# Prepped for PrEP: A pilot intervention to assess the acceptability, feasibility and sustainability of pre-exposure prophylaxis in men who have sex with men, transgender women and discordant couples in Ho Chi Minh City, Vietnam

**Project Title**: USAID/PATH Healthy Markets

**Award Number:** AID-440-A-14-00002

## Abstract

***Background***: HIV prevalence among men who have sex with men (MSM) and transgender women (TGW) in Vietnam is high while coverage of effective HIV prevention services has been inadequate. Studies have measured MSM and TGW demand for pre-exposure prophylaxis (PrEP) services which led to the design of the first ever PrEP program in Vietnam, Prepped for PrEP (P4P).

***Methods*:** In March 2017, PrEP services were offered in Ho Chi Minh City as part of the P4P demonstration project, enabling same day enrolment in three key population (KP)-led clinics and four public clinics. P4P aimed to assess acceptability and feasibility of PrEP services through calculating rate of PrEP enrolment over time, and quarterly measures of continuation and adherence over an 18-month period.

***Results:*** A total of 1069 MSM and 62 TGW enrolled in P4P. Average monthly PrEP enrolment increased five-fold from the first three months (March-June 2017) to the last three months of active enrolment (March-June 2018). Self-reported PrEP adherence was greater than 90% at all time points among MSM but varied from 11.1% to 88.9% among TGW. PrEP continuation was calculated at months 3,6,9,12,15 and 18. For MSM it was 88.7% at month 3, 68.8% at month 12 and 46.6% at month 18 while for TGW it was 87.1%, 54.8% and 52.8%, respectively. Multivariable regression identified that MSM with lower than average income (aOR 2.38 (95% CI:1.59-3.54), p=0.000); older than 30 years of age (aOR 2.03 (95% CI:1.30-3.40), p=0.007); and with increasing number of sex partners (ExpB: 1.06 (1.01-1.11), p=0.011) had greater odds of remaining on PrEP. For TGW being older than 30 years of age was associated with continuing on PrEP (aOR 5.62 (95% CI:1.05-29.9), p=0.043).

***Conclusions:*** We found PrEP to be highly acceptable among MSM and moderately acceptable among TGW. Continuation rates were relatively high for the first roll-out of PrEP; however, those age 30 or younger were much more likely to discontinue services. Scaling-up PrEP through differentiated and community-led and engaged PrEP service delivery will be key to effectively increase access and uptake over the next five years.

## Introduction

Oral HIV pre-exposure prophylaxis (PrEP) has been recommended as a critical prevention strategy among men who have sex with men (MSM), transgender women (TGW), and HIV sero-discordant couples since 2012, and for all populations at substantial risk of HIV since 2015.[1,2] Where PrEP has been offered at scale alongside successful efforts to test and treat people living with HIV (PLHIV), year-on-year declines in new infections have been observed—as much as 50% in San Francisco over five consecutive years and 74% in Uganda and Kenya combined.[3,4,5] However, roll-out has been slow in most lower and middle income (LMIC) Asia-Pacific countries.[6]

In Vietnam, HIV prevalence among MSM has been on the rise since 2011, increasing from 4% to 10.8% in 2018.[7,8,9] While there are no surveillance studies in place among TGW who have sex with men, one cross-sectional study in Ho Chi Minh City (HCMC) measured an HIV prevalence of 18% in 2016.[10]

Overall coverage of HIV prevention and testing efforts among MSM and TGW has been limited, in part due to funding constraints but also because HIV services were relatively uniform and offered primarily in the public sector, with a relatively circumscribed role for MSM and TGW community-based organizations (CBOs).[11] HIV prevention interventions among MSM and TGW were characterized as peer condom distribution and referrals for HIV testing.[12] As a proxy of HIV service reach, annual HIV testing among MSM (there is no such data for TGW) measured through surveillance studies was 33% on average from 2011-2015.[13]

In late 2015, the Ministry of Health in Vietnam approved a pilot for CBO delivered HIV lay-and self-testing. In HCMC and Hanoi, these services significantly boosted uptake of HIV testing among those who had never tested before and were at risk of HIV exposure. The key population (KP)-led community testing intervention utilized online platforms such as Facebook and Grindr to access MSM and TGW who would otherwise not be reached by traditional communication efforts, thereby significantly expanding potential connection with those at risk of HIV. Community HIV testing elevated the role, profile, and growth of KP CBOs, a sub-set of which gained the expertise and resources to establish licensed private clinics in HCMC.[14,15] The first, Glink clinic, was registered in 2016, followed by Galant and My Home clinics.

In the same year, an online and in-person assessment of PrEP acceptability, service preferences, and willingness to pay was conducted in HCMC and Hanoi among MSM and TGW. Using convenience sampling, 799 individuals (727 MSM and 72 TGW) opted to respond to the survey. Of those interviewed, 91% self-assessed as being at risk of HIV and 89% said they would opt for PrEP if available. Importantly, when asked about service preferences, 71% stated a preference for PrEP to be delivered by a KP organization, while

only 13% selected a preference for accessing PrEP through the public sector. In addition, 83.2% responded that they were willing to pay for PrEP and of those 75.6% were willing to pay 0.86 cents, while 63.7% per $1.30 day for PrEP.[1617,18]

In 2016, the Vietnam Administration for HIV/AIDS Control (VAAC), KP leaders, and PATH, through the US Agency for International Development (USAID) funded Healthy Markets project, co-created Vietnam's first PrEP program titled 'Prepped for PrEP' (P4P) which was launched in March 2017. The aim of P4P was to assess acceptability and feasibility of PrEP services among MSM, TGW, and HIV-negative partners of those newly HIV diagnosed, and to ultimately trigger larger adoption and scale-up of PrEP through the US President's Emergency Plan for AIDS Relief (PEPFAR), Global Fund, and Vietnam public sector financing. This paper describes the intervention, methods, results, and implications of a rolling enrolment observational study that was embedded within the P4P program in HCMC, Vietnam from March 2017 to September 2018 to inform national scale-up of PrEP services.

