



Northwest (HHS Region 10)

**ATTC** Addiction Technology Transfer Center Network  
Funded by Substance Abuse and Mental Health Services Administration



Northwest ATTC presents

# Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Among People Who Use Substances



Joanne Stekler, PhD, MPH  
Vanessa McMahan, MS, PhDc



9/26/2018

# Today's Presenters

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## Joanne Stekler, MD, MPH

- Research focuses on HIV testing and prevention
- National expert on HIV tests – acute HIV infection and point-of-care testing
- Started first community-based clinic for HIV PrEP in Seattle



## Vanessa McMahan, MS, PhDc

- Research focuses on PrEP use among those who use methamphetamine
- Hepatitis C Care Advocate, People's Harm Reduction Alliance (PHRA)
- iPrEx study coordinator

# **PRE-EXPOSURE PROPHYLAXIS FOR HIV PREVENTION AMONG PEOPLE WHO USE SUBSTANCES**

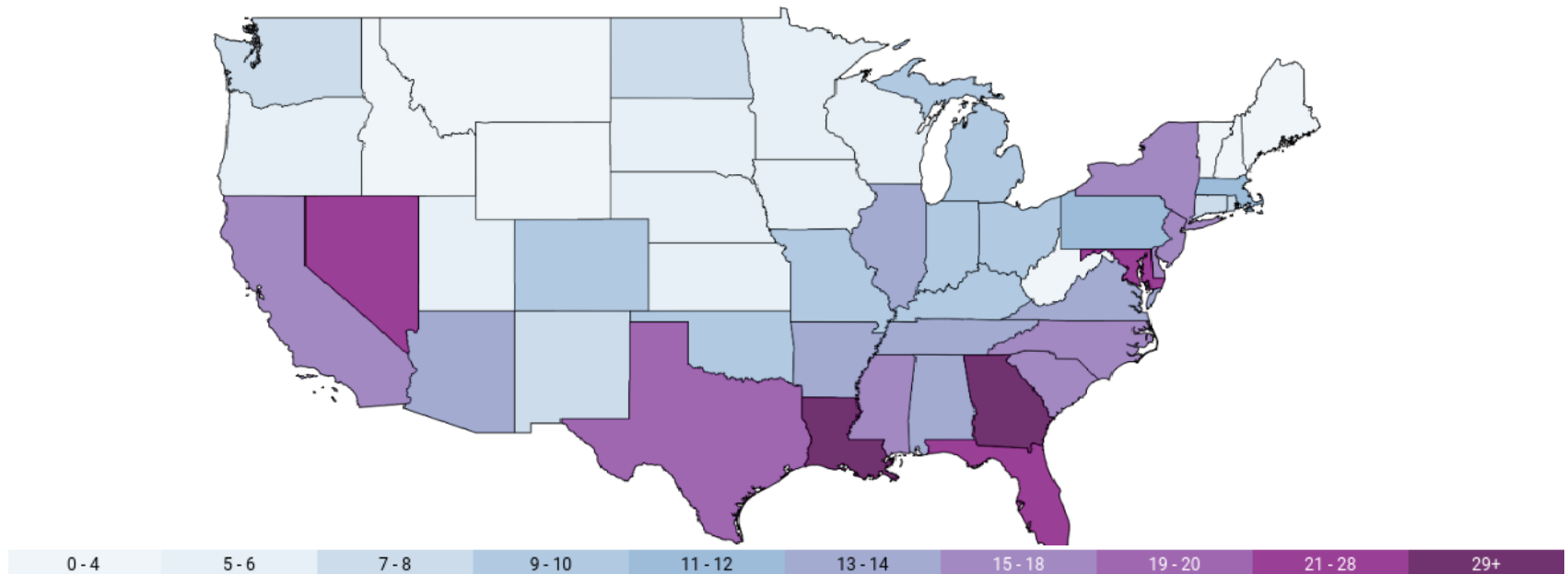
Joanne Stekler, MD MPH  
Vanessa McMahan, MS

NWATTC Webinar Series  
September 26, 2018

# Agenda

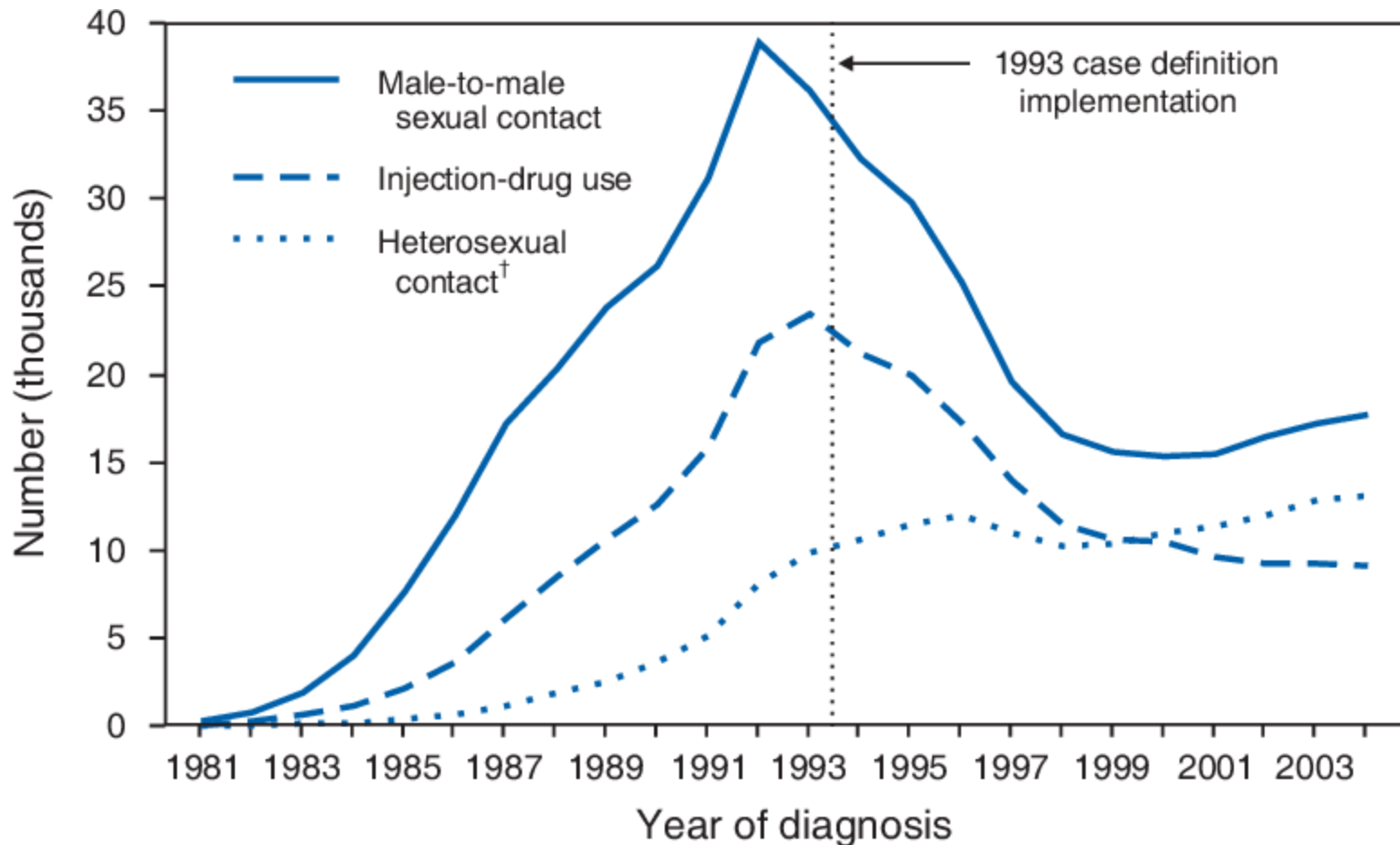
- HIV epidemiology in the United States
  - Cisgender men who have sex with men (cis-MSM) and transgender persons (TG) who use methamphetamine (meth)
  - People who inject drugs (PWID)
- Pre-Exposure Prophylaxis (PrEP)
- PrEP work in Seattle with cis-MSM/TG who use meth
- Questions

