Engaging Black Men Who have Sex with Men (BMSM) in Los Angeles in HIV Pre-Exposure Prophylaxis (PrEP)

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Conflict of Interest & Acknowledgements

- I have no conflicts of interest to report.
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What is PrEP?

• A biomedical intervention that involves the use of existing antiretroviral(s) by HIV uninfected but substantially at-risk individuals to prevent HIV acquisition.
• Has been demonstrated to be an effective HIV prevention strategy.
• The current medication, Truvada® was approved by the FDA in mid-2012.
  – It combines Emtricitabine/Tenofovir (TDF-FTC)
CDC Recommended Indications for MSM PrEP Rx

• Not in a monogamous partnership with a recently tested, HIV-negative man AND at least one of the following:
  – Anal sex without condoms (receptive or insertive) in past 6 months
  – STI diagnosed or reported in past 6 months
  – Is in an ongoing sexual relationship with an HIV-positive male partner
YBMSM are prime PrEP candidates

HIV Diagnoses among MSM age 13-24 by Race/Ethnicity, 2005-2014

- Black/African American
- Hispanic/Latino
- White

Source: Centers for Disease Control and Prevention
Local Experience

• In 2013-15, there were 5 local PrEP studies.
• Anecdotal reports and concerns regarding PrEP knowledge and engagement of Black MSM in local trials.
Response: Round Table Discussion


- Objective:
  - To discuss the best practices for the effective uptake and engagement of BMSM in PrEP.

- Held March 2015

- Subsequent information gathering from a wide range of key informants
Talk Objectives

1. Provide brief information on PrEP and data regarding uptake.
2. Discuss rationale for focus on Black MSM
3. Describe process of gathering information and recommendations from experts.
4. Discuss key recommendations.
Summary of Key MSM Studies

- iPrEx Study
- PROUD
- IPERGAY
- HPTN 073
iPrEx Study

• Seminal clinical PrEP study.
• Multinational – Brazil, Ecuador, Peru, Thailand and USA.
• Evaluated safety and efficacy of once-daily oral Truvada® or TDF/FTC for the prevention of HIV acquisition among men who have sex with men (MSM) and transgender women.
iPrEx Study

• Key findings
  – Provided an average of 44% additional protection against HIV infection among MSM in the intervention arm compared to controls. (Grant, R. M. et al., 2010)
  – Over 90% additional protection for participants with detectable levels of medication in blood.
PROUD

• The first open-label randomized controlled trial of PrEP
• Enrolled HIV-negative MSM who had had anal intercourse without a condom in the prior 90 days.
• Participants were randomly assigned (1:1) to receive daily combined TDF/FTC either immediately or after a deferral period of 1 year
  – Everyone got risk reduction counseling and HIV testing
• Used a pragmatic schedule and procedures to show how PrEP would be used in routine clinical practice.
PROUD: Key Findings

• Deferred arm
  – 20 new infections (9 cases per 100 person-years).

• Intervention arm
  – Just 3 new infections (1.2/100 person-years).

• Based on early evidence of effectiveness, the steering committee recommended offering PrEP to all participants.
Ipergay: Key Findings

- Assessed the efficacy of “on demand” PrEP in high risk MSM (n=414).
- “On Demand” oral PrEP with TDF/FTC was effective, with a 86% (95% CI: 40-99%) reduction in HIV-incidence.
  - Again, trial stopped early because of the strong evidence of effectiveness.
  - “On Demand” PrEP may be an attractive alternative to daily PrEP.
HPTN 073

- A demonstrative study specific to Black MSM
- Planned enrolment of 225 participants in three different cities;
  - Los Angeles, CA, Washington DC & Chapel Hill, NC.
- Primary outcome measures
  - Adherence to PrEP
  - Initiation of PrEP
- Findings to be released at CROI this month
PrEP uptake since FDA Approval

• Increase in PrEP use and access nationally from 2012 to present.
• There also appear to be some increases in use at the local level (Los Angeles County).
• Improved structural access in areas of
  – manufacturer’s assistance program (MAP)
  – increased insurance coverage.
  – LA County mandate
National PrEP Prescription Trend

Bush S. et al., IAPAC Conference, 2015
PrEP knowledge and use in LAC

• HIV-negative and at-risk MSM who had heard about PrEP rose from 39% in 2011 to 82% in 2014.

