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

PACIFIC AIDS Education and Training Center

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Conflict of Interest & Acknowledgements

- I have no conflicts of interest to report.
- The work was spearheaded by the HIV Cluster at Charles R. Drew University of Medicine and Science (CDU) and the CDU Pacific AIDS Education and Training Center (PAETC).
- Reports sponsored by California HIV/AIDS Policy Research Centers: University of California, Los Angeles (UCLA); AIDS Project Los Angeles; Los Angeles LGBT Center
  - *The California HIV/AIDS Research Program*
  - *Grant Number RP11-LA-020 and RP11-APLA-022*
- California HIV/AIDS Policy Research at UCLA & the Center for HIV Identification, Prevention and Treatment Services.

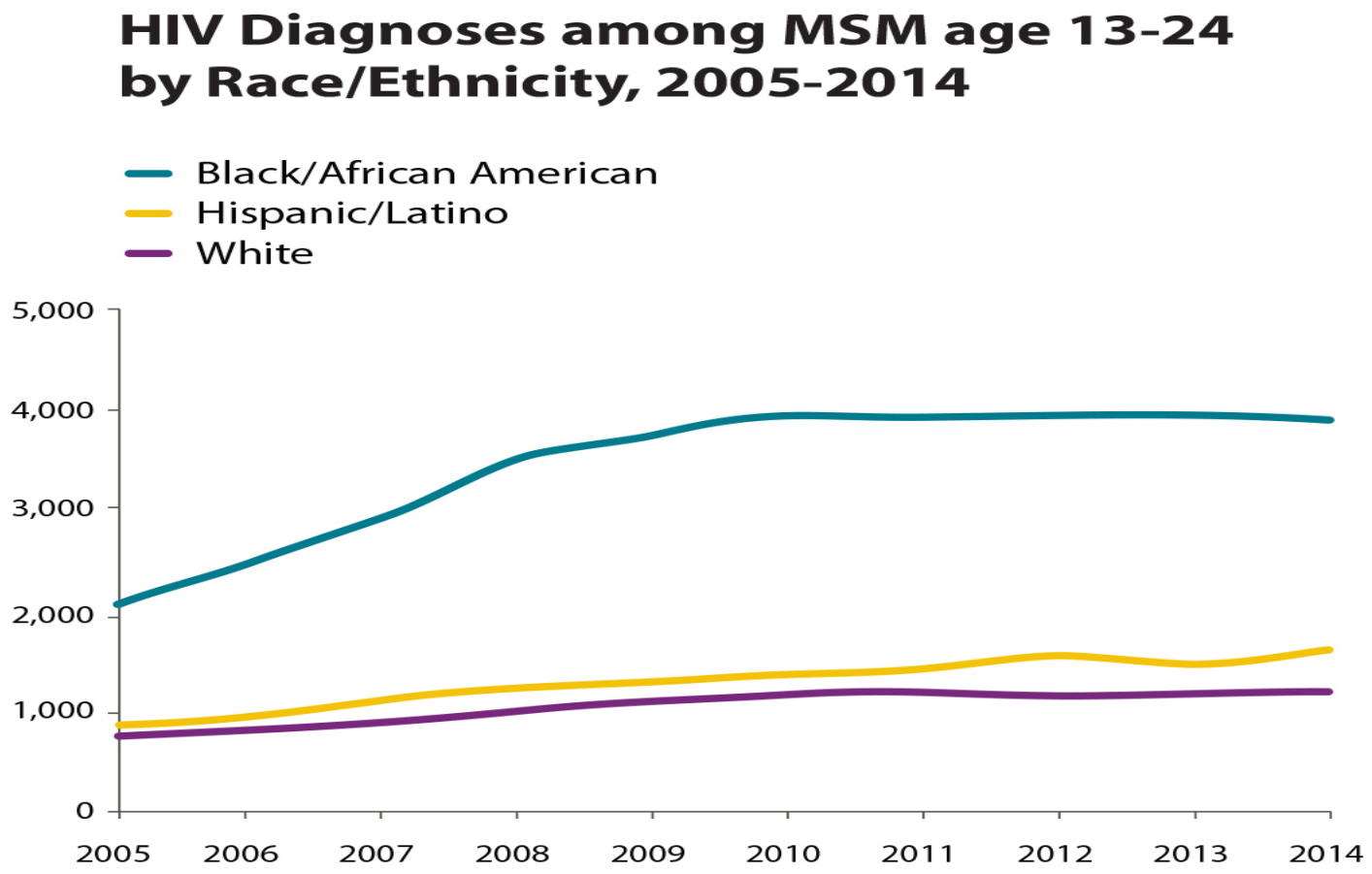
What is PrEP?

