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The Prevalence, Incidence, and Risk Factors for HIV Among Female Sex Workers—A Cohort Being Prepared for a Phase IIb HIV Vaccine Trial in Dar es Salaam, Tanzania

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Background: A cohort of female sex workers (FSWs) was established to determine HIV prevalence and incidence, and associated factors in preparation for a phase IIb HIV vaccine and pre-exposure prophylaxis trial (PrEPVacc).

Setting: A cohort of FSWs in Dar es Salaam, Tanzania.

Methods: FSWs aged 18–45 years were recruited using a respondent-driven sampling method. Social demographic data, HIV risk behavioral assessments, and blood samples for testing of HIV, syphilis, hepatitis B (HBV), and hepatitis C (HCV) infections were collected at baseline and then at 3, 6, 9, and 12 months. Poisson regressions were used to estimate the prevalence ratios for factors associated with HIV prevalence and to estimate the 12-month HIV incidence rate.

Results: Between October and December 2018, a total of 773 FSWs were screened for eligibility and 700 were enrolled. The baseline prevalence of HIV, syphilis, HBV, and HCV was 7.6%, 1.2%, 1.7%, and 1.0%, respectively. HIV prevalence was associated with older age, using illicit drugs, and being infected with syphilis, HBV, or HCV. Attendance at 12 months was 80% (562/700). Twenty-one FSWs seroconverted during follow-up, giving a 12-month HIV incidence rate of 3.45 per 100 person-years at risk (95% CI; 2.25–5.28/100 person-years at risk). The HIV incidence rate was higher among FSWs aged 18–24 years, FSWs who used drugs, and those diagnosed with syphilis, HBV, or HCV.

Conclusion: The high HIV incidence rate and retention rate among FSWs enrolled into the cohort demonstrate that this population is suitable for participation in HIV prevention trials.

Key Words: HIV epidemiology, sex workers, HIV vaccine, HIV incidence, HIV prevalence, Tanzania

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INTRODUCTION

Globally, 1.7 million people were newly infected with HIV in 2019, more than 3-fold higher than the 2020 UNAIDS target.[1] Effective prevention interventions, among them vaccines, are urgently needed to curb the high HIV transmission.[2,3]

Testing for efficacy of new HIV vaccine products and other HIV prevention interventions requires identifying, enrolling, and retaining persons at high risk of HIV infection. Prospective observation cohorts of high-risk groups provide data for the designs and efficiency of conducting HIV prevention trials.[4–6] Studies suggest that female sex workers (FSWs) living in Dar es Salaam are a high-risk group with a

reported HIV prevalence of 15%,[7] which is 2.5 times the prevalence among women aged 15–49 years in the general population.[8]

The PrEPVacc trial is a multi-center, phase IIb, 3-arm, 2-stage randomized HIV vaccine trial that will evaluate the effectiveness of combining pre-exposure prophylaxis (PrEP) with HIV vaccines in preventing new HIV infections.[9] The trial sites include Masaka (Uganda), Maputo (Mozambique), Durban and Verulam (South Africa), Mbeya and Dar es Salaam (Tanzania).[9] In this efficacy trial, 2 experimental HIV vaccine regimens will be compared with a placebo. Vaccinees will also be randomized to receive either daily TAF/FTC (Descovy) or daily TDF/FTC (Truvada). At each of the PrEPVacc trial sites, a cohort of HIV-negative individuals at high risk for HIV infection (PrEPVacc registration cohort) was established.

In this article, we provide data on social demographic and behavioral characteristics, baseline prevalence of HIV and sexually transmitted infections (STI), the 1-year incidence of HIV, and the retention rate of FSWs enrolled into the PrEPVacc registration cohort in Dar es Salaam.

METHODS

Study Design and Setting

The PrEPVacc registration cohort in Dar es Salaam is a prospective, longitudinal observational study conducted at the Muhimbili University of Health and Allied Sciences (MUHAS) HIV Vaccine Clinical Trial Unit. The study site is located within the tertiary and referral facility, Muhimbili National Hospital (MNH), and is easily accessible. To date, a total of 5 phase I/II HIV vaccine trials have been conducted at the study site.[10–17]

Study Population

This study included women self-identifying as street-based, home-based or brothel-based sex workers. They were eligible for inclusion if they met the following criteria: provided consent, aged 18–45 years, resided within Dar es Salaam, reported to have exchanged sexual intercourse for money within the past month, considered themselves to be at increased risk for HIV infection, and were willing to undergo pregnancy testing as well as HIV pretest and post-test counselling.

Screening, Enrolment, and Follow-Up Visits

FSWs were recruited using the respondent-driven sampling (RDS) method[18] as used previously in Dar es Salaam.[7,19,20] RDS recruitment began with purposeful selection of 4 "seeds". The seeds—members of the FSWs community known to the study investigator—were selected based on diversity regarding age, education, and area of residence. Each seed was provided with 3 coupons and instructed to recruit 3 FSWs peers. In turn, each recruited peer recruited 3 other FSWs until the desired sample size was reached. Recruiters and their recruits were linked by unique identifiers written on their recruitment coupon. A research assistant (RDS screener) who was a FSW, determined whether recruits were indeed sex workers. She asked impromptu questions about charges and number of sex acts, client meeting points, and specific idioms used by the FSWs community. Potential participants with valid recruitment coupons were provided with study information and procedures in *Kiswahili* and thereafter willing participants signed an informed consent form.