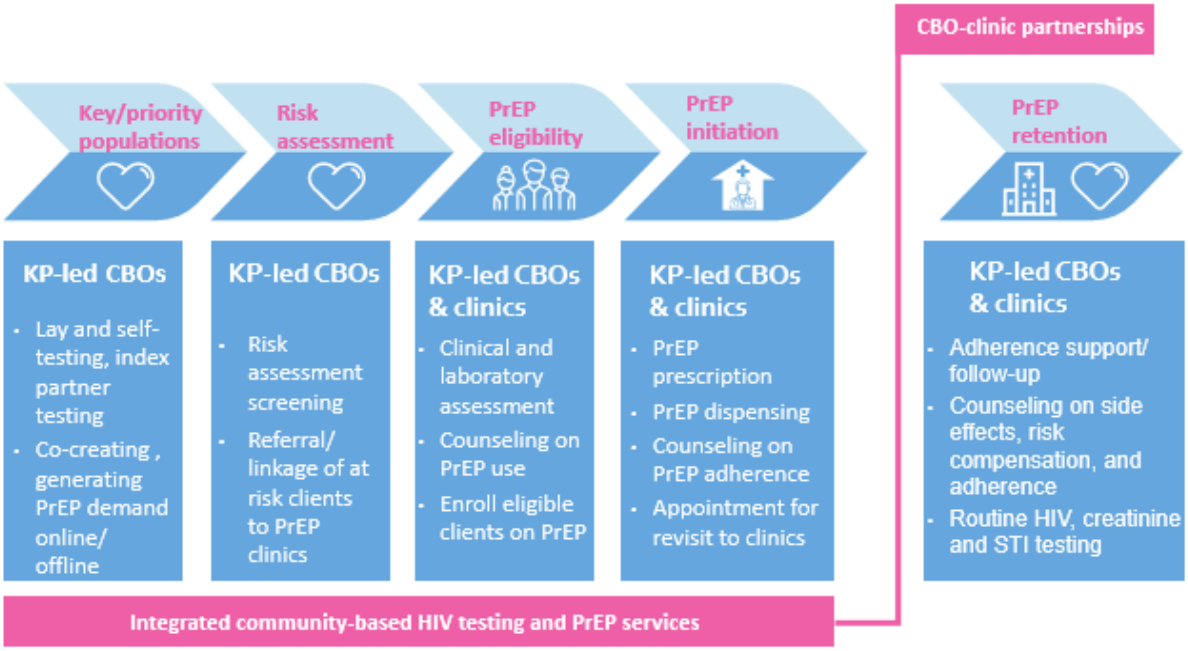
## Methods

The P4P service delivery model was defined through a process of consultation throughout 2016 with KP leaders and organizations, local clinics both private and public, and with the VAAC and HCMC Provincial AIDS Centre. Engagement to shape the PrEP service delivery model was both formal and informal and included a blended online and in-person survey among MSM and TGW to assess PrEP acceptability and service preferences (described above), as well as a study tour to Bangkok to learn from PrEP implementation through the PEPFAR/USAID- and LINKAGES-supported Thai Red Cross PrEP-30 (now PrEP-15) and Princess PrEP services. The study tour enabled the Vietnam delegation to better prepare for PrEP start-up and included representation from KP CBOs, public and private clinics, the HCMC provincial AIDS centre, the VAAC, and USAID.

In February 2017, the VAAC approved implementation of P4P through which daily oral PrEP would be made available to up to 1,200 MSM, TGW, and HIV-negative partners of those that were newly HIV diagnosed and enrolled on antiretroviral therapy (ART) in seven clinics in HCMC. These clinics included three that were KP-led private community clinics—Glink, Galant, and My Home—and four public out-patient clinics (OPCs) in Districts 1, 8, 11, and Thu Duc. The same month, staff from the seven clinics, nine KP CBOs, and the HCMC provincial AIDS centre were trained in PrEP service delivery. The training included screening for PrEP eligibility, PrEP monitoring, and counselling for PrEP continuation. PrEP services through P4P launched in March 2017.[19]

P4P was designed as a partnership between KP-led CBOs, KP-led clinics, and public HIV OPCs. Figure 1 illustrates how KP CBOs and the public and private clinics work together to ensure optimal PrEP access and continuation. Given their extensive role in HIV prevention counselling and HIV lay-, self-, and index-testing, KP CBOs played a critical role in providing information about PrEP to clients that tested HIV negative, doing a pre-screen for eligibility and then referring them for PrEP services at one of the seven participating clinics. In addition, since most KP CBOs are heavily engaged online, they posted information on PrEP and where to go for PrEP services on their social media and websites. Individuals were then enrolled in same-day PrEP at one of the seven clinics and received support from KP CBOs to continue PrEP for as long as they remained at risk and opted for PrEP as their primary method for HIV prevention.

