

Assessment of PrEP eligibility and uptake among at-risk MSM participating in a HIV-1 vaccine feasibility cohort in coastal Kenya

Elizabeth Wahome (✉ ewahome@kemri-wellcome.org)

Kenya Medical Research Institute <https://orcid.org/0000-0001-8386-7555>

Susan M. Graham

University of Washington

Alexander N. Thiong'o

Centre for Geographic Medicine Research Coast

Oscar Chirro

Centre for Geographic Medicine Research Coast

Khamisi Mohamed

Centre for Geographic Medicine Research Coast

Evans Gichuru

Centre for Geographic Medicine Research Coast

John Mwambi

Centre for Geographic Medicine Research Coast

Matt A. Price

International Aids Vaccine Initiative

Eduard J. Sanders

Centre for Geographic Medicine Research Coast

Research article

Keywords: MSM, Receptive anal intercourse, PrEP, Uptake, Risk score, HIV-1

Posted Date: April 25th, 2019

DOI: <https://doi.org/10.21203/rs.2.9313/v1>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License. [Read Full License](#)

Version of Record: A version of this preprint was published at Wellcome Open Research on September 19th, 2019. See the published version at <https://doi.org/10.12688/wellcomeopenres.15427.1>.

Abstract

Introduction Pre-exposure prophylaxis (PrEP) is provided free of costs to a broad range of at-risk populations in Kenya, including men who have sex with men (MSM), but anal intercourse is not an eligibility criterion. We set out to determine PrEP eligibility, uptake and predictors of PrEP uptake among MSM enrolled in an HIV-1 vaccine feasibility cohort in coastal Kenya. **Methods** We compared the number of MSM identified as eligible for PrEP from June - December 2017 by Kenyan Ministry of Health (MoH) criteria, which do not include reported anal intercourse, to those identified as eligible by a published MSM cohort-derived HIV-1 risk score (CDHRS). We determined PrEP uptake and assessed factors associated with PrEP uptake at first offer among eligible MSM followed up monthly for HIV-1 testing, risk assessment, and risk reduction counselling. **Results** Out of 167 MSM assessed for PrEP eligibility, 118 (70.7%) were identified by both MoH and CDHRS eligibility criteria. However, the CDHRS identified 33 (19.8%) more cohort MSM for PrEP eligibility than the MoH criteria, of whom the majority (24 or 72.7%) reported receptive anal intercourse (RAI). Of the 162 MSM eligible for PrEP, 113 (69.7%) accepted PrEP at first offer. Acceptance of PrEP was higher for men reporting RAI (adjusted prevalence ratio [aPR], 1.4; 95% confidence interval [CI], 1.0–1.9), having paid for sex (aPR, 1.3; 95% CI, 1.1–1.6) and group sex (aPR, 1.4; 95% CI, 1.1–1.8), after adjustment for sociodemographic factors. **Conclusions** Assessing PrEP eligibility using a CDHRS identified 20% more at-risk MSM for PrEP initiation than when Kenyan MoH criteria were used. Approximately 70% of eligible men accepted PrEP at first offer, suggesting that PrEP is acceptable among at-risk MSM. MSM reporting RAI, group sex, or paying for sex were more likely to accept PrEP, reinforcing the importance of an informed discussion of HIV-1 risk during PrEP counselling.

Background

Pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine has been recommended for use in prevention of HIV-1 acquisition [1]. In response, several countries have implemented country-specific policies and guidelines on PrEP delivery, uptake and monitoring, and a few have made PrEP available nationally to the public [2, 3]. In Kenya, national PrEP roll-out began in May 2017 after the Ministry of Health (MoH) included guidance on offering PrEP to HIV-1 negative individuals at substantial ongoing risk of HIV-1 acquisition [4]. These guidelines, which include several indications to guide PrEP eligibility and initiation among sexually active HIV-1 negative individuals, do not specifically mention receptive anal intercourse (RAI). Despite this gap, men who have sex with men (MSM) are a key population targeted for PrEP [5, 6].

In 2017, we developed an empiric risk score to guide PrEP targeting among at-risk MSM who were followed in a vaccine feasibility study and had an HIV-1 incidence of 7.0 (95% confidence interval [CI], 5.8–8.6) per 100 person-years. Characteristics of the cohort-derived HIV-1 risk score (CDHRS) included having only male sex partners, RAI, any recent unprotected sex, group sex, and young age (18–24 years) [7]. Although the CDHRS tool had a good performance in detecting HIV-1 acquisition among MSM eligible for PrEP in this cohort, we were interested to compare it to the performance of the MoH PrEP risk criteria to identify at-risk MSM for PrEP uptake in this cohort.

We therefore assessed: 1) performance of the MoH guideline criteria to predict HIV-1 acquisition in at-risk MSM using the historic cohort, 2) eligibility for PrEP by either MoH or CDHRS in the cohort since PrEP programming started in June 2017, and 3) PrEP uptake and factors associated with PrEP uptake among MSM eligible for PrEP who were followed in a HIV-1 vaccine feasibility cohort study in coastal Kenya.

Methods

Study population

Since July 2005, individuals at high risk for HIV-1 acquisition have been recruited for an open cohort study in preparation for a HIV-1 vaccine efficacy trial in a Kenya Medical Research Institute (KEMRI) clinic in Mtwapa town, coastal Kenya. This town, approximately 20 kilometers north of Mombasa, is known for its busy night life and many bars and nightclubs, which are frequented by sex workers [8]. Participants were identified for recruitment into the study by 10–15 trained peer mobilizers who approached individuals through personal networks and at venues where sex workers meet to establish contact with clients [9]. Adults aged 18–49 years were eligible if they met any of the following criteria: HIV-1-negative and reporting any of transactional sex work, a recent sexually transmitted infection (STI), multiple sexual partners, sex with an HIV-1-infected partner, or anal sex during the 3 months before enrolment [9].

