The My PrEP Study: Lessons learnt from a pilot demonstration project and recommendations for scale up

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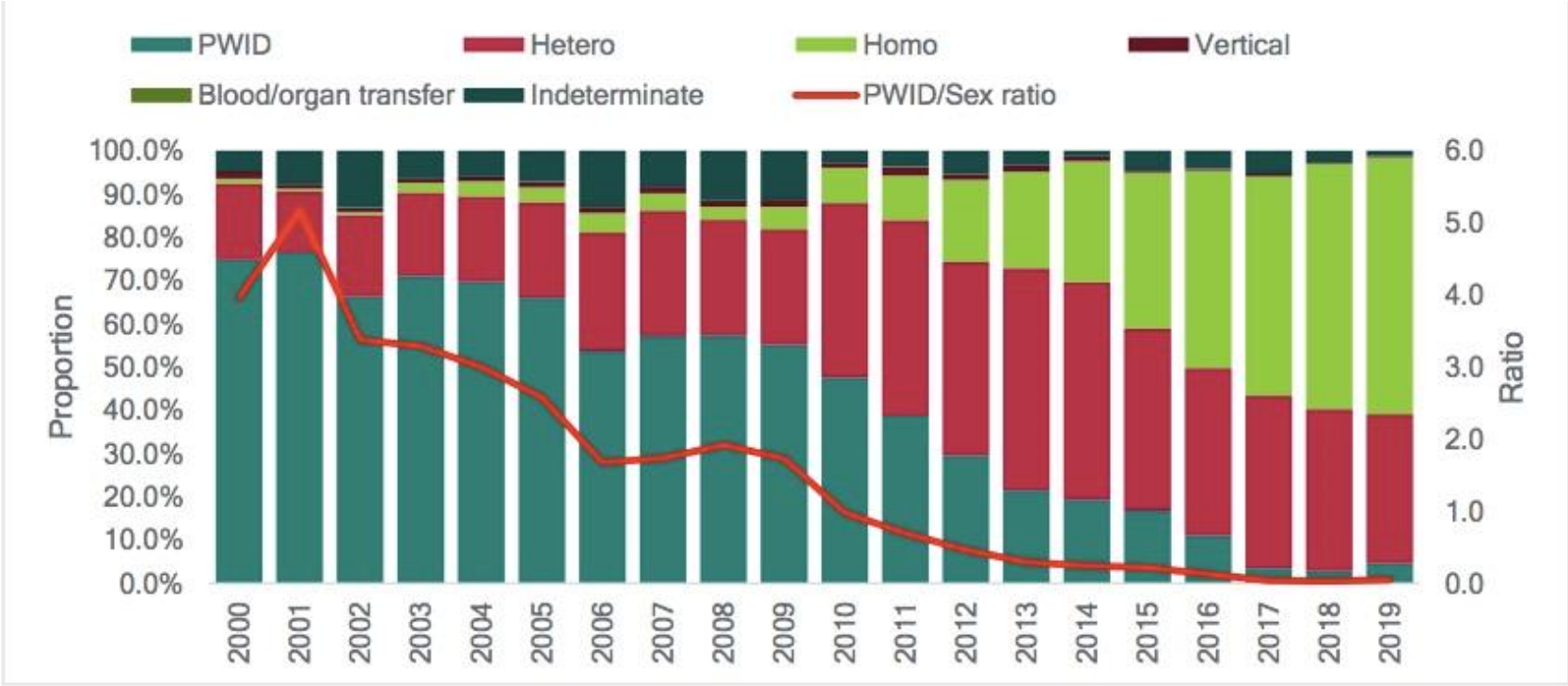
Outline

- Background
- PrEP Timelines
- Results of the My PrEP study
- Lessons Learnt
- Considerations for scale Up
- Next Steps

Trend of HIV infection by Mode of Transmission (2000-2018)



Global AIDS Monitoring Report; Malaysia (2020)

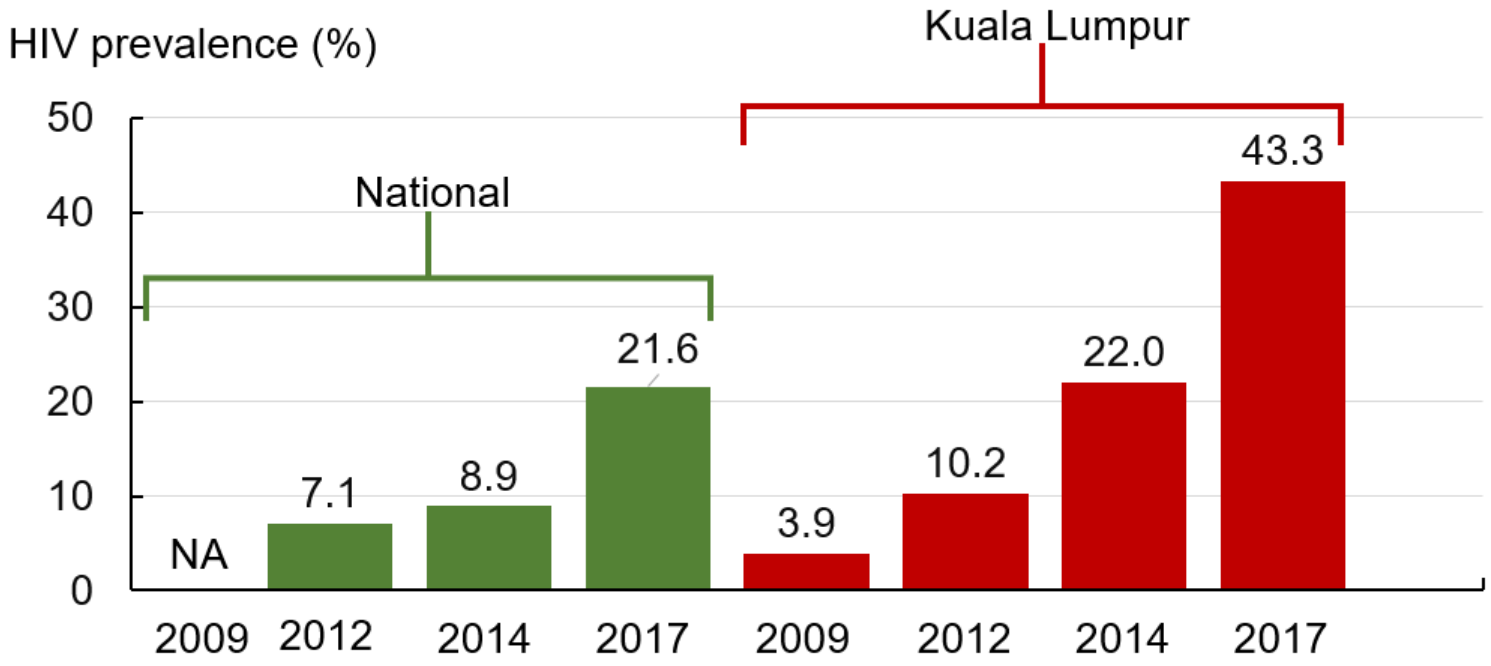
Epidemiology Profile of Key Populations

Target Group	Estimated Population Size	HIV Prevalence* (2012)	HIV Prevalence* (2014)	HIV Prevalence* (2017)
People Who Inject Drugs (PWID)	75,000	**18.9%**	**16.3%**	**13.4%**
Female Sex Workers (FSW)	22,000	**4.2%**	**7.3 %**	**6.3%**
Transgender (TG)	15,000	**4.8%**	**5.6 %**	**10.9%**
Men who have Sex with Men (MSM)	220,000	**7.1%**	**8.9 %**	**21.6%**

