Princess PrEP program: the first key population-led model to deliver pre-exposure prophylaxis to key populations by key populations in Thailand

Nittaya Phanuphak[A,K], Thanthip Sungsing[A], Jureeporn Jantarapakde[A],
Supabhorn Pengnonyang[A], Deondara Trachunthong[A], Pravit Mingkwanrungruang[A],
Waraporn Sirisakyot[A], Pattareeya Phiayura[A], Pich Seekaew[A], Phubet Panpet[B],
Phathranis Meekrua[C], Nanthika Praweprai[D], Fonthip Suwan[E], Supakarn Sangtong[F],
Pornpichit Brutrat[G], Tashada Wongsri[H], Panus Rattakittvijun Na Nakorn[A],
Stephen Mills[I], Matthew Avery[J], Ravipa Vannakit[J] and Praphan Phanuphak[A]

[A]PREVENTION, Thai Red Cross AIDS Research Centre, 104 Rajdumri Road, Pathumwan,
 Bangkok 10330, Thailand.
[B]Rainbow Sky Association of Thailand, 1, 3 Ramkhamhaeng Road, Bangkapi, Bangkok 10240, Thailand.
[C]Service Workers IN Group (SWING) Foundation, 3 Surawongse Road, Bangrak, Bangkok 10500, Thailand.
[D]Sisters Foundation, 417/64-65 Central Pattaya Road, Banglamung, Chonburi 20150, Thailand.
[E]Rainbow Sky Association of Thailand, 97 Nipatsongkroh 2 Road, Hat Yai, Songkhla 90110, Thailand.
[F]MPlus Foundation, 142 Soi Chomchan, Muang, Chiang Mai 50200, Thailand.
[G]SWING Foundation, 45/54 South Pattaya Road, Banglamung, Chonburi 20260, Thailand.
[H]Caremat Foundation, 257/36 Suthep Road, Muang, Chiang Mai 50200, Thailand.
[I]FHI 360 and LINKAGES Project, 19th Floor, Sindhorn Building, Wiresless Road, Pathumwan,
 Bangkok 10330, Thailand.
[J]Office of Public Health, U.S. Agency for International Development Regional Development Mission for Asia,
 25th Floor, Athenee Building, Wireless Road, Pathumwan, Bangkok 10330, Thailand.
[K]Corresponding author. Email: nittaya.p@trcarc.org

Abstract. *Background*: No data are available on the feasibility of pre-exposure prophylaxis (PrEP) delivered by trained key population (KP) community health workers. Herein we report data from the KP-led Princess PrEP program serving men who have sex with men (MSM) and transgender women (TGW) in Thailand. *Methods*: From January 2016 to December 2017, trained MSM and TGW community health workers delivered same-day PrEP service in community health centres, allowing clients to receive one PrEP bottle to start on the day of HIV-negative testing. Visits were scheduled at Months 1 and 3, and every 3 months thereafter. Uptake, retention and adherence to PrEP services and changes in risk behaviours over time are reported. *Results*: Of 1467 MSM and 230 TGW who started PrEP, 44.1% had had condomless sex in the past 3 months. At Months 1, 3, 6, 9 and 12, retention was 74.2%, 64.0%, 56.2%, 46.7% and 43.9% respectively (lower in TGW than MSM at all visits; $P < 0.001$), with adherence to at least four PrEP pills per week self-reported by 97.4%, 96.8%, 96.5%, 97.5% and 99.5% of respondents respectively (no difference between MSM and TGW). Logistic regression analysis identified age >25 years, being MSM and having at least a Bachelors degree significantly increased retention. Condomless sex did not change over the 12-month period (from 47.2% to 45.2%; $P = 0.20$). New syphilis was diagnosed in 4.9% and 3.0% of PrEP clients at Months 6 and 12 (cf. 7.0% at baseline; $P = 0.007$). Among PrEP adherers and non-adherers, there were one and six HIV cases of seroconversion respectively, which resulted in corresponding HIV incidence rates (95% confidence interval) of 0.27 (0.04–1.90) and 1.36 (0.61–3.02) per 100 person-years. *Conclusion*: Our KP-led PrEP program successfully delivered PrEP to MSM and TGW. Innovative retention supports are needed, especially for TGW and those who are young or with lower education levels. To scale-up and sustain KP-led PrEP programs, strong endorsement from international and national guidelines is necessary.

Additional keywords: community health workers, key populations, key population-led health services, men who have sex with men, same-day pre-exposure prophylaxis, transgender women.

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Introduction

Delivery of pre-exposure prophylaxis (PrEP) is the central priority in this era of ending AIDS. No matter how effective PrEP is, it will not work if the pill is not accessible by individuals who need it most. Data from big cities clearly demonstrate the effect of PrEP in reducing the number of new HIV cases when strategically integrated with early and frequent HIV testing and immediate antiretroviral therapy (ART) for those with HIV infection.[1–3]

In Thailand, men who have sex with men (MSM) and transgender women (TGW) contribute more than half of all new HIV cases each year, more than any other key populations (KPs).[4] Marginalisation due to stigma and criminalisation of same-sex relationships, drug use and sex work are generally limiting access to HIV services by KPs and creating reluctance among providers to reach out.[5]

Since 2015, community health workers who are members of MSM and TGW communities in Thailand have been trained to provide high-quality and non-judgmental HIV counselling and testing as part of the key population-led health services (KPLHS) model, supported by the President's Emergency Plan for AIDS Relief under the US Agency for International Development (USAID) LINKAGES Project. In this context, KP leadership means that the services necessary for addressing the HIV epidemic and related health issues are identified by members of the KP community themselves and are therefore needs based, demand driven and client centred.[6] These services are formally linked to the public health sector and follow standards developed in partnership with the Ministry of Public Health (MOPH) for health service delivery.

As a result, in 2017 alone, KP community health workers contributed 38% of the 41 386 HIV counselling and testing services and 26% of 4840 new HIV diagnoses among MSM and TGW in Thailand (Thailand Routine Integrated HIV Information System, unpubl. data, 2016–17). HIV incidence was 5.86 and 2.48 per 100 person-years among MSM and TGW respectively reached under the KPLHS model, indicating they are priority targets for PrEP.[7] Among 349 MSM and TGW PrEP users enrolled during 2015–16 into a small-scale PrEP implementation research conducted in three provinces in Thailand (ClinicalTrials.gov ID: NCT02369887), 60% stated that they would like to receive PrEP from a community-based organisation, whereas 29% preferred receiving PrEP from a hospital (C. Lertpiriyasuwat, N. Phanuphak, C. Manopaiboon, D. Trachunthong, unpubl. data).

The 2017 World Health Organization (WHO) PrEP implementation tool does not specifically recommend that PrEP be prescribed or dispensed by trained community health workers,[8] although the Joint United Nations Program on HIV/AIDS Task Shifting and Sharing for 90–90–90 checklist for implementation provides support for these roles to be performed by community health workers.[9] Therefore, the actual PrEP service delivery models in the field are guided largely by existing local practices in which the role of prescribing antiretroviral drugs is limited to doctors and/or nurses only. There are no data available on the feasibility of PrEP service delivery by trained KP community health workers. Herein we report the uptake, retention and adherence to PrEP services from the KP-led Princess PrEP program implemented by trained MSM and TGW community health workers in community health centres throughout Thailand.

