70	Most of the time	3	BLQ
2	TGW	Consistent	1	1	1	96	All of the time	28	LLOQ-349 (<2doses/wk)
3	MSM	Consistent	1	3	3	90	Most of the time	0	BLQ
4	TGW	Consistent	2	0	0	95	All of the time	1	700-1249 (4-6doses/wk)
5	TGW	Inconsistent	24	6	6	65	Most of the time	6	BLQ
6	MSM	Inconsistent	8	24	24	77	A good bit of the time	0	LLOQ-349 (<2doses/wk)
7	MSM	Consistent	1	0	0	98	All of the time	2	LLOQ-349 (<2doses/wk)
8	MSM	Inconsistent	6	6	6	100	All of the time	0	BLQ
9	MSM	Inconsistent	10	0	0	95	Most of the time	0	BLQ
10	TGW	Consistent	0	6	6	90	Most of the time	6	350-699 (2-3doses/wk)
11	TGW	Consistent	2	3	3	90	A good bit of the time	9	700-1249 (4-6doses/wk)
12	MSM	Inconsistent	96	30	30	10	Some of the time	0	BLQ
13	TGW	Consistent	1	0	0	100	All of the time	1	700-1249 (4-6doses/wk)
14	TGW	Consistent	1	0	0	80	Most of the time	0	BLQ
15	MSM	Inconsistent	14	14	14	100	All of the time	0	BLQ
16	MSM	Inconsistent	15	3	3	45	Some of the time	30	BLQ

Chapter 4

Qualitative Insights from providers, leadership and end-users in Coastal Kenya

**Pre-Exposure Prophylaxis for Transgender Women and Men who have Sex with Men:
Qualitative Insights from healthcare providers, community-organization based-leadership and
end-users in Coastal Kenya**

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Abstract

Transgender women (TW) and men who have sex with men (MSM) in Kenya are disproportionately affected by HIV and would benefit substantially from pre-exposure prophylaxis (PrEP). We conducted focus groups discussions (FGD) with healthcare providers (HCP) and TW/MSM leadership and in-depth interviews (IDI) with PrEP experienced MSM and TW, to learn about perceived and actual barriers to PrEP programming.

Eleven HCP and ten TW/MSM leaders participated in FGDs before PrEP roll-out (January 2018) and 12 months later. Nineteen PrEP end-users (11 MSM and 8 TW) participated in IDI. Topic guides explored PrEP knowledge, HIV acquisition risk, gender identity, motivation for PrEP uptake and adherence and PrEP dispensing venue preferences. Braun and Clarke thematic analysis was applied.

Four themes emerged: limited preparedness of HCP to provide PrEP to TW and MSM, varied motivation for PrEP uptake and persistence among end-users, lack of recognition of TW by HCP, and suggestions for PrEP programming improvement from all stakeholders.

Providers' reluctance to prescribe PrEP to TW and distrust of TW towards providers calls for interventions to improve the capacity of service environments and staff HIV preventive care. Alternative locations for PrEP provision, including community-based sites, may be developed with TW/MSM leaders.

keywords: Transgender women; pre-exposure prophylaxis; MSM; Kenya

Background

Transgender women (TW) and men who have sex with men (MSM) are among key populations with the highest HIV incidences in sub-Saharan Africa (SSA) [115, 178, 179]. A study conducted in coastal Kenya produced one of the first known reports of HIV incidence among TW in SSA, which was estimated at 20.6 (95% confidence interval [CI] 6.6-63.8) per 100 person-years (PY) [115]. Two subsequent studies reporting incidence estimates among TW in Nigeria (23.8 per 100 person-years) [180] and in South Africa (31.0 per 100 person-years) [181] provided corroborating evidence for the high HIV incidence estimate among TW in SSA. The HIV incidence estimate for TW in coastal Kenya was substantially higher (20.6/100 person-years) than that of MSM in the same location (5.1/100 person-years) [115]. HIV incidence in the general population in Kenya has been reported at 0.14 per 100 person-years (95% CI 0.06-0.23) [41]. High HIV incidences for both TW and MSM indicate an unmet HIV prevention need, and that both groups would benefit from pre-exposure prophylaxis (PrEP).

Since 2017, Kenya's National ART Programme has offered PrEP at most government hospitals. [23, 127, 182]. However, MSM and TW are not specifically targeted for PrEP uptake in Kenya, as eligibility criteria do not specify assessment of anal intercourse or same-sex practices as behavioral risk factors [182]. In a study among 459 HIV negative MSM from western Kenya, PrEP awareness was moderate (64.3%), but willingness to use PrEP was relatively low (44.9%) [183]. Individual and interpersonal factors, such as self-efficacy, perceived ability to use PrEP, and indicators of social support, were significantly associated with PrEP awareness and acceptability [183]. This suggests that targeted educational and psychosocial interventions can increase PrEP uptake [129]. In coastal Kenya, almost all MSM and TW who were informed about an upcoming PrEP study expressed the desire to take it when it would be made available [115, 129].

Two studies conducted in coastal Kenya provide insight into challenges with PrEP adherence among MSM and TW. Among participants enrolled in an observational cohort involving monthly follow up, HIV-1 incidence among MSM with access to programmatic PrEP was high (3.9 per 100 person-years) and did not differ by self-reported PrEP use. Additionally, only one in seven MSM participants in the study who reported taking PrEP had protective tenofovir

concentrations, and four out of five MSM who acquired HIV-1 reported PrEP use but did not have detectable tenofovir concentrations in plasma [60]. In the second study, involving 42 MSM and 11 TW who had started PrEP and were in quarterly follow up, almost 40% of TW and no MSM had protective tenofovir concentrations measured 6-9 months post PrEP initiation [184]. Qualitative interviews in the latter study suggested that TW had a more complete understanding of the benefits of PrEP compared to MSM [184].

There are multiple community-based organizations (CBO) exclusively dedicated to TW and MSM programming in Kenya, often supported by bilateral or multilateral donors. Most of these CBOs offer HIV prevention services to their members, and some aspire to offer PrEP. Engaging the leadership of these organisations may give insights on how to improve PrEP programming for TW and MSM in the region, especially as stigma might undermine their interactions with healthcare providers (HCP) [185].

The aim of the present study was to explore the opinions of both HCP and CBO leaders on challenges and suggestions for improvement to PrEP programming in Kenya. Additionally, the study set out to understand the experiences of MSM and TW PrEP end-users. To address this aim, we explored insights from HCP, and TW/MSM CBO leadership on PrEP programming in the area and triangulated these findings with experiences of TW and MSM PrEP end-users. We selected these groups as they are intimately linked to either PrEP service provision or had in-depth knowledge and their opinions could influence future PrEP programming success.

Methods

This qualitative study took place between January 2018-2019 in coastal Kenya. Respondents included HCP from a sub-county hospital, leaders of local MSM/TW-themed CBOs, and PrEP-experienced MSM and TW end-users participating in a cohort study at the Malindi hospital [184]. Data collection venues are described below.

Participants and procedures

Focus group discussions (FGD)

At two time points, i.e. before PrEP availability and 12 months later, we conducted a total of four separate FGDs with 21 participants. Participants were selected based on their role in HIV prevention and care services, and PrEP knowledge and experience either as prescriber or as a user. We intended the two data collection time points to help assess for any changes in attitude over time.

Of the two FGDs, the first involved 11 HCP, who all but one participated at both time points. Respondents had to be involved in the provision of HIV treatment or prevention services. HCP respondents included clinicians, nurses, administrators and records officers. The topic guides explored service providers' recognition of MSM and TW patients, personal values and attitudes towards MSM and TW, perceived impact of PrEP on the local HIV epidemic, risk assessment relevant to PrEP provision, and HCP experiences in PrEP provision to MSM and TW.

Similarly, we conducted two FGDs with the CBO leaders at time points identical to those with HCP. CBO leaders were interviewed in private offices at an MSM-and TW-themed CBO based in coastal Kenya. FGD participants (n=10) comprised the organizations' administrators, TW and MSM representatives and TW peer educators. All respondents from the CBO identified as either MSM or TW. Respondents were purposefully selected as they were strongly connected to the TW and MSM communities in the area. The same respondents participated in FGDs at both timepoints. The discussion explored: PrEP knowledge, understanding HIV acquisition risks, PrEP dispensing venues, perceived and actual challenges experienced by both TW and MSM accessing PrEP, and suggestions to improve PrEP programming for TW and MSM in Kenya. Topic guides were developed with input from an expert in MSM- and TW- related research and piloted among a small group of respondents. Discussions were semi-structured and facilitated by MK, while NM co-facilitated, observed and wrote notes. FGD were conducted in the respondents' preferred language (Kiswahili) and lasted approximately 90 minutes.

In-depth interviews

Nineteen respondents including eight TW and 11 MSM with PrEP experience (end-users) were purposively invited for an in-depth interview (IDI). Respondents were part of a 12-month PrEP provision cohort [186]. Briefly, 53 individuals including MSM and TW made quarterly visits to receive PrEP and provide blood samples to assess tenofovir diphosphate levels 6-9 months following PrEP initiation [184]. The IDI was conducted when respondents returned at month 6 visit. The interview guide covered: PrEP knowledge, motivation for uptake, barriers and facilitators to adherence and perceived support needs to improve PrEP adherence. Additionally, for TW, specific issues such as gender identity, HIV-1 acquisition risk perception, experience with care services by public HCP and both current or past use of feminizing hormones in regard to PrEP adherence were explored. Interviews were conducted by MK in Kiswahili and lasted for an average of 50 minutes each.

Analysis

The FGD and IDI were audio-recorded, and socio-demographic characteristics of each participant obtained. Audio files of the IDI and FGD were transcribed verbatim, and (where necessary) translated by a qualitative researcher with linguistic competency in Swahili and English. Transcripts were deidentified. While audio files with identifiable data were deleted following transcription. Data were managed using NVivo 11.4 [187]. Analyses followed Braun and Clarke's thematic approach for qualitative data [188], which involved systematic coding, identifying and defining concepts emerging from the data across the data set, mapping the concepts, creating typologies, finding associations between concepts and seeking explanations from the data. As themes emerged, they were discussed in order of broad to specific, external to internal, macro-level to the individual level to understand the best strategies for PrEP programming among both MSM and TW communities.

Ethical considerations

Participants were informed about the study aims and provided signed informed consent. Study procedures were approved by the ethical review board at KEMRI and the Kilifi County Department of Health Research Committee (KEMRI/Scientific and Ethics Review Unit Ref:

(KEMRI/SERU/CGMR-C/0073/3418). Participants received 500 Kenyan shillings (approximately US \$5) for their time spent.

Results

Table 1 and 2 provide summary characteristics of the study participants (N=40).

Focus group discussion respondents

In total, 10 HCP and 11 community leaders participated. Most (70%) of the community leaders were under 30 years of age while 40% of HCP were 21-30 years of age. Half of the leadership respondents identified as transgender women. A majority of HCP (72%) had between 1-5 years' experience of service delivery. Almost all (90%) CBO leaders had between 1-5 years' in HIV service delivery.

In-depth Interview respondents

Of the 19 IDI end-user respondents, 8 were TW and 11 MSM. A majority (73%) of respondents were aged between 25 -34 years. Almost half (45%) had only primary level education, and three out of four (78%) reported being single. Most MSM (91%) reported engaging exclusively in insertive anal intercourse while none of the TW did so. Inconsistent condom use during anal sex was equally high in MSM (91%) and TW (88%). At the time of the interview, 83% of respondents reported taking PrEP.

Qualitative findings

Four thematic areas emerged: PrEP provision preparedness; motivation for uptake and persistence among PrEP end-users; limited recognition of the existence of TW and their risk for HIV infection; recommendations for improvement to PrEP programming for MSM and TW. How these thematic areas influence PrEP uptake and adherence are detailed below:

Preparedness to provide PrEP to MSM and TW

Initially, at the start of PrEP roll-out, HCP felt ill-prepared to provide PrEP not just to MSM or TW, but to the general population. They expressed the sentiment that PrEP programming had

been implemented too quickly based on directives from the ministry headquarters without consultation of implementing healthcare providers .

“While the research may have been done and it showed that PrEP works, we are lacking follow up systems. How many of those that we started in PrEP are still negative. We do not have things in place. We need to have tools and mechanism for follow up and how to trace outcomes at intervals. Do we have protocols on how often to retest individuals? I feel like we were not ready for the implementation.” (Cis Male HCP)

This sentiment seemed to have tapered off after one year into PrEP programming. HCP were more receptive towards PrEP programming during the follow-up focus groups. However, they admitted that they had adopted a ‘passive’ approach to PrEP delivery, preferring potential users to present themselves at the facility rather than actively screening and counseling high-risk patients about PrEP uptake and adherence. As noted in the above quote, they admitted that this passive approach was ineffective and hampered PrEP roll-out success. Amongst the reasons for their dampened commitment to PrEP provision was an apparent lack of structural resources and support from hospital management.

“..but how about the availability of the guideline because even in this facility, we only have the soft copies. It means we need computers and internet to get them (guidelines). So, you are in the (comprehensive care clinic) dealing with HIV, but you don’t have hard copy. So, the guidelines may be clear, but it is difficult for someone to understand PrEP management....”

Motivation for PrEP uptake among MSM and TW

Despite structural limitations and challenges in the PrEP provision on the part of HCP, CBO leaders and end-users noted that the desire among MSM and TW to remain HIV negative strongly motivated the demand for PrEP in this group. The most important driver of PrEP uptake was perceiving oneself as having high risk for HIV infection.

“I wish to remain HIV negative. I know that being a trans is putting me at risk for HIV. So, when I heard that PrEP was available here [hospital], I was among the first to ask for it.”
(TW End-User)

However, as currently formulated, both MSM and TW perceived that adherence to daily PrEP would be a challenge and expressed a desire for new formulations that imposed less burden on behaviour and memory to self-administer pills.

... I think it is a nuisance when it comes to the daily dosing. Having to remember when to take PrEP, having to interrupt my fun just to take a drug. That is the nuisance...” (TW End User)

Although a minority viewpoint, there was indication that the protection conferred by PrEP use could lead to increased levels of HIV risk taking such as having a higher number of sex partners.

“... before I knew about PrEP, I had two partners. When I started using PrEP, I added two more [partners] as I felt protected [by PrEP]. Now I have four partners. (MSM End User)

Minimal recognition of TW and acknowledgement of increased risk for HIV infection

HCP minimized the additional risk for HIV acquisition among TW compared to the general population, and some were unaware of TW as a distinct gender identity. For example, a HCP expressed an opinion shared by others in the group:

“...they [TW] are just at the same level as anybody else exposed to HIV... They are not at very a high- risk acquiring HIV...”. (Cis Male HCP)

In contrast, both CBO leaders and end-users were clear in their recognition of increased HIV risk among TW. Additionally, both CBO leaders and end-users advanced strong sentiments about TW’s mistrust and vulnerability to stigma with regard to HCP, resulting in reluctance among TW to seek PrEP and other HIV services at a public hospital. TW participants who were not open about their gender identity expressed frustration due to pressure to assimilate into mainstream society by concealing their gender.

“You’ll find that for a trans to come out is tricky. They often try to blend in with the general community and try to please the system that does not even care about them or their health issues.” (Trans Woman CBO Leader)

Recommendations to improve PrEP programming and reach

HCP felt that PrEP provision to MSM and TW would improve through diversified delivery models. They expressed the sentiment that more hospital staff including nurses and outpatient providers needed training on PrEP to meet the HIV prevention and medication support needs of the local population. The current system, which relied on front-line clinical providers to implement PrEP, imposed a critical bottleneck in PrEP service delivery.

“I think PrEP should have taken a different route like maybe to be dispensed at the outpatient or integrated into public health but not here.” (Cis Female HCP)

“...in each department like outpatient, maternity and in the wards, in each department, at least we have one person who is aware about PrEP so that out there, they can talk about PrEP...” (Cis Male HCP)

Integrating PrEP counseling and delivery in the public pharmacy system was also recommended as a strategy to increase PrEP reach and minimize burdens in the clinical care system.

“I think they should be made available at pharmacies, so that people who do not want to come to the clinic can still access them.” (Cis Male CBO leader)

Notably, HCP additionally expressed a desire to keep their services applicable for the general community population and called for community collaborations with implementing partners to provide tailored linkages for MSM and TW.

“We need to work with organizations that are specialized at working with those populations [MSM and TW] We can engage at the community level (with the ‘general population’) ..., and the Goldstar network [implementing partner] with the KP and their community gatekeepers”. (Cis Female HCP)

To increase PrEP uptake among TW, CBO leaders suggested integration with TW-specific services such as feminizing hormone therapy (FHT). They noted that outreach efforts have been made to address PrEP needs for MSM, but TW have not been included in programs.

“There are some specific needs like those hormones, those therapy, those for legal, because it is very expensive by the way the legal change that can be a plus for us. Plenty has been occurring and it is focusing on those MSMs.” (TW CBO Leader)

Finally, when asked what would be deterrent to PrEP uptake, end-users unanimously expressed an aversion to paying for PrEP.

“If you ask people to pay for prevention services then they just decide to do without those services. So, if you have PrEP in a chemist on sale, the drugs will expire on the shelf.” (TW End User)

Discussion

The overriding theme of this manuscript was to understand how to improve PrEP programming for MSM and TW. Our findings pointed out themes to consider in further efforts to implement PrEP with MSM, TW and other stigmatized populations in Kenya, where PrEP is theoretically available to all populations at risk for HIV infection [23, 127]. However, previous work has demonstrated that omission of receptive anal sex from PrEP guidelines may result in reduced targeting of MSM and TW, at highest risk for HIV acquisition [24]. In this study, HCP did not consider TW to be at increased risk for HIV infection and thus did not prioritize to PrEP provision to them. Consequently, some of the highest-risk populations in Kenya may be systematically excluded at the first step of the PrEP care continuum.