- 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

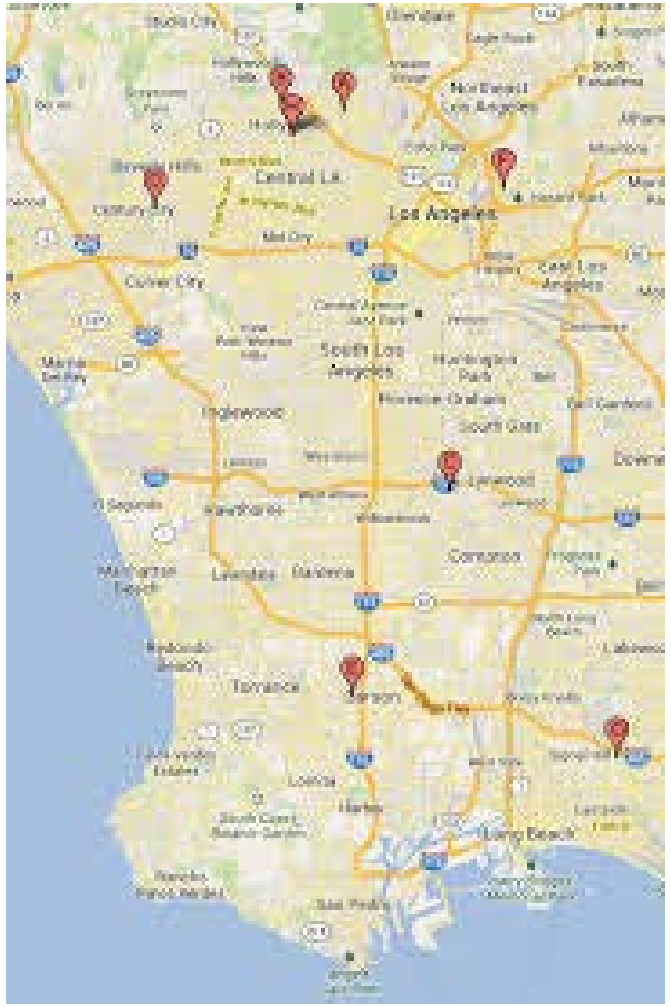
YBMSM are prime PrEP candidates



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

- Organized by CDU HIV Cluster, Pacific AIDS Education and Training Center, and the California HIV/AIDS Policy Center (UCLA/APLA).
- 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