Methods

From January 2016 to December 2017, PrEP was integrated into HIV services delivered by trained community health workers under the KPLHS model in eight community health centres in four key strategic provinces (Fig. 1) in Thailand. KP community health workers had their capacity built by the LINKAGES project and the Thai Red Cross AIDS Research Centre (TRCARC) to provide quality-assured HIV services based on the reach–recruit–test–treat/prevent–retain cascade (Fig. 1).

PrEP in this program was the generic fixed-dose tenofovir disoproxil fumarate (TDF) 300 mg/emtricitabine (FTC) 200 mg combination table, manufactured by the Thai Government Pharmaceutical Organisation (TENO-EM; Pathumthani, Thailand) and Mylan (RICOVIR-EM; Maharashtra, India). Publicly donated money to the Thai Red Cross Princess Soamsawali HIV Prevention Fund was used to procure generic PrEP pills; hence the name 'Princess PrEP' program. The program was implemented under a study protocol approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, which waived the requirement to obtain informed consent from the clients in order to ensure confidentiality and avoid unnecessary disclosure of self-identity by clients receiving HIV-related services.[10]

Reach–recruit–test–treat/prevent–retain cascade and same-day PrEP flow

Reach and recruit steps at all community health centres, except for the Adam's Love Clinic, which reached and recruited clients through collaboration with Adam's Love (www.adamslove.org, accessed 31 Mar 2018), were conducted using the enhanced peer mobilisation (EPM) approach, detailed elsewhere.[11] Briefly, EPM used trained peer outreach workers to recruit cadres of volunteer peer mobilisers from a variety of social and sexual networks of MSM and TGW with high-risk behaviours. These peer mobilisers referred their peers to obtain HIV services. A cash incentive was provided that naturally refreshed the cadres of peer mobilisers to keep only those who could successfully reach emerging high-risk networks and recruit peers into HIV services.

HIV testing was provided by trained KP-community health workers[6] using third-generation HIV rapid diagnostic tests, with results available in 1 h, in accordance with Thai national guidelines.[12] The three rapid tests used were the Alere Determine HIV 1/2 (Alere Medical, Chiba, Japan) as the first test, and DoubleCheckGold Ultra HIV1&2 (Orgenics, Yavne, Israel) and SD Bioline HIV 1/2 (Standard Diagnostics, Yongin-si, Korea) as the second and the third tests respectively. A non-reactive result from the first test allowed confirmation of HIV-negative status if no risk exposure was reported during the 4-week period before testing. A reactive result from the first test would trigger performing of the other two tests to confirm HIV infection. Syphilis screening using the rapid treponemal pallidum haemagglutination (TPHA) test was performed at
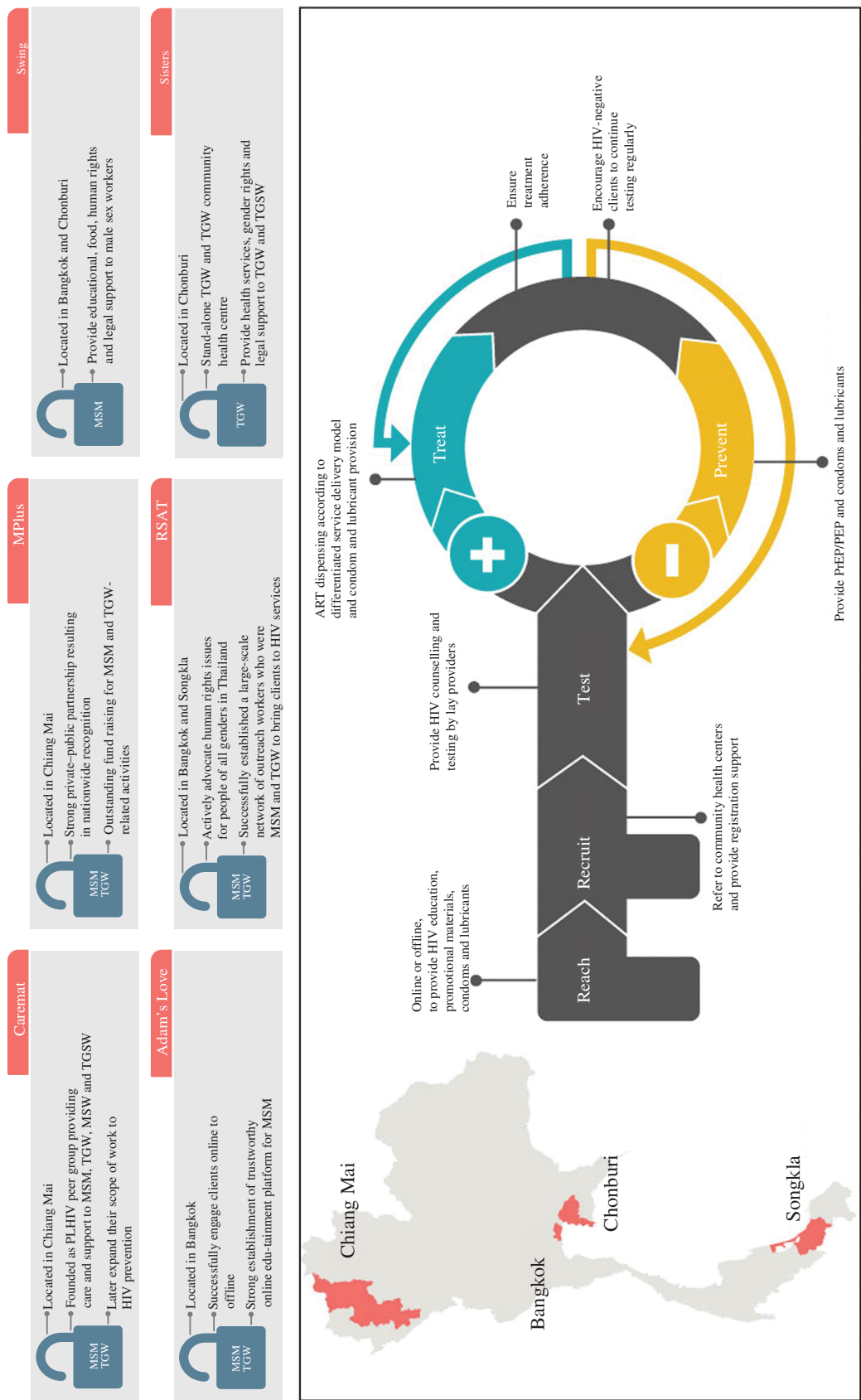
Fig. 1. Community health centres participating in the Princess PrEP program who serve men who have sex with men (MSM) and transgender women (TGW) in four key strategic provinces in Thailand: Bangkok, Chiang Mai, Songkhla and Chonburi. The figure also shows the reach–recruit–test–treat/prevent–retain cascade tailored for key populations in the key population-led health services model. ART, antiretroviral therapy; MSW, male sex workers; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; RSAT, Rainbow Sky Association of Thailand; SWING, Service Workers IN Group; TGSW, transgender sex workers.

baseline and every 6–12 months. Clients with a reactive TPHA result were referred for a rapid plasma reagin (RPR) test and treatment at affiliated public hospitals or clinics. Clients with symptoms indicating other sexually transmissible infections (STI) were also referred for appropriate testing and treatment.