The study nurses and doctors performed the eligibility screening procedures using case report forms. Eligible participants underwent face-to-face baseline interviews in private rooms at the study site. Information on risky sexual behavior practices, HIV risk perception, contraceptive use, and drug and alcohol use were collected. Each interview lasted approximately 30–45 minutes. Participants provided 10 mL of whole blood for rapid HIV, syphilis, hepatitis B, and hepatitis C testing and 5 mL of urine for pregnancy testing. Pretest and post-test counselling were performed by trained nurse counsellors. Participants who were nonreactive to the HIV rapid test were enrolled into the cohort and asked to attend follow-up visits.

Follow-up visits were conducted at 3, 6, 9, and 12 months. HIV counselling and testing were performed at each visit. Follow-up interviews on HIV-related risk behavior were conducted every 6 months.

Laboratory Testing

The HIV testing procedure was based on rapid tests performed at the study site by a trained laboratory scientist and verified in the Microbiology and Immunology laboratory at MUHAS. The Tanzanian HIV testing algorithm[21] was applied, which uses 2 sequential HIV rapid tests, SD Bioline HIV 1/2 (Standard Diagnostics Inc, the Republic of Korea) for screening and Uni-Gold HIV 1/2 (Trinity Biotech, Ireland) for confirmation of infection. Participants who were reactive to both HIV rapid tests were regarded as HIV infected. Enzyme-linked immunosorbent assay (ELISA) tests, Murex HIV Ag/Ab Combination (DiaSorin S.p.A., UK Branch), and Enzygnost HIV Integral 4 ELISA (Siemens Healthcare, Germany) were used to resolve discordant results between the 2 HIV rapid tests.

Syphilis testing was performed using a Laborex rapid treponemal assay (Orient Gene Biotech Co Ltd, Zhejiang, China), and all reactive samples were confirmed on a Treponema pallidum hemagglutination assay (TPHA, Chronolab, Barcelona, Spain). All reactive rapid hepatitis B and C test samples were confirmed using Murex Hepatitis B and Hepatitis C ELISAs (DiaSorin S.p.A., Italy), respectively. A urine pregnancy testing was performed every 6 months by detection of β-human chorionic gonadotrophin (β-HCG) using Laborex pregnancy rapid test (Orient Gene Biotech Co Ltd, Zhejiang, China).

Clinical Referrals

HIV-positive participants were provided with a referral note and escorted to their preferred health care facility to

receive free HIV care and treatment. Participants who tested positive for hepatitis B or C were referred to the hepatitis clinic within MNH for further management. Participants confirmed to have syphilis were provided with a drug prescription and referred to an STI clinic. All pregnant participants were referred to antenatal clinics of their choice.

Data Processing and Statistical Analysis

Case report forms were reviewed for completeness and consistency at the study site. Data were double-entered using a web-based data management system, OpenClinica. Data were analyzed using STATA version 12 (StataCorp, College Station, TX). A RDS analysis tool (RDSAT 7.1) was used to chart RDS recruitment networks.

We used demographic and sexual risk behaviors reported at the enrolment visit to examine factors associated with baseline HIV prevalence and 12-month HIV incidence. Variables were categorized based on their distribution so as to minimize data sparsity. Age was categorized into 3 groups, that is, "18–24 years," "25–34 years," and "35–45 years". Education level was grouped into 3 categories as follows: (1) no formal education or incomplete primary education, (2) completed 7 years of primary education or some secondary education, and (3) completed secondary education, college or any other post-secondary education training. Marital status was also categorized into 3 groups, that is, "never married," "married or cohabiting with a male partner;" and "separated, divorced, or widowed". The number of reported sexual partners in the past 3 months was dichotomized at median value to "50 partners or less" or "51 partners and more". All participants were screened for syphilis, hepatitis B virus (HBV), and hepatitis C virus (HCV) infections before enrolment. A composite variable for the sexually transmitted infections (STI) was generated by grouping those testing positive to at least one of the STIs (syphilis, HBV, or HCV infection) as "positive" and those testing negative to all 3 STIs as "negative". Other sexual risk behavior variables: "condom use during transactional sex," "condom use with a new sexual partner," "condom use with an HIV-infected partner," "history of STI treatment," "rape," and drug use (marijuana, khat, or injectable drugs) were reported as binary or categorical variables (Yes/No/Do not know) as per responses recorded in an enrolment interview questionnaire.

Frequencies and proportions were reported to describe baseline social demographic and sexual behavior characteristics. The chi-square test was used to compare baseline characteristics between those who were HIV positive and HIV negative. We used weighted modified Poisson regression with robust standard error to estimate prevalence ratio (PR) for each baseline characteristic, and the associated 95% confidence intervals (95% CI) were reported. Individuals with missing data for a given variable were excluded from models which included that variable.

The attendance rate was determined as the number of participants who attended a visit divided by the total number enrolled. Poisson regression models were used to estimate the HIV incidence rate. The estimated date for HIV seroconversion was the time halfway between the last HIV nonreactive test and the first HIV-reactive test. Participants were censored at the earliest date of HIV seroconversion, date last seen, or at the 12-month follow-up. The HIV incidence was calculated as the number of seroconversions divided by the total person-years at risk (PYR). Crude rate ratios (RR) and their 95% CI for baseline covariates associated with HIV incidence were estimated. The Nelson–Aalen cumulative hazard curves were plotted to compare HIV cumulative hazards between participants with different risk characteristics.