[1] Ministry of Health Malaysia, Size Estimation of Key Populations Malaysia, 2018

* Results from the Integrated Bio-Behavioural Surveillance (IBBS) 2012 , 2014 in NSPEA 2016-2030, 2017

HIV prevalence among MSM, National and Kuala Lumpur, Malaysia integrated behavioral and biological surveillance, 2009-2017



Source: Kanter et al, 2011; IBBS, Ministry of Health, 2017

PrEP Timelines in Malaysia

Timeline	PrEP Initiative	Lead partner organization(s)
Aug 2015	Inclusion of PrEP in National Strategic Plan (NSP) to End AIDS (2016-2030)	MOH
Sept 2015	Regional PrEP Consultation (PrEPARING Asia), Bangkok	Led by APCOM
March 2016	Online PrEP Survey in MSM	International HIV Alliance
May 2016	**National PrEP Consultation**	MOH, WHO, UNAIDS, International HIV Alliance, APCOM (Global Fund)
May 2016	Formation of PrEP Working Group	
Sept 2016	**Completion of National PrEP and nPEP guidelines**	MASHM Out of pocket PrEP

PrEP Timelines - Cont

Timeline	PrEP Initiative	Lead partner organization(s)
Jan 2017	HIV Connect	MASHM, MAC, MAF
Jan 2017	1st Asia Pacific PrEP Implementation Meeting, Bangkok	USAID, PEPFAR, FHI 360, TRC ARC
Dec 2017	**Price reduction of generic TDF/FTC (generic competition)**	Cipla, Hetero, Medispec
March 2018	**Pilot multi-site PrEP demonstration project in MSM**	UNAIDS/WHO/GF
July 2018	2nd National PrEP Consultation on PrEP	CERIA, WHO
Jan 2019	HIV PrEP Locator	WHO, CERIA
Sept 2020	Community-led PrEP service delivery collaboration with FRHAM	MAC/AFAO (SKPA)

1st National Consultation on PrEP

- 2 day multi-sectorial consultation in May 2016
- Involved community members, CBOs, MOH, Pharma reps, ID physicians, researchers, primary care doctors, APCOM, WHO, UNAIDS, HIV Alliance
- MOH supportive of PrEP as an additional HIV preventive tool
  - Recommended more operational research and a pilot demonstration project to study the feasibility of PrEP implementation in key populations through a number of service delivery models using client paid PrEP
  - Emphasized non-MOH settings – e.g. university hospitals/private sector
  - MASHM to work with MAC to develop national PrEP and nPEP guidelines and training modules on PrEP targeting community friendly primary care public and private clinics

Key Findings: Willingness to use PrEP

- Relative risks & Perception of PrEP
  - Most had low risk perception and felt that their frequency of condom use or being in a
  - above that
  - al barrier
  - arriers in
- As
  - health
  - as promiscuous

Bourne A et al. *Journal of the International AIDS Society* 2017, **20**:21899
http://www.jiasociety.org/index.php/jias/article/view/21899 | http://dx.doi.org/10.7448/IAS.20.1.21899

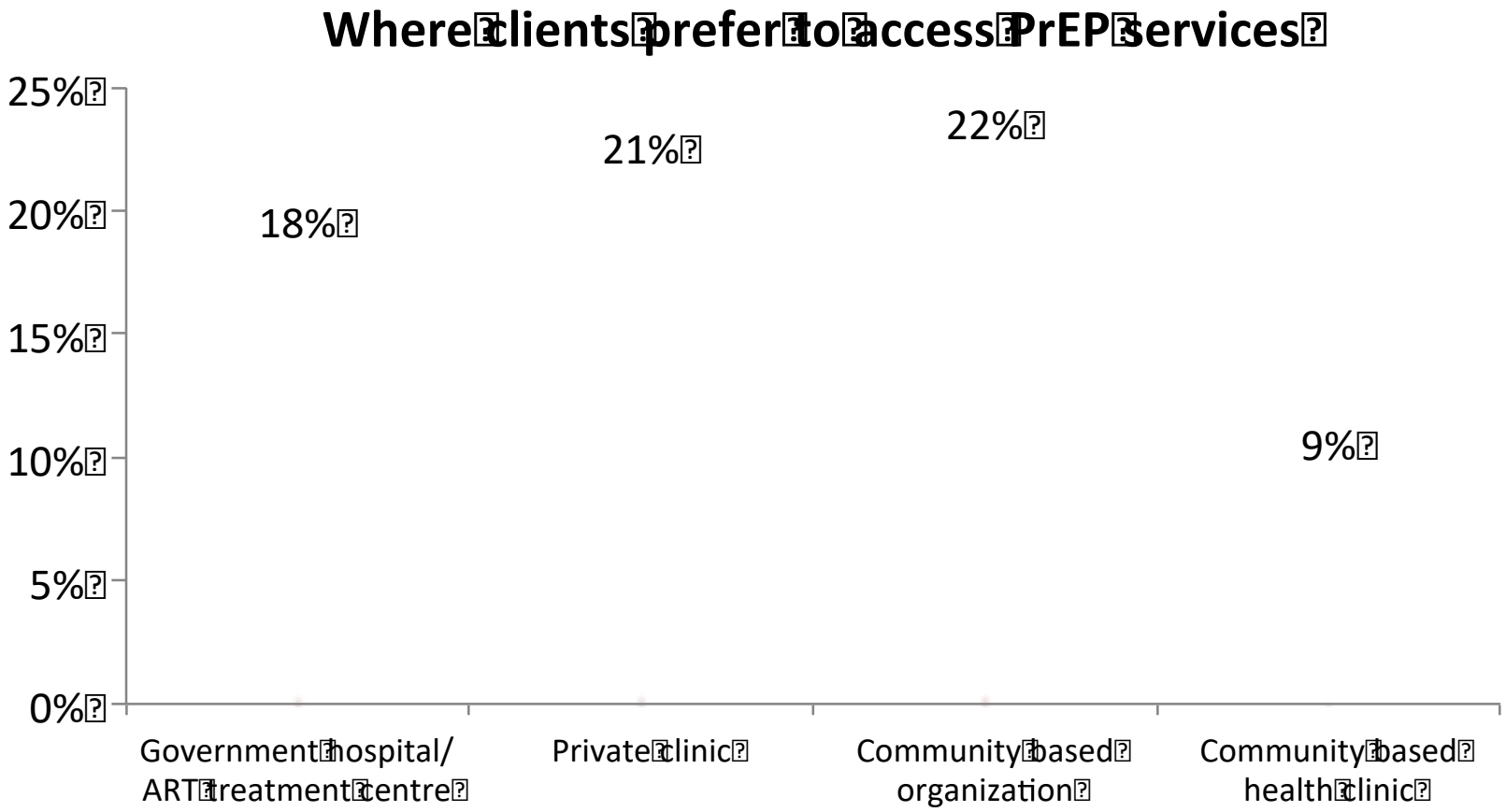
Research article

Willingness to use pre-exposure prophylaxis (PrEP) for HIV prevention among men who have sex with men (MSM) in Malaysia: findings from a qualitative study

Adam Bourne[1,2§], Matteo Cassolato[3], Clayton Koh Thuan Wei[4], Bangyuan Wang[3], Joselyn Pang[5], Sin How Lim[6], Iskandar Azwa[7], Ilias Yee[4] and Gitau Mburu[8]

[§]Corresponding author: Adam Bourne, Australian Research Centre in Sex, Health & Society, La Trobe University, 215 Franklin Street, Melbourne 3000, Australia. (A.bourne@latrobe.edu.au)

Accessing PrEP
Service Preference



Lim et al. Willingness to use Pre-exposure prophylaxis for HIV prevention among men who have sex with men in Malaysia, *PLOS-ONE* 2017