ART regardless of CD4 count was offered to all HIV-positive clients and initiated by physicians either at community health centres or affiliated hospitals. Clients who were stable on ART could select to receive ART maintenance by trained KP community health workers at the community health centres according to the differentiated service delivery model.[13]

A prevention package was offered to all HIV-negative clients and included condoms, lubricants, PrEP and post-exposure prophylaxis (PEP). PrEP was offered to every HIV-negative client who was at risk of HIV infection as mutually assessed by the client and KP community health workers based on any one of the following risks: inconsistent condom use, multiple partners, partners with unsuppressed viral load, STIs, PEP use, drug or substance use and needle sharing in the past 6 months. The client-centred approach ensured that PrEP was offered and the client's decision whether or not to take PrEP was supported by KP community health workers in a non-judgmental and non-coercive manner.

The same-day PrEP flow was used in which HIV-negative clients can receive the first bottle of PrEP, dispensed by KP community health workers, on the same day as receiving an HIV-negative test result (Fig. 2). Serum creatinine (Cr) and hepatitis B surface antigen (HBsAg) were the only two additional tests performed in clients who decided to take PrEP. Blood samples for Cr and HBsAg were sent to an outside laboratory, with a result turnaround time of <1–3 days. Clients were instructed to start PrEP without waiting for estimated glomerular filtration rate (eGFR) and HBsAg results. KP community health workers would inform clients of the results by telephone once the hard or electronic copies of laboratory reports were reviewed by doctors at affiliated hospitals. Clients with an eGFR <60 mL min^{-1} 1.73 m^{-2} would be advised to stop taking PrEP and be referred by KP community health workers for further investigations. Those who tested positive for HBsAg were notified, without discontinuing PrEP if already started, and supported for referral to hepatologists or internists for comanagement. Clients who could continue PrEP were scheduled to come back to see KP community health workers at Months 1 and 3, and every 3 months thereafter. HIV testing was performed at every visit and eGFR was measured every 6 months.

Visit reminders were sent to all clients by KP community health workers within 2 weeks before the scheduled date via popular social networking platforms such as LINE and Facebook. Clients who did not show up received follow-up reminders and telephone calls every week for 1 month and then once a month after that. At every clinic visit, KP community
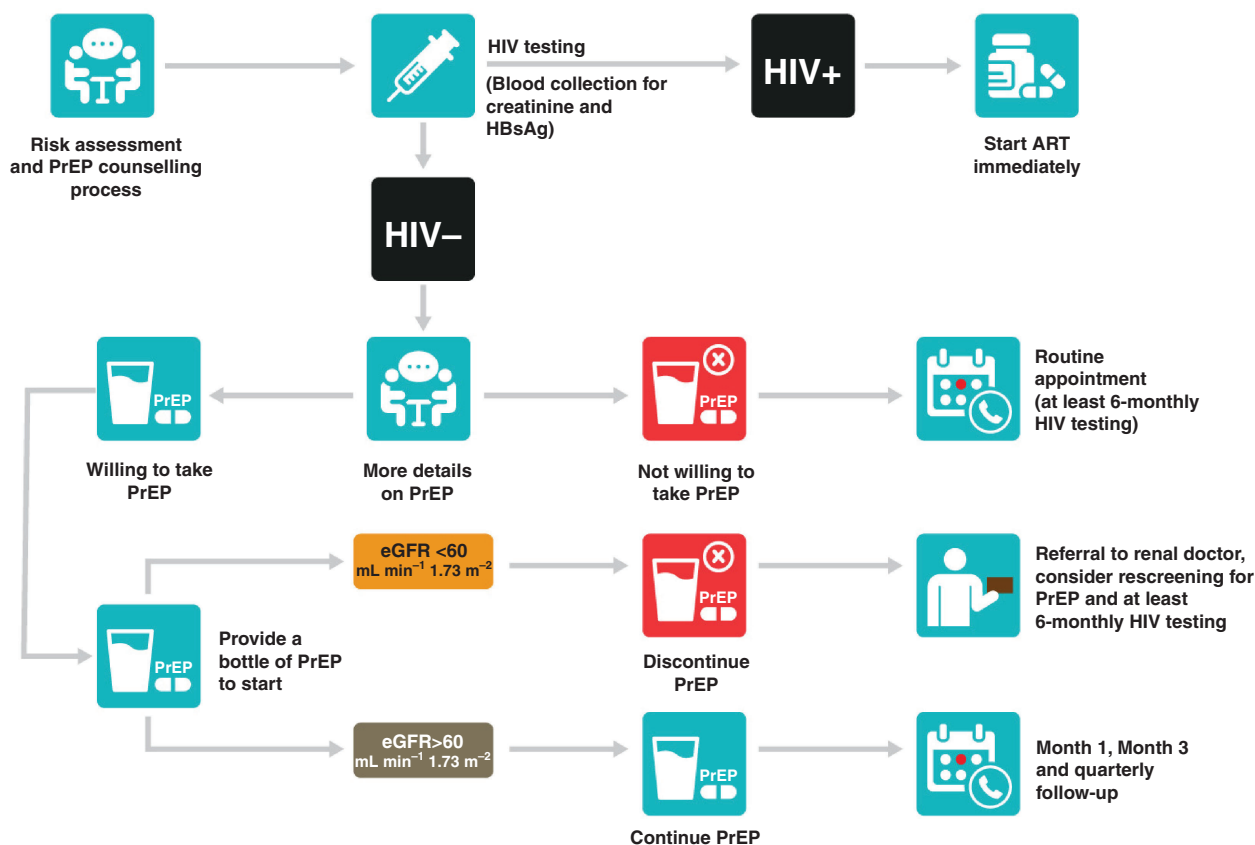

Fig. 2. Same-day pre-exposure prophylaxis (PrEP) flow implemented as part of the key population-led health services model in all participating community health centres. ART, antiretroviral therapy; eGFR, estimated glomerular filtration rate; HBsAg, hepatitis B surface antigen.

health workers counselled PrEP clients about the importance of adherence to PrEP pills and clinic visits based on the life-steps approach, and supported plans to address any challenges identified.[14]

Data collection

PrEP users complete an electronic self-administered questionnaire that collected demographic and risk behaviour data at baseline and every 3 months. KP community health workers recorded self-reported PrEP adherence at every clinic visit in the iClinic data operating system installed at each community health centre. HIV, syphilis, eGFR and HBsAg test results were also recorded in the iClinic system. Data from the iClinic were transferred real time to the central program database.

Data analysis

The proportion of PrEP uptake was calculated based on the number of clients who agreed to take PrEP among those who were offered. Baseline demographic and risk behaviour characteristics of PrEP users were reported among all PrEP users and by gender as frequencies and proportions for categorical variables and as the mean ± s.d. or median with interquartile range (IQR) for continuous variables. Comparisons of continuous variables between groups were made using two-sample *t*-tests or non-parametric tests. Chi-squared or Fisher's exact tests were used for comparisons of proportions of characteristics between groups.

Retention in PrEP clinic visits was reported by visit and gender. PrEP adherence was evaluated based on self-reported number of PrEP pills taken in the past week among those who attended the clinic. Changes in key risk characteristics over time were analysed using trend analysis of proportions. Binary logistic regression analysis was performed to identify factors associated with retention in PrEP services at Months 1, 3, 6, 9 and 12. Factors that were significant ($P = 0.10$) in the univariate model were adjusted for in the multivariate model by the enter method. To evaluate multicollinearity of regression models, we computed correlation coefficients of independent variables by checking related statistics, such as tolerance values or variance inflation factors; model fit was evaluated by computing a goodness-of-fit statistic.