# HIV in the United States



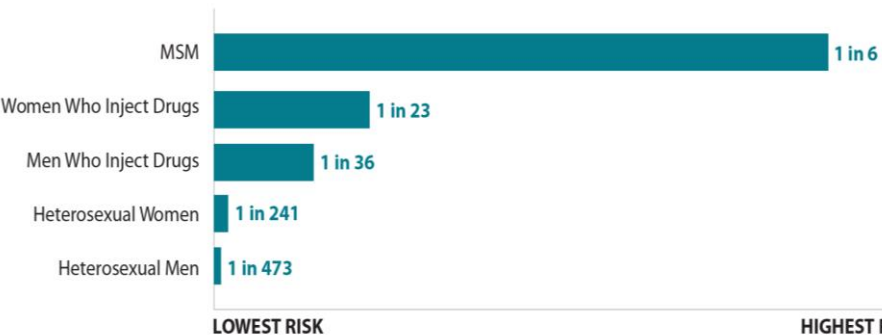
- 67% of new infections are in cis-MSM and 9% are in PWID
- No reliable nationwide data on TG, studies show high rates
- 1 in 7 people with HIV do not know they have HIV
- South accounts for more than half of new cases

# Number of AIDS Cases, by Transmission Category and Year, United States 1981-2004

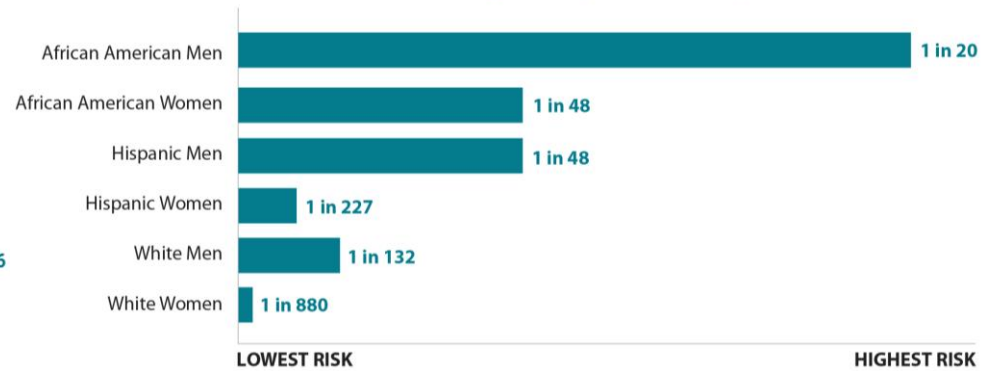


# Lifetime risk of HIV in U.S.

Lifetime Risk of HIV Diagnosis by Transmission Group



Lifetime Risk of HIV Diagnosis by Race/Ethnicity



Lifetime Risk of HIV Diagnosis among MSM by Race/Ethnicity



# Drug Use and HIV Among cis-MSM/TG

- Substance use is prevalent
  - 8% in cis-MSM across 20 NHBS cities
  - ~20% TG women (Los Angeles, CA)
- Meth is associated with HIV risk
- Meth use is increasing in the US



# Seattle: HIV Risk Among MSM who Use Meth

- Among cis-MSM, meth use is a significant risk factor for HIV acquisition in King County, WA:
  - Cis-MSM who use meth are more likely to acquire HIV  
Incidence meth-using cis-MSM – 2.3/100 person-years  
Non-meth using cis-MSM – 0.4/100 person-years
  - Meth use may contribute to
    - ~20% of HIV transmission among cis-MSM
    - 16% of all new infections

# HIV Among PWID

- HIV decreasing among PWID
- Possible slowing/reversing of trend
  - Increase in heroin and meth use
  - More rural drug use
  - Potential for outbreaks (Scott County, IN)

# Seattle: HIV Among PWID

- Historically, more HIV on East Coast
- Concern for increases in HIV on West Coast
  - HIV decreasing less
  - Increase in meth and goofball injection
  - ~45% prevalence among MSM who inject meth
  - Sharing between MSM and non-MSM
  - 2018 Seattle cluster of 10+ new HIV cases

Garfein et al J Urban Health 2004

Ciccarone et al Subst Use Misuse 2003

Banta-Green et al Drug Use Trends in King County 2016

Kral et al Am J Public Health 1998

Glick et al Drug Alcohol Depend 2018

NHBS 2012 and 2015

# What is PrEP?

Pre-exposure prophylaxis =  
HIV-negative people  
taking HIV medications  
before getting exposed  
to prevent them from getting HIV infection.