Ethics Statement

Ethical approval for this study was obtained from the MUHAS Institutional Review Board (Ref. MUHAS-REC-4-2020-200). The PrEPVacc registration cohort received ethical approval from MUHAS Institutional Review Board (Ref. 2018-04-4/AEC/Vol. XII/335) and National Health Research Ethics Committee (Ref. NIMR/HQ/R.8a/Vol.IX/2809). All participants were assured that participation in the cohort was voluntary. Identification numbers were used to protect participants' confidentiality. PrEP was not offered through the project because PrEP was not widely available in Tanzania during the study period. However, participants had access to PrEP through a PrEP demonstration project[22] and other research projects offering PrEP to FSWs within Dar es Salaam. Our cohort participants were provided with education that PrEP is a preventive antiretroviral drug that reduces risk of HIV infection. Cohort participants were informed that PrEP (Descovy and Truvada) will be offered in the future as part of the PrEPVacc HIV vaccine trial. Participants were referred to the family planning clinic within MNH to receive contraceptives. Male condoms were provided free of charge at each visit. Each participant was reimbursed with 3.50 USD and 1.7 USD for transport fee and an incentive for successful recruitment of a peer, respectively. Participants were reimbursed with 6.5 USD for transportation costs and time spent at the study site during the follow-up visits.

RESULTS

Recruitment and Screening of Study Participants

Four seeds initiated the RDS recruitment, and a total of 2202 coupons were issued over 3 months (October to December 2018). A total of 775 women with returned coupons met the recruitment criteria and were screened for study eligibility. The waves of recruitment per seed ranged from 6 to 16 with most of the recruits (82%) emanating from the social networks of one seed (see Figure S1, Supplemental Digital Content, which shows the recruitment tree, http://links.lww.com/QAI/B963). Two women recruited were not screened after self-reporting to be HIV-positive. Therefore, 773 women were included in this study (Fig. 1). All variables had $<1\%$ missing data.

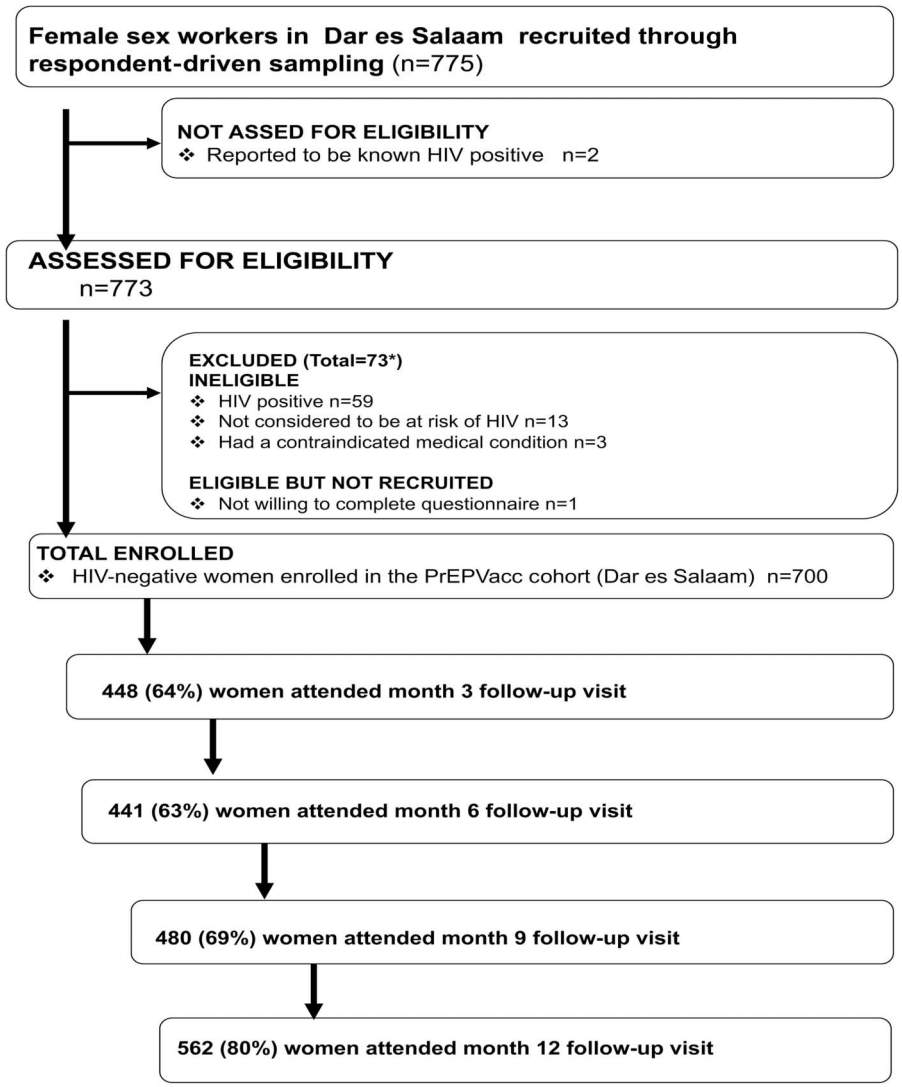

FIGURE 1. Screening, enrolment, and follow-up of female sex workers in the PrEPVacc registration cohort, Dar es Salaam, Tanzania.

Baseline Prevalence of HIV, Syphilis, and Hepatitis B and C Virus Infections

The baseline HIV prevalence was 7.6% (59/773) with a 95% CI of 5.8% to 9.7%. The prevalence of syphilis, hepatitis B virus, and hepatitis C virus infections was 1.2% (9/773, 95% CI: 0.5% to 2.2%), 1.7% (13/773, 95% CI: 0.9% to 2.6%), and 1.0% (9/773, 95% CI: 0.5% to 2.0%), respectively.

Social Demographic and Behavioral Characteristics of Study Participants

The overall median age of the 773 study participants at baseline was 25 years (IQR 21–32 years) (Table 1). The median age was higher among HIV-positive participants compared with HIV-negative participants (33 years versus 25 years). Most of the participants, 638 (83%) of 770 had never been married and 666 (86%) of 770 reported to have had more than 50 sexual partners within the last 3 months. There were 677 (88%) of 773 participants who did not use condoms with one or more sexual partners within the last 3 months, and more than half, 453 (59%) of 770 who did not use a condom during their last sex. Illicit drug use was reported by 97 (13%) of 772 participants.