Results

PrEP uptake

From January 2016 to December 2017, 40 757 MSM and 9349 TGW were reached through EPM at seven community health centres. At these centres, 14 970 MSM and 2711 TGW received HIV testing. Of those tested, 4097 MSM and 743 TGW were walk-in clients. There were 1718 MSM (11.5%) and 237 TGW (8.7%) who tested HIV positive. Of 12 488 HIV-negative MSM and 2463 HIV-negative TGW who were offered PrEP, 1166 (9.3%) MSM and 219 (8.9%) TGW agreed to take it. Of approximately 280 000 people reached through the Adam's Love website, 469 people were successfully linked to HIV testing, and 301 MSM and 11 TGW started PrEP. Overall, through the Princess PrEP program, 572 MSM and 89 TGW started PrEP in 2016 and 895 MSM and 141 TGW started PrEP in 2017.

Demographic and behavioural risk characteristics of PrEP clients

Of 1697 clients who started PrEP, 1467 were MSM and 230 were TGW (Table 1). Mean age was 28.8 ± 7.2 years and 37.6% were <25 years of age. Approximately 4% were non-Thai clients, who were mainly Laotians and Cambodians. More than half had at least a Bachelors degree and 10.3% were sex workers.

Most perceived themselves to be at low (38.0%) risk for HIV infection, whereas 31.3% and 15.4% perceived themselves at moderate and high risk respectively. Multiple sex partners in the past 3 months were reported by 63.9% clients, with a median (IQR) number of 3 (2–6) partners; 44.1% did not use condoms consistently. In the past 3 months, 21.1% had had group sex and 32.8% had used drugs or stimulants (6.2% reporting the use of amphetamine-type stimulants). Symptoms and/or diagnoses of STIs in the past 3 months were reported by 8.4% of clients, and 7.5% were unsure about having STIs. Of 1407 MSM and 219 TGW who had syphilis screening before PrEP initiation, 103 MSM (7.3%) and 10 TGW (4.6%) had active syphilis. HBsAg was positive in 75 of 1397 MSM (5.4%) and five of 186 TGW (2.7%) who had test results available.

TGW were significantly younger, had less education, were more likely to be sex workers, had a higher number of sex partners, but were less likely to use drugs or stimulants compared with MSM (Table 1).

Safety laboratory findings

At baseline, six of 1399 MSM (0.4%) and no TGW had an eGFR <60 mL min^{-1} 1.73 m^{-2}. All subsequently started PrEP. An eGFR of <60 mL min^{-1} 1.73 m^{-2} was not found in any MSM at Months 6 and 12, but was detected in one TGW at Month 6, which necessitated PrEP discontinuation.

Retention and adherence to PrEP

Overall retention at Months 1, 3, 6, 9 and 12 was 74.2%, 64.0%, 56.2%, 46.7% and 43.9% respectively (Fig. 3*a*). Retention was significantly lower for TGW than MSM at all visits ($P < 0.001$ for all). Among clients who attended clinic visits and reported currently taking PrEP, adherence to at least four PrEP pills per week was reported by 97.4%, 96.8%, 96.5%, 97.5% and 99.5% at Months 1, 3, 6, 9 and 12 respectively (Fig. 3*b*). There was no difference in adherence between TGW and MSM.

HIV seroconversion among PrEP clients

There were seven cases of HIV seroconversion among PrEP clients; one among PrEP clients who attended all scheduled visits and reported currently taking PrEP (PrEP adherers) and six among those who missed certain scheduled visits and/or reported taking PrEP intermittently (PrEP non-adherers). All cases with HIV seroconversion were MSM.

PrEP adherers and non-adherers contributed 372.7 and 441.5 person-years respectively for HIV incidence analysis. These cases with HIV seroconversion resulted in HIV incidence rates of 0.27 (95% confidence interval (CI) 0.04–1.90) and 1.36 (95% CI 0.61–3.02) per 100 person-years among PrEP adherers and non-adherers, respectively. HIV incidence rates among MSM only were 0.29 (95% CI 0.04–2.03) and 1.55 (95% CI

Table 1.   Baseline demographic and risk characteristics of pre-exposure prophylaxis (PrEP) clients in the Princess PrEP program

Data are given as the mean ± s.d., *n* (%) or as the median [interquartile range]. MSM, men who have sex with men; STIs, sexually transmissible infections; TGW, transgender women; THB, Thai Baht

	Overall (*n* = 1697)	MSM (*n* = 1467)	TGW (*n* = 230)	*P*-value
Demographic data				
Age (years)	28.8 ± 7.2	29.2 ± 7.4	26.1 ± 5.7	<0.001[A]
Age group				
18–25 (years)	638 (37.6)	526 (35.9)	112 (48.7)	<0.001[C]
>25 (years)	1059 (62.4)	941 (64.1)	118 (51.3)	
Nationality				–
Thai	1616 (95.2)	1406 (95.8)	210 (91.3)	
Laotian	29 (1.7)	13 (0.9)	16 (7)	
Cambodian	23 (1.4)	21 (1.4)	2 (0.9)	
Myanmar	8 (0.5)	8 (0.6)	0 (0)	
Others	7 (0.4)	6 (0.4)	1 (0.4)	
Missing	14 (0.8)	13 (0.9)	1 (0.4)	
Education				<0.001[C]
Less than bachelor degree	578 (34.1)	427 (29.1)	151 (65.7)	
Bachelor degree/above	932 (54.9)	871 (59.4)	61 (26.5)	
Refused to answer/missing	187 (11)	169 (11.5)	18 (7.8)	
Main occupation				<0.001[C]
Unemployed/student	353 (20.8)	311 (21.2)	42 (18.3)	
Employed	1148 (67.7)	1038 (70.8)	110 (47.8)	
Sex worker	175 (10.3)	99 (6.8)	76 (33)	
Refused to answer/missing	21 (1.2)	19 (1.3)	2 (0.9)	
Income (THB)				0.02[C]
≤10 000	238 (14)	189 (12.9)	49 (21.3)	
10 001–20 000	500 (29.5)	431 (29.4)	69 (30)	
20 001–50 000 THB	381 (22.5)	337 (23)	44 (19.1)	
>50 000 THB	89 (5.2)	78 (5.3)	11 (4.8)	
Refused to answer/missing	489 (28.8)	432 (29.5)	57 (24.8)	
Ever had HIV testing/services at the community health centre				<0.001[C]
No	1466 (86.4)	1288 (87.8)	178 (77.4)	
Yes	218 (12.9)	167 (11.4)	51 (22.2)	
Missing	13 (0.8)	12 (0.8)	1 (0.4)	
Risk characteristics at baseline				
Age at first sex (years)	18 [16–21]	18 [17–21]	17 [15–19]	<0.001[B]
Age at first sex				
<18 years	548 (32.3)	442 (30.1)	106 (46.1)	<0.001[C]
Missing	151 (8.9)	124 (8.5)	27 (11.7)	
Male circumcision				
No	1165 (68.7)	1014 (69.1)	151 (65.7)	
Yes	242 (14.3)	228 (15.5)	14 (6.1)	0.002[C]
Age of circumcision (years)	10 [3–20]	10 [3–20]	9.5 [4.5–12]	
Refused to answer/missing	290 (17.1)	225 (15.3)	65 (28.3)	
Self-perceived HIV risk in the past 3 months				0.30[C]
No risk	158 (9.3)	137 (9.3)	21 (9.1)	
Low	645 (38)	571 (38.9)	74 (32.2)	
Moderate	531 (31.3)	450 (30.7)	81 (35.2)	
High	262 (15.4)	227 (15.5)	35 (15.2)	
Missing	101 (6)	82 (5.6)	19 (8.3)	
No. sexual partners in the past 3 months				0.003[C]
No sexual partner	48 (2.8)	43 (2.9)	5 (2.2)	
Single partner	331 (19.5)	306 (20.9)	25 (10.9)	
Multiple partners	1085 (63.9)	929 (63.3)	156 (67.8)	
Did not specify no. sexual partners	124 (7.3)	101 (6.9)	23 (10)	
Refused to answer/missing	109 (6.4)	88 (6)	21 (9.1)	
Had group sex in the past 3 months				0.57[C]
No	1148 (67.7)	997 (68)	151 (65.7)	
Yes	358 (21.1)	315 (21.5)	43 (18.7)	
No. times	2 [1–3]	2 [1–3]	3 [2–3]	0.52[B]
No. partners during each group sex	3 [2–3]	3 [2–3]	3 [2–3]	0.34[B]

