A Global Perspective of PrEP Use and Delivery: 2018

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Competing Interest Disclosure

• I act as a consultant to Merck and GlaxoSmithKline
• I speak at company sponsored events on behalf of Gilead Sciences and Merck
• I have received research grants for my institution from Gilead Sciences, GlaxoSmithKline and Merck.
There are approximately 200,000 high risk individuals taking TDF/FTC as PrEP worldwide.
Estimated number of adults with PrEP indications in the United States: 2015

<table>
<thead>
<tr>
<th></th>
<th>MSM</th>
<th>HET</th>
<th>PWID</th>
<th>Total*</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 States, DC</td>
<td>814,000</td>
<td>258,000</td>
<td>73,000</td>
<td>1,145,000</td>
</tr>
<tr>
<td>Vital Signs estimate</td>
<td>492,000</td>
<td>624,000</td>
<td>115,000</td>
<td>1,232,000</td>
</tr>
<tr>
<td>Lower Limit of VS estimate</td>
<td>212,000</td>
<td>404,000</td>
<td>45,000</td>
<td>661,000</td>
</tr>
<tr>
<td>Upper Limit of VS estimate</td>
<td>772,000</td>
<td>846,000</td>
<td>185,000</td>
<td>1,803,000</td>
</tr>
</tbody>
</table>

*Estimates are rounded and may not sum to the total

Smith et al, CROI 2018  Oral Abstract 86
## Estimated number of adults with PrEP indications by race/ethnicity/risk group in the U.S. in 2015

<table>
<thead>
<tr>
<th>Transmission risk group</th>
<th>Total</th>
<th>Black/African American</th>
<th>Hispanic/Latino</th>
<th>White, non-Hispanic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimated no.</td>
<td>% of Total</td>
<td>Estimated no.</td>
<td>% of risk group total</td>
</tr>
<tr>
<td>MSM</td>
<td>813,970</td>
<td>71.1</td>
<td><strong>309,190</strong></td>
<td>38.0</td>
</tr>
<tr>
<td>HET</td>
<td>258,080</td>
<td>22.5</td>
<td><strong>164,660</strong></td>
<td>63.8</td>
</tr>
<tr>
<td>Men</td>
<td>81,410</td>
<td>7.1</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Women</td>
<td>176,670</td>
<td>15.4</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>PWID</td>
<td>72,510</td>
<td>6.3</td>
<td><strong>26,490</strong></td>
<td>36.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,144,550</td>
<td>100.0</td>
<td><strong>500,340</strong></td>
<td>43.7</td>
</tr>
</tbody>
</table>
Estimated percentage of adults with PrEP indications who are Black/African American by state

Estimated percentage of adults with PrEP indications who are Black/African American by state
Minimal estimate of PrEP coverage in 2015-2016 by region and race/ethnicity
PrEP prescription rates per 100,000 patients seen in 602 ambulatory care practices, overall, NYC 2014-2016

<table>
<thead>
<tr>
<th>Quarter</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>38.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- PrEP prescriptions per 100,000 patients seen
  - Q1 2014: 38.9
  - Q2 2015: 418.5
  - Q1 2016: 2,977/711,343

Source: Salcuni, et al., IDWeek, 2017.
PrEP prescription rates per 100,000 patients seen in 602 ambulatory care practices, by sex, NYC 2014-2016

<table>
<thead>
<tr>
<th></th>
<th>Males</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>89.5</td>
<td>7.4</td>
</tr>
<tr>
<td></td>
<td>220/245,689</td>
<td>29/393,780</td>
</tr>
<tr>
<td>Q2</td>
<td></td>
<td>32.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>142/437,788</td>
</tr>
</tbody>
</table>

- Adjusted for patient age and race/ethnicity, practice location and type, proportion of practice’s patients living in high poverty ZIPs, and number of ID specialists.