TW in this study expressed frustration about feeling invisible. Globally, TW experience systematic erasure of their existence [12, 16] and are often wrongly categorized as MSM [14]. Indeed, in this study, HCP neither knew of TW nor recognized any differential in HIV acquisition risk between TW, MSM or the general population. This is a problematic position as HCP themselves become a barrier to PrEP provision. A 2014 systematic review identified HCP as potential hindrances to introducing new drugs – due either to lack of knowledge or fear of additional workload [189]. Findings from HCP in our study supported both reasons, as they felt the PrEP program implementation had been extremely rushed and noted that PrEP programming would needlessly increase their workload at the facility. Their description of adopting a passive approach to PrEP provision aligns with these noted barriers. Specifically, potential PrEP users were expected to present themselves at the facility, rather than identified by HCPs thorough discussion of risk factors and active listening. Additionally, HCP did not want MSM and TW to access PrEP at the public health facility but instead recommending they be served at other implementing partners' facilities.

HCP, CBO leaders and end-users all seemed to agree that the public health facility to be an inappropriate exclusive venue for PrEP provision, albeit for different reasons. Both end-users and CBO leaders expressed uncertainty about HCP commitment to provide PrEP. A recent scoping review on PrEP delivery recommended diversification of PrEP delivery away from the traditional face-face interaction at a health facility [190]. Since the PrEP scale-up in Kenya began, differentiated delivery methods have been considered [127, 191]. PrEP access from community pharmacies has been suggested as an alternative dispensing venue, which should be considered in future research. To better serve TW, HCP will need sensitivity training, while capacities of TW CBO's should be strengthened [192].

TW in this study expressed a desire for additional services such as gender-affirming therapy, which currently are not available in public health facilities in Kenya. Previously, TW have expressed sentiments prioritizing FHT over other services, including PrEP [193]. When

transgender women programming guidelines are developed, it may be important to consider integration of such services to increase PrEP uptake and retention in follow-up. Indeed, draft guidelines have alluded to the possibility of the provision of gender-affirming therapy for TW in Kenya [194]. There is however a need to exercise caution on PrEP and FHT. Data from the iFACT trial among TW in Thailand demonstrated slightly lowered Tenofovir blood levels among TW receiving PrEP and also on FHT [1], although studies on drug-drug interactions to date have not shown impacts on PrEP protection levels.

Finally, even as end-users expressed strong motivation to take up PrEP, adherence to daily PrEP was cited as challenging. Following the findings of the ANRS IPERGAY trial, event-driven PrEP has been proposed as a solution to challenges of adherence to a daily regimen [195]. The WHO has been promoting the use of event-driven PrEP as an alternative to daily PrEP for MSM but not for TW [196]. Results from the HPTN 083 indicated that in both MSM and TW, long-acting injectable Cabotegravir was statistically superior to daily oral Tenofovir (TFV) containing PrEP [197]. Upon regulatory approval, HCP should be encouraged to offer these alternative PrEP deliveries to end-users. HCP would, however, need to emphasise on the importance of quarterly HIV testing as those on event-driven PrEP would have fewer interactions with HCP.

Limitations of this research must be acknowledged. Firstly, qualitative methods produce inherently subjective data which may impose limits on the transferability of the knowledge uncovered. Secondly, HCP respondents were from a large clinical care center, where concerns on increased workload may not be expressed in smaller facilities. Thirdly, to get varied opinions, HCP respondents included multiple staff of different ranks in the same space. It is possible that hierarchy and power dynamics within groups could have undermined candid discussions. Fourthly, while the study design hoped to capture changes over time in attitude towards PrEP provision, the one-year period may have been insufficient to detect this. Finally, while we made efforts to interview a diverse group of respondents, policy makers, MSM and TW under 18 years and healthcare providers not stationed at the CCC were not included. It would be important in subsequent studies to explore their opinions on PrEP programming.

Conclusion

Despite the availability of PrEP, access continues to be limited for both MSM and TW in Kenya. There is a need to rethink PrEP delivery venues and retrain HCP to accommodate the needs of both MSM and TW. Transgender women programming guidelines, alternative dispensing venues, adequately prepared HCP and comprehensive services are urgently required.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MK, EvdE and EJS conceived and designed the study. NM and MK collected qualitative data. MK developed the manuscript under the supervision of EvdE and EJS. TRdW, SMG, DO, EvdE and EJS provided critical review to the data interpretation and manuscript writing. All authors reviewed and approved the final version of the manuscript.

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Table 1: Social demographic characteristics of healthcare providers and MSM/TW community leadership FGD respondents, Malindi, 2018-2019.

Study ID	Age (years or range)	Role	Years in HIV work	Gender/behaviour Identity or Sex
Community based organisation leadership				
CBO/001	26	Program admin	2	TW
CBO/002	25	Outreach worker	<1	MSM
CBO/003	22	Director	2	MSM
CBO/004	30	Peer educator	<1	MSM
CBO/005	27	Finance officer	<1	MSM
CBO/006	32	Outreach worker	4	MSM
CBO/007	31	Peer educator	10	TW
CBO/008	23	TGNC ¹ focal person	4	TW
CBO/009	22	Field worker	2	TW
CBO/010	22	Peer educator	3	TW
Healthcare providers				
HCP/001	>50	Clinician CCC ²	2	Male
HCP/002	21-30	Records officer	3	Female
HCP/003	31-40	TB ³ clinic community linkage	6	Female
HCP/004	21-30	Records officer	<1	Female
HCP/005	21-30	Data manager	3	Female
HCP/006	41-50	VCT ⁴ counsellor	7	Female
HCP/007	>50	Nurse	5	Female
HCP/008	21-30	Nurse	2	Male
HCP/009	41-50	HIV services coordinator	15	Male
HCP/010	21-30	Clinician CCC ²	2	Male
HCP/011	31-40	Clinician CCC ²	5	Female

TGNC¹-Transgender and gender non-conforming, CCC²-Comprehensive care centre, TB³- Tuberculosis

VCT⁴-Voluntary counselling and testing

Table 2: Comparison of social demographic and sexual risk behaviour characteristics of nineteen MSM and TW PrEP end users in-depth interview respondents, Malindi 2018.

Characteristic	MSM		TW		Total		
	n=11	%	n=8	%	n=19	%	
Age group	18-24	2	18	2	25	4	21
	25-34	9	82	5	62	14	74
	>34	0	0	1	13	1	5
Education	Primary	5	46	4	50	9	47
	Secondary	4	36	3	38	7	37
	Higher	2	18	1	12	1	16
Marital status	Single	9	82	6	75	15	78
	Married	2	18	1	13	3	16
	Separated/ Divorced	0	0	1	12	1	5
Religion	Christian	4	36	4	50	8	42
	None	3	28	0	0	3	16
	Muslim	4	36	4	50	8	42
Condom use	Always	1	9	1	12	2	11
	sometimes	10	91	7	88	17	89
	Never	0	0	0	0	0	0
Anal sex role	Insertive	10	91	0	0	10	53
	Receptive	0	0	5	63	5	26
	Versatile	1	9	3	37	4	21
Sex work	Yes	5	45	6	75	11	58
	No	6	55	2	25	8	42
PrEP persistence	On PrEP	8	73	7	88	15	83
	Stopped PrEP	3	27	1	12	4	17

Chapter 5

Depressive symptoms and problematic alcohol and other substance use in 1476 MSM at three research sites in Kenya

Depressive symptoms and problematic alcohol and other substance use in 1,476 gay, bisexual, and other men who have sex with men at three research sites in Kenya

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ABSTRACT

Objective: Information on mental health and substance use challenges among gay, bisexual and other men who have sex with men (MSM) is needed to focus resources on these issues and optimize services for HIV prevention and care. We determined characteristics associated with depressive symptoms and problematic alcohol and other substance use among MSM in Kenya.

Methods: Self-identified MSM in three HIV research studies in Kenya provided information on depressive symptoms (PHQ-9), alcohol use (AUDIT), and other substance use (DAST). Associations with these outcomes were evaluated using mixed effects Poisson regression.

Results: Of 1,476 participants, 452 (31%) reported moderate to severe depressive symptoms (PHQ-9 ≥ 10), 637 (44%) hazardous alcohol use (AUDIT ≥ 8), and 749 (51%) problematic substance use (DAST-6 ≥ 1). In multivariable analysis, known HIV-positive status was not associated with these outcomes. Transactional sex was associated with hazardous alcohol use (adjusted prevalence ratio [aPR] 1.34, 95% confidence interval [CI] 1.12–1.60). Childhood abuse and recent trauma were associated with moderate to severe depressive symptoms (aPR 1.43, 95% CI 1.10–1.86 and aPR 2.43, 95% CI 1.91–3.09, respectively) hazardous alcohol use (aPR 1.36, 95% CI 1.10–1.68 and aPR 1.60, 95% CI 1.33–1.93, respectively), and problematic substance use (aPR 1.32, 95% CI 1.09–1.60 and aPR 1.35, 95% CI 1.14–1.59, respectively).

Conclusions: MSM in rights-constrained settings need culturally appropriate mental health services. Mental health screening and treatment or referral should be an integral part of programs, including HIV prevention and treatment programs, providing services to MSM.

INTRODUCTION

Male-male sexual behavior is illegal in several African countries, including Kenya [1], where gay, bisexual, and other men who have sex with men (MSM) are targets of discrimination, blackmail, and violence [2,3]. This hostility can lead to high levels of distress, contributing to depression, alcohol use, and other substance use [4–7]. The minority stress theory posits that gay and bisexual individuals experience stress due to social stigma, and attributes poor mental health to this stress [8]. Stressors may be more acute among people with intersecting minority status, such as MSM living with HIV infection and those engaging in transactional sex [9]. In addition, MSM recruited into HIV prevention studies in sub-Saharan Africa report high levels of childhood abuse and more recent abuse [3–5], each of which may contribute to adverse psychosocial outcomes.

Depressed mood, alcohol use, and other substance use are important predictors of sexual risk behavior among MSM in sub-Saharan Africa [7,10,11]. Information on psychosocial and contextual factors leading to these conditions is needed in order to develop and target effective prevention strategies tailored to this population [11]. We hypothesized that living with HIV and engaging in transaction sex would be associated with increased depressive symptoms, alcohol use, and other substance use among Kenyan MSM. Using cross-sectional data from three Kenyan research sites, the present study examines two questions. First, how prevalent are depressive symptoms, alcohol use, and substance use in a diverse population of MSM? Second, to what extent are HIV status, transactional sex, and childhood or recent abuse associated with these three conditions?

METHODS

Study sites

This is a secondary analysis of data abstracted from three studies of self-identified MSM conducted in Nairobi, coastal Kenya, and Kisumu by members of the MSM Health Research Consortium, a collaboration focused on improving HIV prevention and care services for MSM in Kenya. The geographic areas covered represent three distinct regions containing the majority of

Kenya's multiethnic population. Studies in Nairobi and Coastal Kenya targeted recruitment towards MSM engaged in transactional sex.

Nairobi. Participants were recruited for a cross-sectional mixed-methods study sponsored by the Canadian Institutes of Health Research to understand vulnerability to HIV in this population. Recruitment took place between January and May 2016 at two clinics providing tailored services to MSM.

Coastal Kenya. Participants were enrolled in cohorts at the Kenya Medical Research Institute-Wellcome Trust Research Programme in Mtwapa [4,12,13]. Socio-demographic data were collected at cohort enrollment. Mental health data were collected at enrollment or follow-up visits between December 2015 and October 2016.

Kisumu. Participants were recruited for a find, test, link, and retain in care study called “*Anza Mapema*” (Kiswahili for “start early”), sponsored by the U.S. Centers for Disease Control and Prevention. HIV-positive MSM already linked to care were excluded. Baseline mental health data were collected at enrollment visits between August 2015 and September 2016.

Data collection

Data were collected by audio computer-assisted self-interview (ACASI) or computer-assisted personal interview (CAPI) in English, Kiswahili, or Dholuo. A version of the Patient Health Questionnaire (PHQ-9) depression module validated in Kiswahili was used at all sites [14]. Other questions were translated from English to Kiswahili or Dholuo by staff at each site, with back-translation to ensure retained meaning. Questions considered unclear or difficult to translate were edited according to each site's local review process.

Trained interviewers explained procedures, answered questions, and assisted with technical problems. After completing the ACASI/CAPI, participants debriefed with a counsellor, and were provided referrals for mental health services as needed. HIV counseling and testing was then conducted according to Kenyan guidelines [15].

Measures

Outcomes

Depressive symptoms. The Patient Health Questionnaire (PHQ-9), with 9 items rated on a 4-point Likert scale, was used to assess depressive symptoms (Supplemental Table 1) [16]. The standard PHQ-9 responses of “Not at all,” “Several days,” “More than half the days,” and “Nearly every day” were used in Kisumu, while the Nairobi and coastal Kenya sites used a revised response set: “Not at all,” “A few days,” “Several days,” and “Nearly all the days.” Both response sets were summed for a total score ranging from 0–27. Based on PHQ-9 scoring guidelines, a score ≥ 10 defined moderate to severe depressive symptoms [16].

Alcohol use. The Alcohol Use Disorder Identification Test (AUDIT) rates 10 items on a 5-point scale (Supplemental Table 2) [17]. In Nairobi and coastal Kenya, if a participant answered “Never” to question 1 on the frequency of drinking, the final two items were asked (see Supplemental Table 2). In Kisumu, no skip pattern was used. In Nairobi and coastal Kenya, the responses “Never,” “A few days a year,” “Every month,” “Every week,” and “Every day” were used for questions 3–8. In Kisumu, the responses for these items were modified: “Never,” “Monthly or less,” “2–4 times a month,” “2–3 times a week,” and “4 or more times a week.” Both response sets were summed for a total score ranging from 0 to 40. A score ≥ 8 defined hazardous drinking [17].

Other substance use. The Drug Abuse Screening Test (DAST-10) was used in Nairobi and coastal Kenya to measure problematic use of non-prescription substances other than alcohol or tobacco [18]. In Kisumu, a shortened instrument omitted four DAST-10 items (Supplemental Table 3). In Kisumu, a skip pattern was employed so that participants reporting no non-medical substance use were asked no further items. For this analysis, only the 6 items (DAST-6) asked at all sites were used. A positive response on any item defined problematic substance use.

Primary Exposures

HIV status. Self-reported HIV status was compared to HIV test results and separated into three categories: known HIV-positive (i.e. self-reported positive/tested positive), newly diagnosed (i.e. self-reported negative or unknown/tested positive), and HIV-negative (i.e. tested negative).

Transactional sex. Engagement in transactional sex was dichotomized to any engagement vs none. Questions about transactional sex varied across sites (Supplemental Table 4).

Additional Exposures

Childhood abuse. Childhood abuse was measured using the four-item Childhood Experience of Care and Abuse (CECA) scale (Supplemental Table 5) [19]. A positive response to any item was classified as childhood abuse.

Recent trauma. Recent trauma was assessed using the four-item USAID Health Policy Initiative MSM Trauma Screening Tool (Supplemental Table 6) [20]. In Nairobi and coastal Kenya, questions asked about trauma in the past year. In Kisumu, questions asked about trauma in the past 3 months. A positive response to any item was classified as recent trauma.

Confounders

Socio-demographics. Sites asked about age, religion, education, and marital status.

Data analysis

De-identified data from each site were standardized and merged into a unified dataset. For categorical variables, number and percent were calculated and Pearson's chi-square test performed for comparisons across HIV status groups. For continuous variables, median and interquartile range (IQR) were calculated and the Kruskal-Wallis test used to compare across HIV status groups. Spearman's rank-order correlation between outcomes was calculated. "Don't know," "refused" and missing responses were relatively frequent (>10%) for engagement in transactional sex, childhood abuse, and recent trauma. Because participants may have refused or skipped questions for a reason, these responses were coded as a separate category, and data were not imputed.

Mixed effects Poisson regression with a random effect for site was used to produce prevalence ratios (PR) in both univariable and multivariable analyses. HIV status, engagement in sex work, childhood abuse, and recent trauma were included a priori in all multivariable analyses. Age, marital status, education, and religion were included in multivariable analysis when associated

with the outcome of interest at $p < 0.20$. P-values for categorical variables were calculated using Wald tests. Data were analyzed using Stata version 14 (StataCorp, College Station, Texas).

Ethics statement

All participants provided written informed consent. Research protocols were approved by the Kenyatta National Hospital and University of Manitoba (Nairobi); Maseno University, University of Illinois at Chicago, and University of Washington (Kisumu); and Kenya Medical Research Institute and University of Washington (coastal Kenya). All sites formally agreed to share data.

RESULTS

Study population

Results were available for 1,476 participants: 537 (37%) from Nairobi, 241 (16%) from Coastal Kenya, and 698 (47%) from Kisumu (Table 1). Median age was 25 years (IQR 22–29). A majority (932, 63%) reported engagement in transactional sex, as expected due to recruitment targeting MSM engaging in transactional sex at two sites. Two hundred eighty-one participants (19%) reported living with HIV, of whom 264 (94%) tested positive (known HIV-positive) and 17 (6%) tested negative, contrary to their self-reported status. Among 1,195 participants who self-reported as HIV negative or status unknown, 128 (11%) tested HIV positive (newly diagnosed HIV-positive). The remaining 1,085 participants were HIV-negative. Across HIV status categories, hazardous alcohol use was less common among men with known HIV-positive status ($p=0.001$). HIV-negative men had a higher frequency of reported childhood abuse ($p=0.01$).