Daily oral emtricitabine/tenofovir disoproxil fumarate (Truvada) is currently the only medication FDA-approved for PrEP.

## Key HIV PrEP Trials Using Oral Tenofovir (TDF) or Tenofovir-Emtricitabine (TDF-FTC)

Study	Study Population	Study Randomization	HIV Incidence Impact
<b>IPrEx</b> (Brazil, Ecuador, South Africa, Thailand, US)	2499 MSM and transgender women	Daily oral TDF-FTC or placebo	TDF-FTC: 44% ↓
<b>Partners PrEP Study</b> (Kenya, Uganda)	4147 heterosexual HIV discordant couples	Daily oral TDF, TDF-FTC, or placebo	TDF: 67% ↓ TDF-FTC: 75% ↓
<b>TDF2 Study</b> (Botswana)	1219 heterosexual men and women	Daily oral TDF-FTC or placebo	TDF-FTC: 63% ↓
<b>FEM-PrEP</b> (Kenya, South Africa, Tanzania)	2120 women	Daily oral TDF-FTC or placebo	TDF-FTC: no protection
<b>VOICE</b> (South Africa, Uganda, Zimbabwe)	5029 women	Randomized to daily oral TDF, TDF-FTC, oral placebo, TDF vaginal gel, or gel placebo	TDF: no protection TDF-FTC: no protection TDF gel: no protection
<b>Bangkok TDF Study</b> (Thailand)	2413 injection drug users	Randomized to daily oral TDF or placebo	TDF: 49% ↓
<b>IPEGAY</b> (France, Quebec)	400 MSM	Randomized to “on-demand” TDF-FTC or placebo	TDF-FTC: 86% ↓
<b>PROUD</b> (United Kingdom)	545 MSM and transgender women	Randomized to daily oral TDF-FTC immediately or delayed	Immediate TDF-FTC: 86% ↓

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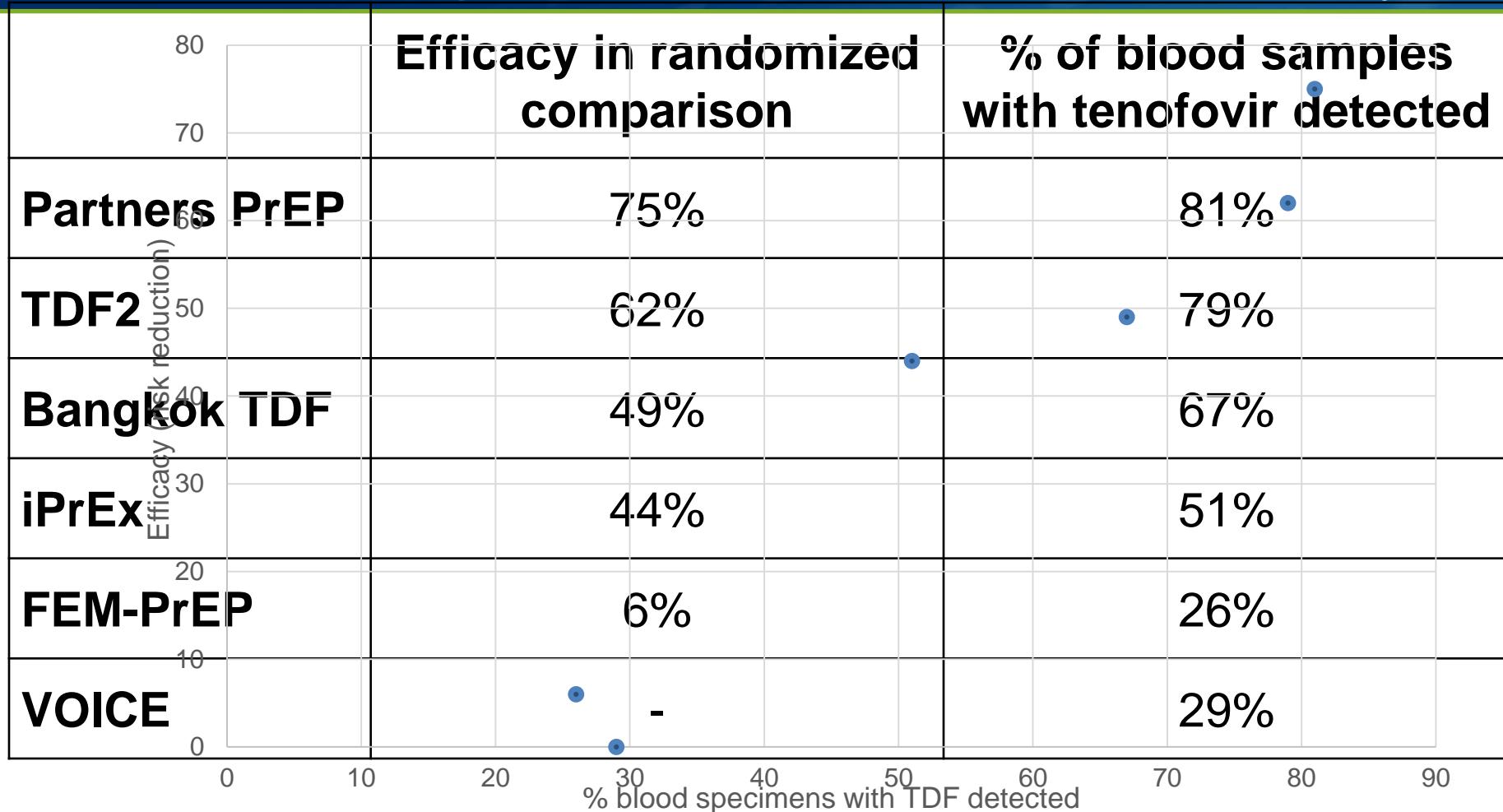
# The Bangkok TDF Study

