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

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University of Malaya
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

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>People Who Inject Drugs (PWID)</td>
<td>75,000</td>
<td>18.9%</td>
<td>16.3%</td>
<td>13.4%</td>
</tr>
<tr>
<td>Female Sex Workers (FSW)</td>
<td>22,000</td>
<td>4.2%</td>
<td>7.3%</td>
<td>6.3%</td>
</tr>
<tr>
<td>Transgender (TG)</td>
<td>15,000</td>
<td>4.8%</td>
<td>5.6%</td>
<td>10.9%</td>
</tr>
<tr>
<td>Men who have Sex with Men (MSM)</td>
<td>220,000</td>
<td>7.1%</td>
<td>8.9%</td>
<td>21.6%</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Timeline</th>
<th>PrEP Initiative</th>
<th>Lead partner organization(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 2015</td>
<td>Inclusion of PrEP in National Strategic Plan (NSP) to End AIDS (2016-2030)</td>
<td>MOH</td>
</tr>
<tr>
<td>Sept 2015</td>
<td>Regional PrEP Consultation (PrEPARING Asia), Bangkok</td>
<td>Led by APCOM</td>
</tr>
<tr>
<td>March 2016</td>
<td>Online PrEP Survey in MSM</td>
<td>International HIV Alliance</td>
</tr>
<tr>
<td>May 2016</td>
<td><strong>National PrEP Consultation</strong></td>
<td>MOH, WHO, UNAIDS, International HIV Alliance, APCOM (Global Fund)</td>
</tr>
<tr>
<td>May 2016</td>
<td>Formation of PrEP Working Group</td>
<td></td>
</tr>
<tr>
<td>Sept 2016</td>
<td><strong>Completion of National PrEP and nPEP guidelines</strong></td>
<td>MASHM Out of pocket PrEP</td>
</tr>
<tr>
<td>Timeline</td>
<td>PrEP Initiative</td>
<td>Lead partner organization(s)</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
</tr>
<tr>
<td>Jan 2017</td>
<td>HIV Connect</td>
<td>MASHM, MAC, MAF</td>
</tr>
<tr>
<td>Jan 2017</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; Asia Pacific PrEP Implementation Meeting, Bangkok</td>
<td>USAID, PEPFAR, FHI 360, TRC ARC</td>
</tr>
<tr>
<td>Dec 2017</td>
<td><strong>Price reduction of generic TDF/FTC</strong> <em>(generic competition)</em></td>
<td>Cipla, Hetero, Medispec</td>
</tr>
<tr>
<td>March 2018</td>
<td><strong>Pilot multi-site PrEP demonstration project in MSM</strong></td>
<td>UNAIDS/WHO/GF</td>
</tr>
<tr>
<td>July 2018</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; National PrEP Consultation on PrEP</td>
<td>CERIA, WHO</td>
</tr>
<tr>
<td>Jan 2019</td>
<td>HIV PrEP Locator</td>
<td>WHO, CERIA</td>
</tr>
<tr>
<td>Sept 2020</td>
<td>Community-led PrEP service delivery collaboration with FRHAM</td>
<td>MAC/AFAO (SKPA)</td>
</tr>
</tbody>
</table>
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 monogamous relationship was sufficient.
  - Participants often viewed PrEP as an additional "layer" of protection over and above that offered by condoms.
  - Condoms were often preferred to PrEP because it represented a visible physical barrier.
  - Concerns about confidentiality & fear of discrimination of sexual identity are barriers in accessing govt health clinics.

- **Assumptions and stigma**
  - Most perceived PrEP as taking responsibility of their own and sexual partners' health.
  - However, there were concerns around other MSM perceiving them negatively as promiscuous or using PrEP as a desire to engage in condomless sex or chemsex.

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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 Bourne¹,², Matteo Cassolato³, Clayton Koh Thuan Wei⁴, Bangyuan Wang⁵, Joselyn Pang⁵, Sin How Lim⁶, Iskandar Azwa⁷, Illias Yee⁴ and Gitau Mburu⁸

¹Corresponding 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

Where clients prefer to access PrEP services

- Government hospital/ART treatment centre: 18%
- Private clinic: 21%
- Community based organization: 22%
- Community based health clinic: 9%

*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®)
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Baseline</th>
<th>Month 1</th>
<th>Month 3</th>
<th>Month 6</th>
<th>Month 9</th>
<th>Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid HIV Ag/Ab</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>HIV POC VL</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Rectal CT/NG</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>RPR/TPHA</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>HBsAg/Ab</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV-Ab</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Questionnaire</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Diary (weekly)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Drug dispensing</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pill count</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Results
**Study Design**