The My PrEP Study

- Pilot demonstration project
- Funded by UNAIDS/WHO/Global Fund
- Partnered with Malaysian AIDS Council
- 150 HIV negative MSM at high risk of HIV infection over 12 months
- Free Generic Truvada based PrEP donated by Medispec & Cipla
- Across 3 sites:
  - University Malaya Medical Centre
  - Private clinic (Red Clinic)
  - Community Based Organization (Community Health Care Clinic, PTF)

Objective of My PrEP Study

- To evaluate retention, adherence, risk behavior, side-effects, STI and HIV breakthrough infections among MSM taking HIV PrEP

- To document delivery of HIV PrEP services to inform national policy, expansion and scale-up

Methods

Population

- Self-selected sample of 150 HIV uninfected MSM at three different service delivery sites in Klang Valley

Eligibility

Inclusion criteria

- Demographic: ≥ 18 years, male sex, Malaysian, living in Klang Valley for the next 12 months
- Sexual Risk Behaviour: Substantial risk for HIV infection
    - Hx of UAI with at least 1 male partner of unknown or HIV positive status
    - Hx of anogenital STI
    - Hx of recreational drug use for sex or transactional sex
    - Used or requested PEP

Exclusion criteria

- Acute or established HIV infection
- Creatinine clearance <60mL/min
- Adverse health conditions

Intervention

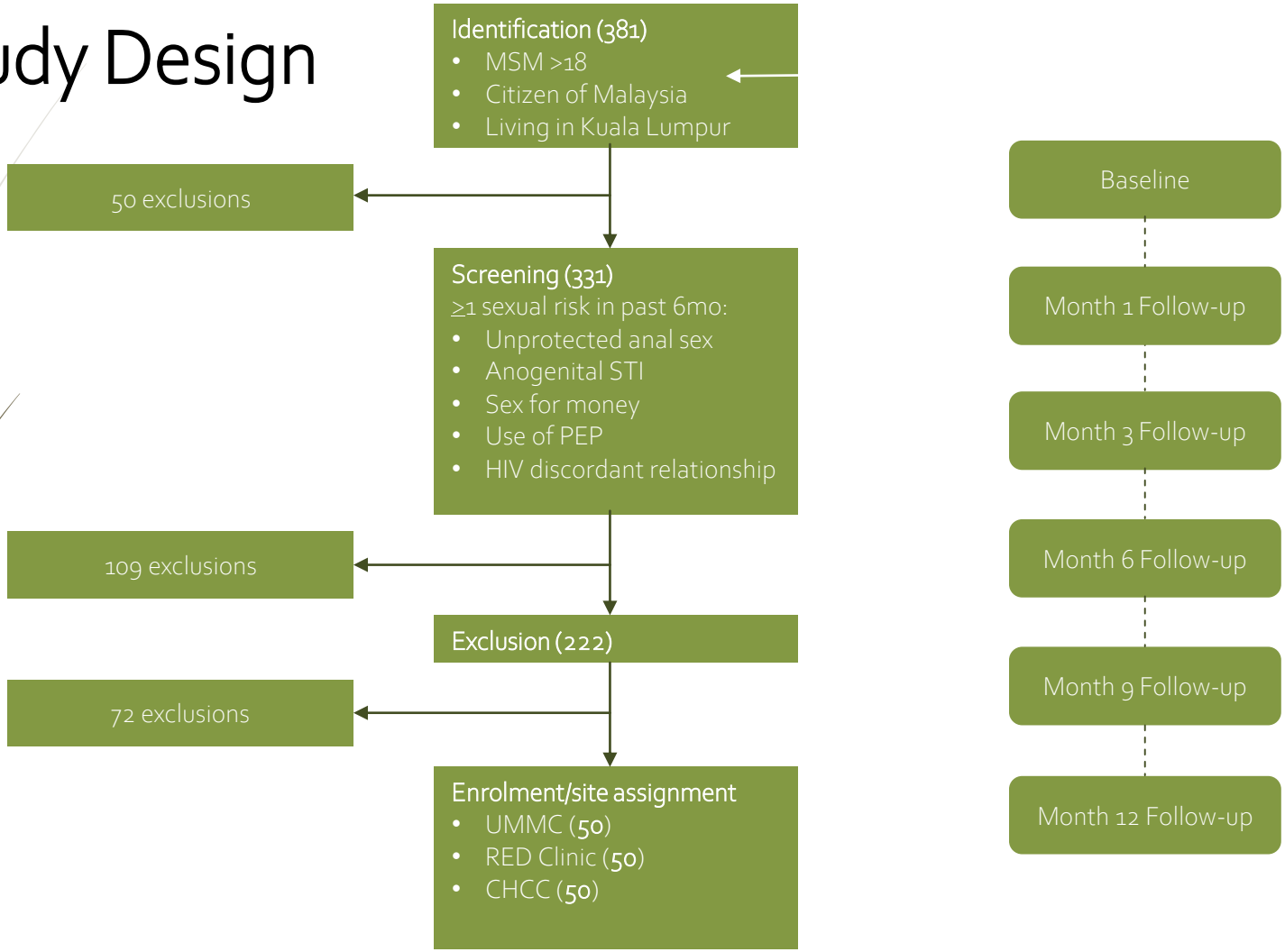
- Single daily oral dose of generically manufactured tenofovir/emtricitabine (Truvada®)

Study Procedures

Procedure	Baseline	Month 1	Month 3	Month 6	Month 9	Month 12
Rapid HIV Ag/Ab	X	X	X	X	X	X
HIV POC VL	X					
Creatinine	X	X		X		X
Rectal CT/NG	X			X		X
RPR/TPHA	X			X		X
HBsAg/Ab	X					
HCV-Ab	X					X
Questionnaire	X		X	X	X	X
Diary (weekly)	X	X	X	X	X	X
Drug dispensing	X	X	X	X	X	X
Pill count		X	X	X	X	X