- 2,413 PWID: daily, oral TDF or placebo
- Followed for 4 years
- Showed PrEP safety & efficacy for PWID
  - 49% reduction in HIV
  - 77% when drug detected
- FDA approval for PWID



# Does PrEP Work?

## The Relationship Between Adherence and Efficacy

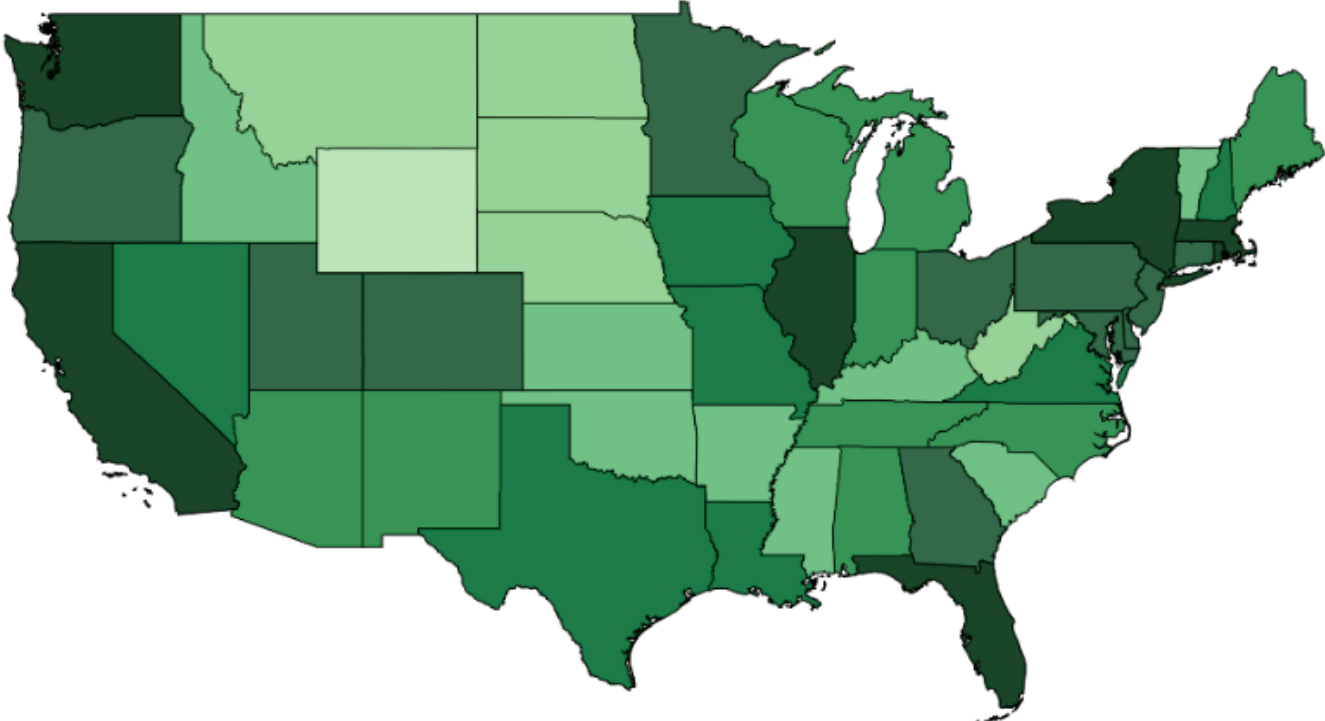


Baeten et al N Engl J Med 2012  
 Grant et al N Engl J Med 2010  
 Choopanya et al Lancet 2013

Van Damme et al N Engl J Med 2012  
 Thigpen et al N Engl J Med 2012  
 Marrazzo et al CROI 2013 #26LB

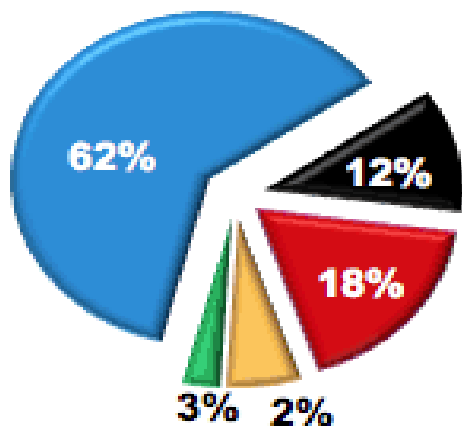


# Rates of PrEP Utilization, 2016

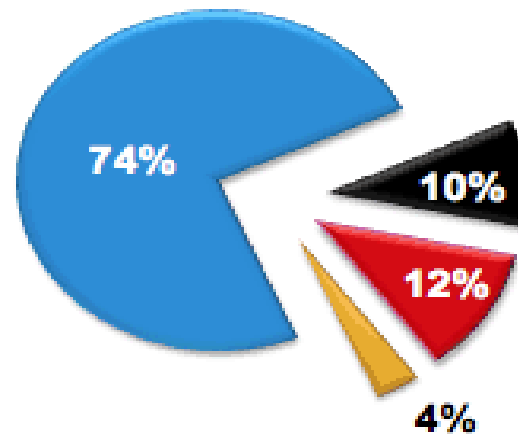


# PrEP Uptake by Race/Ethnicity

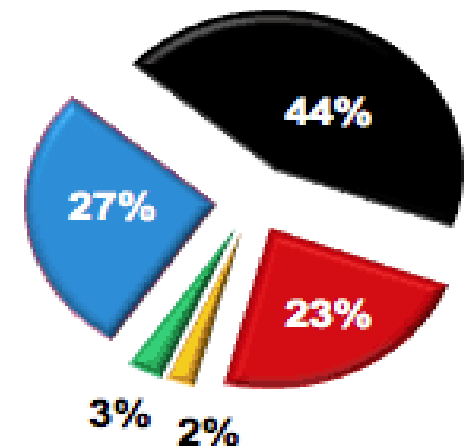
Estimated Population Distribution by Race/Ethnicity, 2014, US<sup>a</sup>