Depressive symptoms, alcohol use, and other substance use

Median PHQ-9 score was 7 (IQR 3–11), and 452 participants (31%) had PHQ-9 ≥ 10 , compatible with moderate to severe depressive symptoms. Median AUDIT score was 6 (IQR 0–14), and 637 participants (44%) had AUDIT ≥ 8 , suggestive of hazardous drinking. Median DAST-6 score was 1 (IQR 0–4), and 749 participants (51%) had at least one positive DAST-6 item (DAST-6 ≥ 1), indicating problematic substance use. AUDIT and DAST-6 scores were weakly correlated with

PHQ-9 scores (PHQ-9/AUDIT $\rho = 0.27$, $p < 0.001$; PHQ-9/DAST-6 $\rho = 0.34$, $p < 0.001$). AUDIT and DAST-6 scores were moderately correlated ($\rho = 0.42$, $p < 0.001$).

Associations with moderate to severe depressive symptoms

In univariable analysis, childhood abuse and recent trauma were associated with PHQ-9 ≥ 10 (Table 2). In multivariable analysis adjusted for religion and education, childhood abuse (adjusted prevalence ratio [aPR] 1.43, 95% confidence interval [CI] 1.10–1.86) and recent trauma (aPR 2.43, 95% CI 1.91–3.09) were associated with PHQ-9 ≥ 10 .

Associations with hazardous alcohol use

In univariable analysis, engagement in transactional sex, childhood abuse, and recent trauma were associated with AUDIT ≥ 8 (Table 3). In multivariable analysis adjusted for age and education, transactional sex (aPR 1.34, 95% CI 1.12–1.60), childhood abuse (aPR 1.36, 95% CI 1.10–1.68), and recent trauma (aPR 1.60, 95% CI 1.33–1.93), were associated with AUDIT ≥ 8 .

Associations with problematic substance use

In univariable analysis, childhood abuse and recent trauma were associated with DAST-6 ≥ 1 . In multivariable analysis adjusted for religion, childhood abuse (aPR 1.32, 95% CI 1.09–1.60) and recent trauma (aPR 1.35, 95% CI 1.14–1.59) were associated with DAST-6 ≥ 1 .

DISCUSSION

Given the multiple stressors faced by MSM across sub-Saharan Africa, a better understanding of factors influencing their mental health and substance use is needed. In a large, diverse population of MSM from three research sites in Kenya, we found that 31% reported moderate to severe depressive symptoms, 44% reported hazardous alcohol use, and 51% reported problematic substance use. Surprisingly, known HIV-positive status was not associated with any of these outcomes. Transactional sex was associated only with hazardous alcohol use. In contrast, both childhood abuse and recent trauma were associated with each of the outcomes studied, highlighting the importance of structural interventions to protect the rights of MSM.

The prevalence of moderate to severe depressive symptoms we found (31%) is higher than the 4.4% prevalence of major depressive disorder or dysthymia found in general population males [21], but similar to the 34% prevalence of moderate to severe depressive symptoms among HIV-positive Kenyan men and women [22]. In addition, the 44% prevalence of hazardous alcohol use is higher than the 5.8% prevalence reported for men in the general Kenyan population [23]. We could find no comparable data on other substance abuse in Kenyan men. Transactional sex was associated with hazardous alcohol use, but not with depressive symptoms or problematic substance use. In qualitative research, men engaging in transactional sex in Kenya have reported drinking to excess as part of their work, which often involves meeting clients in bars [24]. Given the health effects of substance use, including increased risk of HIV acquisition, the high levels of both alcohol and other substance use we found suggest that interventions to address these problems and underlying factors are sorely needed [11]. Over 70% of study participants reported physical or sexual abuse in childhood. Similar to our findings, the 2010 Kenya Violence Against Children Study found that 18% of males reported sexual violence and 73% reported physical violence prior to age 18 [25]. We found that both childhood abuse and recent adult trauma were associated with moderate to severe depressive symptoms, hazardous alcohol use, and problematic substance use. These problems have profound and wide-ranging effects, and abuse counseling should be integral to MSM-focused services in Kenya and other rights-constrained settings [26].

The WHO and Kenya's National AIDS Control Council have called for reducing stigma and discrimination against MSM to improve health outcomes [27,28]. The illegality of same-sex behavior, which provides a license to harass and discriminate, is unacceptable. While a case has been filed in the Kenyan high court by the National Gay and Lesbian Human Rights Commission contesting these laws [29], progress is slow. Although Kenya's Ministry of Health supports programs for MSM [30], MSM still face hostility and discrimination in many healthcare settings [24]. Sensitivity training has been shown to reduce homophobia in Kenyan health care workers [31], and should be scaled up. Interventions to improve resilience and coping strategies have reduced internalized homophobia among U.S. MSM, but have not been assessed among African MSM.

This study has several limitations. First, ACASI/CAPI differences across sites likely increased variability. We attempted to address this problem by including a random effect for site in analyses. Second, since the scales used to measure outcomes have not been validated among MSM in East Africa, applying standard cut points to identify moderate to severe depressive symptoms, hazardous alcohol use, and problematic substance use may overestimate or underestimate prevalence. Validation of mental health measures in this population is needed. Third, we did not assess symptoms of anxiety or post-traumatic stress, which may overlap with depressive symptoms assessed in the PHQ-9. We also did not assess resilience or other factors mitigating mental health problems. Fourth, participants reporting transactional sex may not identify as sex workers. We did not have information on self-identification as a sex worker at all sites, so could not analyze this predictor. Fifth, Kenyan MSM are highly mobile, and it is possible that a small number of men participated at more than one site. Fingerprint scans are used at two sites, but double enrolments could not be checked due to software incompatibility. Sixth, participants were recruited using snowball sampling and peer recruitment, biasing the sample in favor of men known to be MSM. Therefore, this population may not be representative of all Kenyan MSM. Finally, this is a cross-sectional study and therefore associations cannot be interpreted as causal.

In conclusion, MSM in rights-constrained settings need tailored mental health services, in addition to human rights advocacy. Culturally appropriate and affirming mental health screening and treatment or referral should be an integral part of programs, including HIV prevention and treatment programs, providing services to MSM.

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Table 1. Characteristics of participants by HIV status (n= 1,476)

Characteristic	Overall		Known HIV-positive		Newly diagnosed HIV-positive		HIV-negative		p-value
	n (%) or median (IQR)	n (%) or median (IQR)	n (%) or median (IQR)	n (%) or median (IQR)	n (%) or median (IQR)	n (%) or median (IQR)	n (%) or median (IQR)		
Number	1,476	264 (17.9)	128 (8.7)	1084 (73.4)	-				
Transactional sex									0.09
Any	932 (63.1)	165 (62.5)	90 (70.3)	677 (62.5)					
None	504 (34.2)	87 (33.0)	34 (26.6)	383 (35.3)					
Non-response*	40 (2.7)	12 (4.6)	4 (3.1)	24 (2.2)					
Childhood abuse									0.01
Any	1042 (70.6)	175 (66.3)	84 (65.6)	783 (72.2)					
None	396 (26.8)	85 (32.2)	44 (34.4)	267 (24.6)					
Non-response*	38 (2.6)	4 (1.5)	0	34 (3.1)					
Recent trauma ¹									0.15
Any	756 (51.2)	138 (52.3)	58 (45.3)	560 (51.7)					
None	612 (41.5)	115 (43.6)	58 (45.3)	439 (40.5)					
Non-response*	108 (7.3)	11 (4.2)	12 (9.4)	85 (7.8)					
Age (years)	25 (22–29)	28 (24–32)	26 (23–31)	24 (21–28)					<0.001
Currently married to a woman ²	135 (9.2)	24 (9.1)	10 (7.9)	101 (9.3)					0.86
Education ³									0.17
Primary or less	513 (34.8)	105 (39.8)	44 (34.4)	364 (33.6)					
Completed secondary	505 (34.2)	79 (29.9)	38 (29.7)	388 (35.8)					
Some higher education	457 (31.0)	80 (30.3)	46 (35.9)	331 (30.6)					
Religion									0.08
Christian	1,058 (71.7)	200 (75.8)	99 (77.3)	759 (70.0)					
Muslim	186 (12.6)	32 (12.1)	17 (13.3)	137 (12.6)					
Other	112 (7.6)	14 (5.3)	9 (7.0)	89 (8.2)					
None	120 (8.1)	18 (6.8)	3 (2.3)	99 (9.1)					

Depressive symptoms (PHQ-9) ⁴						0.76
Minimal (<5)	478 (32.4)	78 (29.6)	46 (35.9)	354 (32.7)		
Mild (5–9)	545 (37.0)	95 (36.0)	45 (35.2)	405 (37.4)		
Moderate (10–14)	258 (17.5)	51 (19.3)	20 (15.6)	187 (17.3)		
Moderately severe (15–19)	132 (9.0)	25 (9.5)	10 (7.8)	97 (9.0)		
Severe (≥20)	62 (4.2)	15 (5.7)	7 (5.5)	40 (3.7)		
Alcohol use risk level (AUDIT) ⁵						0.001
Zone I (0–7)	828 (56.5)	166 (63.6)	76 (59.4)	586 (54.5)		
Zone II (8–15)	328 (22.4)	65 (24.9)	22 (17.2)	241 (22.4)		
Zone III (16–19)	97 (6.6)	14 (5.4)	8 (6.3)	75 (7.0)		
Zone IV (≥20)	212 (14.5)	16 (6.1)	22 (17.2)	174 (16.2)		
Any problematic substance use (DAST-6≥1) ⁶	912 (61.9)	205 (78.0)	85 (66.4)	622 (57.5)		0.06

Note: Known HIV-positive was defined as self-reported positive and tested positive. Newly diagnosed HIV-positive was defined as self-reported negative and tested positive. HIV-negative was defined as tested negative.

IQR = Interquartile range

* Non-response included “don’t know,” “refused to answer,” and missing responses.

¹ Recent trauma was assessed over the past year in Nairobi and Coastal Kenya and in the past 3 months in Kisumu.

² In Kenya, legal marriage is restricted to heterosexual relationships. Marital status was missing for 4 participants.

³ Education was missing for 1 participant.

⁴ PHQ-9 score was missing for 1 participant.

⁵ AUDIT score was missing for 11 participants.

⁶ DAST-6 score was missing for 3 participants.

Table 2. Characteristics associated with PHQ-9 score ≥ 10

	Univariable		Multivariable	
	Prevalence Ratio (95% CI)	p-value	Adjusted Prevalence Ratio* (95% CI)	p-value
<i>Primary exposures</i>				
HIV status†		0.64		0.37
Known positive	1.14 (0.86 – 1.49)		1.18 (0.94 – 1.49)	
Newly diagnosed positive	0.97 (0.69 – 1.37)		1.03 (0.73 – 1.46)	
Negative	ref		ref	
Transactional sex		0.06		0.51
Any	1.29 (1.05 – 1.59)		1.10 (0.89 – 1.35)	
Non-response‡	1.28 (0.71 – 2.30)		1.33 (0.75 – 2.37)	
None	ref		ref	
<i>Secondary exposures</i>				
Childhood abuse		<0.001		0.02
Any	1.97 (1.53 – 2.54)		1.43 (1.10 – 1.86)	
Non-response	2.08 (1.16 – 3.73)		1.62 (0.92 – 2.86)	
None	ref		ref	
Recent trauma		<0.001		<0.001
Any	2.76 (2.19 – 3.48)		2.43 (1.91 – 3.09)	
Non-response‡	2.35 (1.58 – 3.50)		1.99 (1.35 – 2.93)	
None	ref		ref	
<i>Confounders</i>				
Age	1.01 (0.99 – 1.02)	0.25	-	
Currently married to a woman	0.92 (0.66 – 1.28)	0.62	-	
Education		0.11		0.30
Primary or less	ref		ref	
Completed secondary	0.76 (0.58 – 0.99)		0.83 (0.66 – 1.05)	
Some higher	0.85 (0.58 – 1.27)		0.94 (0.75 – 1.18)	
Religion		0.19		0.41
Christian	ref		ref	
Muslim	1.19 (0.91 – 1.56)		1.13 (0.86 – 1.49)	
Other	0.98 (0.68 – 1.42)		0.97 (0.67 – 1.39)	
None	1.37 (1.00 – 1.88)		1.27 (0.93 – 1.73)	

* Adjusted model includes engaged in transactional sex, childhood abuse, recent trauma, education and religion.

† Known HIV-positive was defined as self-reported positive and tested positive. Newly diagnosed HIV-positive was defined as self-reported negative and tested positive. HIV-negative was defined as tested negative.

‡ Non-response included “don’t know,” “refused to answer,” and missing responses.

Table 3. Characteristics associated with AUDIT score ≥ 8

	Univariable		Multivariable	
	Prevalence Ratio (95% CI)	p-value	Adjusted Prevalence Ratio* (95% CI)	p-value
<i>Primary exposures</i>				
HIV status [†]		0.49		0.17
Known positive	0.87 (0.68 – 1.11)		0.80 (0.62 – 1.02)	
Newly diagnosed positive	0.90 (0.68 – 1.21)		0.87 (0.64 – 1.16)	
Negative	ref		ref	
Transactional sex		<0.001		0.01
Any	1.47 (1.23 – 1.75)		1.34 (1.12 – 1.60)	
Non-response	1.01 (0.55 – 1.83)		0.96 (0.53 – 1.76)	
<i>Secondary exposures</i>				
Childhood abuse		<0.001		0.01
Any	1.63 (1.33 – 2.00)		1.36 (1.10 – 1.68)	
Non-response	1.17 (0.64 – 2.16)		0.98 (0.53 – 1.80)	
None	ref		ref	
Recent trauma		<0.001		<0.001
Any	1.81 (1.52 – 2.15)		1.60 (1.33 – 1.93)	
Non-response	1.53 (1.11 – 2.10)		1.47 (1.06 – 2.04)	
None	ref		ref	
<i>Confounders</i>				
Age	1.02 (1.01 – 1.03)	<0.001	1.02 (1.01 – 1.03)	0.01
Currently married to a woman	0.99 (0.75 – 1.29)	0.92	-	
Education		0.04		0.07
Primary or less	ref		ref	
Completed secondary	0.91 (0.75 – 1.11)		0.99 (0.81 – 1.20)	
Some higher	1.16 (0.96 – 1.41)		1.21 (1.00 – 1.47)	
Religion		0.94		
Christian	ref		-	
Muslim	1.06 (0.84 – 1.35)		-	
Other	1.07 (0.80 – 1.42)		-	
None	1.03 (0.77 – 1.39)		-	

* Adjusted model includes engaged in transactional sex, childhood abuse, recent trauma, age, and education

† Known HIV-positive was defined as self-reported positive and tested positive. Newly diagnosed HIV-positive was defined as self-reported negative and tested positive. HIV-negative was defined as tested negative.

‡ Non-response included “don’t know,” “refused to answer,” and missing responses.

Table 4. Characteristics associated with DAST-6 score ≥ 1

	Univariable		Multivariable	
	Prevalence Ratio (95% CI)	p-value	Adjusted Prevalence Ratio* (95% CI)	p-value
<i>Primary exposures</i>				
HIV status [†]		0.38		0.50
Known positive	0.91 (0.74 – 1.10)		1.07 (0.78 – 1.48)	
Newly diagnosed positive	0.85 (0.64 – 1.13)		1.16 (0.87 – 1.53)	
Negative	ref		ref	
Transactional sex		0.20		0.58
Any	1.15 (0.98 – 1.35)		1.07 (0.91 – 1.26)	
Non-response‡	1.21 (0.78 – 1.88)		1.21 (0.78 – 1.88)	
None	ref		ref	
<i>Secondary exposures</i>				
Childhood abuse		<0.001		0.01
Any	1.48 (1.24 – 1.78)		1.32 (1.09 – 1.60)	
Non-response‡	1.55 (1.01– 2.39)		1.39 (0.89 – 2.15)	
None	ref		ref	
Recent trauma		<0.001		0.002
Any	1.47 (1.26 – 1.72)		1.35 (1.14 – 1.59)	
Non-response‡	1.27 (0.92 – 1.75)		1.18 (0.85 – 1.65)	
None	ref		ref	
<i>Confounders</i>				
Age	1.00 (0.98 – 1.01)	0.98	-	
Currently married to a woman	1.00 (0.77 – 1.29)	0.98	-	
Education		0.69		
Primary or less	ref		-	
Completed secondary	1.08 (0.91 – 1.28)		-	
Some higher	1.05 (0.87 – 1.27)		-	
Religion		0.02		0.03
Christian	ref		ref	
Muslim	1.36 (1.11 – 1.66)		1.35 (1.11 – 1.65)	
Other	0.97 (0.72 – 1.31)		0.95 (0.70 – 1.28)	
None	1.10 (0.84 – 1.43)		1.08 (0.82 – 1.39)	

*Adjusted model includes engaged in transactional sex, childhood abuse, recent trauma, and religion

† Known HIV-positive was defined as self-reported positive and tested positive. Newly diagnosed HIV-positive was defined as self-reported negative and tested positive. HIV-negative was defined as tested negative.

‡Non-response included “don’t know,” “refused to answer,” and missing responses.

Supplemental Table 1. Patient Health Questionnaire-9 (PHQ-9) items by HIV status (n=1,475)

Each item was prefaced with “Over the last two weeks, how often have you...”