(*continued next page*)

Table 1.   (*continued*)

	Overall (*n* = 1697)	MSM (*n* = 1467)	TGW (*n* = 230)	*P*-value
Refused to answer/missing	191 (11.3)	155 (10.6)	36 (15.7)	
Condom use in the past 3 months				0.16[C]
Always or no sex	839 (49.4)	738 (50.3)	101 (43.9)	
Sometimes or no	749 (44.1)	641 (43.7)	108 (47)	
Refused to answer/missing	109 (6.4)	88 (6)	21 (9.1)	
Drug/stimulant use in the past 3 months				0.04[C]
No	1104 (65.1)	940 (64.1)	164 (71.3)	
Yes	557 (32.8)	495 (33.7)	62 (27)	
Refused to answer/missing	36 (2.1)	32 (2.2)	4 (1.7)	
Amphetamine-type stimulant use	105 (6.2)	97 (6.6)	8 (3.5)	0.06[C]
Any symptoms or diagnoses of STIs in past 3 months				0.13[C]
No	1256 (74)	1092 (74.4)	164 (71.3)	
Yes	143 (8.4)	129 (8.8)	14 (6.1)	
Unsure	128 (7.5)	105 (7.2)	23 (10)	
Refused to answer/missing	170 (10)	141 (9.6)	29 (12.6)	

[A]*P*-value for comparison of mean values between groups (two-sample *t*-test).
[B]*P*-value for comparison of median values between groups (Mann–Whitney two-statistic test).
[C]*P*-value for comparison of proportions between groups (Chi-squared test).
[D]*P*-value for comparison of proportions between groups (Fisher's exact test).
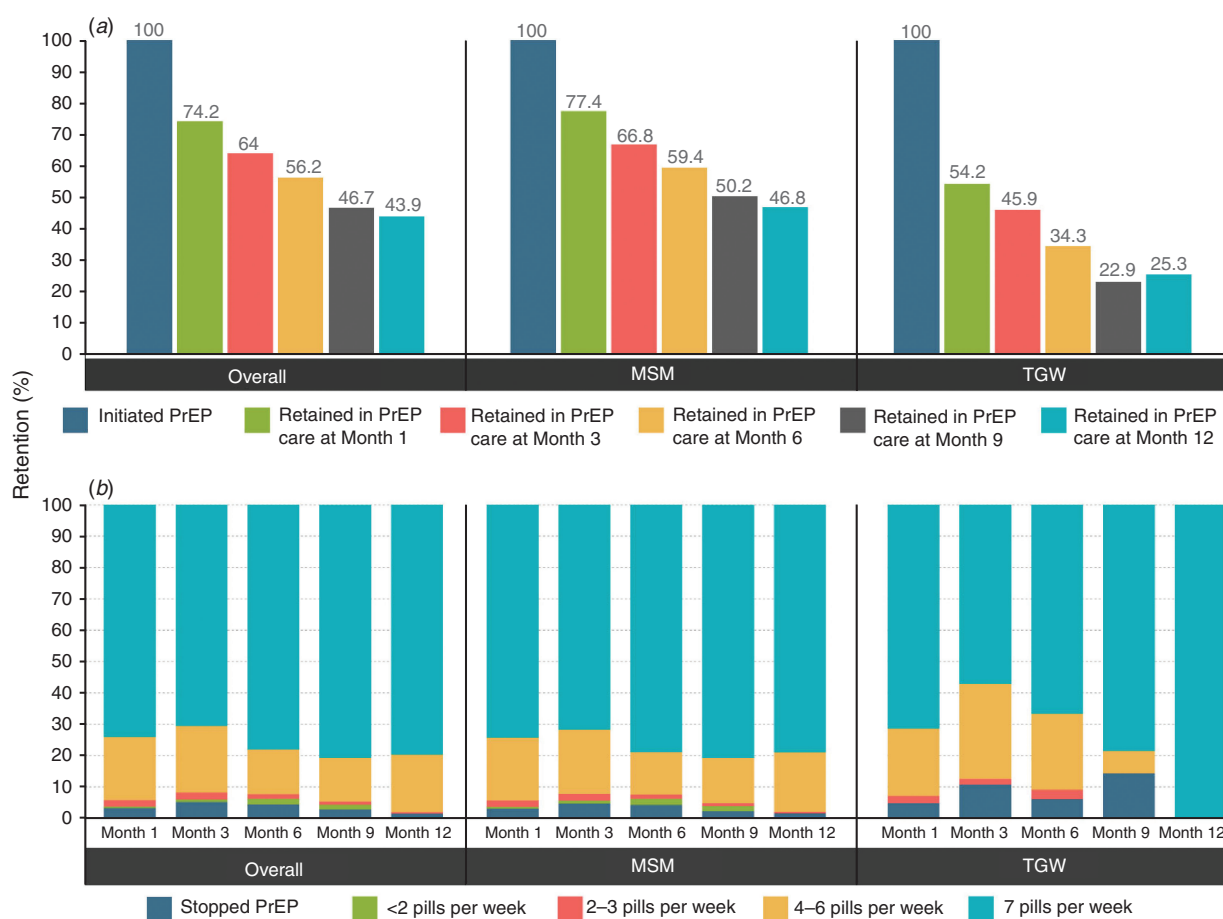

Fig. 3.   Retention in the Princess PrEP program and pre-exposure prophylaxis (PrEP) adherence by (*a*) clinic visit and gender, and (*b*) by the reported number of PrEP pills taken per week by clinic visit and gender. MSM, men who have sex with men; TGW, transgender women.

0.70–3.46) per 100 person-years among PrEP adherers and non-adherers, respectively.

The only case of HIV seroconversion among PrEP adherers was that of a 21-year-old MSM who had reactive results from three third-generation rapid tests at Month 3. He tested non-reactive by the first third-generation rapid test in the testing algorithm at baseline and Month 1 visits. No stored blood samples were available at these two visits for fourth-generation HIV testing and HIV RNA measurement to rule out missed acute HIV infection. At baseline, he perceived himself to be at low risk of getting HIV, although he did report five sexual partners in the past 3 months. He reported using condoms consistently, not using any drugs or stimulants, not having group sex or experiencing STIs in the past 3 months. At the seroconversion visit, he reported having three sexual partners over the 3-month period, one being a regular partner with whom he always used a condom and two being casual partners with whom he only had oral sex without using a condom. One casual partner had reported having group sex 3 months prior to having sex with the MSM who seroconverted. At seroconversion, HIV RNA was 1494 copies mL^{-1} and genotype resistance testing demonstrated an M184I mutation, which was related to high-level resistance to FTC and lamivudine. Another four patients with HIV seroconversion had their HIV-positive status diagnosed 1.5–9 months after discontinuation of PrEP. The last two cases of seroconversion occurred while the clients were on PrEP but after a period(s) of PrEP discontinuation while engaging in high-risk behaviours.