- **Identification (381)**
  - MSM >18
  - Citizen of Malaysia
  - Living in Kuala Lumpur

- **Screening (331)**
  >1 sexual risk in past 6mo:
  - Unprotected anal sex
  - Anogenital STI
  - Sex for money
  - Use of PEP
  - HIV discordant relationship

- **Exclusion (222)**

- **Enrolment/site assignment**
  - UMMC (50)
  - RED Clinic (50)
  - CHCC (50)

**Timepoints**
- Baseline
- Month 1 Follow-up
- Month 3 Follow-up
- Month 6 Follow-up
- Month 9 Follow-up
- Month 12 Follow-up
<table>
<thead>
<tr>
<th>Socio-demographic characteristics</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>85 (56.6)</td>
</tr>
<tr>
<td>Indian</td>
<td>12 (8.0)</td>
</tr>
<tr>
<td>Malay</td>
<td>44 (29.3)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (6.0)</td>
</tr>
<tr>
<td><strong>Age group (years)</strong></td>
<td></td>
</tr>
<tr>
<td>18 – 25</td>
<td>31 (20.7)</td>
</tr>
<tr>
<td><strong>26 – 35</strong></td>
<td>83 (55.3)</td>
</tr>
<tr>
<td>36 and over</td>
<td>36 (24.0)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>15 (10.0)</td>
</tr>
<tr>
<td><strong>Diploma/degree</strong></td>
<td>116 (77.3)</td>
</tr>
<tr>
<td>Post-graduate</td>
<td>19 (12.7)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>122 (84.0)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>24 (16.0)</td>
</tr>
</tbody>
</table>
Existing HIV risk factors* prior to enrollment

- Unprotected sex with HIV+ or unknown: 128
- History of Anogenital STI: 41
- Paid or been paid for sex: 21
- Chemsex: 84
- Accessed PEP: 16

*Multiple risk factors possible
Existing HIV risk factors prior to enrollment

Number of HIV risk factors

- 55 (36.7%) factors
- 60 (40%) factors
- 26 (17.3%) factors
- 7 (4.7%) factors
- 2 (1.3%) factors
Retention

14 HIV infected
23 Declined
8 Clinical

Number of men

Retention rate (%)

Number of men

Retention rate

Months of follow-up

14 HIV infected
23 Declined
8 Clinical

195
150
150
148
145
142
138

2 Lost
3 Lost
3 Dropout
5 Dropout
1 Returned

2 Lost
3 Lost
3 Dropout
5 Dropout
1 Returned
Self-reported weekly PrEP adherence from diaries*

- Took all 7 doses / wk: 87.7%
- Took at least 4 doses / wk (Protective drug levels): 98.6%
- Took 0 - 3 doses / wk: 1.4%

*Based on 5492 (73%) out of 7569 diaries expected throughout the course of the project
### Self-reported medical conditions during the first month after initiating PrEP

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

*More than one condition possible*
Kidney Function Monitoring

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>102.41ml/min/1.73²</td>
<td>60 - 132</td>
</tr>
<tr>
<td>Month 1</td>
<td>99.15ml/min/1.73²</td>
<td>51 - 129</td>
</tr>
<tr>
<td>Month 6</td>
<td>100.89ml/min/1.73²</td>
<td>60 - 131</td>
</tr>
<tr>
<td>Month 12</td>
<td>97.26ml/min/1.73²</td>
<td>59 - 133</td>
</tr>
</tbody>
</table>
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
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 everyday 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.

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.

NO HIV SEROCONVERSIONS 18 MONTHS INTO THE STUDY!!
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

Considerations for scale up of PrEP
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
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

Sponsored by World Health Organization

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

<table>
<thead>
<tr>
<th>PrEP Screening, initiation and early follow-up (0-3 months)</th>
<th>PrEP continuation (+3 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Screening</strong></td>
<td><strong>PrEP initiation visit</strong></td>
</tr>
<tr>
<td>Same-day</td>
<td>Months 1, 3</td>
</tr>
</tbody>
</table>

**WHEN**
- **Service frequency**
  - Same-day

**WHERE**
- **Service location**
  - KP-led clinics
  - Mobile clinics

**WHO**
- **Service provider**
  - KP lay providers dispense PrEP (which is prescribed remotely by doctors)

**WHAT**
- **Service package**
  - Same-day HIV/syphilis testing
  - Cr, HBsAg (results come later)
  - PrEP 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 be 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 require 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
Acknowledgements

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• Frederick Pour
• Dr Andrew Yap