Total FTC/TDF for PrEP Utilization by Race/Ethnicity, Sept 2015, US<sup>b</sup>



Estimated New HIV Infections, 2014, US<sup>c</sup>



■ AA ■ White ■ Hispanics ■ Asians ■ Multiracial/Other

**FTC/TDF for PrEP use among AA and Hispanics is low relative to the rate of new HIV infections**

# PrEP and PWID

- Limited studies on PrEP efficacy among PWID
- Bangkok study had relatively low risk cohort
  - 45% injected during study, 2% shared
- Controversy over offering PrEP in settings without access to syringe exchange (SEPs) and opioid substitution therapy (OST)
- Modeling studies show while effective at prevention, PrEP is not as cost-effective as SEPs and OST

# PrEP Uptake among cis-MSM who Use Stimulants

- Few studies on acceptability & uptake among stimulant-using cis-MSM
  - High rates of familiarity (58-97%)
  - High rates of interest (83%)
  - Low rates of uptake (3-5%)
  - Cost is common barrier (44-72%)

# Seattle: PrEP Uptake among cis-MSM/TG who Use Meth

- Meth-users are under-represented in local PrEP clinics
  - Gay City pilot project (2013-15): 2%
  - Gay City safety net clinic (2015-): 8%
  - Kelley Ross Pharmacy (2015): 3%
  - WA State PrEP DAP (2014-15): 1%

# PrEP Adherence among cis-MSM/TG who Use Stimulants

- Mixed results
  - No difference in adherence in demonstration projects in SF, Miami, DC, and San Diego.
  - Meth associated with suboptimal adherence in analysis of a iPrEx RCT and in Kaiser cohort

# Summary

- Cis-MSM/TG and PWID are disproportionately impacted by HIV, with the majority of US cases among cis-MSM.
- Cis-MSM/TG who use meth are at elevated risk.
- Meth use is increasing and there is concern for emerging risk among non-MSM PWID.
- PrEP is a safe and effective HIV prevention method, with limited data among drug users.
- PrEP uptake is slow among cis-MSM/TG who use meth.

# ADAI Small Grant: Specific Aims

1. To assess the knowledge and perspectives of the NEON peer educators regarding PrEP use among meth-using MSM in Seattle over time.
2. Develop and pilot educational materials regarding PrEP that are targeted to meth-using MSM in Seattle.
3. Increase the knowledge and uptake of PrEP among meth-using MSM in Seattle.