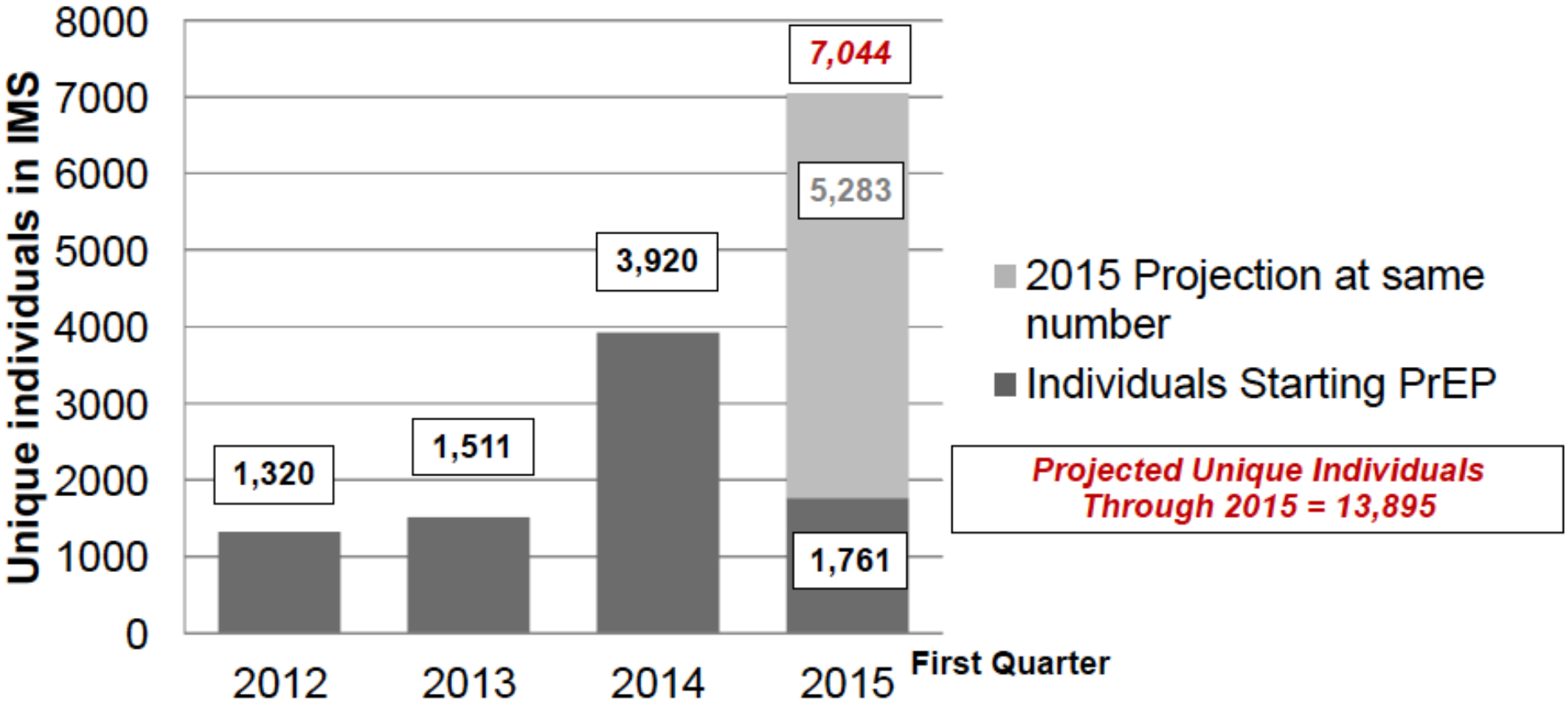
HPTN 073

- 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

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

†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

Number of BMSM in PrEP Demonstration Studies to Date				
Study name	Author(s), Date	Location	Trial population	% BMSM
IPrEX	Grant et al., 2010	Multinational	2499	9
IPERGAY	Molina, J. M. et al., 2015	France, Canada	414	-
PROUD	McCormack et al., 2015	England	544	4
PrEP and Condom Use	Hoff et al., 2015	SF & NYC	48 MSM couples	38
From Efficacy to Effectiveness	Golub et al., 2013	NYC	185	39

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?