**Figure 1. PrEP service delivery: a KP CBO and clinic partnership model**

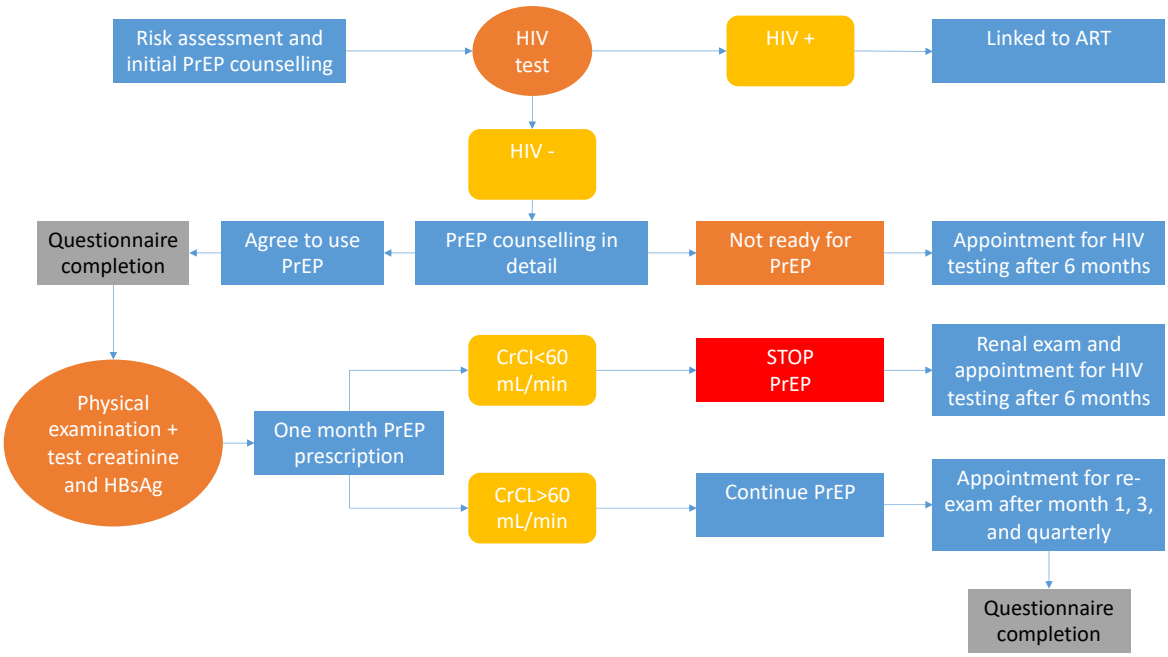



Given P4P was the very first PrEP service delivered in Vietnam, no public or large-scale donor financing was available. Therefore, a pragmatic fee-based approach was put in place based on data generated from the previously described December 2016 PrEP acceptability and willingness to pay survey, and experience from the Thai Red Cross's PrEP-30 program.[20,21] A small donation from Mylan allowed for the first month to be free so clients could try PrEP and then decide if they wanted to continue. Thereafter, the cost for PrEP was $15 a month which covered the price of Mylan's India-manufactured and locally registered RICOVIR-EM [fixed-dose tenofovir disoproxil fumarate (TDF) 300 mg/emtricitabine (FTC) 200 mg - TDF/FTC]. The costs for client consultation and follow-up, and essential laboratory

investigations (HIV, serum creatinine, and hepatitis B), were subsidized by the USAID/PATH Healthy Markets project.

Same-day client enrolment for PrEP was standardised across sites. Clients who sought PrEP services at one of the seven participating clinics were first assessed for HIV risk. Risk factors included one of the following: having insertive and/or receptive condomless anal sex, having sex with someone known to be living with HIV but virally unsuppressed, having multiple sex partners, injecting drugs or using amphetamine-type substances in the past 6 months, or otherwise perceiving themselves at risk of HIV (see Figure 2 for P4P service flow). Those who were eligible then received information on the monthly cost of PrEP, the service package, STI prevention and condom use, and frequency of clinic visits for PrEP monitoring. After this, clients could then opt-in or opt-out of the service. For clients who opted out, HIV prevention counselling was offered based on the client need. For clients who opted in, individuals were screened for acute HIV infection (AHI) influenza-like symptoms and tested for HIV using the rapid 4$^{th}$ generation antigen/antibody test, Alere™ HIV Combo. Individuals found to have HIV were supported to seek a confirmation diagnosis and enrol for ART at the clinic of their choosing.

**Figure 2. PrEP eligibility and service and study flow**




Clients who were HIV-negative and behaviourally eligible for PrEP were also tested for serum creatinine (Cr) levels and hepatitis surface antigen (HBsAg). Results for both tests were returned by the next day. Individuals who had an estimated glomerular filtration rate

(eGFR) of <60 mL min were advised to stop taking PrEP and to see a renal specialist. Those who were HBsAg reactive were referred to a hepatologist for further assessment so that those with chronic hepatitis B virus (HBV) could be managed by a specialist and receive dual benefit of TDF/FTC for HIV prevention and HBV management.

Clients were also counselled on the benefits of testing for syphilis, chlamydia, and gonorrhoea, as well as for hepatitis C virus (HCV), and recommended to seek repeat testing for these diseases at least every 6 months. Testing for STIs and HCV were fee-based and an additional cost to the base monthly payment.

Client follow-up was then conducted at Month 1 (M1), where clients were re-tested for HIV to rule out an AHI, and then again at M3 for another follow-up HIV test. Thereafter, follow-up was conducted quarterly and eGFR every 6 months. Each clinic put in place baseline and follow-up clinical records and logbooks for tracking longitudinal PrEP continuation.

PrEP services were heavily advertised online through two separate dedicated Facebook pages—Rainbow Village for reaching MSM and Be Me Be Happy for reaching TGW—in addition to Grindr adverts, KP CBOs, and word of mouth. The Facebook pages included online peer influencers that screened for HIV testing and PrEP needs and made direct referrals to the three KP-led clinics. The demand for PrEP information was so profound that a Chat Bot was added to both Facebook sites to provide 24/7 responses to routine questions.

### *Study design*

We embedded an observational study into routine PrEP service delivery as part of P4P. The study involved rolling enrolment of new PrEP users over an 18-month period among MSM, TGW, and HIV sero-discordant couples in three KP-led clinics and four public district hospital HIV OPCs in HCMC. For the purposes of this paper, we are focusing only on the study outcomes among MSM and TGW. The primary objective of the P4P study was to assess acceptability and feasibility of PrEP. Herein we define the overall acceptability of PrEP as part of P4P by change in rate of enrolment month-on-month, continuation rates at months 3 through 18, reasons for discontinuation, and factors associated with PrEP continuation.

We also measured self-reported sexual and drug use behaviours at baseline and quarterly, self-reported adherence and HIV sero-conversions during PrEP use and among those that discontinued PrEP (see Table 1 for definitions of key outcomes).

**Table 1. Definition and source of key study outcomes**

| Measure | Definition | Source |
|---|---|---|
| **1.** Change in rate of enrolment | Net increase, plateau, or decrease in new PrEP enrolees quarterly comparing first and last three months of active enrolment | Monthly clinic enrolment reports |
| **2.** PrEP continuation | Returning for next designated appointment and leaving with a PrEP refill/total number enrolled | Clinic records |
| **3.** PrEP discontinuation and reasons for discontinuation | Number and percentage of individuals stopped PrEP use and why they stopped use | Online self-administered survey |
| **4.** Self-reported adherence and HIV sero-conversions | No. of PrEP pills taken in past week<br><br>Number of people who HIV seroconvert while using PrEP | Alternating quarterly health care worker and self-administered online survey; clinic records |

### *Participants, recruitment, and data collection*

Eligibility requirements for the P4P study for MSM and TGW were: self-identified MSM or TGW, being aged 18 years or older, living in HCMC (at least 3 months), HIV negative status, and at least one risk behaviour in the past 6 months. Individuals with abnormal eGFR levels of < 60 ml/min, or those with active HBV that required follow-up care from a hepatologist were ineligible for PrEP and for study enrolment.

MSM and TGW were informed of the study through participating CBOs, clinics, and social media promotion. Access to PrEP was not contingent on study enrolment. Those who opted to participate in the P4P study completed the informed consent process where the study's purpose, process, and potential risks and benefits were discussed. Trained research staff conducted the interviews using computer-assisted personal interviewing at M0, M6, M12, and M18. A self-administered survey was implemented at M3, M9, and M15. PrEP service logbooks were accessed to measure longitudinal continuation over time and clinical records provided information on eGFR results. Finally, a self-administered PrEP discontinuation survey was sent to all those who dropped out of the P4P study.