Cohort procedures

Detailed cohort procedures have been described elsewhere [9, 10]. In brief, during enrollment and monthly follow-up visits, a face-to-face interview using a standardized risk behaviour questionnaire, HIV-1 testing and counseling using rapid point of care antibody tests, risk-reduction counselling, medical history and physical examination were performed. During monthly follow-up visits, participants were re-assessed for HIV-1 acquisition

risks, treated for genital symptoms suggestive of STIs, offered hepatitis B vaccination and provided with risk reduction counselling. For this analysis, only MSM were retained.

Laboratory evaluation

At each study visit, two rapid antibody test kits (Determine, Abbott Laboratories; Unigold, Trinity Biotech) were used in parallel for HIV-1 testing. Discordant rapid HIV-1 test results were resolved using HIV-1 RNA (Xpert® HIV-1 Qual, Cepheid). Pre- and post-seroconversion samples were tested for HIV-1 RNA using Amplicor Monitor 1.5 (Roche) through 2015, then Xpert® HIV-1 Qual (Cepheid) starting in 2016. Gonococcal infection was diagnosed among participants who reported urethral or rectal symptoms by the detection of Gram-negative, intracellular diplococci consistent with *Neisseria gonorrhoeae* in urethral or rectal secretions [9]. Prevalent syphilis infection was diagnosed by a positive rapid plasma reagin (RPR, tested annually) titre confirmed by *Treponema pallidum* haemagglutination assay (TPHA). Incident syphilis was defined as a four-fold increase in RPR titre confirmed by TPHA [9].

Preparing MSM for PrEP uptake

Between January-June 2017, we offered standardized educational messages to cohort participants on benefits, risks, eligibility and upcoming availability of daily PrEP during individual discussions with clinicians at follow-up visits. In addition, weekly group educational sessions led by counselors were provided to cohort participants who had expressed interest in learning about PrEP. In both individual and group sessions, we educated participants about known predictors of HIV-1 acquisition among MSM in our cohort, including RAI, group sex, any recent unprotected sex, having sex with men only and gonorrhoea infection within the past six months [9]. Because younger age (18-24 years) had become an additional independent predictor in our cohort [7], we explained to individuals in this age group their higher risk. Using these identified risk factors in the CDHRS and additional MoH PrEP eligibility criteria [3], we designed an individualized PrEP eligibility score sheet based on risks reported during the previous three months to target PrEP counseling (see Additional file 1).

PrEP rollout

Since June 2017, PrEP has been offered to eligible cohort participants in follow-up. Participants were evaluated for PrEP eligibility as described above. Those who were eligible by either CDHRS or MOH criteria according to the PrEP Eligibility Score Sheet were offered PrEP, and their renal function (i.e. creatinine), hepatitis B surface antigen (HBsAg), and symptoms of acute HIV-1 infection (AHI) assessed according to the Kenyan MoH PrEP guidelines [3]. Participants who tested positive for HBsAg were offered PrEP with close monitoring of liver function while those who tested negative were vaccinated against hepatitis B infection [10]. Participants who had symptoms compatible with AHI, or those meeting specific risk criteria that increased their risk of HIV-1 acquisition (e.g. RAI, or group sex) were tested for HIV-1 RNA (Xpert® HIV-1 Qual, Cepheid) to rule out AHI prior to PrEP initiation. Participants with no contraindication to PrEP were counselled about the risks, benefits and limitations of PrEP, educated about recognizing AHI symptoms, and provided with a 30-day PrEP supply. Individuals who had previously taken PrEP through other organisations were invited to transfer to KEMRI PrEP programme if they so desired.

During monthly follow-up visits, participants not taking PrEP were reassessed for eligibility and offered PrEP if eligible. Participants taking PrEP completed a computer-assisted self-interview to assess PrEP adherence and motivation to continue PrEP and were monitored for adverse effects, offered syndromic STI treatment as clinically indicated, and tested for HIV-1. PrEP adherence and sexual risk reduction counseling were provided prior to PrEP refill. Participants with symptoms or signs compatible with AHI were tested for HIV-1 RNA as described above. Participants who tested HIV-1-positive (either on RNA or rapid antibodies) had PrEP discontinued and were counselled and linked to HIV-1 care and treatment.

Measures

CDHRS eligibility: This variable was defined as having any of the following risk factors at any visit, categorized as either yes or no: age 18-24 years, having only male sex partners, RAI, any recent unprotected sex, and group sex. Individuals who had any of these risk factors in the 3 months before screening were considered eligible for PrEP by CDHRS criteria.

MoH eligibility: This variable was defined as having any of the following characteristics per MoH PrEP guidelines [3] at any visit, categorized as either yes or no: sex with a regular partner of known HIV-1-positive or unknown HIV-1 status in the past week, sex with any partner of known HIV-1-positive or unknown HIV-1 status in the past month, transactional sex (defined as receiving payment for sex with cash, living expenses, or goods) in the past 3 months, sharing needles among intravenous drug users in the past 3 months, sex after alcohol use in the past month, recurrent use of post-exposure prophylaxis (PEP, defined as PEP use more than once in the past 6 months), inconsistent condom use in the past week and recent STI (defined as a positive gram stain of urethral or rectal secretions or a new syphilis diagnosis within 6 months). Individuals who had any of these characteristics were considered eligible for PrEP by MOH criteria.

Other variables evaluated as potential predictors of PrEP uptake included the number of reported sexual partners in the past week; paying for sex with cash, living expenses, or goods in the past 3 months; and demographic data collected at enrollment (e.g., education, religion, marital and employment status).