Changes in risk behaviours and syphilis over time

As indicated in Table 2, there were significant reductions over a 12-month period in the proportion of PrEP clients who, in the past 3 months, reported multiple sexual partners (from 68.3% at baseline to 61.3% at Month 12; $P < 0.001$) or joined group sex (from 23.8% at baseline to 17.6% at Month 12; $P < 0.001$). There were no changes from baseline to Month 12 in the proportion of clients reporting condomless sex (47.2% vs 45.2% respectively; $P = 0.20$) or drug or stimulant use (33.5% vs 35.5% respectively; $P = 0.51$) in the past 3 months. New cases of syphilis were diagnosed in 4.9% and 3.0% of participants at Months 6 and 12 respectively, compared with 7.0% at baseline ($P = 0.007$). Syphilis incidence was 7.2 per 100 person-years.

Factors associated with retention in PrEP services

Binary logistic regression analysis identified age >25 years (odds ratio (OR) 1.51; 95% CI 1.16–1.95; $P = 0.002$), being MSM (OR 1.51; 95% CI 1.16–1.95; $P < 0.001$) and having at least a Bachelors degree education (OR 1.48; 95% CI 1.14–1.93; $P = 0.003$) to be associated with retention of PrEP clients at Month 1 (Table 3). These three factors were also significantly associated with retention at Months 3, 6, 9 and 12 (except for being MSM, which was not significant for retention at Month 12). Reporting no condomless sex was found to significantly increase retention at Month 3 (OR 1.35; 95% CI 1.04–1.75; $P = 0.02$) and almost significantly at Month 1 (OR 1.26; 95% CI 0.99–1.61; $P = 0.06$). In addition, self-perceived HIV risk as moderate and/or high significantly decreased

retention at Months 3, 6, 9 and 12 by 26–51% compared with those who perceived themselves to be at no or low risk.

Discussion

The Princess PrEP program is the world's first KP-led PrEP program that successfully delivers PrEP to MSM and TGW at high risk of HIV infection by MSM and TGW community health workers. Approximately 10% of MSM and TGW who were offered PrEP accepted it. Retention in PrEP services decreased gradually to around 60% at Month 6 and 50% at Month 12, with significantly lower retention seen among TGW than MSM. Self-reported PrEP adherence was very high at all visits among MSM and TGW clients who were retained in the service.

The number of PrEP users increased almost 60% over 2 years in our program. This supports previous data in both resource-rich and resource-limited countries in which the number of PrEP users only started to rise significantly after a few years of implementation.[15,16] According to the 3Ps concept laid out by the WHO's Global PrEP Coalition,[17] PrEP uptake depends on several factors, including demand creation among potential PrEP users, PrEP providers and policy makers. Key factors affecting PrEP uptake could vary among countries and populations. Strong demand from potential PrEP users has been shown to successfully drive the availability of PrEP service in the UK,[18] as well as strong commitment secured from policy makers in Australia.[19] In Thailand, 60% of the overall 6642 PrEP users in the country (N. Phanuphak, D. J. Colby, N. Yaemim, C. Manopaiboon, E. F. Dunne, Q. Kaewpoowat, unpubl. data, December 2017) accessed out-of-pocket PrEP through the Pulse Clinic, which is a KP-led private clinic, and the Thai Red Cross Anonymous Clinic in Bangkok. The KP-led Princess PrEP program run by eight community health centres contributed approximately one-quarter of all PrEP users. Another 10% received PrEP through a few small research projects and only <5% of all PrEP users in the country accessed PrEP through 13 public hospitals in seven provinces supported by the Thai MOPH. This strongly suggests that PrEP needs to be urgently demedicalised to enhance access through KP-led community health centres and clinics.

Over a 12-month period, we did not see any changes in risk behaviours among PrEP clients towards behavioural disinhibition. In fact, the proportion of PrEP clients reporting having multiple sex partners and joining group sex decreased over time. Condom use also remained stable. We found that PrEP clients who were not retained tended to practice and perceive higher risk than those who were retained in the program. Loss of people who practiced high-risk behaviour could balance out the overall changes in risk behaviours even if there was an increasing number of those who practiced 'higher'-risk behaviour. However, the lack of an increase in syphilis diagnoses during the same period supports that the overall changes in risk behaviours were not significant.

Retention of MSM in our program was comparable to the 6-month retention rate of 57% among MSM in the US,[20] but much lower than 12-month retention rate of 83% in Brazil.[21] TGW in our PrEP program had much lower retention rates than MSM at all visits. This does not support previous findings from

Table 2.   Changes in behavioural risk characteristics over the first 12-month period among pre-exposure prophylaxis (PrEP) clients in the Princess PrEP program

Unless indicated otherwise, data are given as *n/N*, where *n* is the number of clients who selected a particular response to each question and *N* is the total number of clients who responded to each question, with percentages in parentheses. IQR, interquartile range; STIs, sexually transmissible infections