	Overall	Known HIV-positive	Unknown HIV-positive	HIV-negative
	n (%)	n (%)	n (%)	n (%)
Experienced little interest or pleasure in doing things				
Not at all*	431 (29.2)	88 (33.3)	43 (33.6)	300 (27.7)
A few days	675 (45.7)	109 (41.3)	52 (40.6)	514 (47.4)
Several days	189 (12.8)	41 (15.5)	9 (7.0)	139 (12.8)
Nearly all the days	180 (12.2)	26 (9.9)	24 (18.8)	130 (12.0)
Felt down, depressed, or hopeless				
Not at all	489 (33.1)	72 (27.3)	42 (32.8)	375 (34.6)
A few days	614 (41.6)	117 (44.3)	56 (43.8)	441 (40.7)
Several days	231 (15.7)	52 (19.7)	15 (11.7)	164 (15.1)
Nearly all the days	142 (9.6)	23 (8.7)	15 (11.7)	104 (9.6)
Had trouble falling or staying asleep, or sleeping too much				
Not at all	541 (36.7)	84 (31.8)	37 (28.9)	420 (38.8)
A few days	596 (40.4)	117 (44.3)	63 (49.2)	416 (38.4)
Several days	195 (13.2)	46 (17.4)	14 (10.9)	135 (12.5)
Nearly all the days	144 (9.8)	17 (6.4)	14 (10.9)	113 (10.4)
Felt tired or had little energy				
Not at all	499 (33.8)	66 (25.0)	43 (33.6)	390 (36.0)
A few days	651 (44.1)	136 (51.5)	61 (47.7)	454 (41.9)
Several days	214 (14.5)	35 (13.3)	16 (12.5)	163 (15.0)
Nearly all the days	112 (7.6)	27 (10.2)	8 (6.3)	77 (7.1)
Had poor appetite or have overeaten				
Not at all	646 (43.8)	106 (40.2)	56 (43.8)	484 (44.7)
A few days	562 (38.1)	105 (39.8)	53 (41.4)	404 (37.3)
Several days	172 (11.7)	38 (14.4)	12 (9.4)	122 (11.3)
Nearly all the days	96 (6.5)	15 (5.7)	7 (5.5)	74 (6.8)
Felt bad about yourself—or that you are a failure or have let yourself or your family down				
Not at all	675 (45.7)	108 (40.9)	59 (46.1)	508 (46.9)
A few days	465 (31.5)	83 (31.4)	40 (31.3)	342 (31.6)
Several days	172 (11.7)	41 (15.5)	17 (13.3)	114 (10.5)
Nearly all the days	164 (11.1)	32 (12.1)	12 (9.4)	120 (11.1)
Had trouble concentrating on things, such as reading the newspaper or watching television				
Not at all	694 (47.0)	124 (47.0)	61 (47.7)	509 (47.0)
A few days	480 (32.5)	83 (31.4)	40 (31.3)	357 (32.9)
Several days	154 (10.4)	34 (12.9)	13 (10.2)	107 (9.9)

Nearly all the days	148 (10.0)	23 (8.7)	14 (10.9)	111 (10.2)
Experienced moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual				
Not at all	798 (54.1)	139 (52.7)	67 (52.3)	592 (54.6)
A few days	451 (30.6)	78 (29.6)	41 (32.0)	332 (30.6)
Several days	140 (9.5)	30 (11.4)	13 (10.2)	97 (9.0)
Nearly all the days	87 (5.9)	17 (6.4)	7 (5.5)	63 (5.8)
Thought that you would be better off dead or of hurting yourself in some way				
Not at all	978 (66.3)	169 (64.0)	81 (63.3)	728 (67.2)
A few days	301 (20.4)	51 (19.3)	32 (25.0)	218 (20.1)
Several days	122 (8.3)	27 (10.2)	8 (6.3)	87 (8.0)
Nearly all the days	75 (5.1)	17 (6.4)	7 (5.5)	51 (4.7)

*Responses in Kisumu: Not at all; Several days; More than half the days; Nearly every day.

Supplemental Table 2. Alcohol use disorders identification test (AUDIT) items by HIV status (n=1,476)

	Overall n (%)	Known HIV-positive n (%)	Unknown HIV-positive n (%)	HIV-negative n (%)
How often do you have a drink containing alcohol				
Never	495 (33.5)	85 (32.2)	53 (41.4)	357 (32.9)
Monthly or less	256 (17.3)	70 (26.5)	20 (15.6)	166 (15.3)
2-4 times a month	303 (20.5)	58 (22.0)	21 (16.4)	224 (20.7)
2-3 times a week	264 (17.9)	29 (11.0)	17 (13.3)	218 (20.1)
4 or more times a week	156 (10.6)	22 (8.3)	17 (13.3)	117 (10.8)
Non-response	2 (0.2)	0	0	2 (0.2)
How many drinks containing alcohol do you have a on typical day when you are drinking				
1 to 2	453 (30.7)	87 (33.0)	31 (24.2)	335 (30.9)
3 to 4	339 (23.0)	62 (23.5)	25 (19.5)	252 (23.3)
5 to 6	137 (9.3)	22 (8.3)	9 (7.0)	106 (9.8)
7 to 9	25 (1.7)	4 (1.5)	3 (2.3)	18 (1.7)
10 or more	25 (1.7)	3 (1.1)	7 (5.5)	15 (1.4)
Non-response	497 (33.7)	86 (32.6)	53 (41.4)	358 (33.0)
How often do you have six or more drinks on one occasion				
Never	565 (38.3)	90 (34.1)	42 (32.8)	433 (39.9)
A few days a year	228 (15.5)	47 (17.8)	18 (14.1)	163 (15.0)
Every month	202 (13.7)	21 (8.0)	17 (13.3)	164 (15.1)
Every week	173 (11.7)	25 (9.5)	12 (9.4)	136 (12.6)
Every day	55 (3.7)	4 (1.5)	9 (7.0)	42 (3.9)
Non-response	253 (17.1)	77 (29.2)	30 (23.4)	146 (13.5)
How often during the last year have you found that you were not able to stop drinking				
Never	686 (46.5)	101 (38.3)	54 (42.2)	531 (49.0)
A few days a year	195 (13.2)	45 (17.1)	14 (10.9)	136 (12.6)
Every month	137 (9.3)	17 (6.4)	10 (7.8)	110 (10.2)
Every week	108 (7.3)	18 (6.8)	10 (7.8)	80 (7.4)
Every day	95 (6.4)	5 (1.9)	10 (7.8)	80 (7.4)
Non-response	255 (17.3)	78 (29.6)	30 (23.4)	147 (13.6)
How often during the last year have you failed to do what was expected of you because of drinking				
Never	753 (51.0)	108 (40.9)	57 (44.5)	588 (54.2)
A few days a year	231 (15.7)	51 (19.3)	13 (10.2)	167 (15.4)
Every month	123 (9.3)	12 (4.6)	17 (13.3)	94 (9.7)
Every week	74 (5.0)	10 (3.8)	6 (4.7)	58 (5.4)
Every day	42 (2.9)	5 (1.9)	5 (3.9)	32 (3.0)
Non-response	253 (17.1)	78 (29.6)	30 (23.4)	145 (13.4)
How often during the last year have you needed a first drink in the morning				

Never	788 (53.4)	135 (51.1)	67 (52.3)	586 (54.1)
A few days a year	171 (11.6)	33 (12.5)	10 (7.8)	128 (11.8)
Every month	71 (4.8)	6 (2.3)	7 (5.5)	58 (5.4)
Every week	91 (6.2)	7 (2.7)	2 (1.6)	82 (7.6)
Every day	102 (6.9)	6 (2.3)	12 (9.4)	84 (7.8)
Non-response	253 (17.1)	77 (29.2)	30 (23.4)	146 (13.5)

How often during the last year have you had a feeling of guilt after drinking

Never	688 (46.6)	96 (36.4)	65 (50.8)	527 (48.6)
A few days a year	268 (18.2)	63 (23.9)	13 (10.2)	192 (17.7)
Every month	104 (7.1)	13 (4.9)	8 (6.3)	83 (7.7)
Every week	92 (6.2)	5 (1.9)	5 (3.9)	82 (7.6)
Every day	70 (4.7)	10 (3.8)	7 (5.5)	53 (4.9)
Non-response	254 (17.2)	77 (29.2)	30 (23.4)	147 (13.6)

How often during the last year have you been unable to remember the night before

Never	732 (49.6)	109 (41.3)	63 (49.2)	560 (51.7)
A few days a year	251 (17.0)	60 (22.7)	11 (8.6)	180 (16.6)
Every month	79 (5.4)	7 (2.7)	7 (5.5)	65 (6.0)
Every week	93 (6.3)	7 (2.7)	9 (7.0)	77 (7.1)
Every day	68 (4.6)	4 (1.5)	8 (6.3)	56 (5.2)
Non-response	253 (17.1)	77 (29.2)	30 (23.4)	146 (13.5)

Have you or someone else been injured because of your drinking

No	1091 (73.9)	217 (82.2)	93 (72.7)	781 (72.1)
Yes, but not during the last year	179 (12.1)	23 (8.7)	12 (9.4)	144 (13.3)
Yes, during the last year	205 (13.9)	24 (9.1)	23 (18.0)	158 (14.6)
Non-response	1 (0.1)	0	0	1 (0.1)

Has someone been concerned about your drinking or suggested you cut down

No	974 (66.0)	176 (66.7)	94 (73.4)	704 (64.9)
Yes, but not during the last year	198 (13.4)	39 (14.8)	10 (7.8)	149 (13.8)
Yes, during the last year	302 (20.5)	48 (18.2)	24 (18.8)	230 (21.2)
Non-response	2 (0.1)	1 (0.4)	0	1 (0.4)

* Non-response included "don't know," "refused to answer," missing responses, and participants who answered "never" to AUDIT item 1.

Supplemental Table 3. Drug Abuse Screening Test (DAST-6) items by HIV status (n=1,476)

	Overall	Known	Unknown	HIV-negative
	n (%)	HIV-positive	HIV-positive	n (%)
	n (%)	n (%)	n (%)	n (%)
Have you used drugs other than those required for medical reasons				
Yes	506 (34.3)	68 (25.8)	40 (31.3)	398 (36.3)
No	970 (65.7)	196 (74.2)	88 (68.8)	686 (63.3)
Non-response*	0	0	0	0
Have you used more than one drug at a time				
Yes	374 (25.3)	79 (29.9)	19 (14.8)	276 (25.5)
No	613 (41.5)	159 (60.2)	71 (55.5)	383 (35.3)
Non-response	489 (33.1)	26 (9.9)	38 (29.7)	425 (39.2)
Have you always been able to stop using drugs when you want to				
Yes	517 (35.0)	108 (40.9)	32 (25.0)	377 (34.8)
No	466 (31.6)	128 (48.5)	58 (45.3)	280 (25.8)
Non-response	493 (33.4)	28 (10.6)	38 (29.7)	427 (39.4)
Have you engaged in illegal activities in order to obtain drugs				
Yes	195 (13.2)	29 (11.0)	17 (13.3)	149 (13.8)
No	792 (53.7)	208 (78.8)	73 (57.0)	511 (47.1)
Non-response	489 (33.1)	27 (10.2)	38 (29.7)	424 (39.1)
Have you ever experienced withdrawal symptoms when you stopped taking drugs				
Yes	267 (18.1)	48 (18.2)	19 (14.8)	38 (29.7)
No	718 (48.6)	188 (71.2)	71 (55.5)	459 (48.6)
Non-response	491 (33.3)	28 (10.6)	38 (29.7)	425 (39.2)
Have you had medical problems as a result of your drug use?				
Yes	193 (13.1)	36 (13.6)	16 (13.6)	141 (13.0)
No	794 (53.8)	201 (76.1)	74 (57.8)	519 (47.9)
Non-response	489 (33.1)	27 (10.2)	38 (29.7)	424 (39.1)

* Non-response included “don’t know,” “refused to answer,” missing responses, and participants who answered “no” to DAST item 1 in Kisumu.

Supplemental Table 4. Questions used to assess engagement in transaction sex by site

Nairobi: How long have you exchanged sex for money, food, clothes or other gifts?
 Kisumu: In the last three months, how often have you had sex with someone in order to get money, food or housing?
 Coastal Kenya: In the last three months, have you been paid for sex with cash, living expenses, or goods?

Supplemental Table 5. Childhood Experience of Care and Abuse (CECA) items by HIV status (n=1,476)

	Overall n (%)	Known HIV-positive n (%)	Unknown HIV-positive n (%)	HIV-negative n (%)
When you were a child or teenager, were you ever hit repeatedly with an implement (such as a belt or stick) or punched, kicked, or burnt by someone in the household?				
Yes	882 (59.8)	146 (55.3)	67 (52.3)	669 (61.7)
No	559 (37.9)	114 (43.2)	61 (47.7)	384 (35.4)
Non-response*	35 (2.4)	4 (1.5)	0	31 (2.9)
When you were a child or teenager, did you ever have any unwanted sexual experiences?				
Yes	513 (34.8)	90 (34.1)	35 (27.3)	388 (35.8)
No	928 (62.9)	170 (64.4)	93 (72.7)	665 (61.4)
Non-response	35 (2.4)	4 (1.5)	0	31 (2.9)
Did anyone force you or persuade you to have sexual intercourse against your wishes before age 17?				
Yes	447 (30.3)	83 (31.4)	36 (28.1)	328 (30.3)
No	997 (67.6)	177 (67.1)	92 (71.9)	728 (67.2)
Non-response	32 (2.2)	4 (1.5)	0	28 (2.6)
Can you think of any upsetting sexual experiences before age 17 with a related adult or someone in authority (e.g. a teacher)?				
Yes	398 (27.0)	81 (30.7)	37 (28.9)	250 (27.0)
No	1046 (70.9)	179 (67.8)	91 (71.1)	776 (71.6)
Non-response	32 (2.2)	4 (1.5)	0	28 (2.6)

*Non-response included “don’t know,” “refused to answer,” and missing responses

Supplemental Table 6. USAID Health Policy Initiative MSM Trauma Screening Tool items* by HIV status (n=1,476)

	Overall n (%)	Known HIV- positive n (%)	Unknown HIV- positive n (%)	HIV-negative n (%)
Has anyone forced or coerced you to have sexual relations against your will?				
Yes	279 (18.9)	62 (23.5)	26 (20.3)	191 (17.6)
No	1147 (77.7)	198 (75.0)	94 (73.4)	855 (78.9)
Non-response**	50 (3.4)	4 (1.5)	8 (6.3)	38 (3.5)
Has anyone slapped you, punched you, hit you, or caused you any other type of physical harm?				
Yes	350 (23.7)	72 (27.3)	30 (23.4)	248 (22.9)
No	1080 (73.2)	186 (70.5)	90 (70.3)	804 (74.2)
Non-response	46 (3.1)	6 (2.3)	8 (6.3)	32 (3.0)
Has anyone insulted you, humiliated you, made you feel inadequate, or yelled at you?				
Yes	628 (42.6)	105 (39.8)	45 (35.2)	478 (44.1)
No	770 (52.2)	152 (57.6)	75 (58.6)	543 (50.1)
Non-response	78 (5.3)	7 (2.7)	8 (6.3)	63 (5.8)
Has anyone made you feel threatened, fearful, or in danger?				
Yes	508 (34.4)	104 (39.4)	39 (30.5)	365 (33.7)
No	963 (65.2)	156 (59.1)	89 (69.5)	718 (66.2)
Non-response	5 (0.3)	4 (1.5)	0	1 (0.1)

*Nairobi and Coastal Kenya questions prefaced with “In the past year,” Kisumu questions with “In the past three months.”

**Non-response included “don’t know,” “refused to answer,” and missing responses

Supplemental Table 7. Other substances used by site

Substance	Overall n=1476 n (%)	Coastal Kenya n=241 n (%)	Kisumu n=698 n (%)	Nairobi n=537 n (%)
Khat	231 (15.7)	63 (26.1)	100 (14.5)	68 (12.7)
Marijuana	261 (17.7)	45 (18.7)	152 (22.1)	64 (11.9)
Hashish	13 (0.9)	6 (2.5)	N/A	7 (1.3)
Inhalants	5 (0.3)	1 (0.4)	N/A	4 (0.7)
Heroin	28 (1.9)	7 (2.9)	14 (2.0)	7 (1.3)
Cocaine	12 (0.8)	2 (0.8)	4 (0.6)	6 (1.1)
Pain medications	29 (2.0)	13 (5.4)	N/A	16 (3.0)
Sleeping medications	33 (2.2)	9 (3.7)	N/A	24 (4.5)
Other	15 (1.0)	8 (3.3)	N/A	7 (1.3)
Rohypnol	3 (0.2)	N/A	3 (0.4)	N/A

N/A: Participants not asked about use of specific substance

General discussion

The four empirical studies in this thesis advance the fields of HIV prevention and public health science by providing an in-depth understanding of the challenges to the provision of HIV preventative services to TW and MSM in coastal Kenya, both of which are key populations that have been historically understudied and overlooked in HIV research and programmatic responses in sSA. The empirical chapters presented here build on and extend the body of research conducted to date on TW and MSM in sSA. There has been growing recognition of HIV risk factors and prevention needs of MSM in Kenya [198] and elsewhere in sSA [113, 114]. However, the research and provision of HIV services for TW is especially challenging in Kenya and throughout sSA due to a lack of recognition for this key population. The situation for including TW in HIV research and programming is further compounded by a conservative culture regarding non-typical gender expression throughout sSA, in which gender expression outside the norm is highly stigmatized and, often, legally prohibited. Consequent to this social disapproval is the development and entrenchment of transphobia within the general population.

Because they are held in high esteem by society, HCP are potentially important allies in improving access to HIV prevention services for TW and MSM. Exploration of opinions by CBO leaders on PrEP programming for these two KPs are valuable for designing and implementing HIV and PrEP programs for TW and MSM.

In this final chapter, I propose measures to address the opportunities for HIV prevention and improve HIV programming for TW and MSM in Kenya. Where appropriate, I also reflect on the implications of findings in other sSA settings. This chapter is broadly divided into four thematic areas: (i) identification of TW as a neglected and “invisible” KP and assessment of the need for PrEP services in this group; (ii) provision of HIV prevention services to TW and MSM; (iii) the challenges to engagement of services and programming for TW and TW in Kenya; (iv) mental health challenges among MSM. I then offer a call to action and concluding remarks.