• Willingness to take PrEP increased from 54% to 69% within the same time period.

• Among very high-risk MSM, however, only 8% had ever used PrEP in 2014 compared to 0% in 2011.

— Source: Sey E. K. et. al., 2014 NHBS. 2015, LA DHSP
## Knowledge and use of PrEP/PEP in Los Angeles, CA. - 2014

<table>
<thead>
<tr>
<th>Knowledge and Use of PrEP and PEP †</th>
<th>White (n=149)</th>
<th>Black (n=102)</th>
<th>Latino (n=211)</th>
<th>Total (n=525)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had heard of PrEP/PEP</td>
<td>76%</td>
<td>67%</td>
<td>52%</td>
<td>63%</td>
</tr>
<tr>
<td>Willing to take daily PrEP/PEP</td>
<td>60%</td>
<td>53%</td>
<td>59%</td>
<td>58%</td>
</tr>
<tr>
<td>Had used PEP</td>
<td>9%</td>
<td>1%</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Had used PrEP</td>
<td>4%</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
</tbody>
</table>

†Included only participants self-reporting HIV-Negative or unknown HIV status; PrEP: Pre-exposure prophylaxis; PEP: Post-exposure prophylaxis.

NHBS, 2014
BMSM lag behind in PrEP usage.

• In a 2014 survey of 398 HIV-negative BMSM by Eaton et al, 60% reported being willing to use PrEP. Yet only 6.8% reported using PrEP.

• Local demonstration projects filled their quotas of Black MSM last but experienced waiting lists for other groups.

• NHBS data indicate somewhat lower knowledge and willingness.
Black MSM in PrEP Trials

<table>
<thead>
<tr>
<th>Study name</th>
<th>Author(s), Date</th>
<th>Location</th>
<th>Trial population</th>
<th>% BMSM</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPrEX</td>
<td>Grant et al., 2010</td>
<td>Multinational</td>
<td>2499</td>
<td>9</td>
</tr>
<tr>
<td>IPERGAY</td>
<td>Molina, J. M. et al., 2015</td>
<td>France, Canada</td>
<td>414</td>
<td>-</td>
</tr>
<tr>
<td>PROUD</td>
<td>McCormack et al., 2015</td>
<td>England</td>
<td>544</td>
<td>4</td>
</tr>
<tr>
<td>PrEP and Condom Use</td>
<td>Hoff et al., 2015</td>
<td>SF &amp; NYC</td>
<td>48 MSM couples</td>
<td>38</td>
</tr>
<tr>
<td>From Efficacy to Effectiveness</td>
<td>Golub et al., 2013</td>
<td>NYC</td>
<td>185</td>
<td>39</td>
</tr>
</tbody>
</table>
Round Table Format
• Two moderators (N. Harawa & D. Butler, MD)
• 16 participants and 2 note-takers:
  – Infectious disease specialists
  – Policy makers
  – HIV/AIDS researchers
  – Gilead representatives
  – Patient advocates & social service providers
• Subsequent information gathering
  – through meetings with primary care and social service providers and additional experts.
  – reviews of scientific and popular literature.
  – priority-setting survey
Summary of Questions

• What has been your experience with recruitment of BMSM for PrEP trials?
• What has been your experience with getting high-risk and/or interested BMSM patients on PrEP?
• What are some of the key patient barriers to PrEP uptake among BMSM?
• What are effective strategies for promoting engagement? Adherence?
Summary of Barriers Raised