Behavioural risk characteristics in the past 3 months	Baseline	Month 3	Month 6	Month 9	Month 12	*P*-value
Overall (*n* = 1697)						
Self-perceived HIV risk						
No risk/low	803/1596 (50.3)	482/699 (69)	318/484 (65.7)	217/323 (67.2)	158/229 (69)	
Moderate/high	793/1596 (49.7)	217/699 (31)	166/484 (34.3)	106/323 (32.8)	71/229 (31)	<0.001
Condom use						
Always	839/1588 (52.8)	437/698 (62.6)	277/483 (57.4)	180/323 (55.7)	126/230 (54.8)	
Sometimes/no	749/1588 (47.2)	261/698 (37.4)	206/483 (42.7)	143/323 (44.3)	104/230 (45.2)	0.20
No. sex partners						
Median [IQR]	3 [2–6]	2 [1–5]	3 [1–5]	2 [1–5]	2 [1–4]	<0.001
Multiple partners	1085/1588 (68.3)	399/698 (57.2)	273/483 (56.5)	184/323 (57)	141/230 (61.3)	<0.001
Group sex						
No	1148/1506 (76.2)	525/629 (83.5)	365/439 (83.1)	239/293 (81.6)	173/210 (82.4)	
Yes	358/1506 (23.8)	104/629 (16.5)	74/439 (16.9)	54/293 (18.4)	37/210 (17.6)	<0.001
Drug/stimulant use						
No	1104/1661 (66.5)	456/691 (66)	304/481 (63.2)	214/318 (67.3)	147/228 (64.5)	
Yes	557/1661 (33.5)	235/691 (34)	177/481 (36.8)	104/318 (32.7)	81/228 (35.5)	0.51
Amphetamine-type stimulant use	105/1661 (6.3)	45/691 (6.5)	33/481 (6.9)	21/318 (6.6)	17/228 (7.5)	0.52
Any symptoms or diagnoses of STIs						
No	1256/1527 (82.3)	585/673 (86.9)	392/470 (83.4)	262/312 (84)	188/223 (84.3)	
Yes/unsure	271/1527 (17.8)	88/673 (13.1)	78/470 (16.6)	50/312 (16)	35/223 (15.7)	0.32
PrEP adherers (*n* = 781)						
Self-perceived HIV risk						
No risk/low	365/750 (48.7)	329/477 (69)	224/340 (65.9)	160/245 (65.3)	121/179 (67.6)	
Moderate/high	385/750 (51.3)	148/477 (31)	116/340 (34.1)	85/245 (34.7)	58/179 (32.4)	<0.001
Condom use						
Always	406/748 (54.3)	295/475 (62.1)	193/339 (56.9)	137/245 (55.9)	97/179 (54.2)	
Sometimes/no	342/748 (45.7)	180/475 (37.9)	146/339 (43.1)	108/245 (44.1)	82/179 (45.8)	0.97
No. sex partners						
Median [IQR]	3 [2–5]	2 [1–5]	3 [1–5]	2 [1–5]	2 [1–4]	<0.001
Multiple partners	511/748 (68.3)	273/475 (57.5)	189/339 (55.8)	143/245 (58.4)	107/179 (59.8)	<0.001
Group sex						
No	532/719 (74)	350/425 (82.4)	250/308 (81.2)	175/223 (78.5)	134/165 (81.2)	
Yes	187/719 (26)	75/425 (17.7)	58/308 (18.8)	48/223 (21.5)	31/165 (18.8)	0.02
Drug/stimulant use						
No	503/763 (65.9)	315/469 (67.2)	210/338 (62.1)	160/242 (66.1)	113/177 (63.8)	
Yes	260/763 (34.1)	154/469 (32.8)	128/338 (37.9)	82/242 (33.9)	64/177 (36.2)	0.48
Amphetamine-type stimulant use	56/763 (7.3)	34/469 (7.3)	25/338 (7.4)	19/242 (7.9)	13/177 (7.3)	0.99
Any symptoms or diagnoses of STIs						
No	606/728 (83.2)	397/456 (87.1)	278/331 (84)	196/238 (82.4)	146/173 (84.4)	
Yes/unsure	122/728 (16.8)	59/456 (12.9)	53/331 (16)	42/238 (17.7)	27/173 (15.6)	0.93
PrEP non-adherers (*n* = 916)						
Self-perceived HIV risk						
No risk/low	438/846 (51.8)	153/222 (68.9)	94/144 (65.3)	57/78 (73.1)	37/50 (74)	
Moderate/high	408/846 (48.2)	69/222 (31.1)	50/144 (34.7)	21/78 (26.9)	13/50 (26)	<0.001
Condom use						
Always	433/840 (51.6)	142/223 (63.7)	84/144 (58.3)	43/78 (55.1)	29/51 (56.9)	
Sometimes/no	407/840 (48.5)	81/223 (36.3)	60/144 (41.7)	35/78 (44.9)	22/51 (43.1)	0.08
No. sex partners						
Median [IQR]	3 [2–8]	2 [1–4.5]	3 [1–5]	3 [1–5]	3 [1–5]	0.001
Multiple partners	574/840 (68.3)	126/223 (56.5)	84/144 (58.3)	41/78 (52.6)	34/51 (66.7)	0.003
Group sex						
No	616/787 (78.3)	175/204 (85.8)	115/131 (87.8)	64/70 (91.4)	39/45 (86.7)	
Yes	171/787 (21.7)	29/204 (14.2)	16/131 (12.2)	6/70 (8.6)	6/45 (13.3)	<0.001

Behavioural risk characteristics in the past 3 months	Baseline	Month 3	Month 6	Month 9	Month 12	P-value
Table 2. *(continued)*						
Drug/stimulant use						
No	601/898 (66.9)	141/222 (63.5)	94/143 (65.7)	54/76 (71.1)	34/51 (66.7)	
Yes	297/898 (33.1)	81/222 (36.5)	49/143 (34.3)	22/76 (29)	17/51 (33.3)	0.91
Amphetamine-type stimulant use	49/898 (5.5)	11/222 (5)	8/143 (5.6)	2/76 (2.6)	4/51 (7.8)	0.91
Any symptoms or diagnoses of STIs						
No	650/799 (81.4)	188/217 (86.6)	114/139 (82)	66/74 (89.2)	42/50 (84)	
Yes/unsure	149/799 (18.7)	29/217 (13.4)	25/139 (18)	8/74 (10.8)	8/50 (16)	0.14

Table 3.   Factors associated with retention in the Princess PrEP program at Months 1, 3, 6, 9 and 12 as determined by binary logistic regression analyses

All models were adjusted by age at first sex. The Month 3 model was adjusted by the number of sex partners and sexually transmissible infections in the past 3 months. The Month 3 and Month 9 models were adjusted by group sex in the past 3 months. The Month 9 and Month 12 models were adjusted by previous HIV testing or services at the community health centre. CI, confidence interval; MSM, men who have sex with men; OR, odds ratio; TGW, transgender women

Factors	Univariable		Multivariable	
	OR (95% CI)	P-value	OR (95% CI)	P-value
Month 1 (*n* = 1660)				
Age >25 years	1.77 (1.42–2.21)	<0.001	1.51 (1.16–1.95)	0.002
Gender				<0.001
TGW	1 (Reference)		1 (Reference)	
MSM	2.89 (2.17–3.86)	<0.001	1.51 (1.16–1.95)	
Education		<0.001		0.003
Less than Bachelors degree	1 (Reference)		1 (Reference)	
Bachelors degree and above	2.06 (1.65–2.58)		1.48 (1.14–1.93)	
Condom use in the past 3 months		0.03		0.06
Always	1 (Reference)		1 (Reference)	
Sometimes/no	1.30 (1.03–1.64)		1.26 (0.99–1.61)	
Month 3 (*n* = 1465)				
Age >25 years	1.92 (1.54–2.38)	<0.001	1.48 (1.13–1.93)	0.005
Gender		<0.001		0.004
TGW	1 (Reference)		1 (Reference)	
MSM	2.37 (1.75–3.22)		1.72 (1.19–2.50)	
Education		<0.001		<0.001
Less than Bachelors degree	1 (Reference)		1 (Reference)	
Bachelors degree and above	2.28 (1.83–2.83)		1.81 (1.38–2.37)	
Self-perceived HIV risk in the past 3 months		<0.001		
No or low risk	1 (Reference)		1 (Reference)	
Moderate	0.65 (0.51–0.84)		0.83 (0.62–1.11)	0.21
High	0.55 (0.4–0.76)		0.64 (0.44–0.94)	0.02
Condom use in the past 3 months		<0.001		0.02
Always	1 (Reference)		1 (Reference)	
Sometimes/no	1.53 (1.23–1.91)		1.35 (1.04–1.75)	
Month 6 (*n* = 1162)				
Age >25 years	1.87 (1.47–2.38)	<0.001	1.41 (1.07–1.86)	0.02
Gender		<0.001		0.001
TGW	1 (Reference)		1 (Reference)	
MSM	2.80 (1.95–4.03)		2.01 (1.32–3.06)	
Education		<0.001		<0.001
Less than Bachelors degree	1 (Reference)		1 (Reference)	
Bachelors degree and above	2.53 (1.99–3.22)		1.97 (1.49–2.61)	
Self-perceived HIV risk in the past 3 months		<0.001		0.002
No or low risk	1 (Reference)		1 (Reference)	

(continued next page)

Table 3. (*continued*)