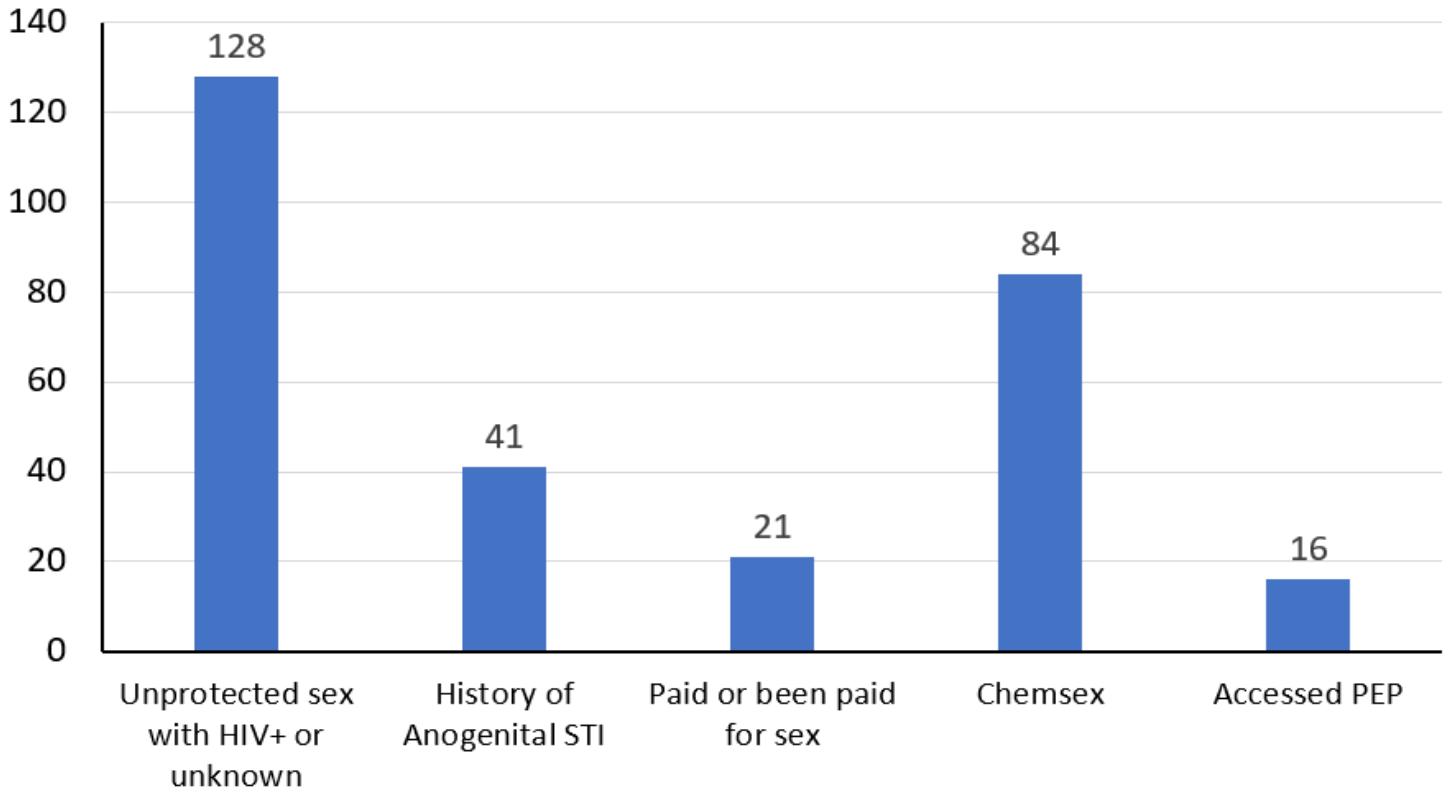
Results

Study Design



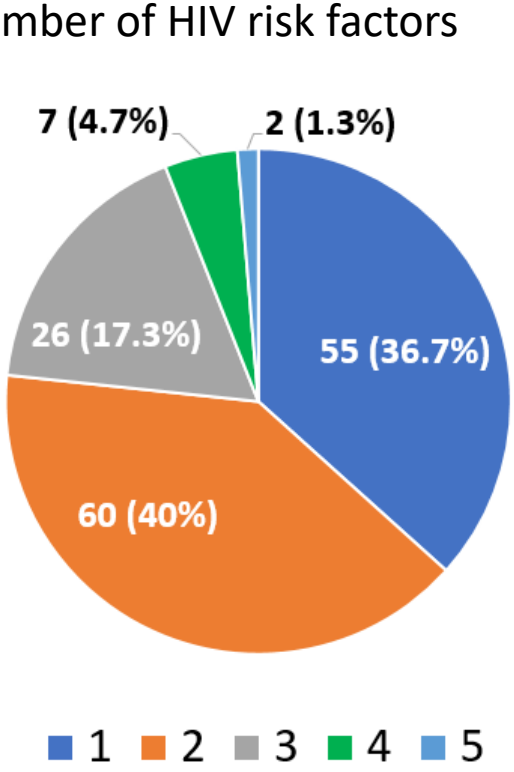
Socio-demographic characteristics	
Ethnicity	n (%)
Chinese	**85 (56.6)**
Indian	12 (8.0)
Malay	44 (29.3)
Other	9 (6.0)
Age group (years)	
18 – 25	31 (20.7)
26 – 35	**83 (55.3)**
36 and over	36 (24.0)
Education	
High school	15 (10.0)
Diploma/degree	**116 (77.3)**
Post-graduate	19 (12.7)
Employment status	
Employed	**122 (84.0)**
Unemployed	24 (16.0)