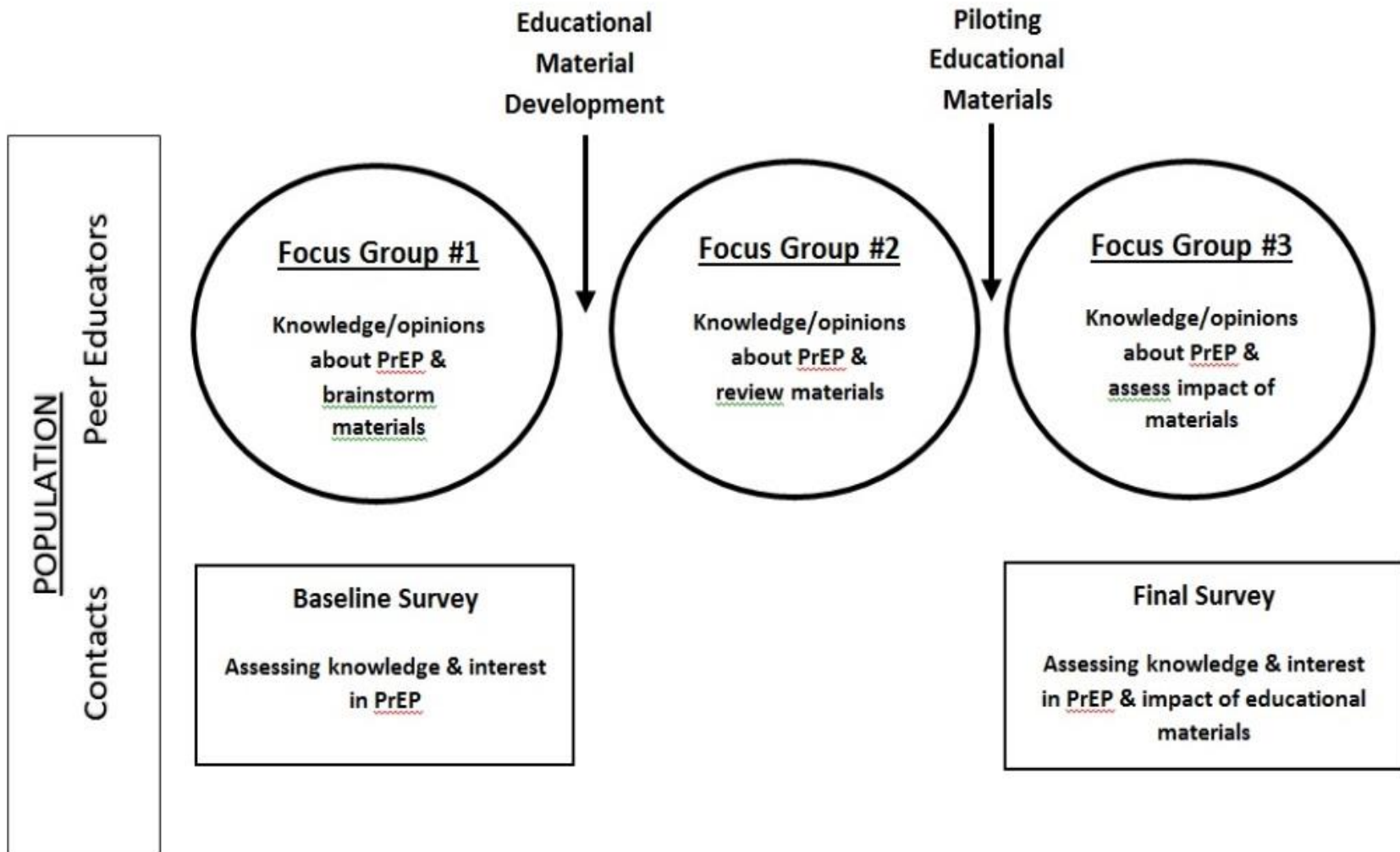


# Project NEON

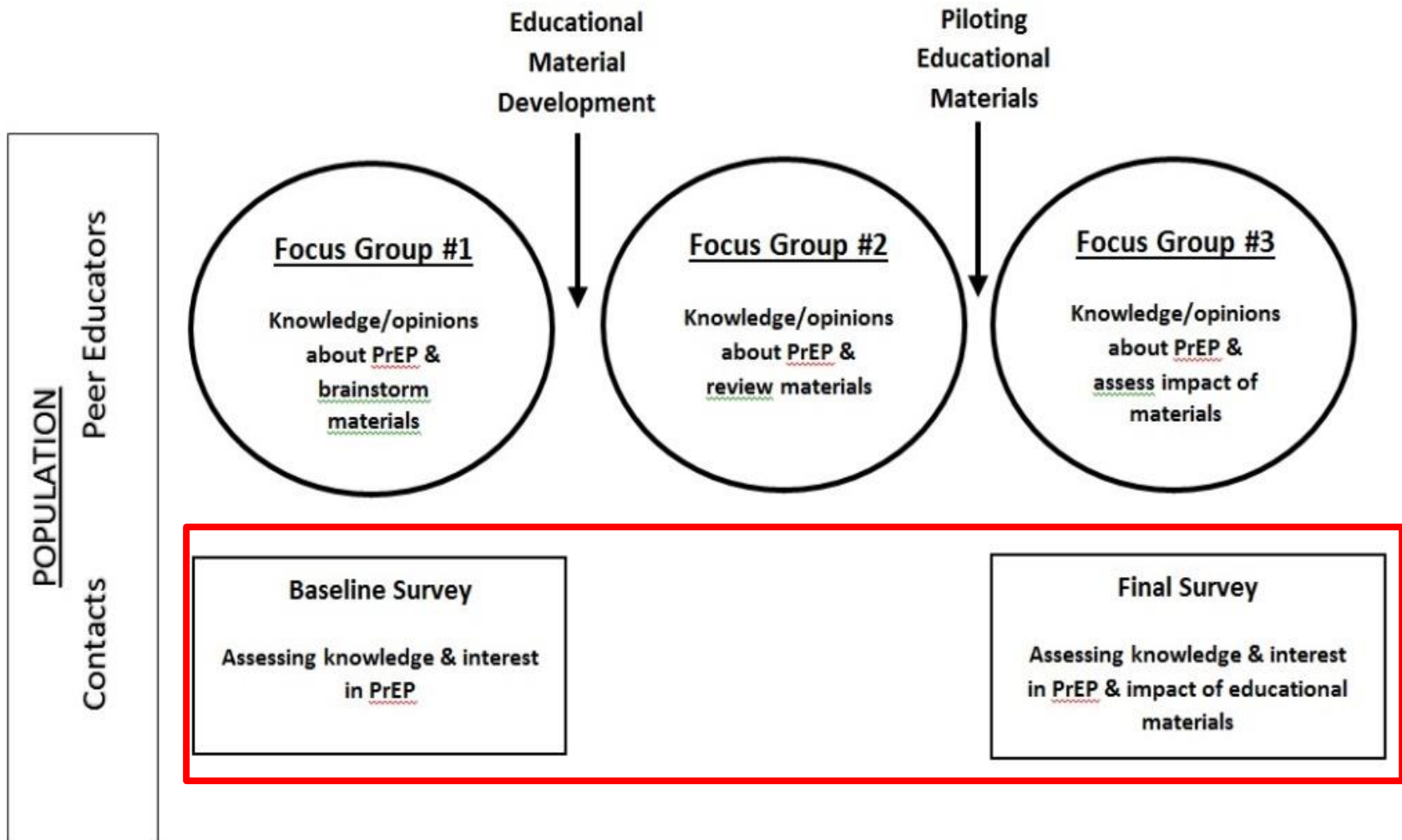
- A harm reduction program for meth users of the Seattle Counseling Service, which promotes LGBTQ wellness.
- Mission
  - Raise awareness about the links between meth and HIV/STIs.
  - Increase use of sterile injection equipment.
  - Promote safer sex practices.
  - Support clients to decrease or discontinue meth use.
- ~10 peer educators
- Recruited for surveys and participated in focus groups



# ADAI Small Grant: Schematic



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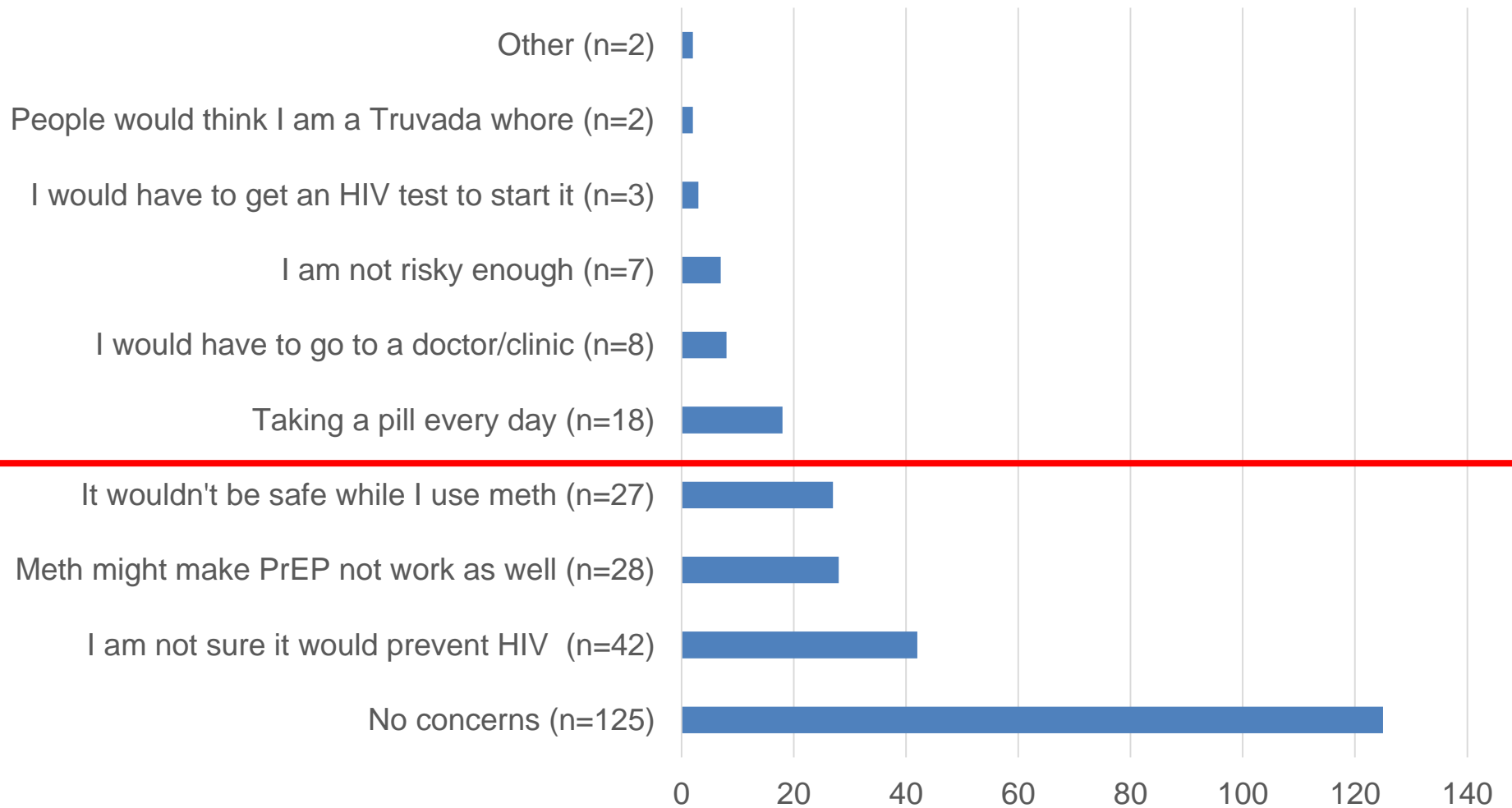