• PrEP knowledge and Access
• Risk Perception and Definition
• Community Opposition
• Provider anxieties
  - Patient adherence
  - Risk of resistant strain emergence
  - The purview paradox
  - Too cumbersome/time-consuming
Survey Responses

Priorities For Policy Makers

- Ease the way for PrEP specialists/PrEP Clinics
- Develop comprehensive PrEP scale up plans
- Provide resources for wraparounds services to those providers who are or will be heavy PrEP...
- Ease reimbursement and approval processes
- Clarify which provider types should provide PrEP
- Decrease co-insurance costs

N = 14
Survey Responses

Priorities For Health Departments

N = 15

- Fund PrEP specialists/PrEP Clinics
- Develop comprehensive plans
- Assist with creating consistent "high-risk"
- Identify providers who see high-risk patients
- Provider education
- Public education
Summary of Recommendations

1. Client Care Coordination
2. Increasing sources of referrals and broadening potential prescribers
3. Increasing Access to PrEP
4. PrEP Education, Marketing and Message Framing
5. PrEP Adherence
1. Client Care Coordination

- Strong need for **wraparound services** to encourage utilization and adherence.
  - Lack of social support, poverty, and transient housing circumstances complicate the lives of many BMSM. Low health literacy is also problematic.
  - Co-Location of social and medical services.
  - HPTN 073 used the C4-Client-Centered Care Coordination model to implement this.

- Policies should address provider compensation for providing these services.
Importance of Client Care Coordination

• Assistance with **housing/transportation access, mental health care services and legal help** have been shown to increase retention in healthcare services.

• Substance abuse treatment, expungement of criminal records, and help accessing or navigating MediCal or other health insurance applications may also improve PrEP adherence.

• Provider compensation will increase willingness of to engage in patient education surrounding PrEP.
2. Increasing Sources of Referrals to PrEP

- Engage HIV testing programs, PEP sites, and STD Clinics
- Engage case managers, drug treatment counselors, mental health workers, peer navigators, as well as NPs and PAs,
- Engage LACDMH, LAUSD & other educational institutions, especially community colleges and the Cal State systems.
- Institute consistent referral criteria for PrEP.
Importance of Increasing Sources of PrEP Referrals

• Many at-risk Black MSM are not engaged in health care systems.
• Many young men are not engaged in regular preventive medical care activities.
• Increases convenience of access to knowledge and care.
3. Supporting PrEP Adherence

• Develop and implement tailored adherence curricula for both providers and patients.
• Engage LACDMH, social workers and mental health providers in efforts/programs to support adherence.
Importance of Supporting PrEP Adherence

• All PrEP efficacy research indicate adherence to be the most important predictor of success.
• 50% of medications for chronic diseases in the US are not taken as prescribed (Viswanathan M., et al., 2012)
• Adherence rates are somewhat lower in Black than other race HIV-positive MSM.
• PrEP is innovative and unprecedented.
AIDS Healthcare Foundation (AHF) has taken the position that the scientific data do not support the large-scale use of Truvada as a community-wide public health intervention.

Overall efficacy was low in all studies due to low adherence. Even in carefully monitored clinical trials, most participants did not take Truvada as prescribed by medical professionals.

AHF Ad Campaign
4. Increasing Real Access to PrEP

- Medication assistance programs should be streamlined and promulgated to both potential providers and patients.
- Encourage appropriate sexual history taking through training and EMR prompts.
- Create and support specialized prevention clinics.
Importance of Increasing “Real Access”

• Although medication assistance programs are available, knowledge of them seems suboptimal.
• Perceived to be complicated and difficult/time-consuming to use.
• Years of efforts to promote routine sexual history taking and HIV testing have met with limited success.
• Specialty prevention clinics can create more targeted and culturally competent spaces.
5. PrEP Education & Social Marketing

Efforts need to be both increased and improved.