Data analysis and statistical methods

Historic cohort 2005-2016

Predicting HIV-1 acquisition:

We censored data for each participant at the end of 2016, at the last visit (for those lost to follow-up) or at the last seronegative and HIV-1-RNA-negative visit (for those who acquired HIV-1 infection during follow-up). We obtained total observation time for all participants in the study by adding up separate observation times and expressing these in terms of pre-PrEP person-years. To assess the performance of the MoH criteria to identify MSM at risk of HIV-1 acquisition in the historic cohort (2005-2016), we assigned a score of one point to each characteristic (described above) reported and summed these scores to generate a total MoH score for each participant visit. A total CDHRS score was also calculated for each visit, following published methodology [7]. We assessed sensitivity, specificity and area under the receiver operator characteristic (ROC) curve (AUC) for the MoH and CDHRS eligibility criteria using a non-parametric ROC analysis. We compared the AUC for the CDHRS eligibility score to the AUC for the MoH eligibility score using a test of equality of ROC areas.

PrEP cohort June-December 2017

PrEP eligibility and uptake:

PrEP provision in limited programmes targeting key populations began in the area around January 2017. Because we did not have reliable data on PrEP use from outside programs, we excluded data collected in the period between January–May 2017. PrEP became available to the KEMRI cohort in June 2017. PrEP baseline was defined as the first study visit by a given participant during June–December 2017. PrEP uptake was defined as acceptance of PrEP by an eligible participant. We censored data for each participant at the end of 2017, at the last visit (for those lost to follow-up) or at the last seronegative and HIV-1-RNA-negative visit (for those who acquired HIV-1 infection during follow-up). Nine MSM who had started PrEP through another program were excluded. We calculated the number and proportion of MSM eligible by MoH vs. CDHRS criteria at PrEP baseline and presented the results using a Venn diagram. We then compared the proportion of MSM eligible for PrEP by each criterion at baseline and at the last visit in 2017 using McNemar's test for paired proportions, to determine consistency of PrEP eligibility over time.

We used descriptive statistics to compare baseline demographic and behavioural characteristics of eligible men who accepted PrEP at baseline to eligible men who did not accept PrEP at first offer. We then used generalized linear modeling with log link Poisson regression and robust error variance to identify factors independently associated with PrEP uptake at baseline. Potential predictors of PrEP uptake significant in bivariable analysis at $P \leq 0.2$ were included in multivariable modeling. P values were 2-sided, and significance was set at $P \leq 0.05$. Data were cleaned, recoded and analyzed using Stata 15.0 (StataCorp LP, College Station, TX).

Ethical considerations

The KEMRI Ethics Review Committee approved the study. All participants provided written informed consent.

Results

Predicting HIV-1 acquisition

From 2005-2016, HIV-1 incidence was 7.0 (95% CI, 5.8-8.6) per 100 person-years. Meeting any of the MoH criteria had a sensitivity of 87.6% and specificity of 16.6%, while meeting any of the CDHRS criteria had a sensitivity of 97.9% and specificity of 16.9% for detecting visits at which men had acquired HIV-1. The AUC for prediction of HIV-1 acquisition for the MoH criteria was 0.58 (95% CI, 0.52-0.64), while the AUC for the CDHRS criteria was 0.76 (95% CI, 0.72-0.80). The comparison between these AUC was significant at $P < 0.001$ (Figure 1).

PrEP eligibility

Of 167 MSM assessed for PrEP eligibility at baseline in the period June–December 2017, 129 (77.2%) and 151 (90.4%) were eligible for PrEP based on the MoH and the CDHRS criteria, respectively, $P < 0.001$. One hundred and eighteen (70.7%) were eligible for PrEP based on both MoH and CDHRS criteria. However, the CDHRS criteria identified 33 (19.8%) more MSM for PrEP eligibility than the MoH criteria, of whom the majority (24, or 72.7%) reported RAI. Eleven (6.6%) men were not identified as eligible by the CDHRS, of whom the majority (6, or 55.0%) reported transactional sex. Five (3.0%) men were not identified as eligible for PrEP by either method, of whom four became eligible for PrEP during follow-up (four based on the MoH criteria and three based on the CDHRS criteria) (Figure 2). The proportion of MSM eligible for PrEP by either the MoH or CDHRS criteria at baseline and the proportion eligible at their last visit in 2017 were not significantly different, $P = 1.0$.

PrEP uptake

Of 162 MSM eligible for PrEP at baseline, 113 (69.7%) accepted PrEP and 49 (30.3%) did not accept PrEP at first offer. Of these 113 who accepted PrEP, 93 (82.3%) and 106 (93.8%) were eligible for PrEP based on the MoH and the CDHRS criteria, respectively, $P = 0.21$. Of these 49 who did not accept PrEP at first offer, 11 (22.4%) accepted PrEP during follow-up after a median of 56, interquartile range (IQR) [32-83] days (Figure 3).

Men who declined PrEP at first offer were more likely to report having only female sex partners (6.1% vs. 0.0%, $P = 0.027$), less likely to report RAI (65.3% vs. 81.4%, $P = 0.026$) and less likely to have paid for sex (8.2% vs. 21.2%, $P = 0.043$) in the past 3 months (Table 1).

In bivariable modeling, PrEP acceptance at first offer was associated at $P \leq 0.2$ with being younger (18-24 years), never married, self-employed, reporting any recent unprotected sex, two or more sexual partners, RAI, having paid for sex, receiving payment for sex and group sex. In multivariable modeling, PrEP uptake was higher for men reporting RAI (adjusted prevalence ratio [aPR], 1.4; 95% CI, 1.0–1.9), men reporting having paid for sex (aPR, 1.3; 95% CI, 1.1–1.6) and men reporting group sex (aPR, 1.4; 95% CI, 1.1–1.8), after adjustment for age, marital status, and employment status. Reporting any recent unprotected sex, the number of reported sexual partners, and receiving payment for sex were not associated with PrEP uptake (Table 2).

None of the 167 MSM who were offered PrEP acquired HIV-1 in the period June–December 2017.