Brief Summary of Empirical Findings

The empirical studies presented in Chapters 2,3 and 4 were carried out in Malindi, a modern resort town in Coastal Kenya. Malindi has a largely conservative society, a majority of whom ascribe to the Muslim faith. In this setting, homophobia is rife and sometimes condoned by law enforcement who hold the view that same-sex relationships are a contravention of the law. The final study was a cross-sectional analysis of common mental health disorders (CMD) and HIV among MSM in three geographically diverse sites in Kenya and provides a snapshot of CMD patterns in Nairobi (the largest and most resourced city in Kenya), Kisumu a less developed and resourced city and in Mtwapa, a small semi-urban site in coastal Kenya.

Overall, findings from these chapters underscored that TW and MSM in coastal Kenya have an alarmingly high risk for HIV, especially TW, and that those TW and MSM who are open about their orientation or gender identity face discrimination [87] and sometimes abuse. Healthcare providers may be unsure of how to appropriately provide services to either TW or MSM [199]. Moreover, HCP who emanate from the local community may have personal values and beliefs that consider same-sex relationships unacceptable [200]. The result could be either mediocre services or even outright service denial to TW and TW at public health facilities [201]. Despite hypothetical interest in PrEP, both groups showed suboptimal PrEP persistence and distinct challenges to PrEP use were reported for TW and MSM as well as from HCPs. Finally, the mental health indicator of MSM revealed an elevated prevalence of depressive symptoms, harmful alcohol use, drug and substance abuse.

Methodological Approaches

In Chapter 2, we estimated HIV incidence in TW and MSM. By deliberately employing the two-step method of gender identification [202], we were able to distinguish between TW and MSM. Further, we enquired on the sex of their partners. We were therefore able to categorize MSM as either exclusively homosexual (MSME) or having sex with both men and women (MSMW). Data were collected using a mixed-methods approach. Quantitative methods were used to both calculate HIV incidence and hypothetical PrEP interest. Using qualitative methods, specifically focus group discussions (FGD) we explored knowledge of PrEP, desire to take up PrEP, and perceived barriers to its use.

Similarly, in Chapter 3 we employed a mixed-methods approach. As this was a pilot study on PrEP uptake and adherence, a convenience sample of 53 TW and TW were enrolled into a PrEP provision cohort. Cohort participants made quarterly refill visits as per national PrEP provision guidelines. Risk assessment and personalized risk reduction counselling was offered at each scheduled study visit. At their month 6 study visit, all participants still on PrEP provided a blood sample for Tenofovir Diphosphate (TFV-DP) level assessment. At the same visit, purposively selected participants were invited to an in-depth interview (IDI). Respondents to the IDI were all TW still in follow up and a conveniently selected sample of MSM. To get a more complete understanding of the PrEP landscape, deliberate efforts were made to seek out and interview cohort participants that had stopped using PrEP. We explored experience while on PrEP, reasons where applicable for stoppage, and suggestions for improvement.

In Chapter 4, data were exclusively qualitatively collected. We invited HCP based at the Malindi county hospital CCC. Data were collected at two-time points i.e. before PrEP roll-out and then 12 months later. We explored knowledge on PrEP, if HCP were aware of an increased HIV risk in MSM and TW, preparedness to provide PrEP to TW and MSM, and finally suggestions for improvement. Similarly, we invited leadership of a TW and MSM community organization. We assessed for PrEP knowledge, perceived and actual challenges to PrEP provision and finally, we sought their suggestions to improve the PrEP program. The reasoning behind the two-time points was to note any changes in attitudes of the respondents over time.

In Chapter 5 all data were collected quantitatively. Previously, it has been demonstrated that respondents are more likely to be truthful to sensitive data when collected through audio computer-assisted self-interview (ACASI) [203]. Accordingly, we used ACASI to collect data on mental health, harmful alcohol and substance use and childhood abuse or trauma, in a community sample of MSM. In chapter 5 all data were collected quantitatively. Previously, it has been demonstrated that respondents are more likely to be truthful to sensitive data when collected through audio computer-assisted self-interview (ACASI) [203]. To collect data on mental health, harmful alcohol and substance use and childhood abuse or trauma we used ACASI. Participants had the option to skip over a question if they felt unable or unwilling to answer.

Relating Main Findings with Syndemics Theory

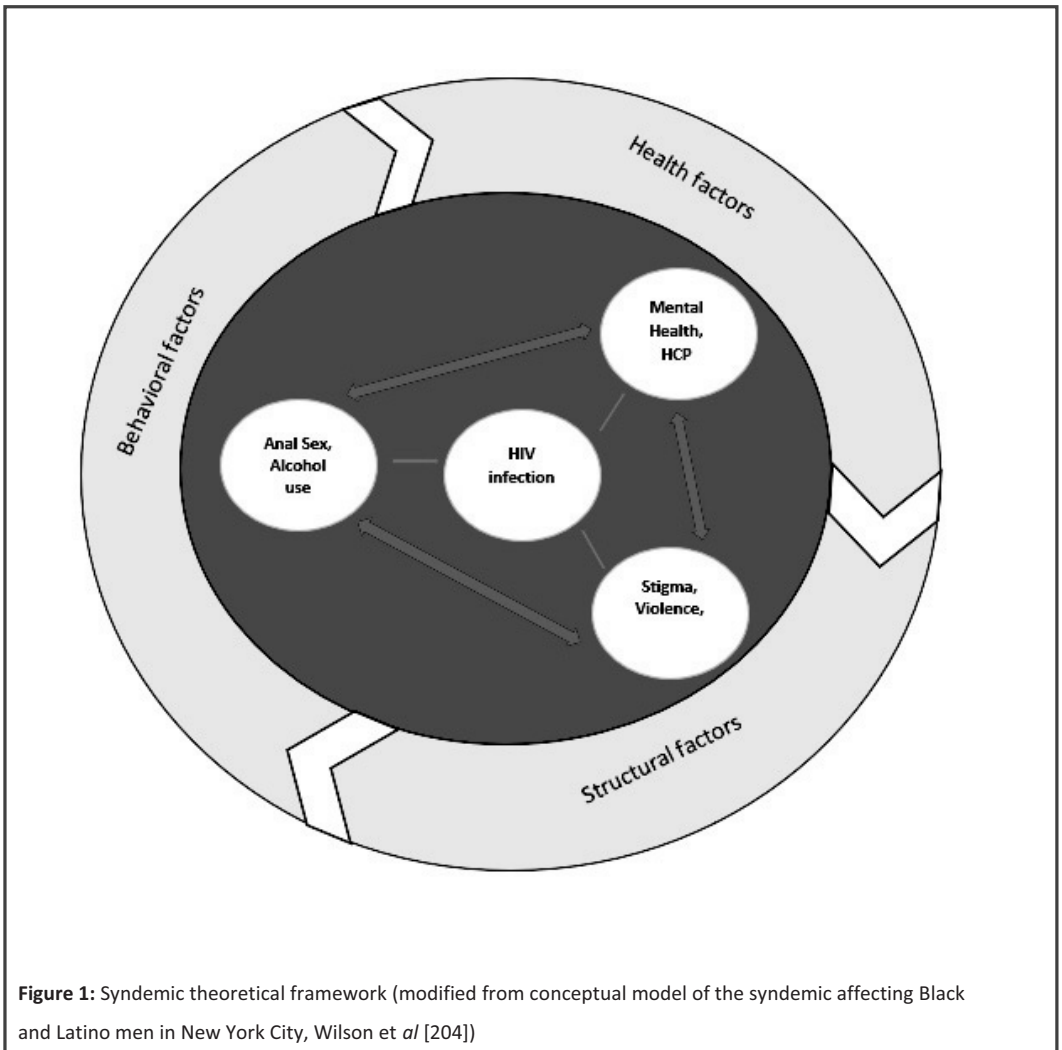
Syndemic framework

As noted in Chapter 1 (Introduction), findings from the four empirical chapters in this thesis indicate the interconnectedness between HIV risk, PrEP interest and uptake, mental health, provider-level and societal stigma as determinants of health for TW and MSM. These findings align with Syndemics Theory, described previously in Chapter 1, which proposes that synergistic interactions between co-occurring adverse health and social conditions can produce exacerbated effects on morbidity and mortality, and posits that targeted and integrated health interventions are necessary to address the complex, multi-faceted nature of syndemic health conditions [141].

Previous research has used Syndemics Theory to understand the determinants of HIV disparities in TW and MSM [142, 204, 205]. In Figure 1, we describe the complex interaction between behavioral, structural, and co-occurring health factors and increased susceptibility to HIV infection in TW and MSM in our study setting. Each factor identified in the Figure can independently predispose TW and MSM in Kenya to HIV infection, but as argued by Singer [141, 206], these factors collectively form an interwoven relationship that shapes the complex determinants of HIV risk and the context for delivery of HIV services for TW and MSM. For example, alcohol use could predispose TW and MSM to condomless anal sex, but similarly could be related to stigma, mental health, and victimization from society.

According to this framework, interventions to support HIV prevention for TW and MSM, including PrEP, must be designed and delivered in ways that consider co-occurrence of other factors within the syndemic. For practical purposes, this framework indicates a need for HIV services to screen, diagnose, and refer PrEP patients with regard to mental health problems, alcohol use problems, and specific challenges related to violence and discrimination. If left unaddressed, these co-occurring health conditions can undermine the potential impact of PrEP or other HIV services. Ideally, these services could be provided in the same setting by trained professional staff with cultural competence for working with TW and MSM.

Informed by Syndemics Theory and based on empirical findings from Chapters 2-5, the next sections of this Discussion Chapter explore specific recommendations for enhanced HIV services to support TW and MSM.



Other behavioural factors not captured in the figure include social behavioural characteristics like age, transactional sex, education level and gender identity. Additional structural factors include childhood abuse.

We hypothesize that there is an interaction between psychological factors and behaviour that increases risk for HIV infection. For example, enacted stigma could dissuade an individual from seeking healthcare. At the same time the individual may be involved in sex work and unable to negotiate for safe sex. This individual could benefit from PrEP but may be avoiding public health facilities. Consequently, all the factors converge to increase risk for HIV infection i.e. the syndemic.

Identification of TW and MSM for PrEP services

Since 2017, the Kenyan Ministry of Health has been promoting the use of PrEP for HIV prevention. To guide HCP on PrEP targeting, the Kenyan National HIV Treatment and Prevention guidelines describe characteristics of the potential PrEP recipient which specifies screening and eligibility criteria for PrEP medications and ancillary services [23]. However, due in part to the prevailing conservative culture in Kenya, neither TW nor TW are explicitly mentioned in HIV prevention guidelines. Similarly missing is a portrayal of specific risk factors for HIV infection including anal intercourse and group sex, as well as group-specific considerations and challenges for engaging and retaining TW and MSM in PrEP programmes [5, 207].

In Chapter 2, we described the identification of TW in a small cohort in Malindi, coastal Kenya, as a high-risk population for HIV infection that warrants inclusion in PrEP programming. Before this work, few HIV research studies had reported on TW in Kenya [198]. Anthropological work from early part of 1900, among communities from Coastal Kenya, report existence of biological males that dressed in female clothing [116]. Such individuals were allowed into normally women-only social spaces. Thus, there seemed to be a level of tolerance and even acceptance by general society of these individuals' gender identity choices. However, it was around the same that the colonialization of much of Africa happened. Alongside establishment of 'Western civilization' was concomitant introduction of Christianity. The introduction of Christianity and imposition of social and moral values prevalent in Europe at the time may have served to entrenched aversion to both homosexuality and gender non-conformity [208].

Probably in response to stigma and to avoid stigmatization, TW may have integrated into MSM networks and, consequently, become socially invisible. Previous studies conducted by

our group had described MSM as having sex with men exclusively (MSME) or having sex with both and women (MSMW) [5, 129]. In a 2013 study, MSME had the highest HIV incidence at 35.2, (95% CI 23.8-52.1)/100py compared to MSMW at 5.8 (95% CI,4.2-7.9)/100py [5].

It is probable that previously TW were misclassified within the MSME sub-category. In Malindi, using the two-step gender identity verification [202], 14 TW were identified [115]. Among TW, high HIV incidence (20.6, 95% CI: 6.6 to 63.8/100py) was demonstrated. Receptive anal intercourse has been previously shown to be a predictor of HIV acquisition among MSM in Kenya [5, 209]. In our study, half of the TW stated being the receptive partner exclusively during anal sex. Risk of HIV infection was associated with exclusive receptive anal sex (aIRR 13.0, 95% CI 1.9 to 88.6). This finding was in keeping with previous estimates. In a study with a larger sample size, Sanders *et al* demonstrated increased risk for HIV infection among MSM, reporting sex exclusively with men (aIRR 3.7, 95% CI 2.1-6.6) and receptive anal sex (aIRR 2.1, 95% CI 1.1-4.1) [5]. The wider confidence intervals demonstrated among TW in our 2019 study can be explained by the smaller sample size. As TW are frequently the receptive partner, HIV prevention interventions are urgently required for these individuals.

However, in accordance with Syndemics Theory and Figure 1, there are challenges to providing such interventions. For example, in rights constrained settings, TW individuals are unlikely to openly admit to being transgender. MSM and TW women who are open about their orientation or gender identity face discrimination [87]. TW may also have co-occurring health conditions including mental health, substance use problems, and trauma due to violence, which can take personal priority over their needs for HIV risk reduction and prevention and undermine TWs' engagement in HIV services.

While our findings confirmed that TW are at the highest risk for HIV infection, findings additionally exposed a gap in the Kenyan HIV prevention response. In addition to the neglect of TW in Kenyan PrEP guidelines, Kenyan HCPs have limited awareness of TW as a population. HCP also may have strong transphobic biases against TW as well as knowledge deficits that undermine their ability to provide effective HIV services including PrEP medications for TW. For example, our findings suggest that there might be some uncertainty

about the potential side-effects of PrEP medications for TW who are also using gender-affirming hormones. Although there exists no clinical evidence for adverse drug-drug interactions related to PrEP and hormones Although there exists no clinical evidence for adverse drug-drug interactions related to PrEP and hormones [1], the perceived risks of co-use of these medications can be a barrier to PrEP for both HCPs prescribers and TW use.

Recently, Wahome *et al.*, described the use of an empiric risk score to target PrEP provision from MSM [24]. By creating a safe space and intentionally employing the two-step method of gender identity verification [202] our study identified 14 TW in Malindi [115]. HIV incidence was highest among the TW at 20.6 (95% CI: 6.6 to 63.8) per 100py compared to the overall HIV incidence of 5.1 (95% CI: 2.6 to 9.8) per 100py in the cohort. Recent findings from diverse African settings involving TW demonstrated similarly high HIV incidence. In Nigeria, among 234 TW in a cohort HIV incidence was 23.8 (95% CI,13.6-39.1)/100py; very similar to our 2019 findings but with a narrower confidence interval [114]. A much higher incidence (31/0 95% CI, 3.7-112.2/100py) was documented among 22 TW in a South African cohort [113]. We strongly believe that the findings are indicative of a need for increased research that is primarily focused on TW. While our findings confirmed that TW are at the highest risk for HIV infection, they additionally exposed a gap in the Kenyan HIV prevention response.

Previously, differential interest to take up PrEP has been demonstrated. In Kenya, data from a 2016 qualitative study using mixed-methods, demonstrated higher PrEP interest in MSMW compared to MSME [129]. However, this was a hypothetical interest in the period before programmatic PrEP was available. In our study, all HIV-negative TW expressed interest to take up PrEP if it was made available [115]. Though not a significant proportion, it is noteworthy that, in our study four MSMW (approximately 3.7%) expressed hesitance to take up PrEP if it were offered to them. It is unclear the reasons for hesitancy but could be linked to fear of drug side effects or reduced risk perception.

Predictors to HIV acquisition specific to either MSM or TW included having exclusively male sex partners, group sex and receptive anal sex. The tool was able to identify more potential PrEP users than when the criteria in the Kenyan national guidelines were followed. That a proportion of MSM would have missed out on PrEP is indicative of a need for more targeted

efforts by HCP to identify MSM individuals that need HIV prevention services. Research by van der Elst et al, demonstrated the positive effects of MSM sensitivity training for improving HCPs' knowledge, comfort, and willingness to provide HIV prevention services to MSM [92, 200, 210]. However, as Chapter 2-5 findings reveal, MSM who are eligible for PrEP might also have syndemic co-occurring health and social risk factors that warrant intervention, as depicted in Figure 1 and in alignment with Syndemics Theory. HCPs and HIV service settings must therefore develop capacities and resources to address the multiple, complex health and social risk factors that MSM experience, in order to engage and maintain MSM in HIV prevention and PrEP programs.

PrEP adherence and retention

In Chapter 3, we present findings from a PrEP cohort for TW and MSM in coastal Kenya. The findings indicated that, while interest to take up PrEP was high in theory, actual uptake by TW and MSM may not be commensurate to their stated interest. Potential PrEP users may have to traverse a series of hurdles to access and adhere to PrEP. This cascade of events is referred to as the PrEP continuum [211, 212]. [211, 212]. The steps a potential user must surmount This cascade of events is referred to as the PrEP continuum [211, 212]. The steps a potential user must surmount include; (1) Identifying individuals at highest risk for contracting HIV (2) Increasing HIV risk awareness among those individuals (3) Enhancing PrEP awareness (4) Facilitating PrEP access (5) Linking to PrEP care (6) Prescribing PrEP (7) Initiating PrEP (8) Adhering to PrEP (9) Retaining individuals in PrEP care

Findings from Chapter 2 addressed the first three steps of the PrEP continuum. Findings from the study in chapter 3 focused on the latter parts of the continuum i.e. PrEP adherence and persistence in TW and MSM.