Factors	Univariable		Multivariable	
	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Moderate	0.68 (0.52–0.89)		0.74 (0.55–0.99)	
High	0.46 (0.31–0.67)		0.49 (0.32–0.74)	
No. sexual partners in the past 3 months		0.004		
Multiple partners	1 (Reference)		1 (Reference)	
No or single sexual partner	1.51 (1.15–1.99)		1.34 (0.99–1.81)	0.055
Had sex in the past 3 months but did not specify no. sexual partners	0.85 (0.57–1.28)		0.96 (0.61–1.52)	0.86
Month 9 (*n* = 927)				
Age >25 years	1.98 (1.51–2.61)	<0.001	1.68 (1.2–2.34)	0.002
Gender				0.004
TGW	1 (Reference)	<0.001	1 (Reference)	
MSM	3.40 (2.16–5.33)		2.21 (1.29–3.78)	
Education		<0.001		<0.001
Less than Bachelors degree	1 (Reference)		1 (Reference)	
Bachelors degree and above	2.85 (2.17–3.74)		1.93 (1.38–2.71)	
Self-perceived HIV risk in the past 3 months		<0.001		
No or low risk	1 (Reference)		1 (Reference)	
Moderate	0.65 (0.48–0.88)		0.76 (0.54–1.07)	0.11
High	0.39 (0.25–0.62)		0.55 (0.33–0.91)	0.02
No. sexual partners in the past 3 months		<0.001		
Multiple partners	1 (Reference)		1 (Reference)	
No or single sexual partner	1.76 (1.3–2.37)		1.54 (1.07–2.21)	0.02
Had sex in the past 3 months but did not specify no. sexual partners	0.76 (0.48–1.23)		0.93 (0.53–1.61)	0.78
Month 12 (*n* = 727)				
Age >25 years	1.95 (1.43–2.65)	<0.001	1.53 (1.08–2.16)	0.02
Gender				0.07
TGW	1 (Reference)	<0.001	1 (Reference)	
MSM	2.61 (1.61–4.21)		1.64 (0.95–2.83)	
Education		<0.001		0.005
Less than Bachelors degree	1 (Reference)		1 (Reference)	
Bachelors degree and above	2.54 (1.87–3.47)		1.69 (1.18–2.43)	
Self-perceived HIV risk in the past 3 months		0.001		0.006
No or low risk	1 (Reference)		1 (Reference)	
Moderate	0.57 (0.4–0.8)		0.58 (0.4–0.84)	
High	0.55 (0.34–0.88)		0.59 (0.36–0.97)	

the iPrEx (Iniciativa Profilaxis Pre-Exposición) and PrEP Brasil, which found retention to be comparable between MSM and TGW.[21,22] Similar to the PrEP Brasil data, we did not see lower PrEP adherence among TGW than MSM. The iPrEx study, however, found lower PrEP adherence among TGW than MSM.[23] Concerns around possible drug interactions between TDF or FTC and gender-affirming hormones were cited as one of the possible reasons behind poor PrEP adherence among TGW.[22] Because gender-affirming hormones used by TGW could differ by country and region, pharmacokinetic studies to confirm the absence of drug interactions when PrEP is used with different hormones at various dosages in each local context are urgently needed.[24] Our findings point to the serious need to focus retention support on younger MSM and TGW and those with less education in Thailand. These factors were not found to predict retention in PrEP programs in the US or Brazil.[20,21] Therefore, retention support would need to be tailored according to local settings and populations, as well as adapted over each individual client's course of PrEP use. Innovative tools, including the use of mobile health technologies, to support PrEP retention and adherence have been explored with preliminary positive results.[21,25,26] Gamification also has high potential to support PrEP retention and adherence, especially among youth.[27] We also found low retention among MSM and TGW who perceived themselves to be at moderate to high risk for HIV, whereas reporting no condomless sex was associated with good retention. Studies on PrEP retention and adherence, accounting for individual's choices, risk perception and dynamic behaviours, should be a high priority research area to support ongoing global PrEP scale-up programs.[28] This certainly is an area where the social sciences could make a very meaningful contribution to further guide PrEP service provision focusing on increasing retention among those who are most vulnerable to HIV infection.

The only client with HIV seroconversion among the PrEP adherers in this study had an FTC-resistant mutation detected in his seroconversion visit sample. We could not retrieve a blood sample from the potential source person of his infection and therefore could not confirm whether this resistant mutation was transmitted or acquired. Available data suggest that TDF and FTC in combination are needed for PrEP to have full

protective effects in MSM. The two studies that demonstrated PrEP efficacy among MSM used TDF and FTC.[29,30] Moreover, there were two reported cases of PrEP failure in MSM who took TDF monotherapy for hepatitis B treatment.[31] The case of HIV seroconversion among the PrEP adherers could be a true case of PrEP failure or a case of acquired FTC-resistant virus, which confirms inadequate protection of PrEP among MSM with only active TDF. Missed acute or early HIV infection could still be the possibility in this case given that he client's seroconversion occurred early, at Month 3 after PrEP initiation. Reported good adherence could also result in delayed seroconversion and a false-negative third-generation HIV rapid test at the Month 1 visit. Therefore, the M184I mutation in this case could be an acquired mutation after 3 months of PrEP use during high viremia. Unfortunately, we did not store blood samples from baseline and Month 1 visits in our PrEP program and could not undertake further investigations to rule out this possibility.

The present study has some limitations. PrEP adherence was self-reported, which could overestimate actual adherence due to social desirability. However, we found only one case of seroconversion among 372.2 person-years contributed by PrEP adherers and six cases among 441.5 person-years of PrEP non-adherers, which likely confirms the accuracy of self-reported adherence. We did not perform regular laboratory screening for gonorrhoea and chlamydia due to the extremely high cost of molecular-based STI testing in Thailand, and therefore could not demonstrate the effect of PrEP use on these two STIs. This is obviously a missed opportunity to test and treat in order to control the epidemics of these common STIs. Although the absence of behavioural risk disinhibition and the lack of an increase in cases of syphilis during the first 12 months of the program were reassuring, one cannot completely exclude the possibility that these issues could become apparent with a longer follow-up time, as suggested by a few programs.[32,33] There is an urgent need for point-of-care STI testing that is affordable and validated for use with samples collected from different anatomical.[34] However, the lack of strong STI screening and treatment systems should not be used as an excuse for not starting PrEP services, because STIs have not been found to undermine PrEP efficacy.[33] In settings where access to molecular-based STI testing is cost-prohibitive, the use of rapid STI testing with in-house validation could be another option to explore.

To ensure high-quality PrEP and other services under KPLHS, the TRCARC is working in collaboration with community-based organisations run by KPs and the MOPH towards establishing a technical assistance platform to provide training and certification of KP community health workers through the USAID Community Partnership program. In addition, the LINKAGES program in Thailand is exploring financing mechanisms to allow domestic funding support for KPLHS. Strong endorsement of KP-led PrEP service delivery in international and national guidelines is crucial for the scale-up and sustainability of this very effective model to bring PrEP to the right people.

Conclusion

PrEP service delivery by KP community health workers is feasible and effective among MSM and TGW in Thailand.

Retention in PrEP programs is a concern, especially among TGW and those who were young or with lower levels of education; innovative tools are needed to support these populations. STI screening and treatment infrastructures must be immediately strengthened and programs and health systems should advocate for access to cheaper molecular-based STI testing. To scale-up and sustain KP-led PrEP programs, strong endorsement from international and national guidelines is necessary.

Conflicts of interest

The authors declare they have no conflicts of interest.

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