Existing HIV risk factors* prior to enrollment

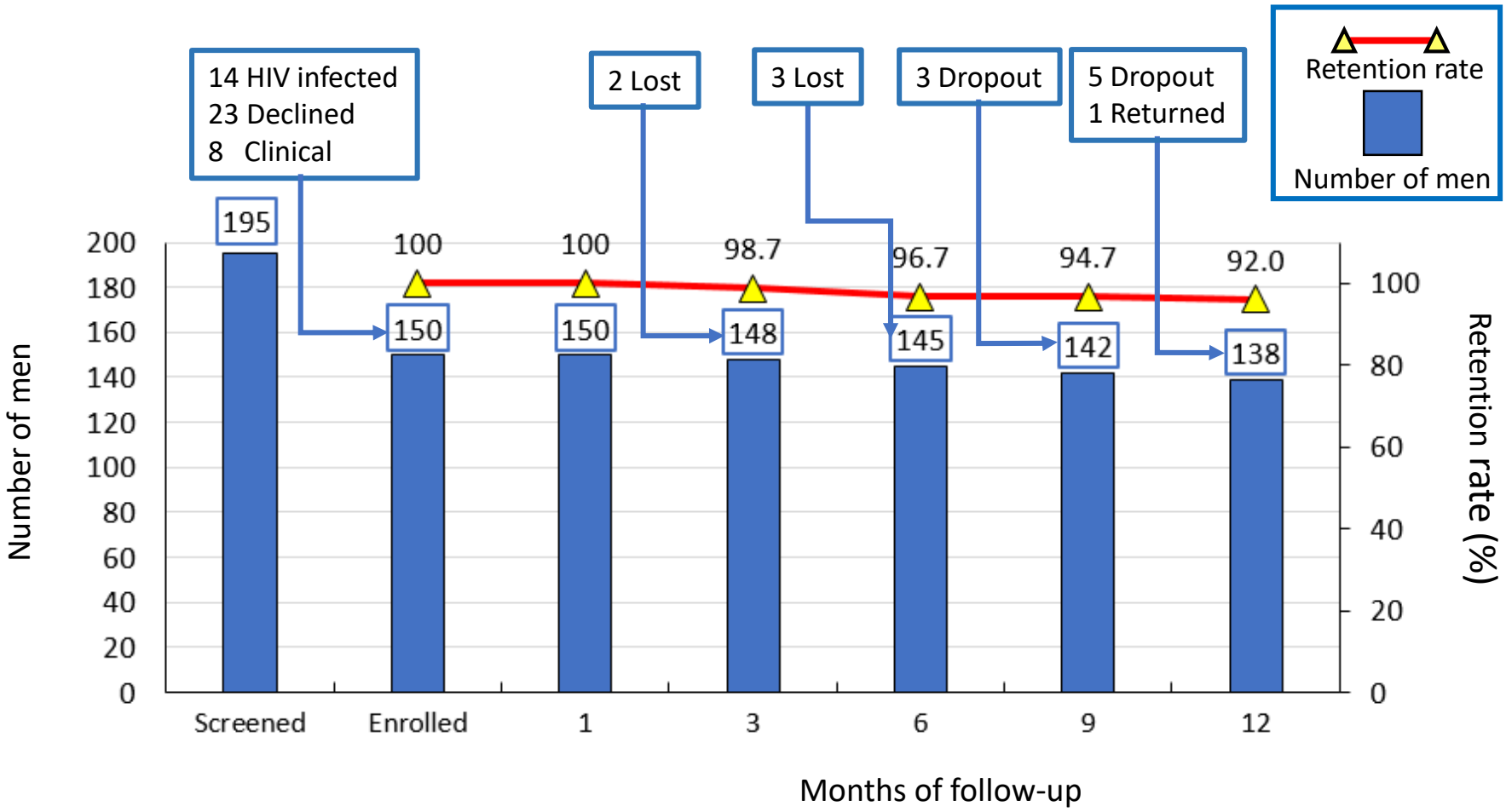


*Multiple risk factors possible

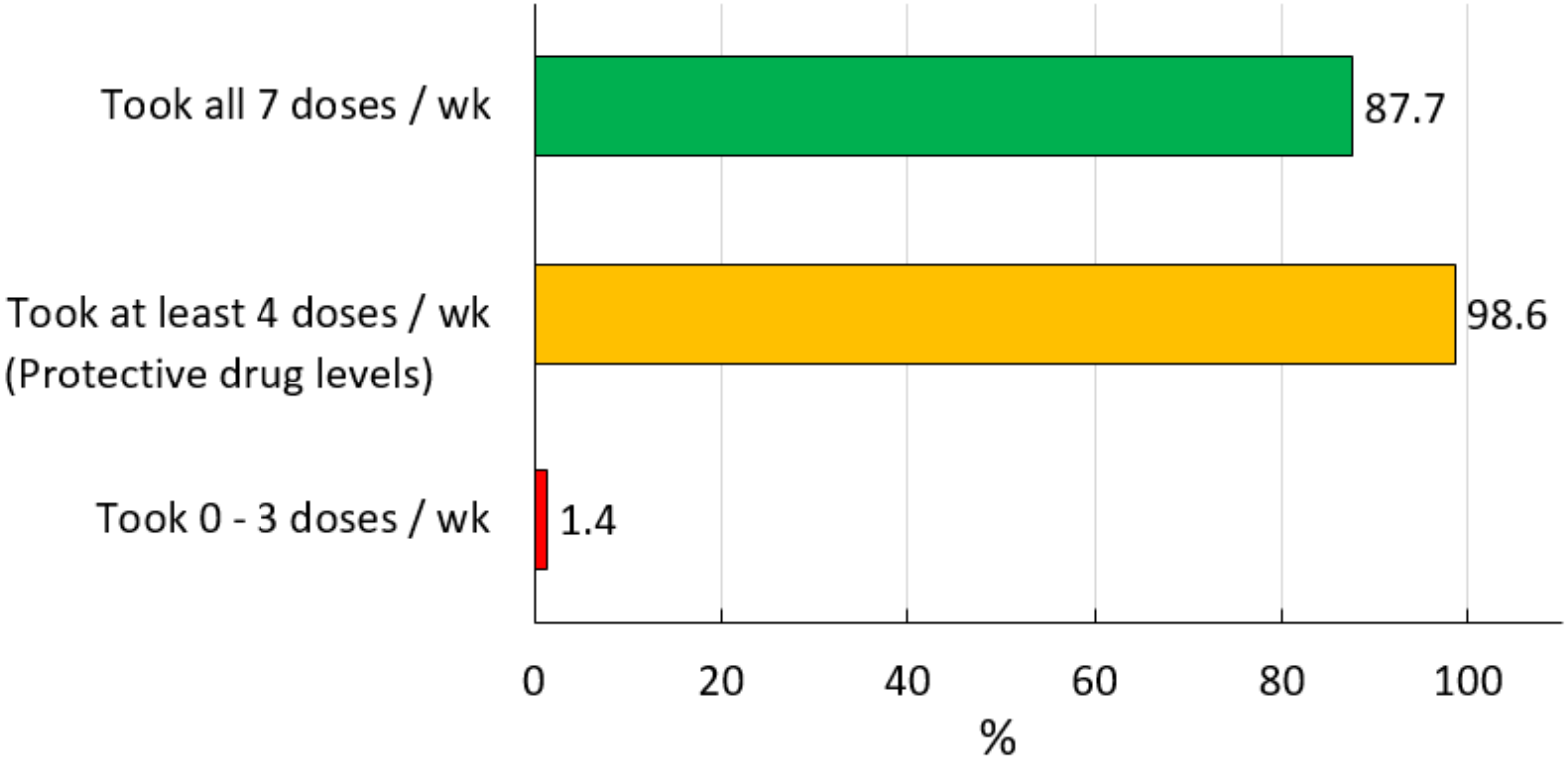
Existing HIV risk factors prior to enrollment



Retention

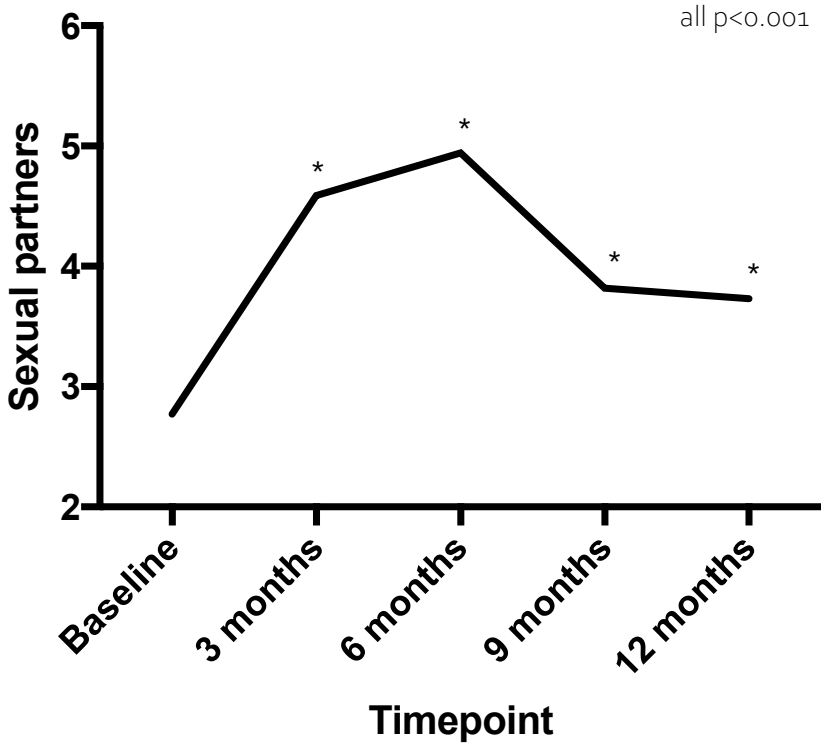

14 HIV infected
23 Declined
8 Clinical
2 Lost
3 Lost
3 Dropout
5 Dropout
1 Returned
Retention rate
Number of men
195
150
150
148
145
142
138
100
100
98.7
96.7
94.7
92.0
200
180
160
140
120
100
80
60
40
20
0
100
80
60
40
20
0
Number of men
Retention rate (%)
Screened
Enrolled
1
3
6
9
12
Months of follow-up

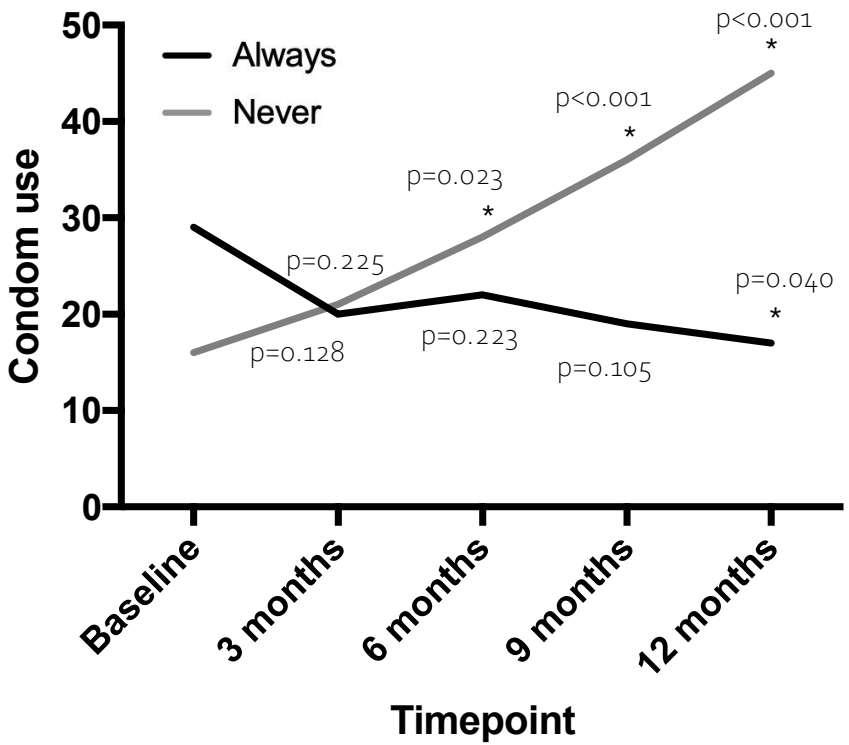
Self-reported weekly PrEP adherence from diaries*