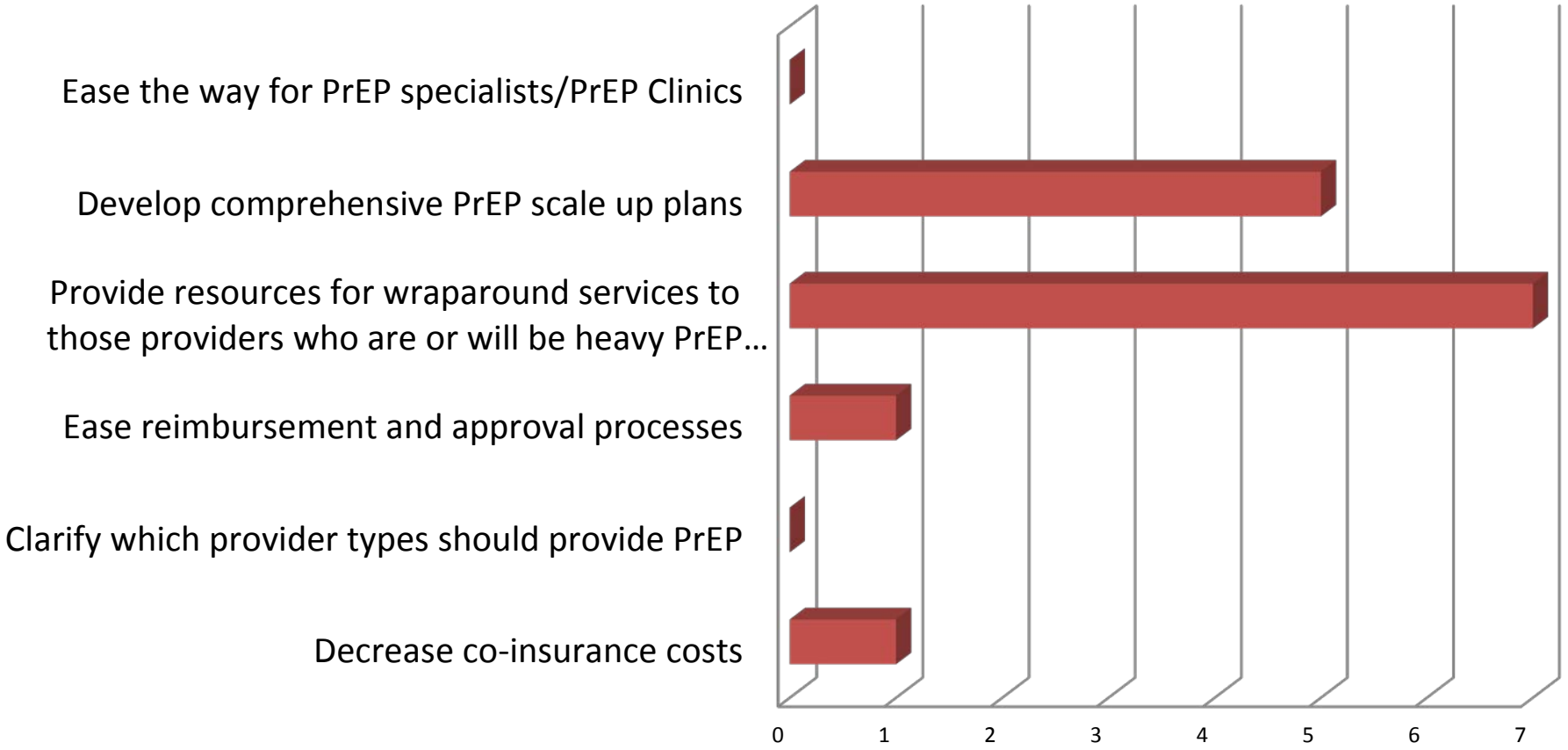
Summary of Barriers Raised

- 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

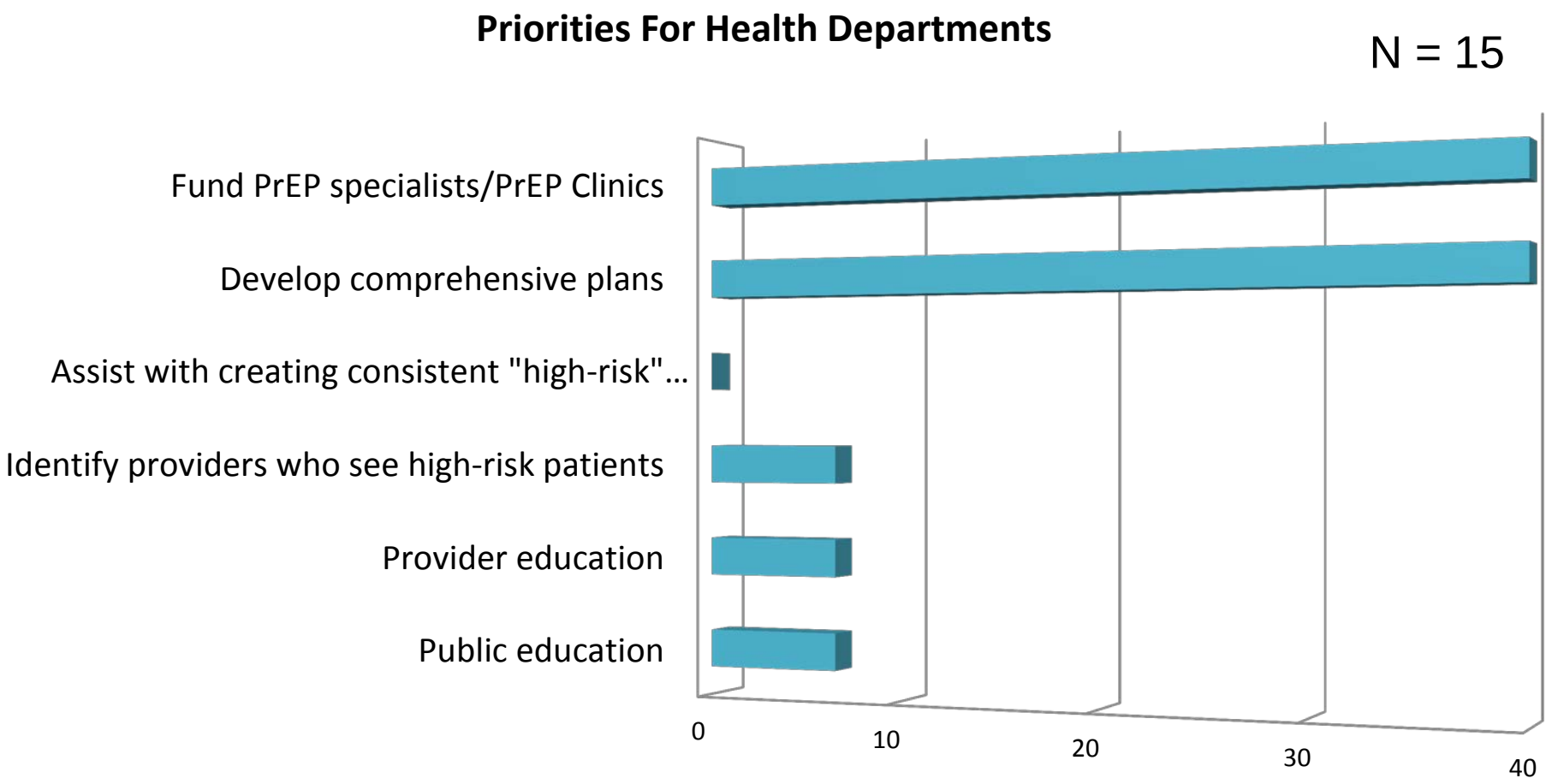
Survey Responses

Priorities For Policy Makers

N = 14



Survey Responses