Since P4P involved rolling enrolment study, clients were able to enrol from the start of the study in March 2017 to the end, in September 2018. However, active enrolment concluded in June 2018 while passive enrolment continued from July-September 2018. A 'take all' method for enrolment was applied, wherein every client who met the abovementioned criteria and opted in for PrEP and to participate in the study was enrolled. Data collected included socio-demographical information; sexual and drug use behaviours; past PrEP use; self-reported adherence to PrEP use (number of pills taken in past 7 days where 4 or more pills was the threshold for optimal adherence among MSM and 7/7 pills in past week optimal adherence for TGW); side effects; baseline and follow-up eGFR; self-reported STIs

and results from STI tests conducted at the clinic; acceptability of quarterly returns for required lab test and prescription pick-up; and willingness to pay.

The study was approved by the Hanoi School of Public Health institutional review board in Hanoi, Vietnam, in December 2016. PATH's research determination committee reviewed the protocol and determined it as non-research. An oral informed consent process was implemented and obtained from all participants.

### *Data analysis*

Paper-based PrEP surveys and medical records were entered into a Kobo Toolbox application that hosts Open Data Kit program. Data were then downloaded from the server and analysed using SPSS Version 22.0.

The main outcome of interest was PrEP continuation over time, and the factors that were associated with PrEP continuation. Univariable logistic regressions were conducted to identify socio-behavioural factors independently associated with PrEP continuation and were analysed separately for MSM and TGW. Variables found to be statistically associated with a p-value of <0.05 were included in the multivariable logistic regression model. The final model was generated using backward elimination of variables with a p-value of <0.05.

Both survival analysis and actual continuation data post-conclusion of the study were employed because enrolment of study participants was rolling overtime. The life table method was used to estimate the probability of participant continuation. The probabilities estimated from each of the intervals were used to estimate the overall probability of the continuation occurring at different time points.

Repeated measurement: this study followed participants over time and measured behaviours, side-effects, and adherence at baseline and quarterly until M18. For continuous variables, the number of sexual partners and the number of condomless anal sex acts were not normally distributed. The generalised linear mixed model was used to test if there was a statistically significant change in the mean of these variables over time. For binary variables such as Adherence: Yes/no and Doing sex work: Yes/no, generalised estimating equations were used to test if there was a statistical change in the percentage of these variables over time. Data to inform HIV sero-conversion were collected from clinical records.

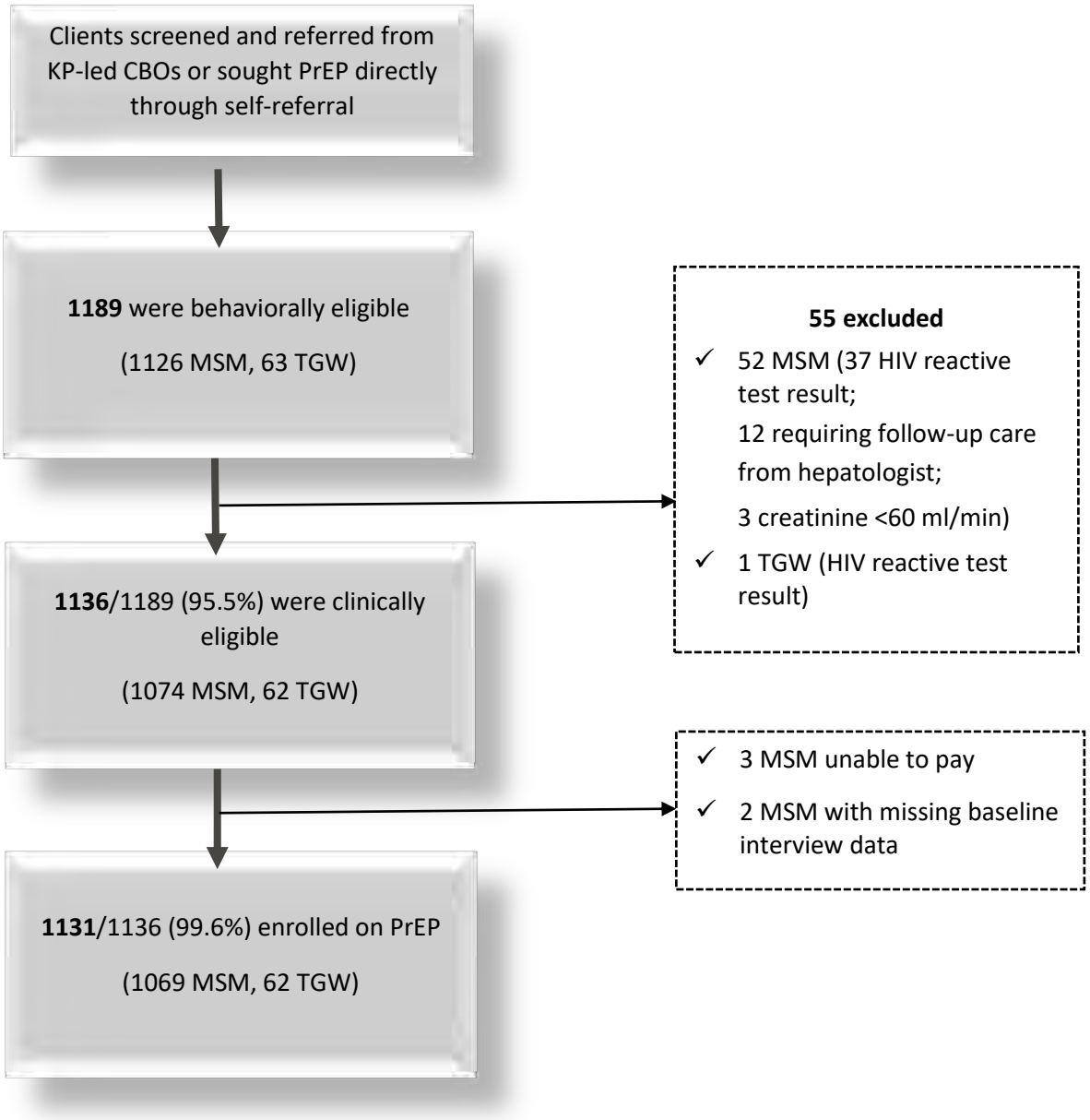
## Results

### *Enrolment*

In total, 1069 MSM and 62 TGW participated in the P4P study. 52 MSM were excluded from the study because 37 tested HIV positive at enrolment, 12 were separately undergoing

treatment for chronic hepatitis B, 3 had abnormal eGFR values (<60 mL $min^{-1}$ 1.73 $m^{-2}$), 3 were not able to pay, and 2 did not complete the baseline interview. For TGW, only one person was excluded as they tested HIV positive at enrolment (see Figure 3). Active study recruitment ended in June 2018 with eight additional MSM and two TGW enrolling from July through September 2018. All those who tested HIV positive were supported with ART enrolment at a preferred facility. The survey completion rate was high among respondents: all the variables had a response rate higher than 95% except for the number of male sex partner in the past 6 months where the response rate was about 80%. However, only 54% (191/358) of MSM and 62% (18/29) of TGW dropping out of P4P responded to the reasons for discontinuation survey.