*Based on 5492 (73%) out of 7569 diaries expected throughout the course of the project

Sexual risk behaviour





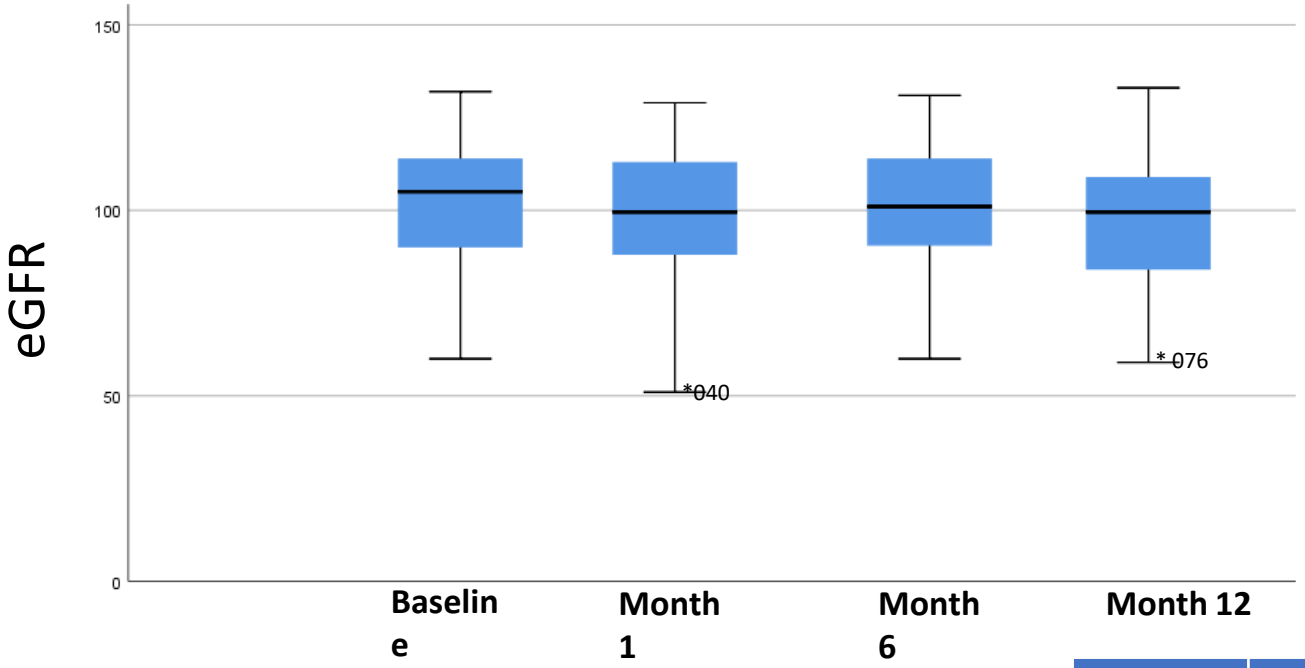
Rankin K. Is risk compensation real? The effect of perceived level of HIV transmission risk on risk behavior in an open-label pilot PrEP-based intervention in men who have sex with men in Malaysia. *APACC* 2020

Self-reported medical conditions during the first month after initiating PrEP

Condition*	n (%)
Diarrhea	27 (18.2)
Nausea	24 (16.2)
Decreased appetite	10 (6.8)
Dizziness/headache	16 (10.8)
Fever	6 (4.1)
Abdominal cramping	7 (4.7)
Flatulence	23 (15.5)
Sore throat	17 (11.5)

*More than one condition possible

Kidney Function Monitoring

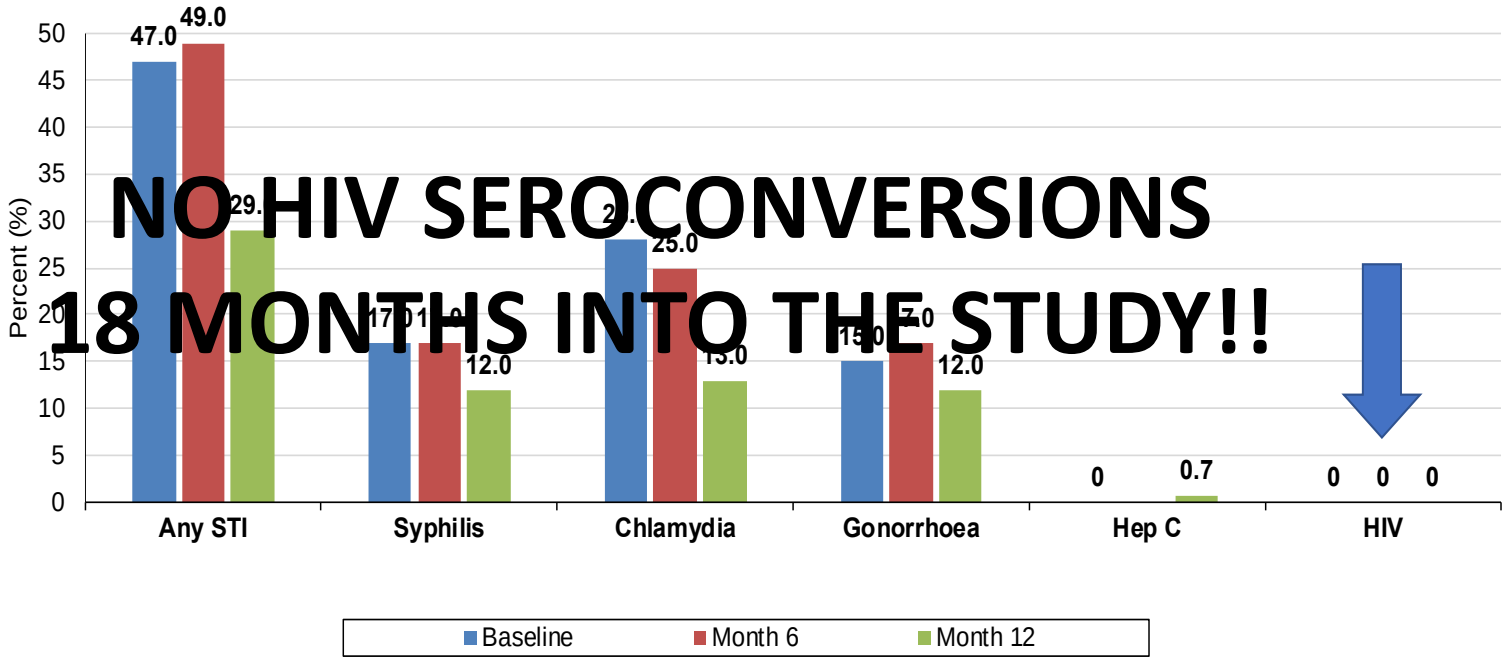


Timeline	Mean	Range
Baseline	102.41ml/min/1.73^2	60 - 132
Month 1	99.15ml/min/1.73^2	51 - 129
Month 6	100.89ml/min/1.73^2	60 - 131
Month 12	97.26ml/min/1.73^2	59 - 133