Discussion

We showed that among at-risk MSM followed in a historic cohort in the period 2005-2016, MoH criteria for PrEP eligibility were sub-optimal in targeting MSM at risk of HIV-1 acquisition, mainly due to the failure to include RAI as a PrEP eligibility criterion. When programmatic PrEP was offered to eligible MSM cohort participants using the CDHRS, 20% more at-risk MSM were identified for PrEP initiation than when MoH criteria were used. In our setting, 70% of the MSM accepted PrEP at first offer, and uptake was associated with reporting RAI and group sex, suggesting that PrEP is acceptable among high-risk MSM in Kenya. Of interest is the association of paying for sex with PrEP uptake, as this is not an eligibility criterion included in either the MoH or in our CDHRS tool. While these men met other PrEP eligibility criteria, it could be that paying for sex increases the perception of risk for HIV-1 acquisition among Kenyan MSM.

That the MoH criteria did not identify MSM at risk for HIV-1 among the historic cohort was expected because risk behaviours (e.g., RAI and group sex) [7, 9, 11, 12] and sociodemographic factors (i.e., young age) [7, 13] known to influence HIV-1 acquisition risk among MSM are not specifically included in Kenyan guidelines. Previously, MSM reporting RAI have been documented to have a 4-9-fold increased risk of HIV-1 acquisition, independent of other risk factors in Kenya [7, 9, 11]. Elsewhere, Baggaley et al [14] documented the important role played by unprotected anal

intercourse in HIV transmission, highlighting the need to include RAI when assessing PrEP eligibility among MSM. The CDHRS tool, on the other hand, omits transactional sex (i.e. receiving payment), which has not been independently associated with HIV-1 acquisition risk in our cohort. The small number of MSM who reported receiving payment for sex but not RAI were therefore captured in the MoH criteria but not in the CDHRS tool.

In the MoH guidelines, healthcare providers are required to assess and discuss HIV-1 acquisition risk without judgment [3, 15]. As adult male same-sex behaviour is illegal in Kenya and stigma towards MSM is pervasive in health care settings [16, 17], many providers may not feel comfortable asking men about same-sex partners or anal sex, leading to missed opportunities for PrEP provision. Moreover, although RAI is also practiced by women, HIV-1 acquisition risk due to RAI in women is underappreciated [18, 19]. If the Kenyan MoH PrEP guidelines can be updated to include RAI as an indicator for PrEP eligibility, this would help normalize discussions on anal sex and ensure that all individuals at high risk for HIV-1 acquisition are offered PrEP. In addition, sensitization training of health care providers should be facilitated to reduce homophobic attitudes [20] and improve MSM healthcare services [21].

We report a relatively high PrEP uptake at first offer (70%) among eligible MSM in our study, with higher uptake among those who reported RAI, group sex or paying for sex. Although RAI and group sex were part of the CDHRS criteria for PrEP eligibility in our cohort [7], paying for sex has not been found to be a risk factor for HIV-1 infection in our cohort and is not a risk criteria in MoH guidelines. It could be that men who pay for sex have heightened risk perception due to the sexual activities they offered payment for. Of note, the question in our risk assessment questionnaire captures payment for sex without specifying whether a male or female partner was paid. Asking men whether they have paid for sex may be one way to identify men who engage in other high-risk sexual behaviors, without pressuring them to admit to male-male sex.

With respect to the uptake rate of PrEP in our study, our findings are consistent with results documented in other settings in which PrEP uptake ranged between 60% and 93% [22-24] among MSM reporting condomless RAI [23] or condomless anal sex [25]. Although we did not find significant differences in PrEP eligibility at baseline compared to the end of the follow-up period in our study, four men became eligible during follow-up, highlighting the importance of period reassessments of HIV risk. We did not encourage men to discontinue PrEP if they no longer met criteria at a follow-up assessment, as we assumed that risk in our cohort would remain substantial.

About a third of the eligible MSM participants did not accept PrEP when it was first offered. Of note, 1 in 5 of these men accepted PrEP later in follow-up after the initial refusal. Upon review of their counseling records at baseline, the majority of men who delayed PrEP initiation reported that they were not ready to start. Others opted to continue using condoms, after considering the risks and benefits of PrEP. Further research to understand barriers and facilitators of PrEP uptake among MSM is needed, to target optimal interventions supporting PrEP uptake and adherence among MSM at high risk of HIV-1 acquisition in Kenya [26].

Conclusions

Assessing PrEP eligibility in an HIV-1 vaccine feasibility cohort study of high-risk MSM using a CDHRS identified 20% more at-risk MSM for PrEP initiation than when MoH criteria were used. About 70% accepted PrEP at first offer, suggesting PrEP is acceptable among MSM reporting high-risk behavior. Consideration should be given to incorporating established risk factors for HIV-1 acquisition among MSM, especially RAI and group sex, into MoH guidelines, to enhance impact of PrEP programming among MSM and other key populations in Kenya. Our results show that men at high risk are interested in PrEP and that men who pay for sex are also interested in this HIV prevention intervention.

Abbreviations

AHI	Acute HIV-1 infection
aPR	adjusted prevalence ratio
AUC	Area under the curve
CDHRS	Cohort-derived HIV-1 risk score
HBsAg	Hepatitis B surface antigen

HIV-1	Human immunodeficiency virus
IQR	Interquartile range
KEMRI	Kenya Medical Research Institute
MSM	Men who have sex with men
MoH	Ministry of Health
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
RAI	Receptive anal intercourse
ROC	Receiver operator characteristic curve
RPR	Rapid plasma reagin
STI	Sexually transmitted infection
TPHA	Treponema pallidum haemagglutination assay

Declarations

Ethics approval and consent to participate

The KEMRI Ethics Review Committee approved the study. All participants provided written informed consent.

Consent for publication

The study is published with permission from the director of KEMRI

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that their research was conducted in the absence of any commercial or financial relationship that could be construed as a potential conflict of interest.

This paper has not been submitted elsewhere. Preliminary results were presented at the 22nd International AIDS conference (# WEPEC256).