HIV Prevalence and Associated Factors

In the univariate analysis, older age was associated with higher HIV prevalence (Table 1). Compared with participants aged 18–24 years, those aged 25–34 years had a HIV prevalence nearly 4 times higher (PR 3.68, 95% CI: 1.87 to 7.75), while those aged 35–45 years had a HIV prevalence that was 6 times higher (PR 6.04, 95% CI: 2.75 to 13.27). The HIV prevalence was 3 times higher among participants with HBV infection (PR 3.13, 95% CI: 0.98 to 10.01) and nearly 11 times higher among those with HCV (PR 10.83, 95% CI: 4.65 to 25.18). Participants who were using drugs had nearly 3 times the HIV prevalence (PR 2.59, 95% CI: 1.46 to 4.60) and those who had been raped had twice the HIV prevalence (PR 2.04, 95% CI: 1.17 to 3.56).

TABLE 1. Social and Behavioral Characteristics by HIV Status and HIV Prevalence Among Female Sex Workers Screened for Enrolment Into the PrEPVacc Registration Cohort in Dar es Salaam, Tanzania (N = 773)

Characteristic	N (n, Col %)	HIV Positive (n, Row%)	HIV Negative (n, Row %)	Prevalence Ratios (95% CI)
Overall	773(100)	59(8)	714(92)	—
Median age (IQR)	25(21–32)	33(26–38)	25(21–31)	—
Age (years)				
18–24	340(44)	9(3)	331(97)	Ref
25–34	308(40)	30(10)	278(90)	3.68(1.75–7.75)
35–45	125(16)	20(16)	105(84)	6.04(2.75–13.27)
Education				
None/Incomplete primary education	103(13)	19(19)	84(81)	Ref
Complete primary/Incomplete secondary education	523(68)	35(7)	488(93)	0.36(0.21–0.63)
Complete secondary education or higher	147(19)	5(3)	142(97)	0.18(0.07–0.49)
Relationship status				
Never married	638(83)	34(5)	604(97)	Ref
Married/Cohabiting	24(3)	2(8)	22(92)	1.56(0.38–6.51)
Separated/Divorced/Widowed	111(14)	23(21)	88(79)	3.88(2.29–6.60)
Syphilis test				
Negative	764(99)	57(8)	707(92)	Ref
Positive	9(1)	2(22)	7(78)	2.98(0.72–12.20)
Hepatitis B virus test				
Negative	760(98)	56(7)	704(93)	Ref
Positive	13(2)	3(23)	10(77)	3.13(0.98–10.01)
Hepatitis C virus test				
Negative	765(99)	53(7)	712(93)	Ref
Positive	8(1)	6(75)	2(25)	10.83(4.65–25.18)
History of STI treatment in the past 3 months				
No	723(94)	55(8)	668(92)	Ref
Yes	50(6)	4(8)	46(92)	1.05(0.38–2.90)
Total number of sexual partners in the past 3 months [1]				
≤50	104(14)	12(12)	92(88)	Ref
51+	666(86)	46(7)	620(93)	0.60(0.32–1.13)
Number of new sexual partners in the past 3 months [1]				
Less than 10	122(16)	11(9)	111(91)	Ref
>10	648(84)	47(7)	601(93)	1.80(0.42–1.55)
Sex without a condom with 2 or more partners in past 3 months				
No	96(12)	6(6)	90(94)	Ref
Yes	677(88)	53(8)	624(92)	1.25(0.54–2.91)
Sex without a condom with a new sex partner in the past 3 months				
No	161(21)	15(9)	146(91)	Ref
Yes	612(79)	44(7)	568(93)	0.77(0.43–1.39)
Sex with HIV-infected partner in the past 3 months [2]				
No	11(1)	1(9)	10(91)	Ref
Yes	20(3)	3(15)	17(85)	1.65(0.17–15.86)
Do not know	737(95)	52(7)	685(93)	0.78(0.11–5.61)
Condom use at the last sex [1]				
No	453(59)	32(7)	421(93)	Ref
Yes	317(41)	24(8)	293(92)	1.07(0.63–1.82)
Alcohol use in the past 3 months				
Never	161(21)	10(6)	151(94)	Ref
4 times a month or less	104(13)	8(8)	96(92)	1.24(0.49–3.14)
Twice a week or more	508(66)	41(8)	467(92)	1.30(0.65–2.59)
Never	38(5)	3(8)	35(92)	Ref

(*continued on next page*)

TABLE 1. (*Continued*) Social and Behavioral Characteristics by HIV Status and HIV Prevalence Among Female Sex Workers Screened for Enrolment Into the PrEPVacc Registration Cohort in Dar es Salaam, Tanzania (N = 773)

Characteristic	N (n, Col %)	HIV Positive (n, Row%)	HIV Negative (n, Row %)	Prevalence Ratios (95% CI)
History of having sex when drunk [3]				
Sometimes	289(37)	27(9)	262(91)	1.16(0.36–3.90)
Frequent/always	194(25)	17(9)	177(91)	1.11(0.33–3.79)
Drug use in the past 3 months [4]				
No	675(87)	43(6)	632(94)	Ref
Yes	97(13)	16(16)	81(84)	2.59(1.46–4.60)
Rape in the past 3 months [5]				
No	627(81)	39(6)	588(94)	Ref
Yes	142(18)	18(13)	124(87)	2.04(1.17–3.56)
Contraceptive use [6]				
No	277(36)	23(8)	254(92)	Ref
Yes	494(64)	34(7)	460(93)	0.83(0.49–1.41)
Pregnancy test				
Negative	730(94)	56(8)	674(92)	Ref
Positive	43(6)	3(7)	40(93)	0.91(0.28–2.91)

Totals and percentages may not add up due to missing values. [1] 3 missing data. [2] 5 missing data. [3] Only reported among 521 of 773 women reporting to use alcohol. [4] 1 missing data. [5] 4 missing data. [6] 2 missing data.