**Figure 3. Study enrolment flow among MSM and TGW**




### *Characteristics of MSM and TGW PrEP users*

The median age of MSM and TGW enrolling on PrEP was 26 and 24.5 years, respectively. Among MSM, 78.6% had completed high school and engaged in higher education course work, while 62.9% of TGW had done the same. Average monthly income among MSM was 7,107,350 Vietnamese Dong (VND) ($300.67) and 5,516,160 VND ($238.01) for TGW. Health insurance coverage among MSM was 81.7% and 64.5% for TGW (see Table 2).

In terms of HIV-related risk factors as baseline, TGW overall were at greater risk than MSM with a higher average number of condomless anal receptive sex events in the past three months (17.9) than among MSM (5.7); amphetamine-type substances use in the past six months (37.1% among TGW versus 19.8% for MSM), having ever engaged in sex work (37.1% for TGW compared to 11.5% for MSM) and self-reported STI (21% for TGW versus 9% for MSM). Overall HIV risk scored were also higher among TGW than MSM (19.2 Compared to 17.1).

**Table 2. Baseline demographic and risk characteristics of MSM and TGW enrolled in P4P**

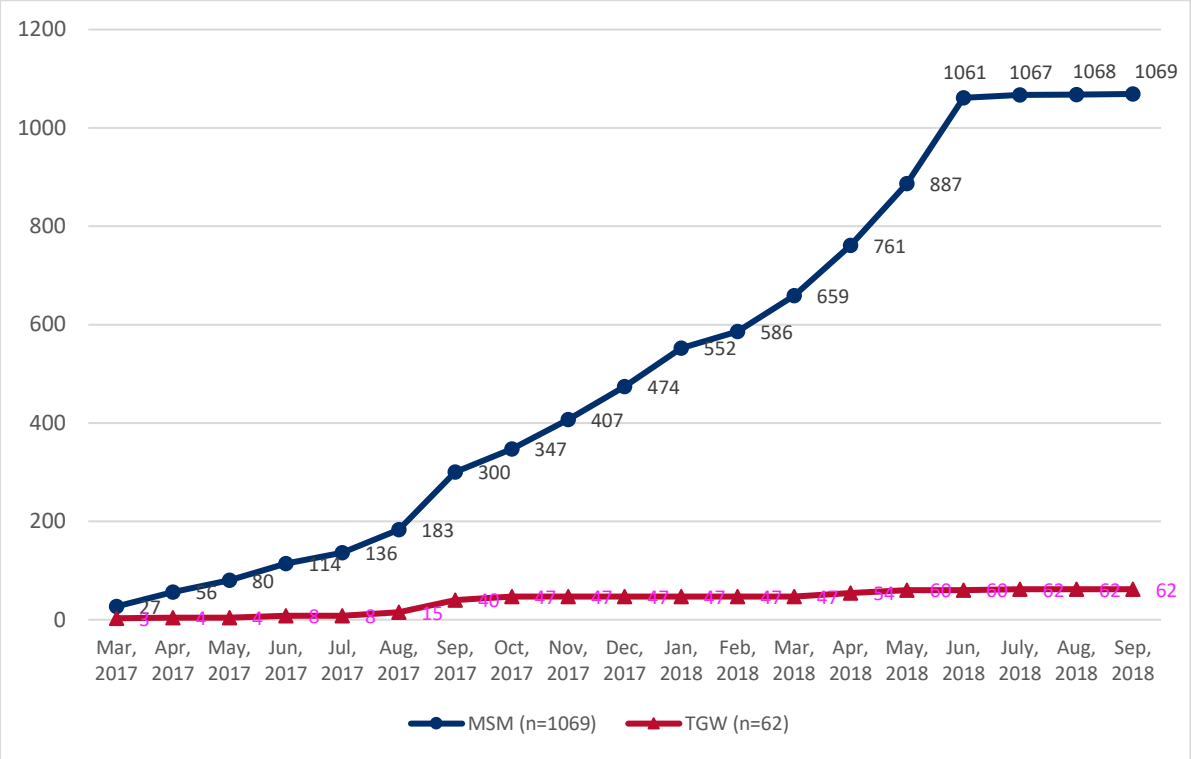
| Characteristics | MSM (n=1069) | TGW (n=62) |
|---|---|---|
| **Age in year (mean)** | **27.2** | **25.5** |
| **Median** | **26** | **24.5** |
| **Educational level (%)** | | |
| **No schooling** | **0.2** | **0.0** |
| **Primary School (Grade 1-5)** | **0.5** | **4.8** |
| **Secondary school (Grade 6-9)** | **3.0** | **17.7** |
| **High School (Grade 10-12)** | **17.8** | **14.5** |
| **Higher education** | **78.6** | **62.9** |
| **Monthly income in VND and USD (mean)** | | |
| | **7,107,350 ($306.67)** | **5,516,160 ($238.01)** |
| **Enrolled in social health insurance (%)** | | |
| **Yes** | **81.7** | **64.5** |
| **Risk characteristics** | | |
| **# of sex partners in past three months (mean)** | **5.1** | **5.6** |

| | | |
|---|---|---|
| **# of times having receptive condomless anal sex in past three months (mean)** | **5.7** | **17.9** |
| **# of times having insertive condomless anal sex in past three months (mean)** | **5.2** | **2.4** |
| **Engaged in sex work ever (YES %)** | **11.5%** | **37.1%** |
| **Used amphetamine-type substances in past three months (YES %)** | **19.8%** | **37.1%** |
| **STI in past three months (YES %)** | **9%** | **21%** |
| **Total HIV risk score** | **17.1** | **19.2** |

### *PrEP uptake and rate of enrolment in P4P*

PrEP enrolment increased over time from an average of 27 MSM per month in the first three months (March-June 2017) to 134 per month in the last three months (March-June 2018). However, among TGW, PrEP enrolment was very slow and did not improve significantly over time (Figure 4).