Kidney function

- - Participant 040
  - Baseline eGFR = 60
  - Month 1 eGFR = 51 – 2 weeks after PrEP start, on creatine supplement, used methamphetamine. PrEP stopped and repeated eGFR after 2 weeks, remains < 60, off PrEP for 4 weeks. eGFR normalized and PrEP was restarted
  - Month 6 eGFR = 60
  - Month 12 eGFR = 60
- - Participant 076
  - Baseline eGFR: 70
  - Month 1 eGFR: 68
  - Month 6 eGFR: 71
  - Month 12 eGFR: 59 – Started creatine supplement 1 month prior, used methamphetamine. PrEP stopped for 2 weeks along with creatine supplement. Repeated eGFR after 2 weeks. Normalized and restarted PrEP

Sexually Transmitted Infections and HIV



Chemsex (aHR 1.46 (95% CI 1.03- 2.08) (p=0.036) and receptive AI (aHR 1.55 (95% CI 1.04- 2.30) (p=0.03) were significant predictors of STI positivity on multivariate analyses

Summary

- A sample of 150 MSM was successfully enrolled at three different PrEP service delivery sites in Klang Valley
- Men were in majority Chinese, young, well educated, employed and at very high risk for HIV infection
- Project retention and drug adherence were high (>90%), exceeding international standards
- Only minor changes in sexual risk behaviors were observed
- Some self-reported medical conditions following PrEP initiation seem to be elevated compared to one would expect in every-day life
- Decreases in kidney function below the eGFR threshold (<60) were associated with use of creatine supplements
- There were high rate of asymptomatic STIs at baseline, which preceded the initiation of PrEP

Lessons Learnt from CBO based PrEP delivery services (CHCC, PTF)

- Client centred care
- **"Know the market as they are the market"**
- Trusted by key populations
- First site that completed the enrolment in My PrEP study
- More flexible opening hours
- High retention rate

- Limitation of resources - funding, laboratory support
- Lack of recognition and certification of CBO staff as potential PrEP providers
- Medico-legal issues around de-medicalization of PrEP
- Training capacity
- Cost

Courtesy of DR Sazali Basri

Lessons learnt and recommendations from My PrEP demonstration project (1)

- ***PrEP is a powerful biochemical HIV prevention strategy*** – no HIV infections reported in the cohort
- ***Messaging of "safer sex" in the era of PrEP needs to change to reduce stigma***
  - It is likely that with the perceived HIV protection offered by PrEP, rates of condomless sex are likely to increase over time.
  - The messaging of "safe sex" in the era of PrEP needs to evolve so that patients are not shamed or stigmatized by HCWs/policy makers for not using condoms if they feel adequately protected from HIV by adhering to PrEP
  - PrEP use needs to be re-framed as a positive and responsible option to remain HIV negative and that potential PrEP users are seen as taking control of their sexual health
- ***Chemsex users should be a priority population for PrEP***
  - 40% of participants used substances in the sexualized context (engaged in chemsex), mostly crystal meth with increasing use of GHB over time
  - Despite this, chemsex use did not appear to impact on overall PrEP adherence

Lessons Learnt (2)

- ***The preferred and most accessible sites for accessing PrEP (if all other factors were equivalent) was either the private clinic or the community based clinic.***
  - HIV treatment clinics offering PrEP in the hospital setting may be early adopters in providing PrEP but in the long term, PrEP provision is best delivered in key population clinics or private clinics which are already being accessed by key populations.
  - Task shifting to trained nurses or empowered members of key populations should be considered as part of de-medicalization of PrEP service delivery models.

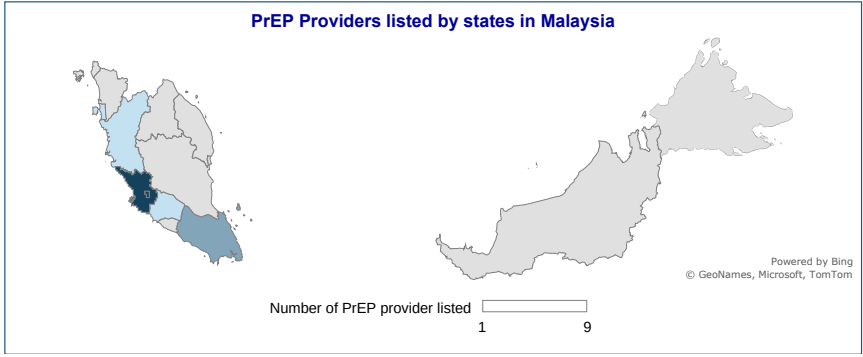
Lessons Learnt (3)

- ***PrEP is an opportunity for STI control and prevention***
  - There was a **high prevalence of baseline STIs** which **preceded the initiation of PrEP**, most of which were **asymptomatic**, re-enforcing that we are reaching those at higher risk of HIV/STIs and emphasizing the importance of regular screening of extra-genital STIs and syphilis within MSM irrespective of symptoms

- ***National Guidelines need to be updated to include on-demand PrEP***
  - Although most patients agreed to take daily PrEP as part of the study, there was an increasing number of participants who had less frequent sex who expressed an interest to take on-demand PrEP

- ***PrEP Stigma was not assessed formally in this study*** but this should be looked into future implementation considerations and how this can impact on access to PrEP services

Emerging PrEP Service Delivery Models



- Primary Care (Klinik kesihatan) (5)
- ID Clinics (4)
- Community Based Organizations (CBO) (2)
- Private sector (20 private clinics, mostly private GP clinics)
- Demonstration projects (1)

Mainly urban areas in Malaysia

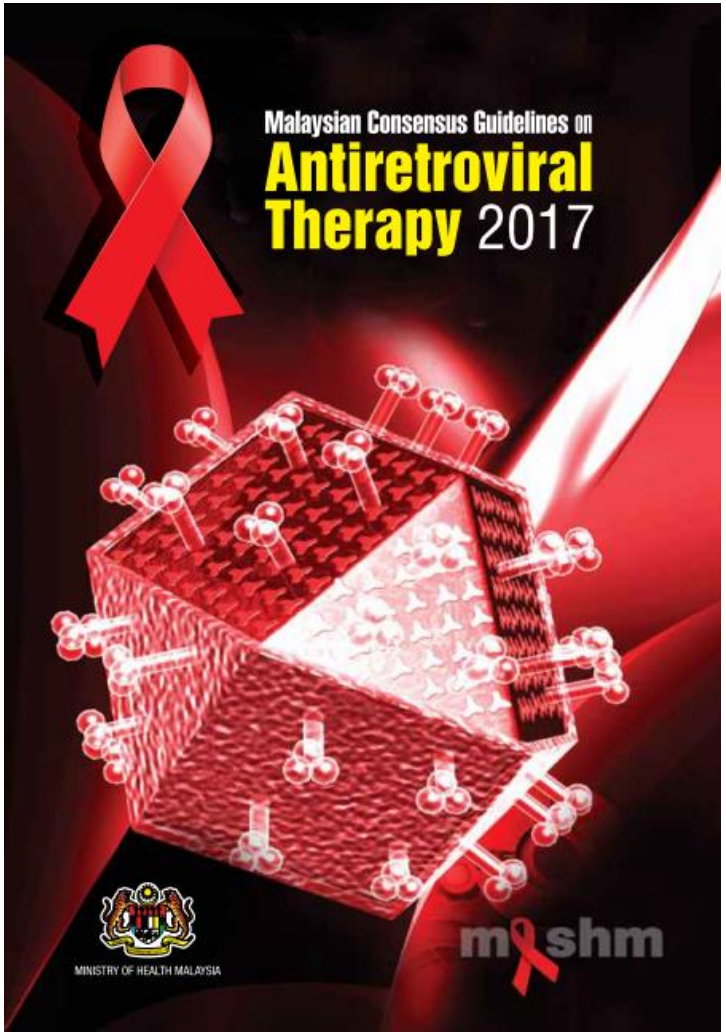
Providing PrEP to < 2000 patients

PrEP Locator Google Analytics : Accessed Aug 2020

Considerations for scale up of PrEP

Malaysian Guidelines

Updated 2017



2 new chapters

TABLE OF CONTENTS

www.mashm.net

***** 2020 PrEP Guideline Updates to include guidance on on-demand and same Day PrEP and greater emphasis on STI screening***