# Baseline Survey (August 2016)

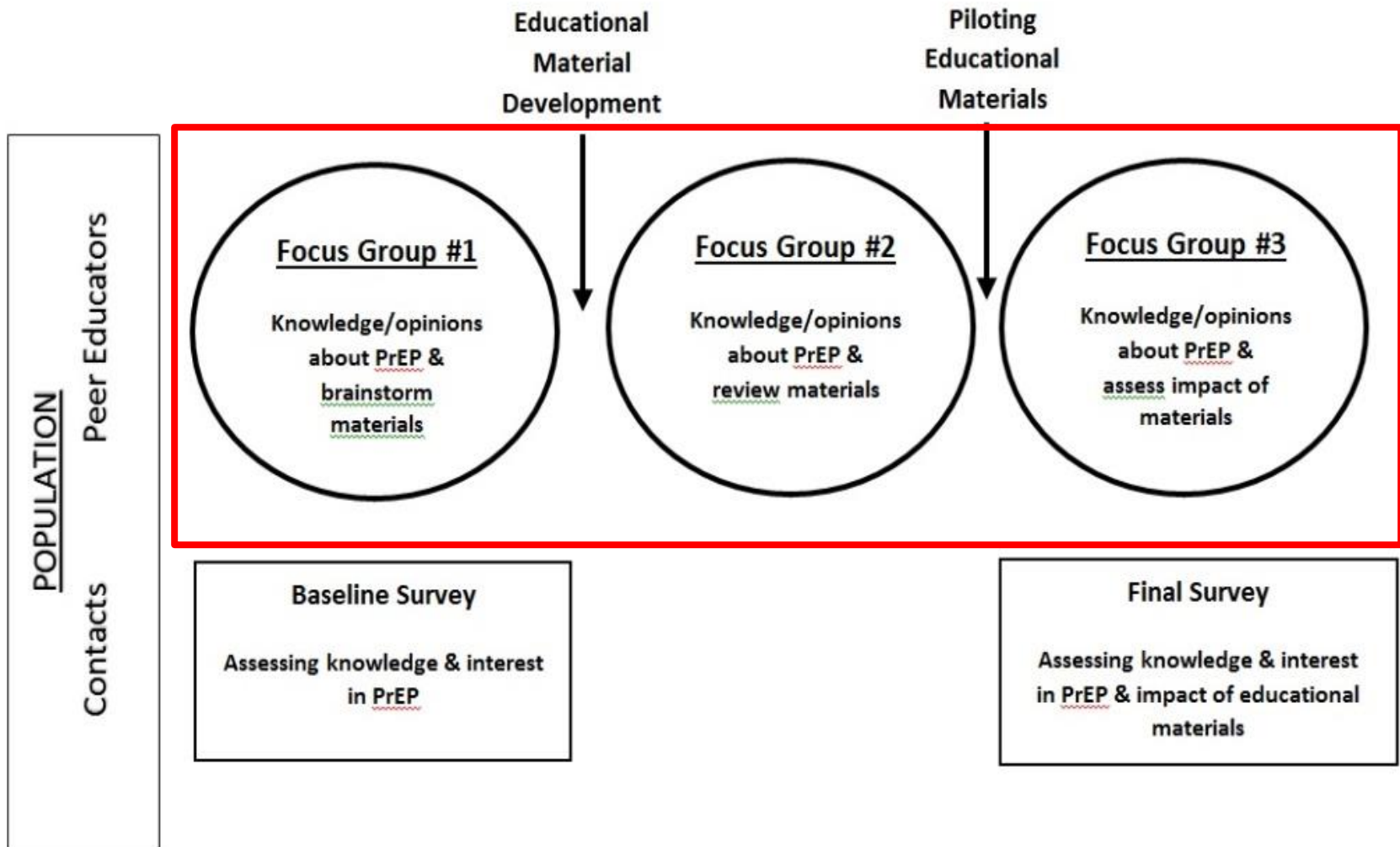
- Heard of PrEP = 213 (97%)
- Used PrEP = 7 (3%) and 5 (71%) using it now
- Know where to get it = 192 (93%)