Funding

This work was supported by the International AIDS Vaccine Initiative (IAVI) and the University of Washington Center for AIDS Research, a National Institutes of Health (NIH)–funded program [R01AI124968], which is supported by the following NIH institutes and centers (NIAID, NCI, NIMH, NIDA, NICHD, NHLBI, NCCAM). SMG was also supported by the University of Washington / Fred Hutch Center for AIDS Research, an NIH-funded program under award number AI027757 which is supported by the following NIH Institutes and Centers: NIAID, NCI, NIMH, NIDA, NICHD, NHLBI, NIA, NIGMS, NIDDK. The KEMRI Wellcome Trust Research Programme at the Centre for Geographical Medicine Research–Kilifi is supported by core funding from the Wellcome Trust (grant # 203077/Z/16/Z). This study was made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of the study authors and do not necessarily reflect the views of USAID, NIH, the United States government, or the Wellcome Trust. This report was published with permission from the director of KEMRI.

Authors' contributions

E.S. and S.G. designed the research study. A.T., O.C., and K.S. collected the data. E.W. managed and analysed data and wrote the original draft of the manuscript. E.W., S.G., A.T., C.O., K.S., E.G., J.M., M.P. and E.S. reviewed and edited the manuscript. All authors have read and approved the final manuscript.

Acknowledgements

We would like to thank the participants and research team for their contributions to the study. We wish to acknowledge previous support to Elizabeth Wahome from the University of California, San Francisco, through its International Traineeships in AIDS Prevention Studies (ITAPS), US NIMH, R25MH064712, and the Starr Foundation Scholarship Fund.

This work was also supported in part through the Sub-Saharan African Network for TB/HIV Research Excellence (SANTHE), a DELTAS Africa Initiative (grant # DEL-15-006). The DELTAS Africa Initiative is an independent funding scheme of the African Academy of Sciences (AAS) Alliance for Accelerating Excellence in Science in Africa (AESA) and is supported by the New Partnership for Africa's Development Planning and Coordinating Agency (NEPAD Agency) with funding from the Wellcome Trust (grant # 107752/Z/15/Z) and the UK government. The views expressed in this publication are those of the authors and not necessarily those of AAS, NEPAD Agency, Wellcome Trust, or the UK government.

References

1. WHO expands recommendation on oral pre-exposure prophylaxis of HIV infection (PrEP). https://apps.who.int/iris/bitstream/handle/10665/197906/WHO_HIV_2015.48_eng.pdf;jsessionid=BFF6CD3A70A75369CCE21F417B37C330?sequence=1. Accessed December 10, 2018.
2. Country Updates. <https://www.prepwatch.org/country-updates/>. Accessed 11 March 2019.
3. Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya. https://www.nascop.or.ke/?page_id=2744. Accessed 10 December 2018.
4. Masyuko S, Mukui I, Njathi O, Kimani M, Oluoch P, Wamicwe J, et al. Pre-exposure prophylaxis rollout in a national public sector program: the Kenyan case study. *Sex Health*. 2018;15(6):578-86.
5. Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya. https://www.prepwatch.org/wp-content/uploads/2017/05/Kenya_PrEP_Implementation_Framework.pdf. Accessed December 10, 2018.
6. KENYA AIDS STRATEGIC FRAMEWORK 2014/2015 - 2018/2019. https://nacc.or.ke/wp-content/uploads/2015/09/KASF_Final.pdf. Accessed December 10, 2018.
7. Wahome E, Thiong'o AN, Mwashigadi G, Chirro O, Mohamed K, Gichuru E, et al. An Empiric Risk Score to Guide PrEP Targeting Among MSM in Coastal Kenya. *AIDS Behav*. 2018;22(Suppl 1):35-44.
8. Geibel S, van der Elst EM, King'ola N, Luchters S, Davies A, Getambu EM, et al. 'Are you on the market?': a capture-recapture enumeration of men who sell sex to men in and around Mombasa, Kenya. *AIDS*. 2007;21(10):1349-54.
9. Sanders EJ, Okuku HS, Smith AD, Mwangome M, Wahome E, Fegan G, et al. High HIV-1 incidence, correlates of HIV-1 acquisition, and high viral loads following seroconversion among MSM. *AIDS*. 2013;27(3):437-46.
10. Wahome E, Ngetsa C, Mwambi J, Gelderblom HC, Manyonyi GO, Micheni M, et al. Hepatitis B Virus Incidence and Risk Factors Among Human Immunodeficiency Virus-1 Negative Men Who Have Sex With Men in Kenya. *Open Forum Infect Dis*. 2017;4(1):ofw253.
11. Price MA, Rida W, Mwangome M, Mutua G, Middelkoop K, Roux S, et al. Identifying at-risk populations in Kenya and South Africa: HIV incidence in cohorts of men who report sex with men, sex workers, and youth. *J Acquir Immune Defic Syndr*. 2012;59(2):185-93.
12. Sanders EJ, Graham SM, Okuku HS, van der Elst EM, Muhaari A, Davies A, et al. HIV-1 infection in high risk men who have sex with men in Mombasa, Kenya. *AIDS*. 2007;21(18):2513-20.
13. Volz EM, Le Vu S, Ratmann O, Tostevin A, Dunn D, Orkin C, et al. Molecular Epidemiology of HIV-1 Subtype B Reveals Heterogeneous Transmission Risk: Implications for Intervention and Control. *J Infect Dis*. 2018;217(10):1522-29.
14. Baggaley RF, White RG, Boily MC. HIV transmission risk through anal intercourse: systematic review, meta-analysis and implications for HIV prevention. *Int J Epidemiol*. 2010;39(4):1048-63.
15. Hoornenborg E, Krakower DS, Prins M, Mayer KH. Pre-exposure prophylaxis for MSM and transgender persons in early adopting countries. *AIDS*. 2017;31(16):2179-91.
16. van der Elst EM, Gichuru E, Omar A, Kanungi J, Duby Z, Midoun M, et al. Experiences of Kenyan healthcare workers providing services to men who have sex with men: qualitative findings from a sensitivity training programme. *J Int AIDS Soc*. 2013;16 Suppl 3:18741.