There was no statistical evidence to suggest that the number of sexual partners or condom use reported by participants was associated with prevalent HIV infection.

HIV Incidence and Factors Associated With HIV Acquisition

The 700 participants enrolled into the PrEPVacc Registration cohort contributed to a total of 609 PYR (mean = 10 months, median = 12 months). A total of 21 participants seroconverted with an overall HIV incidence rate of 3.45 per 100 PYR (95% CI: 2.25 to 5.29/100 PYR; Table 2, Fig. 2). The HIV incidence rate was high among the youngest (18–24 years) and oldest (35–45 years) age groups (4.31/100 PYR and 4.13/100 PYR, respectively); however, there was no statistical evidence of an age effect on HIV incidence.

Owing to the few cases of HIV seroconversion, a fully comprehensive analysis of the general risk factors for HIV acquisition was not performed. An attempt to use a parsimonious multivariable hazard regression model adjusting for 2 covariates which were associated with prevalent HIV infection at baseline ("age" and "STI infection") did not yield different estimates from the crude rate ratios summarized in Table 2.

DISCUSSION

The 12-month HIV incidence rate among FSWs in the PrEPVacc registration cohort in Dar es Salaam was high (3.45, 95% CI: 2.25 to 5.29/100 PYR). The prevalence of HIV, syphilis, and hepatitis B and C virus infections was 7.6%, 1.2%, 1.7%, and 1.0%, respectively. The results demonstrate that FSWs in Dar es Salaam are indeed a high HIV risk population, and the 80% retention rate suggests that the population is suitable for participation in HIV vaccine trials.

The HIV prevalence in our study was substantially lower than the 15%, 32%, and 31% reported from cross-sectional surveys of FSWs living in Dar es Salaam conducted in 2018, 2013, and 2010, respectively.[7,19,20] The methodological difference in sampling can explain the disparity of the HIV prevalence estimates. Moreover, participants in our study were younger (age restricted to 18–45 years) and were better educated. The proportion of participants in our study who had completed secondary education was higher than that in the 3 previous surveys.[7,19,20] Nevertheless, the decline of HIV prevalence among FSWs in the region over the decade may be attributed to the implementation of the national guideline for HIV prevention, care, and treatment among key populations,[23] which promotes HIV risk reduction and condom use.

The HIV incidence estimated in our cohort is comparable with that estimated from similar cohorts in Tanzania and other settings in sub-Saharan Africa.[5,24–28] However, the incidence was lower than the 10.4% incidence reported from a cohort of FSWs in Iringa, Tanzania.[29] The higher HIV incidence among FSWs in Iringa can be explained by the high HIV burden in the general population in that region (HIV prevalence of 11.2% in Iringa versus 4.3% in Dar es Salaam[8]), which is largely contributed by sex-trade along the Tanzania–Zambia highway, a major long-distance truck route. For this reason, the second PrEPVacc trial site in Tanzania is based in the Mbeya region, located close to Iringa in the Tanzania–Zambia highway. Preliminary data from the Mbeya site cohort have recorded a higher number of HIV seroconversion cases as compared with the PrEPVacc site in Dar es Salaam.

TABLE 2. HIV Incidence and Associated Factors Among HIV-Negative Participants Enrolled in the PrEPVacc Cohort in Dar es Salaam, Tanzania (N = 700)

Characteristic	PYRs	HIV Cases	Rate per 100 PYRs	Crude RR (95% CI)
Overall	609	21	3.45	—
Age (years)				
18–24	278	12	4.31	Ref
25–34	234	5	2.14	0.50(0.17–1.41)
35–45	97	4	4.13	0.96(0.31–2.97)
Education				
None/Incomplete primary education	74	3	4.05	Ref
Complete primary/Incomplete secondary education	416	12	2.89	0.71(0.20–2.53)
Complete secondary or higher	119	6	5.03	1.24(0.31–4.97)
Relationship status				
Never married	511	18	3.52	Ref
Married/Cohabiting	21	0	0.00	—
Separated/Divorced/Widowed	76	3	3.90	1.11(0.33–3.76)
Total number of partners in the past 3 months				
≤50	75	3	3.98	Ref
51+	533	18	3.38	0.85(0.25–2.88)
Sex without a condom with 2 or more partners in the past 3 months				
No	73	4	5.47	Ref
Yes	536	17	3.17	0.58(0.19–1.72)
Sex without a condom with a new sex partner in the past 3 months				
No	122	6	4.91	Ref
Yes	487	15	3.08	0.63(0.24–1.61)
Sex with HIV-infected partner in the past 3 months				
No	10	1	10.00	Ref
Yes	14	1	7.18	0.72(0.04–11.48)
Do not know	584	19	3.25	0.33(0.04–2.43)
Condom use at the last sex				
Yes	252	7	2.78	Ref
No	357	14	3.92	1.41(0.57–3.50)
STI diagnosis at baseline				
Negative	589	19	3.22	Ref
Positive	20	2	10.04	3.11(0.72–13.37
Alcohol use in the past 3 months				
Never	124	6	4.86	Ref
4 times a month or less	81	12	2.48	0.51(0.10–2.52)
Twice a week or more	405	13	3.21	0.66(0.25–1.74)
History of having sex when drunk				
Never	26	1	3.8	Ref
Sometimes	229	6	2.6	0.68(0.08–5.66)
Frequent/always	155	5	3.2	0.84(0.10–7.16)
Drug use in the past 3 months				
No	539	18	3.34	Ref
Yes	71	3	4.25	1.27(0.37–4.32)
Pregnancy test at baseline				
Negative	576	19	3.30	Ref
Positive	33	2	6.02	1.83(0.43–7.84)

PYRs; person-years at risk; LRT, Likelihood ratio test; RR, rate ratio; 95% CI, 95% Confidence interval.