**Figure 4. Monthly PrEP study enrolment among MSM and TGW**



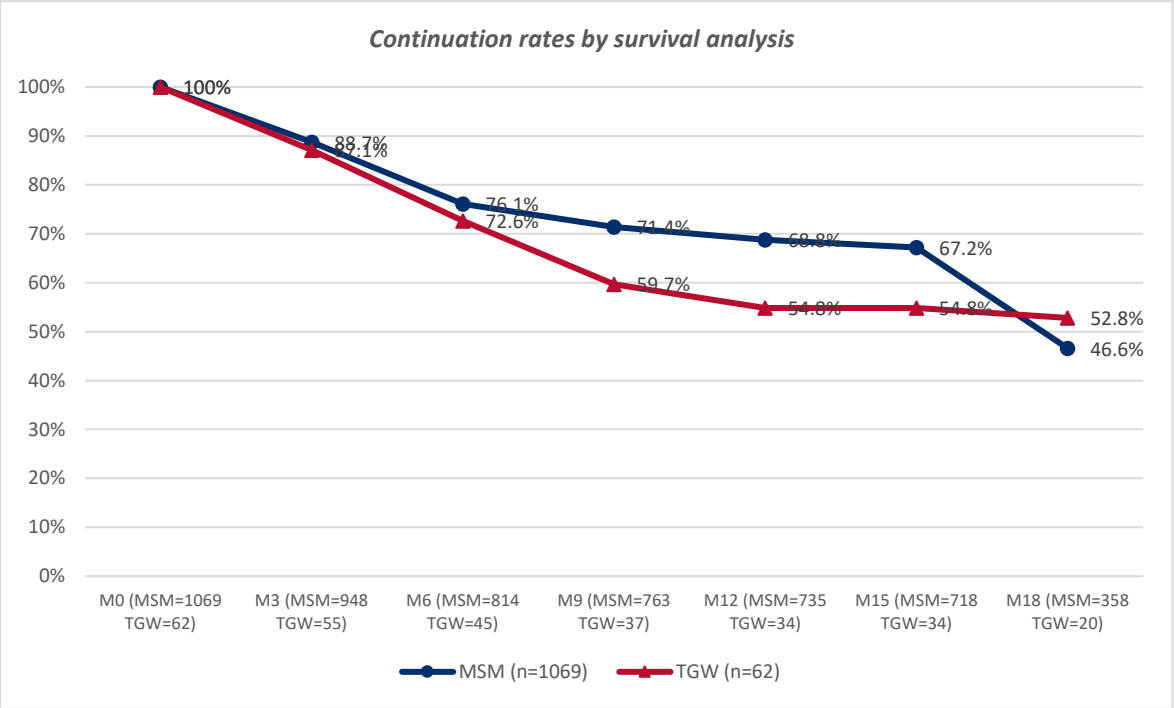

### *eGFR values over time*

In addition to the 3 MSM that tested with abnormal eGFR values (<60 mL $min^{-1}$ 1.73 $m^{-2}$) at baseline, two additional MSM presented with abnormal eGFR values (Month 6, age 26 and 12, age 27) which required discontinuation of PrEP.

### *PrEP continuation rates and survival analysis*

PrEP survival analysis for PrEP continuation indicated by M3 88.7% for MSM and 87.1% of TGW continued on PrEP. By M12, 68.8% of MSM and 54.8% of TGW continued on PrEP, and by 18 months, continuation plateaued to 52.8% for TGW but declined further to 46.6% for MSM.

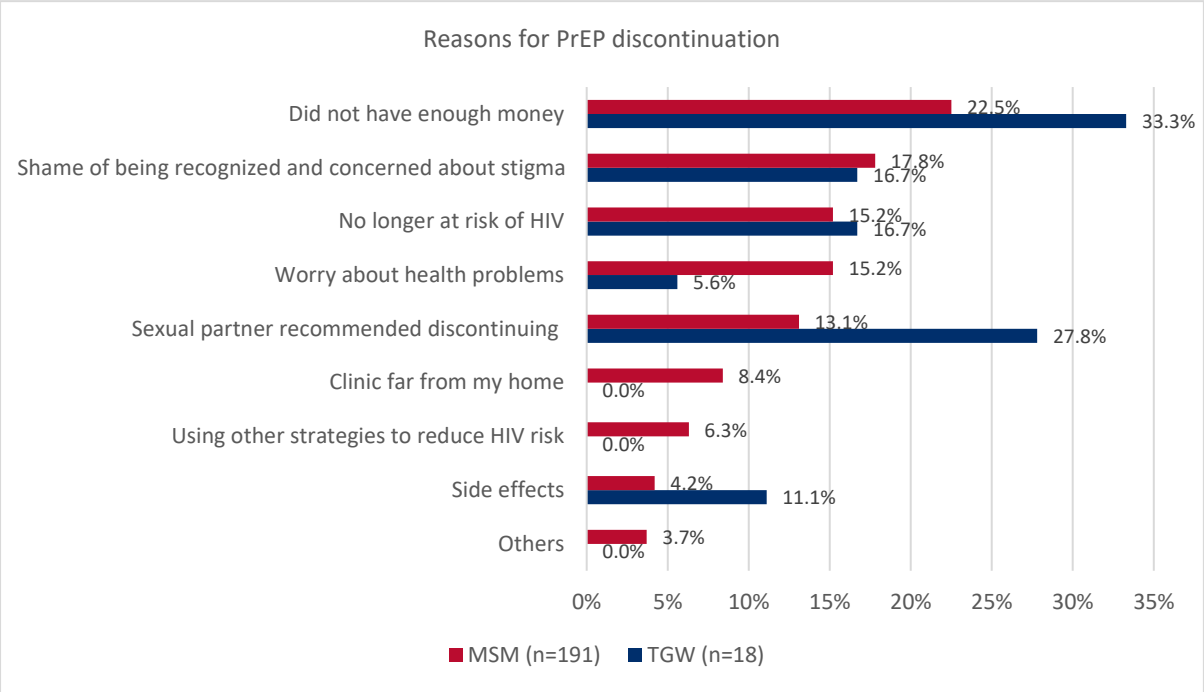
**Figure 5. PrEP continuation rates by survival analysis**




### *PrEP discontinuation and reasons for discontinuation*

There were a total of 387 drop-outs; of which 191 MSM and 18 TGW responded to a follow-up online survey. Among MSM and TGW, 16.7% and 15.2% respectively stopped PrEP because they perceived themselves to no longer be at risk of HIV. Other primary reasons for PrEP discontinuation among MSM were not having enough money to pay for PrEP (22.5%), shame of being seen using PrEP (16.7%), and worry about health problems associated with long-term use of PrEP (15.2%). For TGW, not having enough money to pay for PrEP (33.3%) and sexual partner recommending discontinuing PrEP (27.8%) were the main reasons for stopping. Among all MSM and TGW that dropped out of PrEP, one MSM reported sero-converting after stopping PrEP.