17. Mugo NR, Ngure K, Kiragu M, Irungu E, Kilonzo N. PrEP for Africa: What we have learnt and what is needed to move to program implementation. *Curr Opin HIV AIDS*. 2016;11(1):80-6.
18. Duby Z, Colvin C. Conceptualizations of heterosexual anal sex and HIV risk in five East African communities. *J Sex Res*. 2014;51(8):863-73.
19. Grijsen ML, Graham SM, Mwangome M, Githua P, Mutimba S, Wamuyu L, et al. Screening for genital and anorectal sexually transmitted infections in HIV prevention trials in Africa. *Sex Transm Infect*. 2008;84(5):364-70.
20. van der Elst EM, Smith AD, Gichuru E, Wahome E, Musyoki H, Muraguri N, et al. Men who have sex with men sensitivity training reduces homophobia and increases knowledge among Kenyan healthcare providers in coastal Kenya. *J Int AIDS Soc*. 2013;16 Suppl 3:18748.
21. van der Elst EM, Gichuru E, Muraguri N, Musyoki H, Micheni M, Kombo B, et al. Strengthening healthcare providers' skills to improve HIV services for MSM in Kenya. *AIDS*. 2015;29 Suppl 3:S237-40.
22. Hoagland B, Moreira RI, De Boni RB, Kallas EG, Madruga JV, Vasconcelos R, et al. High pre-exposure prophylaxis uptake and early adherence among men who have sex with men and transgender women at risk for HIV Infection: the PrEP Brasil demonstration project. *J Int AIDS Soc*. 2017;20(1):21472.
23. Grant RM. An observational study of preexposure prophylaxis uptake, sexual practices, and HIV incidence among men and transgender women who have sex with men. 2014;14(9):820-9.
24. Chan PA, Glynn TR, Oldenburg CE, Montgomery MC, Robinette AE, Almonte A, et al. Implementation of Preexposure Prophylaxis for Human Immunodeficiency Virus Prevention Among Men Who Have Sex With Men at a New England Sexually Transmitted Diseases Clinic. *Sex Transm Dis*. 2016;43(11):717-23.
25. Morgan E, Moran K, Ryan DT, Mustanski B, Newcomb ME. Threefold Increase in PrEP Uptake Over Time with High Adherence Among Young Men Who Have Sex With Men in Chicago. *AIDS Behav*. 2018;22(11):3637-44.
26. Wahome E, Mwashigadi G, Kombo B, Kimani M, Mohamed K, Brockman M, et al. Factors associated with refusing or stopping PrEP among at-risk MSM in Kenya. Poster presented at: Conference on Retroviruses and Opportunistic Infections (CROI); 2019 March 4-7; Seattle, Washington.

Tables

Table 1. Characteristics of 162 MSM eligible for PrEP at baseline, Kilifi, 2017.

Characteristics	Overall	(n =	Declined PrEP at first	Accepted PrEP at first	P-value
	162)		offer	offer	
	n (%)	(n = 49)	n (%)	(n = 113)	
	n (%)		n (%)	n (%)	
Age group (years)					0.168
18-24	66 (40.7)		16 (32.7)	50 (44.2)	
25+	96 (59.3)		33 (67.3)	63 (55.8)	
Education					0.845
Primary/none	62 (38.3)		20 (40.8)	42 (37.2)	
Secondary	84 (51.9)		25 (51.0)	59 (52.2)	
Higher/tertiary	16 (9.9)		4 (8.2)	12 (10.6)	
Marital status					0.084
Never married	143 (88.3)		40 (81.6)	103 (91.2)	
Ever married	19 (11.7)		9 (18.4)	10 (8.8)	
Religion					0.367
Christian	88 (54.3)		24 (49.0)	64 (56.6)	
Muslim	38 (23.5)		15 (30.6)	23 (20.4)	
Other/none	36 (22.2)		10 (20.4)	26 (23.0)	
Employment					0.210
None	27 (16.7)		12 (24.5)	15 (13.3)	
Self	107 (66.0)		29 (59.2)	78 (69.0)	
Formal	28 (17.3)		8 (16.3)	20 (17.7)	
Sex of partner in past 3 months					0.027
Men only	93 (57.4)		28 (57.1)	65 (57.5)	
Both men and women	66 (40.7)		18 (36.7)	48 (42.5)	
Women only	3 (1.9)		3 (6.1)	0 (0.0)	
Sexual exposure and protection with condoms in past week					0.454
No activity	64 (39.5)		22 (44.9)	42 (37.2)	
All protected	66 (40.7)		20 (40.8)	46 (40.7)	
Any unprotected	32 (19.8)		7 (14.3)	25 (22.1)	
Number of sex partners in past week					0.150
0	71 (43.8)		23 (46.9)	48 (42.5)	
1	35 (21.6)		14 (28.6)	21 (18.6)	
2 or more	56 (34.6)		12 (24.5)	44 (38.9)	
Receptive anal intercourse (RAI) in past 3 months	124 (76.5)		32 (65.3)	92 (81.4)	0.026
Insertive anal intercourse (IAI) past in 3 months	111 (68.5)		32 (65.3)	79 (69.9)	0.562
Paid for sex with cash, living expenses, or goods in past 3 months	28 (17.3)		4 (8.2)	24 (21.2)	0.043
Received payment for sex with cash, living expenses, or goods in past 3 months	104 (64.2)		27 (55.1)	77 (68.1)	0.112
Group sex in past 3 months	3 (1.9)		0 (0.0)	3 (2.7)	0.250
Alcohol use in past month	73 (45.1)		23 (46.9)	50 (44.2)	0.752
Sex after alcohol use past month	44 (27.2)		16 (32.7)	28 (24.8)	0.301
Been raped in past 3 months	1 (0.6)		1 (2.0)	0 (0.0)	0.128
Intravenous drug use in past 3 months	0 (0.0)		0 (0.0)	0 (0.0)	-
Recurrent use of post-exposure prophylaxis (PEP)†	3 (1.9)		2 (4.1)	1 (0.9)	0.166
Recent sexually transmitted infection‡	3 (1.9)		1 (2.0)	2 (1.8)	0.906
Circumcised	162 (100.0)		49 (100.0)	113 (100.0)	-

†Defined as PEP use more than once in the past 6 months.