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

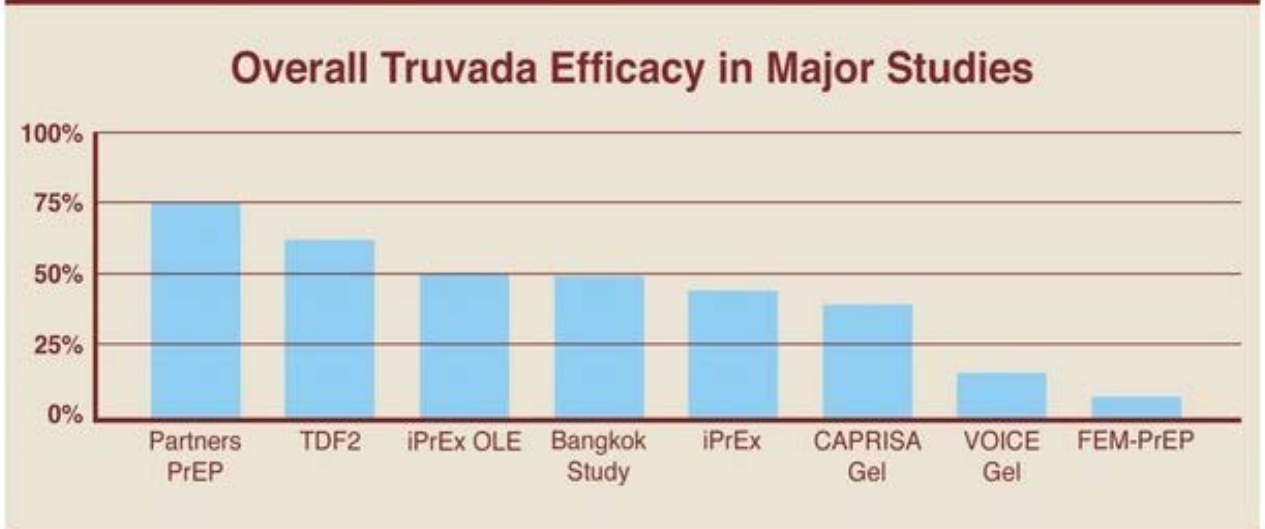
- Develop and implement tailored adherence curricula for both providers and patients.
- Engage LACDMH, social workers and mental health providers in efforts/programs to support adherence.

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.

*Efficacy measures whether Truvada works under the best possible conditions (e.g., a clinical trial).

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 clin**ics 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%.