**Figure 6. Reasons for discontinuing PrEP**




### *Self-reported PrEP adherence and HIV sero-conversions*

Among MSM, self-reported use of four or more pills in the past week was 91.6% at M3, 91.8% at M6, 92.6% at M9, 95.3% at M12, 97.4% at M15, and 69.8% at M18. For TGW, self-reported adherence of seven pills a week was 70.9% at M3, 68.2% at M6, 87.0% at M9, 84.2.3% at M12, 11.1% at M15, and 88.9% at M18. There were three HIV sero-conversions among MSM during the P4P study period which were all detected in the first month on PrEP. These newly HIV diagnosed individuals were successfully enrolled on ART and virally suppressed.

**Table 3. Self-reported adherence by quarter and population**

| Adherence | KP Group | Month 3 | Month 6 | Month 9 | Month 12 | Month 15 | Month 18 |
|---|---|---|---|---|---|---|---|
| | MSM (n) | 905 | 596 | 337 | 299 | 270 | 250 |
| | TGW (n) | 55 | 44 | 23 | 19 | 18 | 9 |
| **No. of PrEP pills taken in past week** | MSM (≥ 4 days/week) | 91.6% | 91.8% | 92.6% | 95.3% | 97.4% | 96.8% |
| | TGW (7days/week) | 70.9% | 68.2% | 87.0% | 84.2% | 11.1% | 88.9% |

### *Factors associated with continuing on PrEP among MSM*

In the univariable regression analysis, having health insurance, lower than the mean income, having higher education level, being older than age 30, ATS use, engaging in sex work, higher average number of sex partners and condomless receptive anal sex were positively associated with PrEP continuation (p <0.05). Factors associated with greater odds of continuing on PrEP that remained statistically significant in the adjusted multivariable analysis (Table 4) were: having a lower than average income (aOR 2.38 (95% CI:1.59-3.54), p=0.000); being older than 30 years of age (aOR 2.03 (95% CI:1.30-3.40), p=0.007); and with increasing number of sex partners (ExpB: 1.06 (1.01-1.11), p=0.011).

**Table 4. Factors associated with MSM continuing on PrEP**

| Factor | | % Continuation | Univariate analysis | p value | aOR (95% CI) | p value |
|---|---|---|---|---|---|---|
| **Health insurance** | No | 27.3% | Ref | | Ref | |
| | Yes | 42.5% | 1.972 (1.388 - 2.802) | .000 | 1.75 (1.00 -3.08) | 0.05 |
| **Income per month (mean = US$ 295)** | > mean | 34.9% | Ref | | Ref | |
| | <= mean | 46.0% | 1.53(1.2-1.9) | .001 | 2.38 (1.59-3.54) | **<0.001** |
| **Education level** | High school and lower | 25.9% | Ref | | Ref | |
| | Higher education | 45.3% | 2.375 (1.714 - 3.291) | .000 | 1.76 (0.998 - 3.12) | 0.051 |
| **Age group** | <25 years | 37.4% | Ref | | Ref | |
| | 25-30 years | 39.3% | 1.081 (0.817 - 1.431) | .584 | 1.19 (0.77 -1.83) | 0.421 |
| | >30 years | 50.7% | 1.716 (1.227 - 2.400) | .002 | 2.03 (1.3 -3.4) | 0**.007** |

| | | | | | | |
|---|---|---|---|---|---|---|
| **ATS use** | No | 37.6% | Ref | | Ref | |
| | Yes | 55.0% | 2.022 (1.491 - 2.742) | .000 | 1.39 (0.891-2.17) | 0.147 |
| **Sex work** | No | 40.2% | Ref | | Ref | |
| | Yes | 48.8% | 1.418 (0.973 - 2.067) | .069 | 1.55 (0.862 -2.8) | 0.143 |
| # of sex partners | Mean | 5.1 | 1.110 (1.071 - 1.152) | .000 | Exp(B)=1.06 (1.01-1.11) | 0**.011** |
| # of times having receptive condomless anal sex (mean) | Mean | 5.7 | 0.985 (0.971 - 0.998) | .034 | Exp(B)=0.99 (0.97-1.006) | 0.244 |
| # of times having insertive condomless anal sex (mean) | Mean | 5.2 | 1.005 (0.990 - 1.021) | .465 | Exp(B)=1.015 (0.99-1.034) | 0.105 |
| | | | | | | |

### *Factors associated with continuing on PrEP among TGW*

The univariable regression analysis (see Table 5) were determined being older than 30 years of age as associated with continuing on PrEP (OR 5.56 (95% CI:1.23-25.75), p=0.027) which remained statistically significant in the adjusted multivariable analysis (aOR 5.62 (95% CI:1.05-29.9), p=0.043).

**Table 5. Factors associated with TGW continuing on PrEP**

| Factor | | % Continuation | Univariate analysis | p value | aOR (95% CI)* | p value |
|---|---|---|---|---|---|---|
| Health insurance | No | 27.3% | Ref | | Ref | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Yes | 47.5% | 2.412 (0.783 - 7.431) | .125 | 2.62 (0.68 -10.1) | 0.160 |
| Income per month<br>mean = US$ 295 | <= mean | 40.0% | | | Ref | |
| | >mean | 40.9% | 1.038 (0.359 - 2.995) | .944 | 1.38 (0.35 -5.40) | 0.635 |
| Education level | High school and lower | 39.1% | Ref | | Ref | |
| | Higher education | 41.0% | 1.082 (0.377 - 3.100) | .883 | 0.89 (0.23 -3.35) | 0.869 |
| Age group | <25 years | 32.3% | Ref | | Ref | |
| | 25-30 years | 35.0% | 1.130 (0.344 - 3.709) | .839 | 1.26 (0.33 -4.77) | 0.730 |
| | **>30 years** | **72.7%** | 5.599 (1.217 - 25.75) | .027 | **5.62 (1.05 -29.9)** | **0.043** |
| ATS use | No | 30.8% | Ref | | Ref | |
| | Yes | 56.5% | 2.924 (1.004 - 8.516) | .049 | 1.81 (0.41 -7.85) | 0.428 |
| Sex work | No | 28.2% | Ref | | Ref | |
| | Yes | 60.9% | 3.959 (1.331 - 11.77) | .013 | 3.40 (0.83 -13.8) | 0.087 |

## Discussion

PrEP was delivered for the first time in Vietnam through the P4P demonstration project and despite being new, the rate of enrolment increased five-fold from the first three months (March-June 2017) to last three months (March-June 2018) of enrolment. These increases, however, were seen primarily among MSM. PrEP enrolment by TGW was relatively flat overtime suggesting barriers to PrEP access and acceptability among this population that need to be further explored and addressed as part of PrEP scale-up in Vietnam.