‡Defined as a positive gram stain of urethral or rectal secretions or a new syphilis diagnosis within 6 months.

Table 2. Factors associated with PrEP uptake among 162 MSM eligible for PrEP at baseline.

Characteristics	Bivariable analysis		Multivariable analysis	
	PR (95% CI)	P value	aPR (95% CI)	P value
Age group (years)†				
18-24	1.2 (0.9-1.4)	0.159	1.1 (0.9-1.4)	0.236
25+	Reference		Reference	
Education				
Primary/none	Reference		-	-
Secondary	1.0 (0.8-1.3)	0.749		
Higher/tertiary	1.1 (0.8-1.5)	0.548		
Marital status†				
Never married	Reference	0.162	Reference	0.216
Ever married	0.7 (0.5-1.1)		0.8 (0.5-1.2)	
Religion				
Christian	Reference		-	-
Muslim	0.8 (0.6-1.0)	0.211		
Other/none	1.0 (0.8-1.3)	0.955		
Employment†				
None	Reference		Reference	
Self	1.3 (0.9-1.9)	0.137	1.3 (0.9-1.9)	0.127
Formal	1.3 (0.9-1.9)	0.232	1.4 (0.9-2.0)	0.126
Sex of partner in past 3 months				
Both men and women	Reference			
Men only	1.0 (0.8-1.2)	0.964	-	-
Sexual exposure and protection with condoms in past week†				
No activity	Reference		Reference	
All protected	1.1 (0.8-1.3)	0.621	1.0 (0.7-1.4)	0.869
Any unprotected	1.2 (0.9-1.5)	0.182	1.2 (0.9-1.7)	0.263
Number of sex partners in past week†				
0	Reference		Reference	
1	0.9 (0.6-1.2)	0.459	0.8 (0.6-1.2)	0.346
2 or more	1.2 (0.9-1.4)	0.164	1.0 (0.8-1.4)	0.780
Receptive anal intercourse (RAI) in past 3 months†				
No	Reference		Reference	
Yes	1.3 (1.0-1.8)	0.059	1.4 (1.0-1.9)	0.039
Insertive anal intercourse (IAI) past in 3 months				
No	Reference		-	-
Yes	1.1 (0.8-1.3)	0.574		
Paid for sex with cash, living expenses, or goods in past 3 months†				
No	Reference		Reference	
Yes	1.3 (1.1-1.6)	0.010	1.3 (1.1-1.6)	0.004
Received payment for sex with cash, living expenses, or goods in past 3 months				
No	Reference		Reference	
Yes	1.2 (0.9-1.5)	0.136	1.1 (0.8-1.4)	0.543
Group sex in past 3 months†				
No	Reference		Reference	
Yes	1.4 (1.3-1.6)	<0.001	1.4 (1.1-1.8)	0.007
Alcohol use in past month				
No	Reference		-	-
Yes	1.0 (0.8-1.2)	0.754		
Sex after alcohol use past month				
No	Reference		-	-
Yes	0.9 (0.7-1.1)	0.333		
Recurrent use of post-exposure prophylaxis (PEP)‡				
No	Reference		-	-

Yes	0.5 (0.1-2.4)	0.362
Recent sexually transmitted infections		
No	Reference	-
Yes	1.0 (0.4-2.1)	0.911

PR, prevalence ratio; aPR, adjusted prevalence ratio

†Only factors significant at $P \leq 0.2$ in the bivariable analysis were included in the multivariable model.

‡Defined as PEP use more than once in the past 6 months.

§ Defined as a positive gram stain of urethral or rectal secretions or a new syphilis diagnosis within 6 months.

Figures

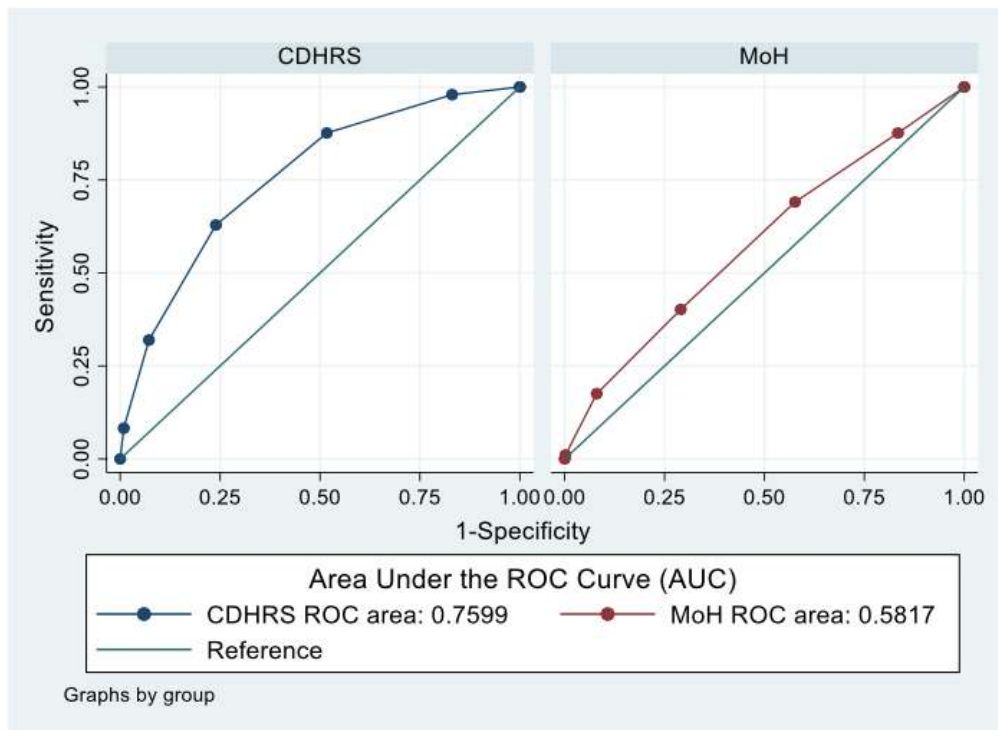


Figure 1

Performance of Ministry of Health (MoH) criteria and cohort-derived HIV-1 risk score (CDHRS). Figure 1 legend: Comparison based on historical data, 2005-2016, Kilifi, Kenya.