Salcuni, et al., IDWeek, 2017.
PrEP prescription rates per 100,000 males seen in 602 ambulatory care practices, by race/ethnicity, NYC 2014-2016

- **White**: 2508.5 (1,396/55,650)
  - Q1: 2508.5
  - Q2: 868.6 (357/41,100)
  - Q3: 709.5 (545/76,817)
  - Q4: 654.8 (254/54,210)

- **Black**: 112.6 (23/20,428)

- **Hispanic/Latino**: 51.8 (33/63,704)

- **API**: 44.0 (17/38,671)

- **Other**: 39.5 (18/45,552)

*Salcuni, et al., IDWeek, 2017.*
HIV Prevention Continuum in NYC

Sexual Health Survey, Spring 2016
Aggregate Online and In-person Sample
(n=677)

- PrEP Candidate†‡: 100%
- Provider visit, past 6 months: 83%
- Sexual hx and provider visit,^ past 6 months: 69%
- Discussed PrEP with provider, past 6 months: 53%
- On PrEP, past 6 months: 30%

*Sample includes sexually active MSM aged 18-40 years and who report HIV-negative/unknown status
†PrEP candidates defined as reporting diagnosis of an anal STI in the past year or any of the following in the previous 6 months: unprotected anal intercourse, transactional sex, use of cocaine, crack, methamphetamines, or injection drugs, using PEP or having had an HIV-positive partner. Definition mirrors NYS PrEP guidance. ‡PrEP candidates represent 83% of all HIV-negative respondents. ^Sexual history ever taken by a provider visited in past 6 months
PrEP uptake in a national cohort of gay and bisexual men in the U.S.

Parsons et al J Acquir Immune Def Syndr 2017
Oral PrEP initiations
*Disaggregated by age, gender, and province*

Of the **3 880 oral PrEP initiations** to date:

- **0.4%** were between the ages of 0-15 years
- **3%** were between the ages of 16-18 years
- **29%** were between the ages of 19-24 years
- **43%** were between the ages of 25-34 years
- **24%** were **35 years or over**

Two-thirds (2 577) of PrEP users identified as female when they initiated, and around exactly a third identified as male (1 296), and a very small number (8) reported themselves as transgender.

*Oral PrEP initiations by province*  
*June 2016 – December 2017*
Oral PrEP Implementation
Oral PrEP and ART commencements by site type

### June 2016 – December 2017
**SW sites**
- 44,822 Total HIV tests conducted at implementing SW sites
- 5,879 (13%) Pos. HIV tests
- 2,884 (49%) ART initiations
- 3,037 (12%) PrEP initiations

### April 2017 – December 2017
**MSM sites**
- 5,486 Total HIV tests conducted at implementing MSM sites
- 286 (5%) Pos. HIV tests
- 290 (101%) ART initiations
- 818 (48%) PrEP initiations

### October 2017 – December 2017
**University sites**
- 2,059 Total HIV tests conducted at implementing campus clinics
- 27 (1%) Pos. HIV tests
- 49 (181%) ART initiations
- 43 (2%) # offered PrEP
- 26 (60%) PrEP initiations
Oral PrEP expansion: She Conquers priority sub-districts secondary school and TVET clusters

Providing PrEP to at-risk adolescent girls and young women will be a key component of the next phase of PrEP implementation. Beginning implementation in the She Conquers priority sub-districts ensures that combination prevention, including PrEP, will be available to young people at highest risk. The cluster system, described below, will reach a large numbers of AGYW.

*In each sub-district, a focal facility will be selected based on the following criteria:*

1. **Education institutions**
   - Clinics closest to clusters of Q1-Q3 secondary schools, TVETs, and universities were prioritised.

2. **Catchment**
   - The selected facility should ideally be located as close as possible to the largest number of educational institutions, ensuring that learner/student catchment is high.

3. **Distance**
   - The distance between educational institutions and the focal health facility is critical to both uptake of services and retention in care.

4. **Facility audit and selection**

5. **School cluster selection**

6. **Health facility capacitation and sensitisation**

7. **Demand generation in selected schools through She Conquers, HEAIDS, and partner activities**

8. **Provision of PHC, family planning, and combination prevention services – including PrEP**

9. **Appointing or electing peer “youth champions” to continuously promote and normalise clinic services**
PUBLIC HEALTH

HIV infections are spiking among young gay Chinese
Officials strive to understand infection routes and promote prevention and testing

Risky rise
Surveys of different populations at risk of HIV/AIDS in China have charted a steep rise in the percentage of men who have sex with men (MSM) living with HIV.
# HIV incidence among MSM in China
(at least 400 patient years)