Older FSWs had a higher HIV prevalence compared with younger FSWs, which may reflect a longer duration of sexual activity and a potential for longer exposure to HIV. A high HIV prevalence among older FSWs has been reported in several studies across sub-Saharan Africa.[7,30–33] Given the relatively high incidence observed among younger FSWs (4.31/100 PYR), recruitment strategies for the future HIV trials should target FSWs in

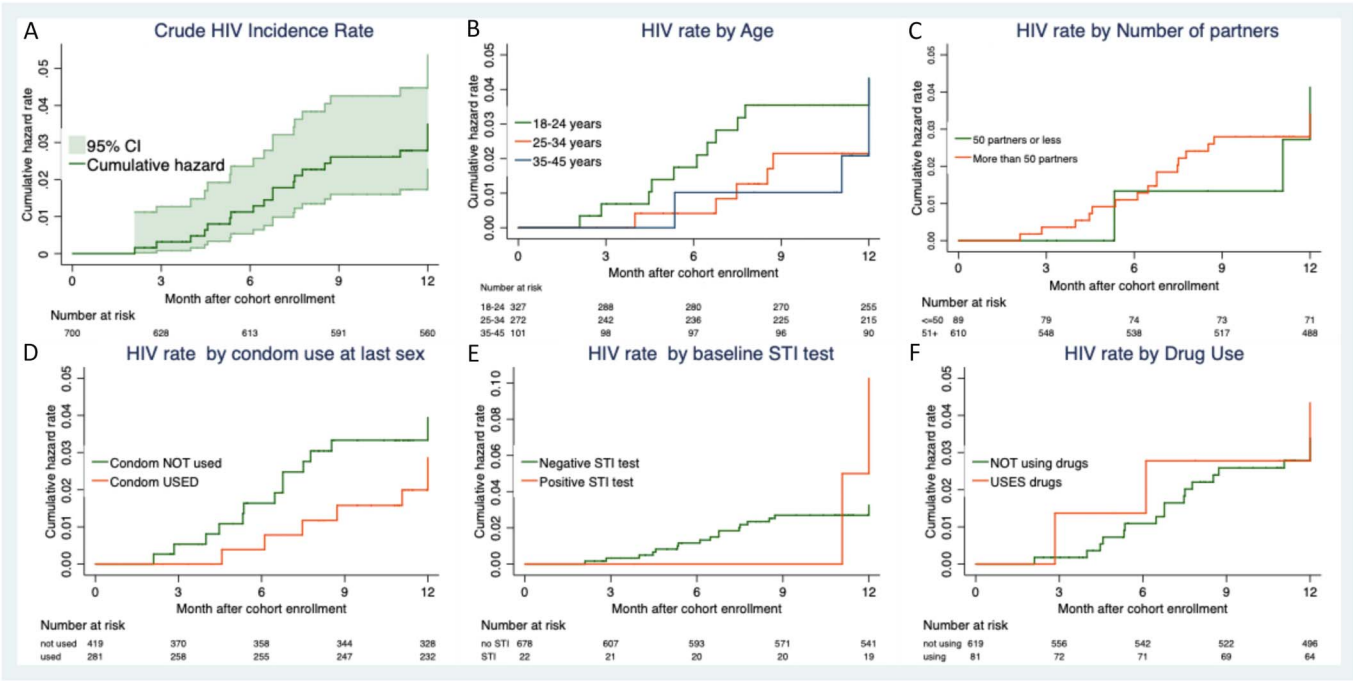

FIGURE 2. Cumulative hazard curves showing HIV incidence among female sex workers enrolled in the PrEPVacc cohort, Dar es Salaam, by social demographic and behavioral characteristics.

this subpopulation. Other studies have also observed a higher HIV incidence among younger high-risk women,[4,5,24–26,28,34] emphasizing the vulnerability of this group to HIV acquisition.

Inconsistent condom use and higher number of partners were not statistically associated with a higher HIV prevalence among FSWs in our study. The lack of a statistical association between HIV prevalence and sexual risk behaviors may stem from a misclassification error resulting from self-reporting of risky behaviors.[35] It is possible that participants under-reported or over-reported the number of partners and condom use. This may have consequently biased the observed prevalence ratio toward the null and resulted in an apparent reduction in the strength of association. The presence of STIs and pregnancy among participants suggest that unprotected sex was certainly being practiced. We noted that consistent condom use among participants was low and comparable with other studies among FSWs in Tanzania.[7,24,36] Inconsistent use of condoms among FSWs stresses the need for PrEP among FSWs. PrEP was not offered in the PrEPVacc registration cohort. PrEP use was not officially endorsed by the Tanzanian Ministry of Health as an interventional measure against HIV until September 2021. In the PrEPVacc trial, all participants will receive PrEP (Truvada or Descovy) and their adherence will be monitored.