• Improved message framing.
• Broader outreach and promotion.
• Provider education on the potential benefits and address stated provider concerns.
• Education of providers and potential referrers especially on risk history taking and PrEP criteria.
• Incorporation of PrEP into medical education.
Importance of Education & Social Marketing

- LA County data indicate somewhat lower awareness in BMSM.
- Lack of awareness and resistance among providers common in Black communities.
- PrEP awareness has been associated with higher rates of HIV testing and knowledge, and lower rates of exchange sex. (Eaton et al., 2015)
- PrEP providers report benefits beyond HIV prevention.
Not enough health care providers know about PrEP.

Pre-exposure prophylaxis (PrEP) is a medicine taken daily that can be used to prevent HIV infection. PrEP is for people without HIV who are at very high risk for acquiring it from sex or injection drug use.

- **90%**  
  Daily PrEP can reduce the risk of sexually acquired HIV by more than 90%.

- **70%**  
  Daily PrEP can reduce the risk of HIV infection among people who inject drugs by more than 70%.

- **1 in 3**  
  1 in 3 primary care doctors and nurses haven’t heard about PrEP.


Any prescribing health care provider can deliver PrEP care.

1. **Test** for HIV including acute infection.
   - If HIV negative, ask about sex and drug use behaviors.
   - If HIV positive, provide or refer patient for HIV treatment and other services to maintain health and prevent further spread of HIV.

2. **Order** recommended tests if patient is interested in PrEP and could benefit from it.
   - If tests show reason not to prescribe PrEP (e.g., abnormal kidney function), discuss other prevention methods.

3. **Help** patient apply for insurance or other programs to pay for PrEP.
   - Most public and private insurance programs cover PrEP, and patients can get help with their co-payments.

4. **Prescribe** PrEP and instruct patient to take one pill every day.
   - Drug assistance programs can help patients without insurance pay for PrEP.

5. **Follow-up** Schedule appointments every 3 months for follow-up, including HIV testing and prescription refills.
   - Currently Truvada®* is the only medicine approved by the FDA for PrEP.
   - *Tenofovir disoproxil fumarate/emtricitabine

**Have questions?**

Call the PrEP Clinician Helpline:
(855) 446-7737 or (855) HIV-PrEP

Want PrEP?

You may need to provide a little “PrEP 101” to your doc first.

My PrEP experience
myprepexperience.blogspot.com

Pre-exposure prophylaxis (PrEP) is a daily pill that can help prevent HIV infection. It is available for some people who are HIV-negative and are at risk of getting HIV. PrEP reduces the risk of getting HIV by up to 92-96% when taken daily. For more information, visit PrepFacts.org.

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Short-Term Actionable Items

- Widely distribute PrEP assistance hotline information (855 HIV PrEP or 855-448-7737) and directory of local PrEP providers.
- Identify and educate potential PrEP providers (i.e., those serving at-risk BMSM).
- Develop a social media campaign geared toward and informed by YBMSM.
- Develop a culturally tailored PrEP adherence curriculum.
Conclusions

• Encouraging PrEP engagement for Black MSM will likely increase uptake for all.
• However, special attention must be paid to where the experiences of Black MSM differ from others at-risk of HIV.
• Successes and failures related to uptake of routine HIV testing may be informative.
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- Tony Mills, MD
- Leo Moore, MD
- Phil Meyer, MSW
- David Lee, MPH
References


Currently enrolling

Your voice. Your relationships. Your health.

A voluntary health study for women

323-379-2050

Eligible participants get cash and gift cards.

FemAleS
www.females.org

Preparation date: 8/15/2014, Approval date: 8/1/2014.
CDU IRB# 12-04-2354
Passport to Wellness
Start your journey today!

GET YOUR LIF

You are invited to participate in a research project investigating a holistic approach to wellness and sexual health for Black men. Your “Passport” is a customized plan to help you achieve better health through referrals to culturally-appropriate social, spiritual and bio-medical services. Your information will be kept PRIVATE. Eligible participants will receive compensation.

323-451-9491

David Geffen School of Medicine

Date of Preparations: February 12, 2015
CDU IRB#: 14-11-2444-00
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