The data were collected at the key populations' clinic within the Malindi sub-County hospital. The site clinic is specifically designed to be MSM and TW friendly. Staff have training on providing services to MSM and TW respectfully. Malindi Desire Initiative (MDI), a transgender lead CBO is also hosted at the clinic. TW are able to access the site discreetly which also serves as a community safe space. PrEP was provided in a cohort. In the cohort, 42 MSM and revealed disappointing levels of both adherence and persistence.

By the month 6 visit, almost 21% of participants (n=11) had either stopped PrEP or were lost to follow-up. In interviews with participants that had stopped PrEP, lack of disclosure on PrEP use was cited as a reason. Similarly, even amongst the 42 participants still on follow-up, only 3 TW and no MSM had TFV-DP levels corresponding to protective drug levels. There were diverse reasons advanced by both MSM and TW varied adherence patterns, described in detail in Chapter 3.

The effectiveness of PrEP is a function of adherence [20, 213]. Consistent with Syndemics Theory, multiple co-occurring health and social risk factors can reduce the ability for TW and MSM to adhere to PrEP medications and the continuum of PrEP services. While the current standard dosing is a single daily oral pill, PrEP use is only indicated when there is an on-going risk for HIV infection. On-going risk is problematic to define, as risk perception varies between individuals. Due to their likelihood of having other subjectively prioritized health or social risks, TW and MSM might minimize their risk for HIV as well as discontinue PrEP adherence due to lower perceived risk relative to other issues (e.g., mental health, violence and safety, economic distress).

Encouraging findings from trials on injectable PrEP are fueling optimism that long-acting PrEP may soon be available. If shown to be effective, long-acting PrEP removes the burden on user to administer daily medications, which can be of substantial utility for TW and MSM whose complex health and social risk profiles undermine adherence to PrEP daily medications. Preliminary results from the HPTN 083 trial [197] released in 2020, showed that there were fewer incident infections among trial participants in the injectable long-acting Cabotegravir (CAB LA) arm (n=12) compared to those in the daily oral tenofovir + Emtricitabine (TDF/FTC) arm. Participants in the CAB LA arm were 66 times less likely to acquire HIV infection compared to those in the daily oral TDF/FTC arm (HR 0.34, 95% C.I 0.18-.62)[197]. Even as injectable long-acting PrEP awaits regulatory approval, on-demand PrEP is available. WHO has been promoting event-driven oral PrEP as an alternative to daily oral PrEP [196]. It is however currently only recommended for MSM. Dubbed the 2+1+1 strategy, it involves taking two TDF/FTC pills 2-24 hours before sexual activity, a pill 24 hrs later and a last one 48 hours after the initial two[196]. It is conceivable long-acting and/or event-driven PrEP may improve prevention effects among users face with adherence to daily oral PrEP, such as TW and MSM. However, these relatively less-burdensome PrEP

formulations do not directly address other syndemic health and social risk factors (e.g., mental health, violence) that can affect continued engagement in HIV services among TW and MSM.

Both MSM and TW participants in our cohort struggled with PrEP adherence, persistence and retention in care. However, TW had more complete PrEP knowledge and adhered better. Seemingly, TW had a clearer grasp of their HIV infection risk and hence adhered better to PrEP. On qualitative interviews to assess for challenges to PrEP adherence, respondents expressed the desire to access long-acting PrEP formulations as mitigation to the challenges of daily oral PrEP.

In the PrEP demonstration projects, a majority of HIV infections occurred in participants that were not adherent [20, 213]. However, in a real-world setting, adherence to PrEP is difficult to quantify. While the standard dosing is a single daily oral pill, PrEP use is only indicated when there is an on-going risk for HIV infection. On-going risk is problematic to define as risk perception varies between individuals. There is also currently no agreed-upon gold standard method for assessing for PrEP adherence. In our study, we adopted keeping to appointment schedule as a proxy indicator to PrEP adherence. We also asked participants about individual PrEP use including missed doses. Most participants self-reported their adherence as either good or excellent [186]. However, we only report on objective measures as previous work has shown demonstrated the subjective measures are of lower utility on their own [214]. Due to social desirability bias, respondents may overstate their levels of adherence.

Challenges to PrEP programming for TW and MSM in Africa

In Chapter 4, we present findings on a qualitative exploration of the opinions of key informants into PrEP programming. This chapter delved into understanding the challenges current PrEP programming faces and additionally suggestions for improvement, and findings align with the Syndemics Framework which point to the complex and co-occurring health and social risk factors that TW and MSM experience, and reveal that HCPs do not currently have the capacity or resources to address these issues in health settings.

In Kenya, the Ministry of Health opted to have PrEP services provided by HCPs alongside their current roles within comprehensive care centres (CCCs). Focus group discussions with

HCP felt unprepared for PrEP programming, due in large part to the “hurried” manner in which PrEP programmes were implemented. They felt overwhelmed by this additional responsibility, which did not take into account their current workload. Similar sentiments have been recorded in the United States, where HCPs also felt PrEP provision was additional work and difficult to do correctly within their current workload. They desired additional staff that were specifically mandated with PrEP delivery [215]. Besides being unprepared for PrEP provision, HCPs in Malindi also lacked comprehension of the increased risk for HIV infection in MSM and TW, compared to the general population. Notably, a year after collecting this first round of data, HCP appeared to have accepted PrEP programming. However, this willingness to provide PrEP was generally extended only to the negative partner in a serodiscordant heterosexual couple, and not to TW and MSM. HCPs expressed the sentiment that TW would be better served outside the public hospital - possibly at community-based partner organizations. In previous work, HCPs in the United States expressed a similar sentiment. They were more likely to prescribe PrEP to the negative partner in a serodiscordant heterosexual couple to facilitate safe conception as opposed to MSM [216]. This opinion may be rooted in the sentiment that MSM may be needlessly and deliberately putting themselves at risk for HIV infection.

Programming for TW and MSM according to HCP, was better outsourced to community-based organizations (CBO) away from the CCC. On the surface, it would appear that there was a change of attitude among HCP, over time towards the delivery of PrEP. However, it is more likely that they had resigned themselves to the fact that PrEP programming would continue. That they were unwilling to program for MSM and TW indicates some resistance persisted. It appears HCP in our study struggled with balancing homophobia and the mandate to provide services. Training curricula in Kenya do not prepare HCP to provide services to TW or TW. Consequently, the onus is upon the individual HCP to make the decision as to whether and how to provide services to TW and MSM, based on his/her value and belief systems. Previous work has shown that HCP may have homophobic sentiment but are responsive to sensitivity training [91]. The resistance from HCP in this study is indicative of a need for increased engagement and sensitization on MSM and TW health needs.

Separately, ten leaders of an MSM and TW CBO also participated in two FGDs to explore their understanding of PrEP programming, specifically for MSM and TW. In contrast to HCP,

the CBO leadership were very conscious of the increased risk of HIV acquisition, especially for TW. This finding is not surprising considering that the respondents may have been speaking from lived-life experiences. The struggle to 'come out' as a TW was described as very difficult. The respondents described TW opting to blend into the larger society. Community leaders felt the CCC was an inappropriate PrEP dispensing venue. They sensed HCP not being comfortable serving either MSM or TW. The CBO leadership and their members may have picked up on the indifference towards MSM and TW from HCP at the public health facility. This finding resonates with prior research on PrEP services for sexual minorities. In previous work among African-American MSM, almost half (48%) admitted having mistrust towards HCP [217]. MSM that had increased mistrust for HCP were more likely to have longer intervals between their clinic visits [217]. Avoidance of healthcare facilities may result in TW and TW missing out on opportunities to access HIV prevention. Availability of alternative PrEP dispensing venues away from the public health facility may be needed to keep TW and MSM engaged in care services.

Nineteen MSM and TW end-users were also invited to participate in in-depth interviews to discuss their PrEP experience. There were varied motivations for PrEP uptake between MSM and TW. Similar to CBO leadership, TW end-users were very aware of their increased risk for HIV infection. Indeed, a primary motivation for PrEP uptake was the desire to remain HIV negative. In contrast, MSM end-users were motivated to take up PrEP to facilitate worry-free condomless sex. However, despite being highly motivated to take up PrEP, respondents emphasized that they would not take up PrEP if they had to pay for it.

To describe the healthcare access landscape for TW, the TransAlliance Kenya, with support from the Ministry of Health, carried out a survey called the National Transgender Discrimination Situational Analysis [218]. The survey employed cluster randomized sampling in 9 purposively selected counties. They enrolled 279 respondents of whom 129 (46%) identified as TW, the others being MSM and gender non-binary. Among the key findings among TW included, 41% could only access healthcare at public health facilities. Over a third of all respondents (32%), reported having been denied services at a health facility due to their gender expression. About 10% of all respondents reported being HIV positive, though this was self-reported and not confirmed by testing. However, the data were not disaggregated by current gender identity, and thus TW-specific findings are not available

[218]. In addition to HIV prevention and treatment services, TW and gender non-binary individuals also desire to access gender affirmation therapy and mental health support. Over half (51%) of the respondents in the national transgender discrimination survey reported experience of being attended to by HCPs who were unprepared to discuss their transgender identity [218].

In addition to a higher risk for HIV infection, TW also have a higher prevalence of sexually transmitted infections (STI) infection. Preliminary results from the TRANSFORM study, that enrolled 36 TW in Nairobi demonstrated TW had a higher prevalence of symptomatic anal gonorrhoea compared to MSM (18% vs 7% respectively) [219]. Recently published data from two South African cities, documented a high prevalence of both rectal gonorrhoea (21.4% 95% CI 0.0-42.9) and chlamydia (28.6% 95% CI 4.9-52.2) in TW [220]. More importantly, 91% of rectal gonorrhoea cases in this study were clinically asymptomatic. Additionally, 10% of study participants had either more than one STI causative organism or had multiple infections sites [220]. It is important that HCP have the competency and confidence to enquire about sexual practices that predispose both TW and MSM to STI, including condomless anal and oral sex. In addition, where possible, routine screening among TW for asymptomatic STI at clinic visits should be encouraged. Finally, both TW and MSM would benefit from continuous risk reduction counselling and male condom provision especially for those in sex work. These services may not be part of routine outpatient standard of care packages. Consequently, guidelines for tailored healthcare services for TW are required.

While PrEP is available, both MSM and TW will need specific support for uptake, adherence and persistence in care. There is a need for TW specific programming guidelines. TW have healthcare needs that are not being met by current healthcare services in Kenya.

Mental health and risk for HIV infection for MSM

In Chapter 5, we looked into the prevalence of common mental health conditions (CMD) specifically depression, problematic alcohol use, and substance abuse among Kenyan MSM. Additionally, we assessed if there was an association between HIV status, childhood abuse, victimization and transactional sex with the selected CMD.

The cross-sectional data for this study were abstracted from records at three MSM specific facilities in three locations in Kenya. By collecting data from three geographically diverse

sites, from almost 1500 individual MSM, the study was adequately powered to detect statistically significant differences between depressive symptoms, HIV status and involvement in transactional sex. Associations were controlled for social-demographic characteristics that could introduce confounding including age and religion. The use of computer-aided data interviews (either ACASI or CAPI) has been previously shown to help collect accurate information on sensitive or potentially embarrassing issues [203]. In this study, we set out to collect sensitive data including childhood abuse history, recent trauma and involvement in transactional sex.

Of the 1476 participants, almost a fifth (n=280) acknowledged being HIV positive. However even more interesting is the revelation that a further 128 individuals were living with HIV but unaware until testing was done specifically for this study. This is confirmatory of a significant unmet HIV prevention, diagnosis and treatment need among at-risk MSM in Kenya.

The prevalence of CMD was higher than in the general population. About a third of respondents (31%) had symptoms corresponding to moderate depression, which is roughly seven-fold higher than that documented in the general population of males in Kenya [148]. Importantly, this prevalence of depressive symptoms was similar to that shown in PLHIV within the general population [221]. However, in our study, the prevalence of depressive symptoms did not differ by HIV status. The finding that, in general, MSM have about the same burden of depressive symptoms as a section of the general population living with a chronic illness again indicative of significant healthcare gaps.

Similar to depressive symptoms, in this Chapter, we found that 44% of MSM reported harmful alcohol use. This was almost tenfold higher than has been documented in the general male population [222]. Perhaps as a coping mechanism, harmful alcohol use was associated with transactional sex among our participants, and we speculate that alcohol use behaviour serves as a coping mechanism for mental health problems among MSM. Recent work among at-risk fishing communities in Uganda demonstrated an association between harmful alcohol use and sexual risk-taking behaviour [223]. A similar finding was demonstrated among MSM and TW in South America where heavy alcohol use was

associated with reduced condom use, concomitant drug abuse and engaging in transactional sex [224].

While data on mental health among TW are not available locally, data from a 2020 multisite study (Brazil and India) found that 60% of TW reported episodes of suicidal ideation while 40% admitted to having made plans to commit suicide [225]. Similarly, in a multi-African country study involving 937 TW about 40% reported any use of non-prescription intravenous drug use, and 19% reported having suicidal ideation. At least 57% had depressive symptoms [226].

In this chapter, we demonstrated raised prevalence of depressive symptoms, and harmful alcohol use among MSM increasing their risk for engagement in risky sexual activity. Additionally, in the same cohort, a tenth of those living with HIV were not aware of their status and over two-thirds of the cohort were involved in transactional sex. There is a need for multipronged HIV prevention interventions in MSM in Kenya. We also recognize a need to collect mental health data specific to TW as it is conceivable that they may have different challenges compared to MSM.

Overall Strengths and Limitations of this Thesis

To the best of our knowledge, this is the first piece of work that assessed interest, uptake, and adherence to PrEP in both MSM and TW in Kenya. Chapter 2 contributed to the first known HIV incidence estimate among TW in sub-Saharan Africa. There have since been two more studies reporting HIV incidence rates among TW in Nigeria and South Africa that were in the same range as the Kenyan study. This is also to the best of our knowledge the first Kenyan study to triangulate opinions of HCP, MSM/TW community leadership and PrEP end-users. By involving a diverse group of stakeholders, we completed a first landscape analysis of PrEP programming for TW in Malindi.

We additionally investigated the prevalence of common mental disorders. We demonstrated that MSM had a much higher prevalence of depression and harmful alcohol use when compared to the general population.

This study was conducted in a study site assimilated within a public hospital setting. This lends credence to the notion that incorporation of services for MSM and TW within public health facilities is possible.

Finally, this work was conducted with an MSM- and TW-led community organization, *AMKENI*. Peer mobilizers from *AMKENI* were instrumental in the identification and tracing of participants that were lost to follow up. This work demonstrates the strengths and benefits that can accrue from working closely with community organisations. Indeed, by leveraging on our partnership with community-based organisations, we were able to keep in contact with study participants when movement restrictions to prevent COVID-19 infections had disrupted normal clinic operations.

There are however limitations that must be acknowledged. First, all TW were from a single study site. Their experiences may not necessarily represent those of TW in other geographical locations in Kenya. Second, participants in the cohort study were a small convenience sample. Third, tenofovir drug level was assessed by dried blood spots, which measure recent PrEP drug use i.e within the last 3-7 days but do not allow for inference about PrEP adherence over a longer time period. Fourth, HCP respondents in the FGDs were at different seniority levels. Respondents at lower seniority levels may felt constrained to agree with the opinions of those senior to them, thus limiting the potential variability of the data. Finally, in the mental health study, all respondents were MSM; gender identity was not been assessed in the study protocol, and thus there might have been “invisible” TW in this sample who were categorized as MSM.

Call to action for operational research

Findings presented in this thesis call for the need to implement enhanced and targeted initiatives to address the urgent needs for HIV prevention programmes for TW and MSM in Kenya.

a. Need for comprehensive HIV programming guidelines for TW

The Ministry of Health has developed key population programming guidelines that provide a generic template for HCP to apply when providing services. However, TW are not recognized as a key population and do not appear in the Kenyan guidelines

for key population programming. Additionally, TW have specific healthcare needs that do not fit into generic templates. Guidelines for transgender programming in Kenya have been in development since December 2019. A preliminary draft indicates there is possibility of inclusion of gender-affirming therapy as part of the package of care. The current draft does not specify who would provide gender affirming therapy, and the training necessary to support equitable and effective services for TW.

It is important that findings from the studies in this thesis are communicated to policymakers at the national level. While there have been dissemination meetings a more formal communication will need to be developed. I plan to engage with leadership at NASCOP and develop a policy brief about the studies in this thesis. The policy brief would aid in the development of comprehensive guidelines that are responsive to the needs and expectations of the PrEP end-users i.e. TW.

b. Provision of HCP sensitivity training towards TW

HIV training curricula in Kenya currently do not prepare HCP to provide services to either TW or MSM. As homosexuality is still criminalized in Kenya and transgender populations remain invisible in this society, HCP may not be aware of the presence of these populations. They therefore may lack the imperative to provide culturally sensitive services to TW and MSM. Additionally, there are no social consequences for denying TW or MSM healthcare services.

Globally, HCP are held to a higher moral standard by society. There is a general expectation that HCP should put the welfare of those seeking healthcare services before their own personal value systems. This moral code is further reinforced by the wording in ceremonial oaths of conduct taken by HCP upon qualification from institutions of learning. Previously, it has been shown that with training, it was possible to motivate HCP to apply non-discriminatory attitudes towards MSM [92]. The opinions of HCP in our study may represent the knowledge level and attitudes of other HCP on TW. It is important that proposed transgender programming guidelines include specific recommendations for HCP training. The development of

programming guidelines, without commensurate sensitivity training for HCP, may render them redundant.