The retention rate in the cohort was satisfactory (80% at 12 months) despite the high mobility of this population. Comparable retention rates have been reported in similar cohorts in Tanzania and elsewhere in sub-Saharan Africa,[5,24,25,29,34] highlighting the logistical challenges when dealing with HIV high-risk populations. It is likely that we underestimated the HIV incidence rate at 12 months as a result of loss-to-follow-up among "higher-risk" participants. We found that compared with those remaining in this study, participants who did not attend the 12-month visit (n = 138) were younger, a group known to be at higher HIV risk ($P = 0.01$, see Table S1, Supplemental Digital Content, http://links.lww.com/QAI/B964 which compares participants who completed 12 months visit and those lost to follow-up). To improve cohort retention, we selected a small group of cohort participants as trackers who either belonged in the same RDS recruitment chain or worked in the same neighborhood as that of a participant who missed a visit. This went hand-in-hand with the updating of contact and locator information so as to facilitate tracking.

Our study faced several limitations. We observed only 21 HIV seroconversions. This limited the statistical power of this study to determine factors associated with HIV incidence. Second, self-reports on sexual behaviors, both for the purpose of determining eligibility and assessment of risk inherently induced bias. Third, our study was conducted in an urban setting, and therefore, our results are of limited generalizability to FSWs working in rural settings, border areas ,and truck stops who may have different social networks and risk factors. Our study makes no claim for representativeness of HIV prevalence estimate among FSWs in Dar es Salaam. This study deliberately identified and recruited a cohort to detect an HIV incidence suitable for participation in a future HIV vaccine trial. Fourth, participants were recruited using a peer chain referral (RDS), and therefore, it is likely that FSWs in this study were part of a larger network, had better health-seeking behavior compared with those in their wider community. Finally, although the cohort enrolment eligibility criteria were not shared with the RDS seeds (and their

recruits), we do not know whether recruits preferentially invited peer FSWs whom they knew to be HIV negative. Because respondent-driven sampling employs the use of incentive system whereby recruits are reimbursed for successfully recruiting eligible peers, recruits may have preferentially invited peer sex workers whom they knew to be HIV negative. This might explain the lower HIV prevalence observed in our study compared with that reported in previous surveys among FSWs[7] and the high eligibility rate. In a subset analysis performed among 18 HIV prevalent cases in this study, only 3 had a prior awareness of their positive HIV diagnosis. This observation may imply that those who had tested negative in their last HIV test were more likely to show up for eligibility screening.

The major strength of this study was the longitudinal design. This temporal diagnosis of HIV infection provides an accurate HIV incidence estimation compared with the use of cross-sectional HIV recency incidence assays. The HIV incidence was estimated from a largely PrEP-"naïve" population and could be used to estimate power/sample size for potential HIV vaccine trials among FSWs.

CONCLUSIONS

The high HIV incidence rate and 80% retention rate at 12 months among FSWs enrolled into the PrEPVacc registration cohort in Dar es Salaam, demonstrate that this population is suitable for participation in HIV vaccine trials. The higher incidence of HIV among younger FSWs highlights the continued vulnerability of this group and that they may contribute to the sustained HIV epidemic in the country. This high HIV incidence should spur efforts by the Ministry of Health to roll out PrEP in this population to reduce the number of new HIV infections in Tanzania.