The PrEP continuation survival analysis indicated that PrEP use declined more significantly from enrolment to month nine and then plateaued through to month 18 and remained higher among MSM than TGW except in the last three months where continuation dropped to 46.6% among MSM while remaining relatively level at 52.8% for TGW. Among MSM, self-reported adherence to PrEP (4 or more times a week) was consistently very high (>90%)

over the study period. However, among TGW, self-reported adherence varied significantly, from 11.1% to 88.9%. These variations may have been influenced by the smaller sample size overall and among those who were followed on PrEP for entire 18 months (n=9).

The PrEP continuation rates calculated through the survival analyses were higher in comparison PrEP roll-out in other similar settings. The Princess PrEP program in Thailand reported 46.8% of MSM and 25.3% of TGW remaining in PrEP by month 12.[22] In the United States, data from Gilead Sciences shows an increase in PrEP continuation to month 6 over time, growing from 10% at first roll-out to >60% by 2017.[23] Pyra et al posit this may be due to increase knowledge of PrEP and support for those on PrEP. In Vietnam, real world PrEP continuation in MOH and USAID/PATH Healthy Markets supported PrEP clinics (n=18) measures a month 6 continuation of 63% and 12 month of 50%. The KP-led clinics among these have consistently higher rates of month 6 (76%) and month 12 (61%) continuation than public PrEP clinics.[24] The KP-led clinic PrEP continuation rates align with was found through P4P. This suggests that continuation rates have been relatively stable from the start of P4P through scale-up to PrEP in 18 clinics and three provinces.

We found that age was significantly associated with PrEP continuation, with those older than age 30 more likely to stay in care. Other studies in Asia among MSM and TGW have identified younger age as a primary factor associated with increased probability of discontinuing PrEP use. [25, 26] This suggests that further understanding of barriers to PrEP continuation among younger MSM and TGW is needed to ensure that services work for them.

Among the MSM and TGW participating in P4P, there were 3 MSM with abnormal eGFR that were unable to enrol in PrEP services and an additional 2 MSM that were measured with abnormal eGFR and who were required to discontinue PrEP. This represents a 0.19% occurrence in MSM enrolled in P4P while eGFR was measured as normal among TGW. Our findings were similar to those reported by the Princess PrEP Program. [27]

There are several limitations associated with the data presented in this paper. This was a pragmatic demonstration project where study enrolment was rolling requiring continuation over, therefore, we were not able to follow the entire enrolled sample over an 18-month period. Since the model was partially fee-based, only MSM and TGW who could afford the monthly price of the PrEP ARVs were able to participate. As such, the results presented only reflect those of a sub-set of MSM and TGW who had the means to pay 0.50 cents a day. While cost of PrEP was only a limiting factor for 3 MSM at enrolment, 22.5% of MSM and 33.3% of TGW who dropped out of PrEP said they did so because of cost. We also found higher income was associated with PrEP continuation suggesting that the cost of PrEP

impacted continuation. This underscores the importance of making available a range of PrEP models following a total market approach, ranging from free, to partially subsidized to fully commercial models to allow for access, equity and choice.

In addition, the sample size among TGW was small (n=62) which resulted in limitations when running multivariable regressions and led to wide confidence intervals. Lack of free STI testing was another limitation. We were not able to measure the true degree of asymptomatic STIs at baseline and through follow-up. Finally, self-reported adherence is a subjective measure and may not align with actual behaviour. However, we only identified three HIV sero-conversions among those on PrEP which were missed AHI found at the month one re-testing for HIV.

Despite these limitations, this study provided very first results related to PrEP implementation in Vietnam and the acceptability of PrEP among MSM and TGW. Key findings from P4P informed national discourse related to service delivery design and scale-up. Importantly, PrEP was encoded in national guidelines by December 2017, nine months into P4P service delivery and incrementally scaled-up in subsequent years.[28] P4P provided a blueprint for a collaborative service delivery model between KP-led CBOs, private and public clinics and local and national HIV program leaders. By end of September 2020, there were 10,097 people on PrEP and 13,265 people who used PrEP at least once in the past twelve months ever on PrEP, and 111 clinics offering free PrEP services across 27 provinces[29 30]. Vietnam is now among three countries in Asia-Pacific with more than 10,000 people cumulatively using PrEP and with a national PrEP program in place.[31]

To guide PrEP scale-up for impact, the MOH has developed an exciting plan with ambitious targets for increasing PrEP uptake over the next five years. [32] The plan describes the need for innovation and creativity in PrEP service delivery to ensure there are a range of models in place that differentiate, simplify and further de-medicalize how PrEP services are offered. Many of the differentiated service delivery strategies defined in the national scale-up plan (such as telehealth, delivery of PrEP medicines and home lab sample collection), were temporarily applied during COVID-19 outbreaks so there is already a foundation from which to build. The plan also calls for considerations in how to finance PrEP before external donor support declines so service delivery and coverage can be sustained.

## Conclusions

Through the P4P demonstration project, we found PrEP to be highly acceptable among MSM. Additional effort is needed to tailor PrEP services to the needs of TGW. Continuation rates were relatively high for first roll-out of PrEP, however MSM and TGW age 30 or younger were more likely to discontinue services. Ensuring there is choice in service models, and further differentiating and adapting PrEP delivery among MSM and TGW seeking PrEP,

will be essential as part of PrEP scale-up, and in enabling Vietnam to achieve its goal of ending AIDS by 2030.

## Conflict of interests

The authors have no competing interests to declare.

## Acknowledgements

The authors would like to acknowledge the significant contributions of the owners and staff of three key population-led and owned clinics in Ho Chi Minh City (Glink Clinic, Galant Clinic, and My Home Clinic) and the community-based organizations that partner with them (Glink, G3VN, Aloboy, M4M, Color of Life, Smile, Vuot Song, Real Life, and The Boy); Life Center; Ho Chi Minh City Provincial AIDS Center; and District Health Centers of districts 1, 8, 11, and Thu Duc that pioneered PrEP introduction in Vietnam. We thank USAID for their support and funds for the Prepped for PrEP pilot. We are grateful to Elaine Ung and Zoe Humeau for their edits to the manuscript. Finally, we thank USAID for funding this pilot as part of the USAID/PATH Healthy Markets project.

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