Training modules can be integrated into an existing online MSM sensitivity training module (<https://www.marps-africa.org/>). The training material content can be developed by supporting TW to express their healthcare needs. Currently, a needs assessment and landscape analysis of health needs for TW in Malindi is in development. The project will be led by the membership of Malindi Desire Initiative (MDI) a small transgender- CBO. We hope that the findings from this project can help to inform on the implementation of targeted healthcare provision for TW.

c. Increase partnership with community-based organizations

Key populations have sometimes been referred to as hard to reach populations. However, in recently released language guidelines by the NIH, this terminology is considered outdated and inappropriate [227]. Recommended NIH language is ‘hardly reached or unsuccessfully engaged populations’. By employing such language, the responsibility of engaging key populations is placed upon the service provider. The service provider must then be innovative and intentional in their efforts to reach key populations.

Accordingly, TW in Africa are an example of ‘hardly reached populations. By partnering with *AMKENI* CBO, we were able to identify a cohort of previously unknown key populations of TW. To identify and engage hardly reached populations, community-based organisations would afford researchers relatively trouble-free recruitment.

Recent work has demonstrated that MSM who were linked to an affiliation group had better quality of life, better social support systems and were more likely to engage in healthcare services [161]. It is conceivable that similar to MSM, TW are

more likely to have better health outcomes if they are members of an affinity group or transgender community organisation.

Recently, the membership of the TW-led CBO MDI that we are in a partnership with expressed the desire to transition to more than just being study participants. I am currently planning on capacity building projects that TW could benefit from this kind of meaningful involvement. Among the activities, I am planning for a training on research methods. Specifically, I plan to transfer to them, skills in qualitative data collection, analysis and reporting. Additionally, members will receive training on presentation skills and report writing. It is hoped that this partnership will empower the CBO membership to conceptualize, design and conduct research that is relevant and beneficial for their healthcare needs.

d. Promote long-acting PrEP

In July 2020, a press release announced that long-acting injectable Cabotegravir was superior to oral Truvada (tenofovir plus emtricitabine). The results are especially exciting as the trial (HPTN 083) involved both TW and MSM as research participants. Injectable PrEP will probably become available in the near future. Recently, HIV treatment using Cabenuva, a cabotegravir containing injection, received approval from the food and drug administration (FDA) in the United States, as a complete alternative regimen HIV treatment in virally suppressed infected adults. That a Cabotegravir containing ART regimen has received regulatory approval may be indicative of future approval of a similar long-acting PrEP formulation.

The availability of injectable long-acting PrEP in Kenya could alter the PrEP landscape. With funding from Merck Sharp & Dohme, beginning in April 2021, we will conduct a cross-sectional study to assess preferences for HIV prevention products among MSM and TW in Kenya. This qualitative study seeks to determine HIV primary prevention preferences, including formulation and delivery mode among MSM and TW. We hope the results could inform the planning and

development of optimized HIV prevention services, including formulations for TW and MSM.

Going by the challenges demonstrated to daily oral PrEP, it is likely long-acting PrEP is likely will be an attractive option to both TW and MSM.

e. Provide alternative PrEP dispensing venue

It is important to normalize PrEP in health care settings in Kenya and to make it a public health intervention similar to condoms. There has been a push from the Kenya pharmaceutical society to make PrEP available at pharmacies as an over the counter prescription. The main challenge to this avenue would be cost, as users may be unwilling to pay for PrEP. There may be a need for the Kenya Ministry of health to consider subsidizing the cost of over the counter PrEP to increase demand.

PrEP could also be delivered at drop-in centres located at community organisations. Potential users, especially TW and MSM, would be more likely to accept accessing PrEP at such safe spaces. Adherence and retention in care might be easier if users are affiliated with a CBO. An objective assessment of PrEP uptake and persistence in alternative dispensing venues compared to the public health setting could better inform future programming.

f. Avail gender-affirming therapy

As TW expressed a strong desire to access feminizing hormone therapy (FHT), it is important to consider the engagement of endocrinologists in the drafting of TW programming guidelines. It is likely that in Kenya, TW already access FHT from clandestine sources. Surreptitious FHT faces challenges including possible sub-standard formulations, dosing challenges, absence of hormone level assessment, poor management of side effects and potential drug-drug interactions.

It will be important to make access to FHT safe and from verifiable sources. If FHT were made available at specific facilities, it may then be possible to offer other HIV prevention modalities including PrEP, within the same setting.

The proposed TW health needs assessment project in Malindi could provide baseline data on sources of FHT and incorporate suggestions from users to make access safer.

Conclusion

The novel work presented in this thesis demonstrates that despite the success of HIV prevention programs in Kenya in reducing HIV risk in the general population, TW and MSM experience alarming high HIV incidence and warrant targeted HIV prevention interventions. In addition, TW are an unrecognized vulnerable population that has not been targeted for HIV prevention, and that must be acknowledged as a unique key population separate from MSM. Findings also revealed the nature of HIV syndemics, such that HIV incidence in these populations co-occurs with other health and social risk factors including mental health problems, stigma, alcohol use, and violence. The key conclusions include:

First, there is a need to recognize the existence of TW in Kenya. Additionally, TW are not part of MSM and both HCP and researchers must intentionally but respectfully inquire about the current gender identity of their clients/participants in addition to recording the sex assigned at birth.

Second, PrEP uptake and PrEP adherence are distinct issues in TW and MSM. While interest for PrEP uptake may be high, adherence and persistence are often a challenge. There is a need to provide long-acting PrEP to participants who are behaviourally vulnerable to HIV including TGW and MSM

Third, even while PrEP is available, there are institutional barriers to PrEP access for TW and MSM and a need to consider multiple PrEP availability locations. HCP who should be advocates of PrEP provision and uptake may, by their actions and attitudes, dissuade potential users especially TW.

While there is a gap in HIV prevention for TW, also significantly missing is the provision of gender-affirming treatment options. In reports from the United States, TW expressed a strong desire to access FHT and even prioritized it over other medical interventions. It is very likely that similar desire to access FHT is present among TW in Kenya. It is important to provide FHT within a controlled medical environment. There is a need for training of healthcare providers on provision of comprehensive medical services to TW.

Finally, there is a high prevalence of common mental health challenges in MSM, including depression and harmful alcohol use, compared to the general population. These co-

occurring conditions exist in the context of rampant stigma toward MSM. As this dissertation does not report on mental health in TW, it would be important to demonstrate the interplay between depression, anxiety, alcohol use, past and other drug use, on-going stigma and violence among TW as co-occurring with HIV discrimination and the risk in this group. There is a need for comprehensive health services including for HIV infection. Finally, even as the mental health needs are demonstrated, there is a need for comprehensive health services including mental healthcare.

Future prospects

New research should be conducted around gender-affirming therapy to TW. Specifically, it is important to understand the current sources of FHT in Kenya. We hypothesize that TW especially in larger urban settings have clandestine access to FHT. We would like to determine the type of hormones used and the dosing levels. We would like to understand if there is sharing of injectable FHT with consequent increased risk for HIV infection. Additionally, we would like to determine TW opinions on FHT and PrEP use. We would like to understand if TW prioritize FHT over PrEP.

Secondly, we propose to explore mental health in TW. Specifically, we would like to determine the prevalence of depressive symptoms, harmful alcohol use and substance use. We hope to understand the link between mental health and risk for HIV infection.

I trust that results from these proposed studies will strengthen HIV prevention programming for TW in Kenya and contribute to dialogue and greater recognition of TGW and MSM in sub-Saharan Africa.

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Addendum

English and Dutch Summaries

English summary

The Kenyan Ministry of Health recognizes the impact that HIV has on the economy and society, and has prioritized HIV prevention, including provision of Pre-Exposure Prophylaxis (PrEP), as part of their prevention and care programme. Significant effort has also been put into providing HIV prevention for key populations including men who have sex with men (MSM). However, the prevention efforts have failed to include all populations at risk for infection. Globally transgender women (TW) are at highest risk for HIV infection. However, in Kenya TW are not a recognized key population.

PrEP is antiretroviral therapy (ART) offered to HIV negative individuals to compliment HIV prevention efforts. Kenya was the second African nation to provide PrEP to populations vulnerable to HIV infection. However, the guidelines fail to specifically mention risk behaviour that puts both TW and MSM at greater risk for HIV infection (e.g. receptive anal intercourse). Consequently, TW or MSM who would most benefit from PrEP may not be targeted to receive it.

Mental health services are woefully inadequate in Kenya. While mental conditions are complex and multiple, the World Health Organisation (WHO) has prioritized three conditions due to their high prevalence. They include depressive disorders, anxiety disorders and harmful alcohol and substance use disorders. Collectively these three are classified as common mental disorders (CMD). In Kenya even the recognition, diagnosis and management CMD in both TW and MSM has been largely ignored. Additionally, the intersection between mental health and risk for HIV infection especially in TW and MSM has not been addressed.

This thesis presents the findings from three studies on PrEP programming for MSM and TW in coastal Kenya and a single multi-site study documenting CMD and HIV in MSM in Kenya.

Chapter 1 describes the HIV epidemic in Kenya. It tracks the history of HIV in Kenya, the national response and the current situation. It describes the studies that demonstrated PrEP effectiveness for HIV prevention and the availability of programmatic PrEP in Kenya. Additionally, the chapter describes TW within the Kenyan context. Finally, the chapter makes clear the link between mental health and HIV infection in MSM.

Chapter 2 describes a cohort of known HIV negative TW and MSM. In the cohort, MSM were further divided into either men who have sex with men exclusively (MSME) or those that also have sex with women (MSMW). Of the 168 cohort participants, 14 were TW, 42 identified as MSME, and 112 were MSMW. Over a one year follow up period nine incident HIV infection occurred. Three HIV infections were in TW and translated to a high HIV incidence of 20.6 (95% CI, 6.6 to 63.8/100py). This finding provided what is to the best of our knowledge the first HIV incidence estimate for TW in sub-Saharan Africa. This high incidence is indicative of an unmet HIV prevention need in TW in Kenya.

Chapter 2 also describes the hypothetical PrEP interest among both TW and MSM. Almost all respondents (98.8%) were interested in initiating PrEP if it were offered to them. On focus group discussions (FGD), TW expressed anticipated barriers to PrEP especially stigma and discrimination by healthcare providers (HCP). This study concludes that there is a need to provide tailored PrEP services for TW who are especially vulnerable to HIV infection.

Chapter 3 is a report on findings from a 12-month PrEP provision cohort. Of the 53 participants included 11 TW and 42 MSM. Participants made quarterly clinic visits to collect PrEP. At the month 6 visit, participants still on PrEP provided a blood sample for Tenofovir Diphosphate (TFV-DP) drug level assessment. Additionally, at this visit, all TW and purposively selected MSM were invited to in-depth interviews (IDI). At the IDI we explored motivation for PrEP uptake, experience on PrEP and suggestions for program improvement. Of the 42 participants still on PrEP at the month 6 visit, 3 TW (~38%) and none of the MSM had TFV-DP corresponding to protective drug levels. TW had better understanding of their risk for HIV infection. The desire to remain HIV negative was voiced as the motivation for PrEP uptake. That TW, at greater risk for HIV infection had both a better understanding of PrEP and better adherence is promising for the future of HIV prevention in this population.

Chapter 4 describes focus groups discussions (FGD) with healthcare providers (HCP) and TW/MSM leadership and in-depth interviews (IDI) with PrEP experienced MSM and TW, to learn about perceived and actual barriers to PrEP programming.

Eleven HCP and 10 TW/MSM leaders participated in separate FGDs at two-time points i.e. before PrEP roll out and 12 months later. Nineteen PrEP experienced TW and MSM participated in IDI. The topics explored included PrEP knowledge, HIV acquisition risk,

gender identity, motivation for PrEP uptake and adherence and PrEP dispensing venue preferences.

Four themes emerged: limited preparedness of HCP to provide PrEP to TW and MSM, varied motivation for PrEP uptake and persistence among end-users, lack of recognition of TW by HCP, and suggestions for PrEP programming improvement from all stakeholders.

Providers' reluctance to prescribe PrEP to TW and distrust of TW towards providers calls for interventions to improve the capacity of service environments and staff HIV preventive care. Alternative locations for PrEP provision, including community-based sites, may be developed with TW/MSM leaders.

Chapter 5 reports findings from a secondary data analysis on mental health and substance use in almost 1500 MSM in Kenya. The data were collected at sites in Nairobi, Kisumu, and Kilifi, through audio computer-assisted self-interview (ACASI), and using standardised measures for depressive symptoms, alcohol use, substance use and childhood trauma.

Over one third of respondents (n= 452) reported moderate-to-severe depressive symptoms while 44% (n=637) reported hazardous alcohol use. More than half (n=749) reported a history of substance use. On multi-variable analysis, hazardous alcohol use was associated with involvement in transactional sex, recent trauma and history of childhood abuse.

The study concludes that hazardous alcohol use and transactional sex could predispose to increased risk for HIV infection in MSM. There is a need for mental health interventions specifically for depressive symptoms and harmful alcohol use in MSM.

Chapter 6 is a synthesis of the findings from the studies in the thesis. I present the need for development and implementation of comprehensive programming guidelines for TW in Kenya. Further, I call for competency training for HCP to prepare them to provide services for TW. I also make a case for stronger and more meaningful partnerships with TW organisations. Such partnership will result in ownership of programs by TW and the implementation of appropriate HIV prevention interventions. There is a need for mental health interventions specifically to address high prevalence of depressive symptoms and harmful alcohol use in MSM. The lack of data on mental health in TW needs to be addressed

to inform appropriate interventions. Finally, I call for the promotion of long acting PrEP formulations and where possible, provision of FHT for TW that desire it.

Samenvatting

Het Keniaanse Ministerie van Gezondheid onderkent de invloed van HIV op de economie en maatschappij en geeft prioriteit aan HIV preventie, waaronder het beschikbaar stellen van pre-exposure prophylaxis (PrEP) als onderdeel van het programma. Een belangrijke bijdrage is het beschikbaar stellen van HIV preventie aan kwetsbare bevolkingsgroepen, waartoe mannen die sex met mannen hebben (MSM) behoren. Maar deze preventie heeft niet alle kwetsbare groepen kunnen bereiken. Wereldwijd, behoren transgender vrouwen (TV) tot de meest kwetsbare bevolkingsgroep. In Kenia worden TV niet erkend als een op zichzelf staande kwetsbare bevolkingsgroep.

PrEP is een antiretroviraal medicijn dat wordt aangeboden aan HIV negatieve personen ter ondersteuning van andere HIV preventiemethoden. Kenia was het tweede Afrikaanse land dat PrEP ter beschikking stelde aan kwetsbare bevolkingsgroepen. Maar Keniaanse PrEP richtlijnen benoemen niet de specifieke gedragingen die MSM en TV extra kwetsbaar maken zoals receptieve anale sex. Als gevolg hiervan worden MSM en TV die het meest baat zouden hebben bij PrEP niet benaderd.

De geestelijke gezondheidszorg in Kenia is niet sterk ontwikkeld. Terwijl geestelijke gezondheidsproblemen complex en meervoudig zijn, heeft de Wereldgezondheidsorganisatie drie psychische problemen benoemd die het meest voorkomen: depressies, angststoornissen, en overmatig alcohol en druggebruik. Gezamenlijk worden deze 'vaak voorkomende geestelijke gezondheidszorg problemen' genoemd of 'common mental disorders' (CMD). Kenia negeert grotendeels de erkenning, diagnose en het management van CMD onder TV en MSM. Ook is het raakvlak tussen HIV en de geestelijke gezondheid onder TV en MSM niet goed uitgezocht.

Dit proefschrift beschrijft de bevindingen van drie studies onder TV en MSM in het kustgebied van Kenia naar het aanbieden van PrEP en MSM en één studie die CMD en HIV in kaart brengt onder MSM in een aantal Keniaanse steden.

Hoofdstuk 1 beschrijft het begin en het verloop van de Keniaanse HIV epidemie en de nationale bestrijding ervan. Ook wordt de effectiviteit en het aanbieden van PrEP in Kenia beschreven. Tevens beschrijft hoofdstuk 1 dat TV bestaan in Kenia en wordt de connectie tussen HIV en de geestelijke gezondheid onder MSM uitgemeten.

Hoofdstuk 2 beschrijft een cohortstudie die bestaat uit TV en MSM die niet met HIV geïnfecteerd zijn. MSM zijn onderverdeeld in twee groepen; mannen die alleen sex met mannen hebben ('MSME-exclusief') en mannen die sex met mannen en vrouwen hebben ('MSMW-bisexueel'). De cohortstudie had 168 deelnemers, waaronder 14 TV, 42 MSME en 112 MSMW. Er waren negen nieuw gediagnostiseerde HIV infecties, waarvan drie onder de TV. Dit gaf een geschatte HIV incidentie van 20.6 (95% betrouwbaarheidsinterval, 6.6 to 63.8) per 100 persoonsjaren. Dit was naar onze beste inzichten de eerste HIV incidentie schatting onder TV uit een land onder de Sahara. Deze hoge incidentie laat tevens zien dat HIV bestrijding onder TV in Kenia noodzakelijk is.

Ook beschrijft hoofdstuk 2 de hypothetische interesse van TV en MSM om PrEP te gaan gebruiken. Bijna alle deelnemers (98.8%) wilden PrEP nemen als het ze aangeboden zou worden. In focusgroep discussies (FGD) gaven TV aan te verwachten door gezondheidswerkers gediscrimineerd te zullen worden. Slotconclusie van deze studie was dat het noodzakelijk is om PrEP speciaal aan TV aan te bieden gezien hun speciale kwetsbaarheid voor HIV.

Hoofdstuk 3 rapporteert over de bevindingen van een cohortstudie onder 53 deelnemers (11 TV en 42 MSM) die met PrEP begonnen en een jaar lang werden vervolgd. Studiedeelnemers bezochten elke 3 maanden de kliniek en ontvingen PrEP. Na zes maanden werd bij de deelnemers die PrEP gebruikten een bloedmonster afgenomen om te testen hoeveel werkzame PrEP (Tenofovir Diphosphate) er in het monster zat. Ook werden de TV en een selectie van de MSM uitgenodigd voor een persoonlijk gesprek om te praten over hun ervaringen met PrEP inclusief redenen waarom te stoppen of door te gaan en aanbevelingen hoe het PrEP programma te verbeteren.