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REFERENCES

1. UNAIDS. *Seizing the Moment: Tackling Entrenched Inequalities to End Epidemics*. Joint United Nations Programme on HIV/AIDSUNAIDS) Geneva; 2020.
2. Fauci AS. An HIV vaccine is essential for ending the HIV/AIDS pandemic. *Jama*. 2017;318:1535–1536.
3. Medlock J, Pandey A, Parpia AS, et al. Effectiveness of UNAIDS targets and HIV vaccination across 127 countries. *Proc Natl Acad Sci U S A*. 2017;114:4017–4022.
4. Kamali A, Price MA, Lakhi S, et al. Creating an African HIV clinical research and prevention trials network: HIV prevalence, incidence and transmission. *PLoS One*. 2015;10:e0116100.
5. Price MA, Rida W, Mwangome M, 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. *JAIDS J Acquired Immune Deficiency Syndromes*. 2012;59:185–193.
6. van Loggerenberg F, Mlisana K, Williamson C, et al. Establishing a cohort at high risk of HIV infection in South Africa: challenges and experiences of the CAPRISA 002 acute infection study. *PLoS One*. 2008;3:e1954.
7. Mizinduko MM, Moen K, Likindikoki S, et al. HIV prevalence and associated risk factors among female sex workers in Dar es Salaam, Tanzania: tracking the epidemic. *Int J STD AIDS*. 2020;31:950–957.
8. Ministry of Health CD. *Gender, Elderly and Children, Tanzania and Ministry of Health, Zanzibar. Tanzania. Tanzania HIV Impact Survey (THIS) 2016-2017: Final Report*. TanzaniaDecember: Dar es Salaam; 2018.
9. ClinicalTrials.gov. A combination efficacy study in Africa of two DNA-MVA-env protein or DNA-env protein HIV-1 vaccine regimens with PrEP (PrEPVacc) NCT04066881. Available at: https://clinicaltrials.gov/ct2/show/NCT04066881?term=NCT04066881.&draw=2&rank=1. Accessed November 18, 2020.
10. Bakari M, Aboud S, Nilsson C, et al. Broad and potent immune responses to a low dose intradermal HIV-1 DNA boosted with HIV-1 recombinant MVA among healthy adults in Tanzania. *Vaccine*. 2011;29:8417–8428.
11. Joachim A, Nilsson C, Aboud S, et al. Potent functional antibody responses elicited by HIV-I DNA priming and boosting with heterologous HIV-1 recombinant MVA in healthy Tanzanian adults. *PLoS One*. 2015;10:e0118486.
12. Munseri PJ, Kroidl A, Nilsson C, et al. Priming with a simplified intradermal HIV-1 DNA vaccine regimen followed by boosting with recombinant HIV-1 MVA vaccine is safe and immunogenic: a phase IIa randomized clinical trial. *PLoS One*. 2015;10:e0119629.
13. Joachim A, Bauer A, Joseph S, et al. Boosting with subtype C CN54rgp140 protein adjuvanted with glucopyranosyl lipid adjuvant after priming with HIV-DNA and HIV-MVA is safe and enhances immune responses: a phase I trial. *PLoS One*. 2016;11:e0155702.
14. Joachim A, Munseri PJ, Nilsson C, et al. Three-year durability of immune responses induced by HIV-DNA and HIV-modified vaccinia virus ankara and effect of a late HIV-modified vaccinia virus ankara boost in Tanzanian volunteers. *AIDS Res Hum Retroviruses*. 2017;33:880–888.
15. Viegas EO, Kroidl A, Munseri PJ, et al. Optimizing the immunogenicity of HIV prime-boost DNA-MVA-rgp140/GLA vaccines in a phase II randomized factorial trial design. *PLoS One*. 2018;13:e0206838.
16. Joachim A, Ahmed MIM, Pollakis G, et al. Induction of identical IgG HIV-1 envelope epitope recognition patterns after initial HIVIS-DNA/MVA-CMDR immunization and a late MVA-CMDR boost. *Front Immunol.* 2020;11:719.
17. Msafiri F, Joachim A, Held K, et al. Frequent anti-V1V2 responses induced by HIV-DNA followed by HIV-MVA with or without CN54rgp140/GLA-AF in healthy african volunteers. *Microorganisms*. 2020;4:8.
18. Malekinejad M, Johnston LG, Kendall C, et al. Using respondent-driven sampling methodology for HIV biological and behavioral surveillance in international settings: a systematic review. *AIDS Behav*. 2008;12:S105–S130.
19. National AIDS Control Program (NACP) Ministry of Health Tanzania. *HIV Behavioral and Biological Surveillance Survey Among Female Sex Workers in Dar Es Salaam*; 2011.
20. National AIDS Control Program (NACP). Ministry of health and social welfare Tanzania. *HIV STI Biol Behav Survery. A Study of Female Sex Workers in Seven Regions: Dar Es Salaam, Iringa, Mbeya, Mwanza, Shinyanga*. Tabora and Mara; 2013.
21. Lyamuya EF, Aboud S, Urassa WK, et al. Evaluation of simple rapid HIV assays and development of national rapid HIV test algorithms in Dar es Salaam, Tanzania. *BMC Infect Dis*. 2009;9:19.
22. AVAC. *PrEPWatch*. Available at: https://www.prepwatch.org/country/tanzania/. Accessed December 31, 2020.
23. National AIDS Control Programme (NACP) Ministry of Health Tanzania. *National Guideline for Comprehensive Package of HIV Interventions for Key Populations*. Ministry of Health and Social Welfare; 2014.
24. Kapiga SH, Ewings FM, Ao T, et al. The epidemiology of HIV and HSV-2 infections among women participating in microbicide and vaccine feasibility studies in Northern Tanzania. *PLoS One*. 2013;8:e68825.
25. Vallely A, Hambleton IR, Kasindi S, et al. Are women who work in bars, guesthouses and similar facilities a suitable study population for vaginal microbicide trials in Africa? *PLoS One*. 2010;5:e10661.

26. Watson-Jones D, Baisley K, Weiss HA, et al. Risk factors for HIV incidence in women participating in an HSV suppressive treatment trial in Tanzania. *AIDS*. 2009;23:415–422.
27. Evidence for Contraceptive O, Consortium HIVOT. HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: a randomised, multicentre, open-label trial. *Lancet*. 2019;394: 303–313.
28. McKinnon LR, Izulla P, Nagelkerke N, et al. Risk factors for HIV acquisition in a prospective nairobi-based female sex worker cohort. *AIDS Behav.* 2015;19:2204–2213.
29. Kerrigan D, Mbwambo J, Likindikoki S, et al. Project shikamana: community empowerment-based combination HIV prevention significantly impacts HIV incidence and care continuum outcomes among female sex workers in Iringa, Tanzania. *J Acquir Immune Defic Syndr.* 2019;82:141–148.
30. Kerrigan D, Mbwambo J, Likindikoki S, et al. Project shikamana: baseline findings from a community empowerment-based combination HIV prevention trial among female sex workers in Iringa, Tanzania. *J Acquir Immune Defic Syndr.* 2017;74(suppl 1):S60–S68.
31. Augusto Âdo R, Young PW, Horth RZ, et al. High burden of HIV infection and risk behaviors among female sex workers in three main urban areas of Mozambique. *AIDS Behav*. 2016;20:799–810.
32. Coetzee J, Jewkes R, Gray GE. Cross-sectional study of female sex workers in Soweto, South Africa: factors associated with HIV infection. *PLoS One*. 2017;12:e0184775.
33. Schwitters A, Swaminathan M, Serwadda D, et al. Prevalence of rape and client-initiated gender-based violence among female sex workers: kampala, Uganda, 2012. *AIDS Behav*. 2015;19(suppl 1):S68–S76.
34. Ramjee G, Kapiga S, Weiss S, et al. The value of site preparedness studies for future implementation of phase 2/IIb/III HIV prevention trials: experience from the HPTN 055 study. *JAIDS J Acquired Immune Deficiency Syndromes*. 2008;47:93–100.
35. Ramjee G, Weber AE, Morar NS. Recording sexual behavior: comparison of recall questionnaires with a coital diary. *Sex Transm Dis*. 1999; 26:374–380.
36. Faini D, Hanson C, Baisley K, et al. Sexual behaviour, changes in sexual behaviour and associated factors among women at high risk of HIV participating in feasibility studies for prevention trials in Tanzania. *PLoS One*. 2020;15:e0231766.