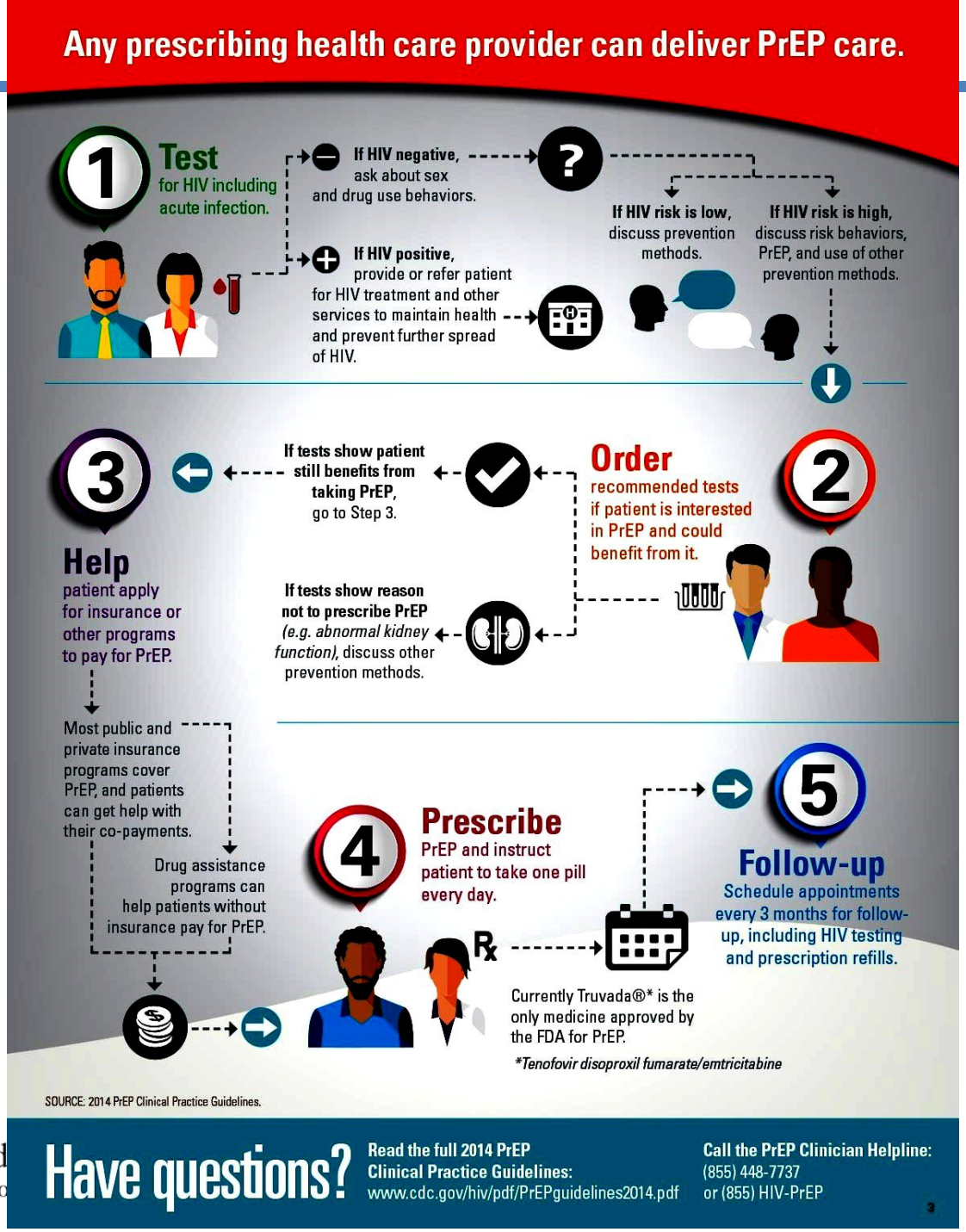
1 in 3

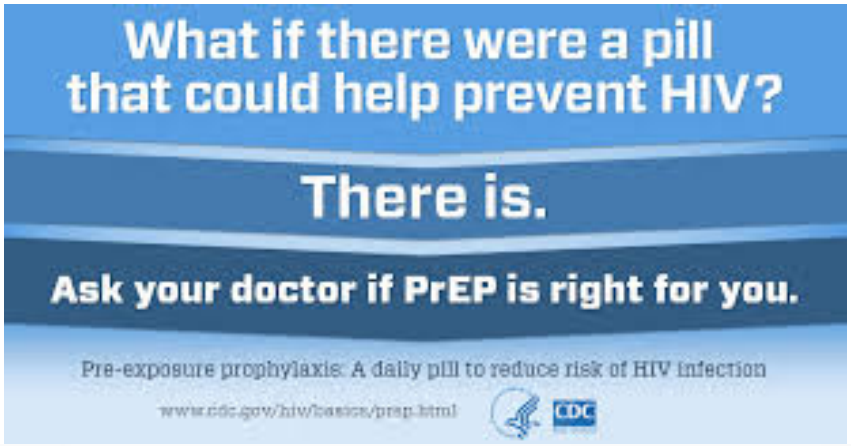
1 in 3 primary care doctors and nurses haven't heard about PrEP.