Na zes maanden waren er nog 42 deelnemers die PrEP gebruikten, waaronder 3 TV (38%) en geen enkele van de MSM voldoende PrEP in hun bloed hadden om bescherming te bieden. Uit persoonlijke gesprekken bleek dat TV in vergelijking tot MSM beter begrip hadden van

het HIV besmettingsgevaar. TV gaven aan dat het verlangen om HIV negatief te willen blijven hen motiveerde om PrEP te nemen. Deze bevindingen geven hoop voor de toekomst van HIV preventie onder TV.

Hoofdstuk 4 presenteert de bevindingen van focusgroep discussies met gezondheidsmedewerkers, vertegenwoordigers van ondersteunende organisaties en persoonlijke gesprekken met TV en MSM die PrEP gebruikten om inzicht te verkrijgen in veronderstelde en ondervonden barrières van het PrEP programma.

Discussies werden gevoerd met 11 gezondheidsmedewerkers en 10 vertegenwoordigers van ondersteunende organisaties voor, en een jaar na het starten van het PrEP programma. Negentien TV en MSM met PrEP ervaring deden aan de discussies mee. Onderwerpen waren: kennis over PrEP, HIV risico, seksuele identiteit, motivatie voor het nemen van PrEP, pillentrouw en voorkeuren wat betreft plaatsen waar PrEP wordt aangeboden.

Vier thema's kwamen uit de discussies naar voren: gezondheidsmedewerkers waren niet goed voorbereid om PrEP voor te schrijven aan TV en MSM; er was wisselende motivatie om PrEP te nemen en vol te houden onder gebruikers; onvoldoende erkenning van TVs door gezondheidsmedewerkers en alle deelnemers hadden suggesties voor verbeteringen van het PrEP programma.

De weerstand van de gezondheidsmedewerkers om PrEP voor te schrijven aan TV en het wantrouwen van TV jegens gezondheidsmedewerkers vraagt om interventies de serviceverlening en capaciteit van HIV preventie te verbeteren. Vertegenwoordigers van de ondersteunende organisaties kunnen helpen bij het creëren van alternatieve locaties om PrEP te verstrekken.

Hoofdstuk 5 rapporteert de uitkomsten van een analyse over geestelijke gezondheidszorgproblemen onder 1500 MSM in Kenia. Gegevens werden gestandaardiseerd verzameld d.m.v. een vragenlijst die per computer werd aangeboden (ACASI) aan de deelnemers uit drie steden in Kenia (Nairobi, Kisumu, and Kilifi). Vragen werden gesteld naar symptomen van depressie, jeugdtrauma's en misbruik en alcohol- en druggebruik.

Meer dan een derde van de deelnemers (n=452) rapporteerde gemiddeld tot ernstige symptomen van depressie, terwijl 44% (n=637) overmatig alcoholgebruik melden. Meer dan de helft (n=749) rapporteerde gebruik van verdovende middelen in het verleden. In een statistische analyse was het overmatig gebruik van alcohol gecorreleerd met sexwerk en het hebben ervaren van een recent- of jeugdtrauma. De studie concludeert dat overmatig alcoholgebruik en sexwerk deelnemers mogelijk blootstelt aan verhoogd HIV-risico. Het is daarom van groot belang de geestelijke gezondheidszorgproblemen, en met name depressies, van MSM te ondervangen en overmatig alcoholgebruik te bestrijden.

Hoofdstuk 6 is the synthese van de studiebevindingen in deze thesis. Ik presenteer de noodzaak voor het ontwikkelen en implementeren van een uitgebreid gezondheidsprogramma voor TV in Kenia. Met name gezondheidsmedewerkers moeten speciale training krijgen om betere zorg aan TV aan te bieden. Ook moeten er samenwerkingsverbanden met organisaties die TV vertegenwoordigen tot stand gebracht worden. Zulke samenwerkingsverbanden zullen deze organisaties kunnen versterken opdat verbeterde HIV bestrijding aangeboden kan worden. Onder MSM moet de behandeling van depressies en overmatig alcoholgebruik worden verbeterd. Voor TV moet verder worden onderzocht wat de geestelijke gezondheidsproblemen zijn voordat verbeteringen kunnen worden voorgesteld. Als laatste stel ik voor dat aan TV langwerkende PrEP producten worden aangeboden en waar mogelijk hormoonbehandeling voor hen die daaraan behoefte hebben.

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Dr. Elise van der Elst; I think we had a connection from the first time that we met in 2015 when I first visited Kilifi. Almost as if you could see the future, when I came in for my studentship interview, you gave me a copy of your then still new thesis and said it would inspire my work. I have often referred to that book when I need direction especially on anthropology sections of my thesis. I am grateful for the period when we shared an office. We have had many academic and non-academic conversations that have helped shaped who I am within the key population research group here at KEMRI. The Malindi cohort that features in three of the studies in this thesis was thanks to your consistent engagement and connection to the MSM and TW community.

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the belief that *'It can be done'*. This has been a useful mantra to me especially towards the end when deadlines were close and deliverables were many.

Dr. Susan Graham; You may not have been on my core supervision team, but I am grateful that you just like Ed were willing to take a chance on me and included me on the mental health project. You have over the last four years provided constructive criticism of my work with the overall aim of improving the output. Thank you for that.

I would like to extend special appreciation to the staff all staff at the Malindi key populations clinic. Included here are staff that have since taken up different opportunities outside the project (Bernadette, Clifford, and Winston) Present staff lead by Oscar, Nana, Shally and Abdalla. At the Kilifi office Lucie, Evans, Dan and Jennifer who did a lot of important administrative, logistical and regulatory background work that ensured the study activities proceeded seamlessly.

To SANTHE, I am thankful for continuous study funding and access to multiple training opportunities.

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I dedicate this thesis to my mum and dad who have always believed in me.

PhD Portfolio

PhD Training

Activity

	<u>Training courses</u>	<u>Institution/location</u>	<u>Date</u>	<u>Hours/ETS</u>
1.	Using EndNote	Online/ Thompson Reuters	November 2016	8 hrs/0.3
2.	Introduction to scientific writing	University of Kwa Zulu Natal Durban	February 2017	40 hrs/1.4
3.	Introduction to qualitative data analysis	KEMRI-Wellcome/Brown University	June 2017	24 hrs/0.9
4.	Grant application writing	SANTHE, Gaborone	Sept 2017	24 hrs/0.9
5.	Biostatistics and inference	University of Kwa Zulu Natal Durban	October 2017	40 hrs/1.4
6.	Bioethics in a developing country	Medical Research Council, Harare	February 2018	24 hrs/0.3
7.	Data protection training	KEMRI-Wellcome Trust, Kenya	May 2018	8 hrs/0.3
8.	Systematic reviews and research analysis	Liverpool of Tropical Medicine, Kenya	July 2018	32 hrs/1.2
9.	Clinical management of HIV	University of Washington, Online	June 2018	80 hrs/2.9
10.	Qualitative data analysis and Interpretation	In-depth research, Nairobi	March 2019	40 hrs/1.4
11.	Data management	TIBA Kenya, Kilifi	June 2019	40 hrs/1.4
12.	HIV in Transgender Communities	NIH, Division of AIDS, Online	June 2019	8 hrs/0.3
13.	Project management	University of Washington, Online	Sept 2019	96 hrs/3.5
14.	Qualitative research methods	University of Amsterdam, Online	August 2020	80 hrs/2.9
15.	Global Health	Erasmus University, online	August 2020	20 hrs/0.7
16.	Social Epidemiology	Erasmus University, online	August 2020	20 hrs/0.7
17.	Practice of Epidemiologic analysis	Erasmus University, online	August 2020	20 hrs/0.7
18.	Leadership and Management	University of Washington, Online	Sept 2020	96 hrs/3.5

Presentations

	<u>Meeting</u>	<u>Topic</u>	<u>Date</u>	<u>Type/Hrs/ECTS</u>
1.	1 st SANTHE ACM, Nairobi	Depression stigma and alcohol use in MSM at three sites in Kenya	Sept 2016	Oral/14/0.5
2.	R4P, Chicago	Depression stigma and alcohol use in MSM at three sites in Kenya	October 2016	Poster/14/0.5
3.	UoN/UoM annual collaborative meeting	Assessment of the Care Continuum for key populations	January 2017	Oral/14/0.5

4.	IAVI SBR meeting, Kilifi	PrEP Implementation Research in Malindi	May 2017	Oral/14/0.5
5.	PhD Pre-registration	PhD proposal- Assessment of the prevention and care continuum in key populations in coastal Kenya	June 2017	Oral/14/0.5
6.	2 nd SANTHE ACM, Gaborone	PrEP uptake interest in MSM and TW	October 2017	Poster/14/0.5
7.	AIDS Impact, Cape Town	PrEP Interest in MSM and TW	November 2017	Poster/14/0.5
8.	TAMBA Pwani potential partnership. Kilifi	PrEP cohort description and challenges to PrEP programming	August 2018	Oral/14/0.5
9.	PhD Up-grading seminar	PhD progress since registration- The prevention continuum in MSM and TW in coastal Kenya	December 2018	Oral/14/0.5
10.	CROI, Boston, USA	HIV incidence in MSM and TW	March 2018	Poster/14/0.5
11.	SANTHE/IAVI trainees open day, Kilifi	HIV incidence and PrEP incidence in MSM and TW	April 2018	Oral/14/0.5
12.	Ideal Conference, Nairobi	Barriers to PrEP access	June 2018	Oral/14/0.5
13.	3 rd SANTHE ACM, Kigali	PrEP Cohort description	October 2018	Poster/14/0.5
14.	IAVI/USAID visit, Kilifi	PrEP programming for TW in coastal Kenya	November 2018	Oral/14/0.5
15.	UoN/UoM Collaborative meeting, Nairobi	Experiences in PrEP Programming for Transgender Women in Coastal Kenya: A Qualitative Assessment	January 2019	Oral/14/0.5
16.	4 th SANTHE ACM, Nairobi	PrEP use in MSM and TGW: Qualitative insights from users, providers and leadership	October 2019	Oral/14/0.5
17.	University of Washington annual meeting, Mombasa	Pre-Exposure Prophylaxis (PrEP): It is available, but who is taking it?	November 2019	Oral//14/0.5
18.	UoN/UoM Collaborative meeting, Nairobi	Pre-Exposure Prophylaxis (PrEP): It is available, but who is taking it?	January 2020	Oral/14/0.5
19.	Program Seminar	PrEP programming for MSM and TW in coastal Kenya	February 2020	Oral/14/0.5
20.	CROI, Boston, USA	Pre-exposure prophylaxis adherence and persistence in Kenyan MSM and transgender women	March 2020	Poster and oral themed discussion/14/0.5
21.	Virtual SANTHE research day	PrEP uptake and adherence in Gays, Bisexuals and Transgender Women (GBT): qualitative insights	June 2020	Oral/14/0.5

22. USAID/IAVI virtual visit	Current and prospective TW studies in Malindi	December 2020	Oral/14/0.5
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Speaking invitations

<u>Audience</u>	<u>Topic</u>	<u>Date</u>	<u>Hours/ ECTS</u>
1. Radio listeners	HIV infection prevention	October 2018	<i>Baraka FM</i> radio Studio, Mombasa, Kenya 2 hours/0.1
2. Graduate students	Gender, Sexual Minorities and HIV	May 2019	Durban, South Africa 2 hours/0.1
3. Science journalists	Programing for TW in Kenya	November 2020	Online conference 2 hours/0.1
4. R4P 2021 satellite symposium	Spectrum of sexual and gender minorities affected by HIV in Africa	January 2021	R4P Virtual Symposium 2 hours/0.1

Awards and Recognitions

<u>Award/Recognition</u>	<u>Details</u>	<u>Date</u>
1. Best poster presentation	2 nd SANTHE ACM, Gaborone	October 2017
2. Most progressed study	Virtual SANTHE open day meeting	June 2020
3. Best group work presentation	Erasmus University summer program	August 2020

Supervision and Mentoring

<u>Student supervision</u>	<u>Topic</u>	<u>Graduation Year</u>	<u>Award</u>
1. Sarah Wawa	Prevalence and socio-demographic correlates of depression among students at the Kenya Methodist university.	2018	MPH
2. Apollo Kamau	Factors influencing willingness to use pre-exposure prophylaxis among male homosexuals at the sex workers outreach program clinic	2019	MPH

Mentorship

Abstract mentor for submissions from both English and non-English speaking sub-Saharan Africa

Meeting

International AIDS Society Conferences

Year

2019, 2020 and 2021

Appointments

<u>Position</u>	<u>Institution</u>	<u>Date</u>	<u>Duration</u>
1. Board of directors	Health Right Kenya	June 2020	2 years
2. Reviewer	KEMRI Ethics review committee	July 2019	3 years

Publications

1. **Kimani M**, van der Elst EM, Chirro O, Wahome E, Ibrahim F, Mukuria N, de Wit TFR, Graham SM, Operario D, Sanders EJ. "I wish to remain HIV negative": Pre-exposure prophylaxis adherence and persistence in transgender women and men who have sex with men in coastal Kenya. *PLoS One*. 2021 Jan 19;16(1):e0244226.
2. Umviligihozo G, Mupfumi L, Sonela N, Naicker D, Obuku EA, Koofhethile C, Mogashoa T, Kapaata A, Ombati G, Michelo CM, **Makobu K**, Todowede O, Balinda SN. Sub-Saharan Africa preparedness and response to the COVID-19 pandemic: A perspective of early career African scientists. Version 3. *Wellcome Open Res*. 2020 Dec 10 [revised 2020 Jan 1];5:163.
3. **Kimani M**, van der Elst EM, Chiro O, Oduor C, Wahome E, Kazungu W, Shally M, Rinke de Wit TF, Graham SM, Operario D, Sanders EJ. PrEP interest and HIV-1 incidence among MSM and transgender women in coastal Kenya. *J Int AIDS Soc*. 2019 Jun;22(6):e25323.
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5. Lajoie J, Birse K, Mwangi L, Chen Y, Cheruiyot J, Akolo M, Mungai J, Boily-Larouche G, Romas L, Mutch S, **Kimani M**, Oyugi J, Ho EA, Burgener A, Kimani J, Fowke KR. Using safe, affordable and accessible non-steroidal anti-inflammatory drugs to reduce the number of HIV target cells in the blood and at the female genital tract. *J Int AIDS Soc*. 2018 Jul;21(7):e25150.
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10. Juno JA, Stalker AT, Waruk JL, Oyugi J, **Kimani M**, Plummer FA, Kimani J, Fowke KR. Elevated expression of LAG-3, but not PD-1, is associated with impaired iNKT cytokine production during chronic HIV-1 infection and treatment. *Retrovirology*. 2015 Feb 13;12:17
11. McKinnon LR, Nyanga B, Kim CJ, Izulla P, Kwatampora J, **Kimani M**, Shahabi K, Mugo N, Smith JS, Anzala AO, Kimani J, Kaul R. Early HIV-1 infection is associated with reduced frequencies of cervical Th17 cells. *J Acquir Immune Defic Syndr*. 2015 Jan 1;68(1):6-12
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14. Card CM, Rutherford WJ, Ramdahn S, Yao X, **Kimani M**, Wachihi C, Kimani J, Plummer FA, Ball TB, Fowke KR. Reduced cellular susceptibility to in vitro HIV infection is associated with CD4+ T cell quiescence. *PLoS One*. 2012;7(9):e45911.
15. Ghadially H, Keynan Y, Kimani J, **Kimani M**, Ball TB, Plummer FA, Mandelboim O, Meyers AF. Altered dendritic cell-natural killer interaction in Kenyan sex workers resistant to HIV-1 infection. *AIDS*. 2012 Feb 20;26(4):429-36.
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Curriculum vitae

PROFESSIONAL PROFILE

Medical doctor with training in global public health

WORKING HISTORY

1. **PhD candidate, 2016-2021.**
Thesis title: Strengthening HIV preventive care services for Transgender Women and Men who have Sex with Men in Coastal Kenya
 2. **Research elective: mental health and substance use assessment in MSM in Kenya (April-August 2016)**
Conducted data cleaning and analysis; and presented a poster at R4P, Chicago, Illinois, October 2016.
 3. **Lecturer at the Kenya Methodist University (KeMU) -October 2013-July 2016**
 - Department of Public Health (Nairobi campus)
 - Primarily tasked with training undergraduate students in basic epidemiology, demography, communicable and non-communicable disease control
 - Interim tasks: departmental examinations officer and coordinator for the MPH program.
 - Co-supervised 2 masters' students (MPH and MSc.) to completion.
 4. **Clinical trials physician. Sex Worker Outreach Programme (SWOP), Nairobi (July 2007-September 2013),** in collaboration with the University of Nairobi and University of Manitoba.
 - Overall in charge of SWOP clinic.
 - Attended to female sex workers, and male sex workers (since 2009).
 - Provision of routine outpatient care, STI screening, and collection of study samples
 - Ensuring data integrity and adherence to SOPs
 - Trainer on research ethics and Good Clinical Practice (ICH GCP)
 4. **Senior House Officer:** Accident and Emergency department, Aga Khan University Teaching Hospital, Nairobi, October 2006-July 2007
 5. **Medical officer, 2004-2006**
 - Government employee at the Kisii District hospital (now Kisii County referral and teaching hospital) and the Rachuonyo district hospital in Western Kenya, and as the medical superintendent, Rachuonyo district Hospital (Now Rachuonyo level 4 hospital).
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