HIV Connect:
Comprehensive training for GPs

- In collaboration with MMA, AFPM & MAF
- Modular training (9 modules)
  - Online modules (Phase 1)
  - Face-face training/workshops (Phase 2)
  - Clinical attachments (Phase 3)
- On completion
  - Certificates, CPD points

75% of GPs are from Klang Valley
35% are private GPs
1200 have enrolled. 457 have completed online modules, 78 have attended workshop

MALAYSIAN MEDICAL ASSOCIATION

AFPM
Academy Of Family Physicians Of Malaysia

National Directory of PrEP Providers

- Increasing trend of users from age group 18-24 years
- An increase in users from Indonesia after integration of Malay language in My PrEP Locator
- Majority of the users accessed My PrEP Locator via mobile device.

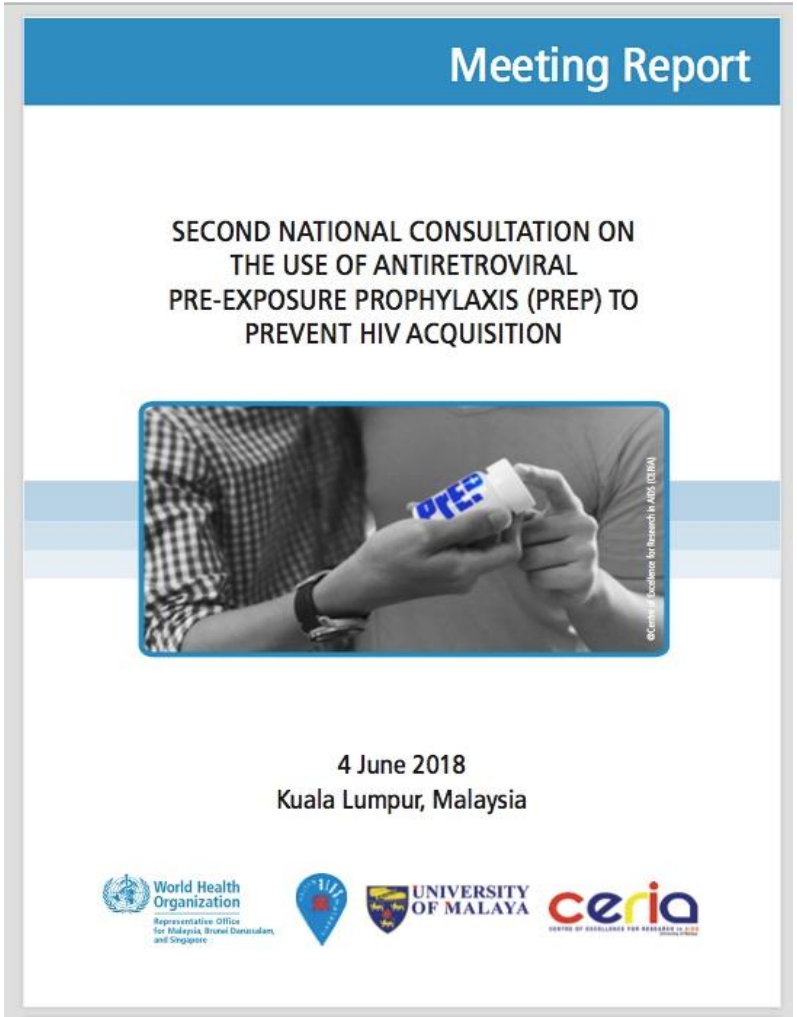
Sponsored by

World Health Organization
Representative Office for Malaysia, Brunei Darussalam, and Singapore

www.mypreplocator.com

2nd National Consultation on PrEP

Recommendations



- The purpose of PrEP must remain on reducing HIV incidence, **and concerns of risk compensation need to be addressed with all stakeholders.**
- For PrEP to achieve large-scale coverage to impact HIV incidence, **greater collaboration, engagement, and sensitization is necessary within the Ministry of Health on PrEP-related policies and guidance for all key populations**.
- Cost of PrEP is no longer a barrier as low-cost generic ARVs are available, yet the **lack of information on the cost of PrEP is a barrier**, as many potential clients perceive PrEP as a costly drug
- **Community advocacy and leadership should drive PrEP access**.
- **Clinics led by key populations represent the most accessible service delivery model**, however regulatory and policy change will be required for this to be implemented and sustained outside research.

We need to simplify the way we deliver PrEP Post-COVID

Differentiated **PrEP** service delivery

	PrEP Screening, initiation and early follow-up (0-3 months)			PrEP continuation (+3 months)
	Screening	PrEP initiation visit	Initial follow-up	Routine clinical follow-up
WHEN *Service frequency*	Same-day		Months 1, 3	Every 3 months/6 months
WHERE *Service location*	KP-led clinics Mobile clinics		KP-led clinics	KP-led clinics/Telehealth
WHO *Service provider*	KP lay providers dispense PrEP (which is prescribed remotely by doctors)		KP lay providers	KP lay providers
WHAT *Service package*	• Same-day HIV/syphilis testing • Cr, HBsAg (results come later) • PrEP counseling		• HIV testing • PrEP counseling	• Xpress, self-sampling/testing for HIV/STIs • Syphilis testing and Cr (every 6 months) • PrEP/effective use counseling

USAID LINKAGES project, September 2020.

Courtesy of Nittaya Phanuphak

Next Steps……

- Increasing community-led PrEP services
  - Collaboration with FRHAM (Family Planning)
- Formation of National PrEP Task Force
- Strengthening linkage of PrEP providers, HIV Connect, My PrEP locator, DHSKP & HIV ST interventions
    - Use of PrEP navigators
- Increase in PrEP demand generation activities
    - use of community PrEP ambassadors/influencers
    - Positive re- branding of PrEP
- Increase functionality of my PrEP Locator
- Centralized & competitive PrEP procurement negotiations with Pharma
- Strengthen government commitment & setting of national PrEP targets

Summary

- There is an urgent need to prioritize PrEP as an HIV prevention tool alongside increased HIV testing and treatment as prevention in Malaysia
- We have made some progress but it has been very slow
- PrEP service provision should be linked to HIV testing services
- Concerns of risk compensation need to addressed with all stakeholders
  - PrEP use needs to be re-framed as a positive and responsible option to remain HIV negative
- Community based & Key population led/involved clinics are the most accessible service delivery model but will requite regulatory and policy changes to make it sustainable

Summary

- Community empowerment, advocacy and leadership must drive PrEP access
- Future work should look at:
  - implementation research in TGs, sex workers and PWID
  - Novel and accessible PrEP service delivery models (e.g. on-line models)
  - M & E PrEP indicators and PrEP cascade

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