<table>
<thead>
<tr>
<th>First author</th>
<th>Study Period</th>
<th>Location</th>
<th>Person-Years</th>
<th>Incidence (per 100 py)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jia ZW</td>
<td>2007-12</td>
<td>Beijing</td>
<td>6,809</td>
<td>7.1</td>
<td>Sci Rep 2015</td>
</tr>
<tr>
<td>Liu GW</td>
<td>2009-2012</td>
<td>Beijing</td>
<td>1046</td>
<td>5.9</td>
<td>PLOS One, 2015</td>
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<tr>
<td>Li, DL</td>
<td>2009-2010</td>
<td>Beijing</td>
<td>593</td>
<td>8.1</td>
<td>BMJ Open, 2012</td>
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<tr>
<td>Zhao, T</td>
<td>2010-12</td>
<td>Nanjing</td>
<td>587</td>
<td>3.4</td>
<td>China J AIDS and STI 2013</td>
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<tr>
<td>Fu, ZH</td>
<td>2010-12</td>
<td>Suzhou</td>
<td>487</td>
<td>4.9</td>
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<td>Nanjing</td>
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<td>Beijing</td>
<td>445</td>
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<td>CJP, 2011</td>
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<td>Wang, Y</td>
<td>2009-2013</td>
<td>Mianyang</td>
<td>437</td>
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<td>Sex Health, 2015</td>
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<td>Li, DL</td>
<td>2006-2008</td>
<td>Beijing</td>
<td>425</td>
<td>2.6</td>
<td>AIDS Pt Care STDs 2010</td>
</tr>
</tbody>
</table>

Compiled by Yumeng Wu, Aaron Diamond AIDS Res Ctr
Response to epidemic among MSM in China

- Increased HIV testing and condom use
- ART for HIV-infected individuals
  - Earlier treatment: median CD4 at treatment initiation increased from 100 in 2006 to 300 in 2015
  - No STR provided by the government sponsored programs
  - Must have a positive Western Blot to enroll in the government program
  - TDF-3TC-EFV is the only regimen provided for first line therapy
  - Limited numbers of centers that provide ART
- Access to PEP or PrEP
  - Access is a challenge via select hospitals
  - Limited knowledge of PEP and PrEP due to recent crackdowns on foreign NGOs aiming to provide education, testing, prevention, and treatment-
    - Recent online survey of 6,500 Chinese MSM-60% never heard of PrEP
  - PEP is very costly- $750 U.S. for the drugs and clinical care
  - PrEP cost is approximately $350/month and not approved as PrEP
  - No primary care physicians to provide continual care for HIV-uninfected individuals
  - ARVs need to be prescribed by HIV physicians only
- Currently no support for use of TDF/FTC as PrEP by China Ministry of Health
- Plans to test TDF/FTC daily vs. on demand TDF/FTC as per IPERGAY vs choice of no PrEP
- MSM and TGW are a highly stigmatized and marginalized population
Early Lessons

• Once past the first wave of early users, novel strategies need to be developed to address “harder to reach” populations

• Increased self-awareness of risk and acceptance of a biomedical approach to prevention is needed
  • “Health maintenance” and “Sex positive” messaging as opposed to “medicalization” and “fear based”

• Health care systems must adapt to meet the challenges of providing PrEP to large numbers of high risk individuals

• Health care providers must be educated and integrate sexual health and well being into their assessments of patients

• Cost issues must be addressed
  • Drug
  • STI monitoring
  • Effective HIV testing algorithms

• Need to decriminalize and destigmatize high risk groups

• Need to destigmatize PrEP use
The Future of PrEP Globally

• Testing of novel PrEP agents
  • Streamlined and novel study designs to reduce size, cost, and duration

• PrEP agents
  • Oral FDC TDF/FTC versus TAF/FTC
    • Daily versus intermittent
  • Injectable
    • Cabotegravir 600 mg every 8 weeks
      • Establish efficacy
      • Understand the significance of the tail as it affects drug resistance
  • Implantable
    • TAF
    • EFdA
  • Infusible/injectable
    • Monoclonal antibodies
BE PrEPARED!

PrEP IS A SAFE, LEGAL, AND EFFECTIVE OPTION FOR PREVENTING HIV.

PrEP: Pre-Exposure Prophylaxis. Truvada is currently the only drug approved by the FDA for PrEP. When taken as directed, Truvada is more than 90% effective at preventing HIV infection. Consult the manufacturer’s website for a full list of side-effects and indications.
Acknowledgements

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