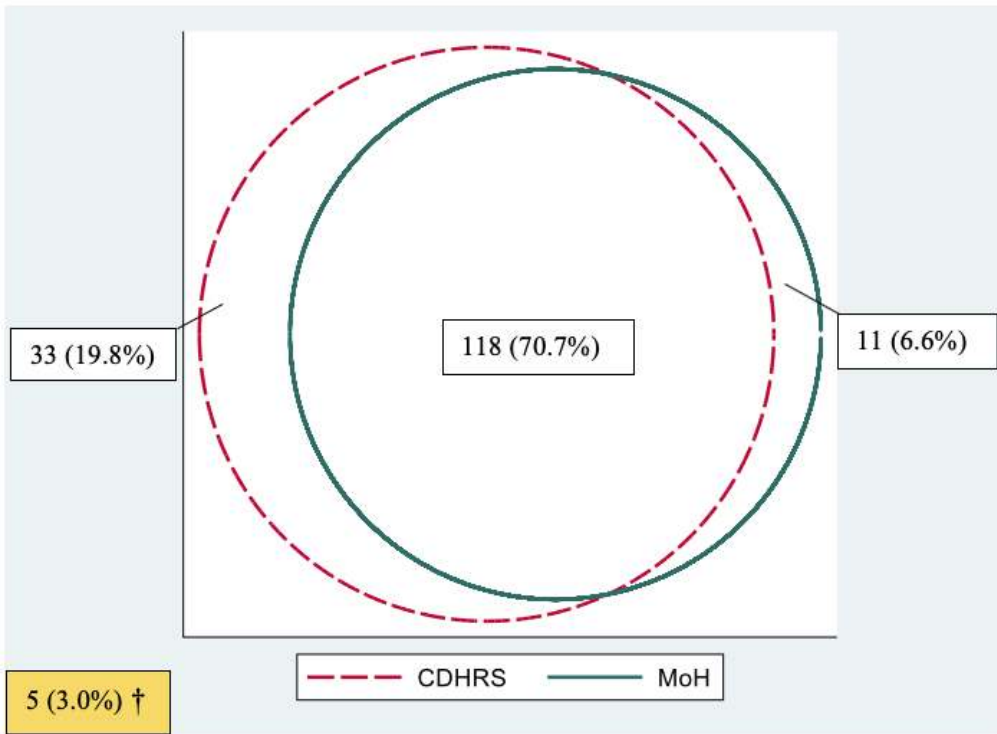


Figure 2

Comparison of PrEP eligibility at baseline among 167 MSM, Kilifi, 2017. Figure 2 legend. †Denotes MSM not identified as eligible for PrEP by either the Ministry of Health (MoH) or the cohort-derived HIV-1 risk score (CDHRS) criteria.

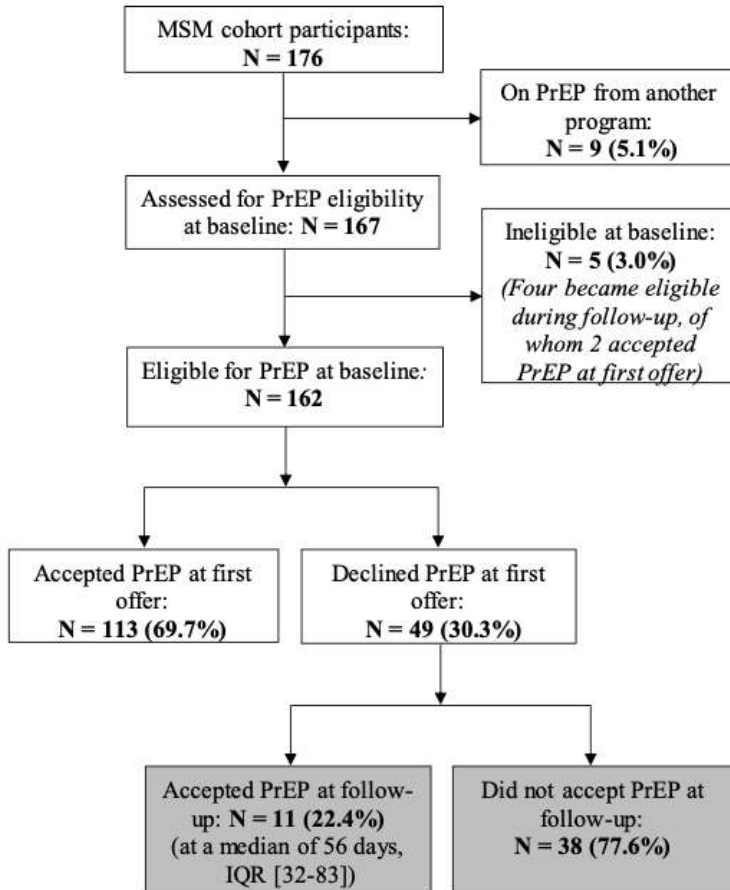


Figure 3

PrEP eligibility and uptake among MSM at baseline, Kilifi, 2017.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Additionalfile1PrEPeligibilityScoreSheet.docx](#)