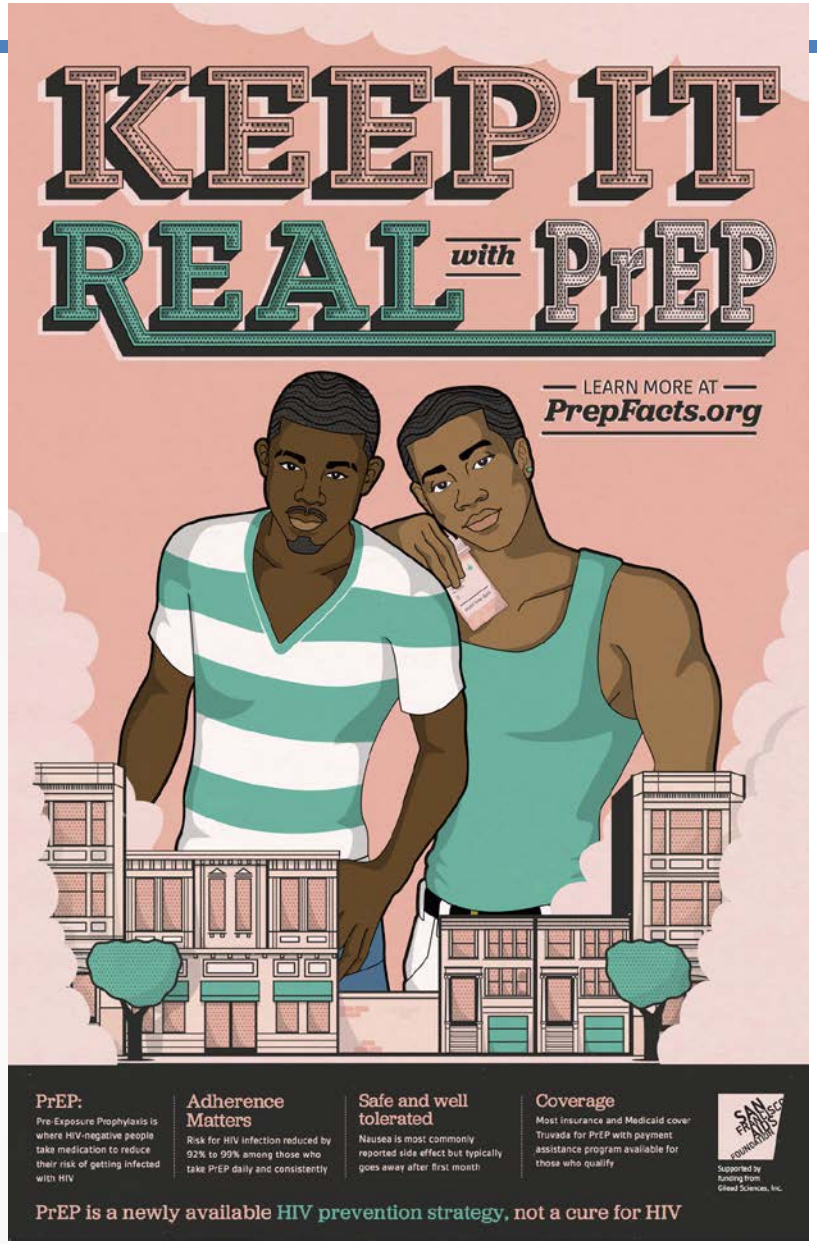
SOURCE: CDC Vital Signs, Dec. 2015.

CDC Vitalsigns™

www.cdc.gov/vitalsigns/HIVPrEP


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.
If HIV risk is low, discuss prevention methods.
If HIV risk is high, discuss risk behaviors, PrEP, and use of other prevention methods.
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.
If tests show patient still benefits from taking PrEP, go to Step 3.
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.
Drug assistance programs can help patients without insurance pay for PrEP.
4
Prescribe
PrEP and instruct patient to take one pill every day.
Currently Truvada®* is the only medicine approved by the FDA for PrEP.
*Tenofovir disoproxil fumarate/emtricitabine
5
Follow-up
Schedule appointments every 3 months for follow-up, including HIV testing and prescription refills.
SOURCE: 2014 PrEP Clinical Practice Guidelines.
Have questions?
Read the full 2014 PrEP Clinical Practice Guidelines:
www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf
Call the PrEP Clinician Helpline:
(855) 448-7737
or (855) HIV-PrEP


What if there were a pill that could help prevent HIV?
There is.
Ask your doctor if PrEP is right for you.
Pre-exposure prophylaxis: A daily pill to reduce risk of HIV infection
www.cdc.gov/hiv/basics/prep.html
CDC


KEEP IT REAL with PrEP
LEARN MORE AT
PrepFacts.org
PrEP:
Pre-Exposure Prophylaxis is where HIV-negative people take medication to reduce their risk of getting infected with HIV
Adherence Matters
Risk for HIV infection reduced by 92% to 99% among those who take PrEP daily and consistently
Safe and well tolerated
Nausea is most commonly reported side effect but typically goes away after first month
Coverage
Most insurance and Medicaid cover Truvada for PrEP with payment assistance program available for those who qualify
Supported by funding from Gilead Sciences, Inc.
PrEP is a newly available HIV prevention strategy, not a cure for HIV


Want PrEP?
You may need to provide a little "PrEP 101" to your doc first.
My PrEP experience
myprepexperience.blogspot.com

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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