# Baseline Survey: Concerns about PrEP

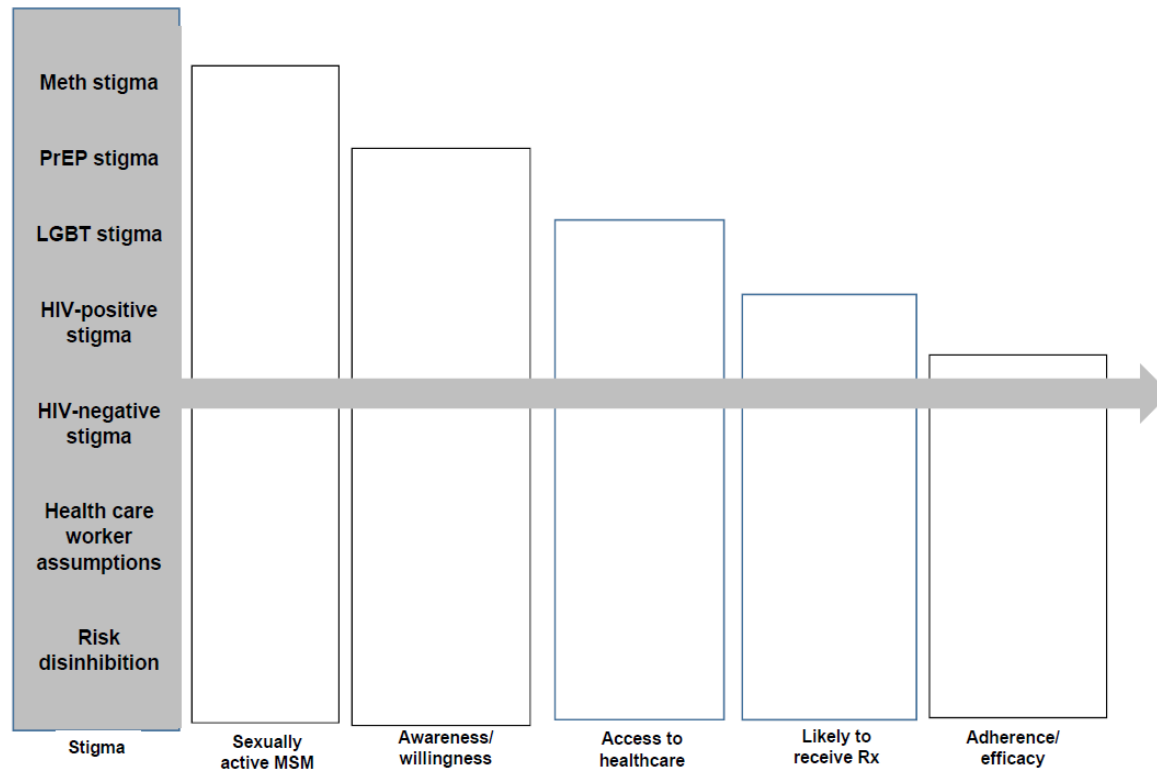


# ADAI Small Grant: Schematic



# Focus Groups: Main Findings (9/16-4/17)

- Need for accurate information
- Meth-specific barriers to uptake and adherence
- Stigma barrier to PrEP engagement across the continuum



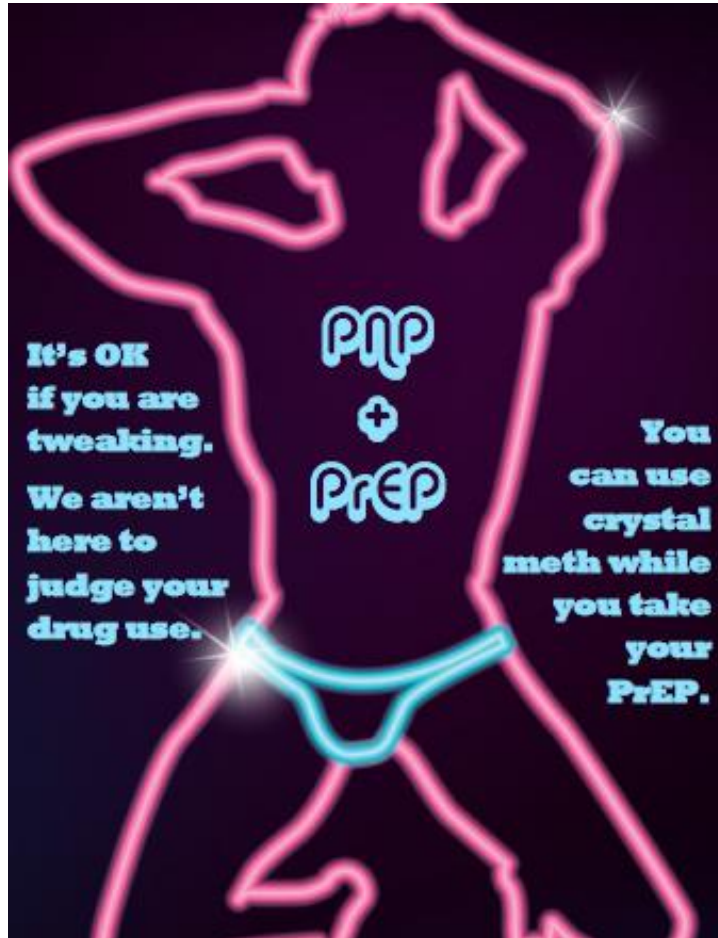
## Focus Groups: Main Findings (9/16-4/17)

*“I make sure my doctor doesn’t know that I use meth. I mean, that is just an outright.... They don’t need to know that. I would never admit to it. Because if you do, I mean there’s all sorts of consequences.” (Focus Group #1)*

*“Most people I talk to about [PrEP].... They’re afraid that they’re not gonna be able to keep up the consistent use of it while they’re doing drugs, because when you do drugs, particularly if you’re injecting, you know, it – you lose focus on anything except for whatever you’re gonna do, like the sex or whatever.” (Focus Group #2)*



# Educational Materials



**It's OK if you are tweaking. We aren't here to judge your drug use.**

**PrEP + PrEP**

**You can use crystal meth while you take your PrEP.**

**PrEP is a daily pill for HIV-negative people to prevent them from getting HIV.**

## **TIPS FOR TAKING PrEP**

- \* You take your PrEP every day.**
- \* Match your PrEP to a daily routine.**
- \* See your doctor every 3 months to check in and renew your PrEP.**

**PrEP prevents HIV, but it does not prevent other STDs.**

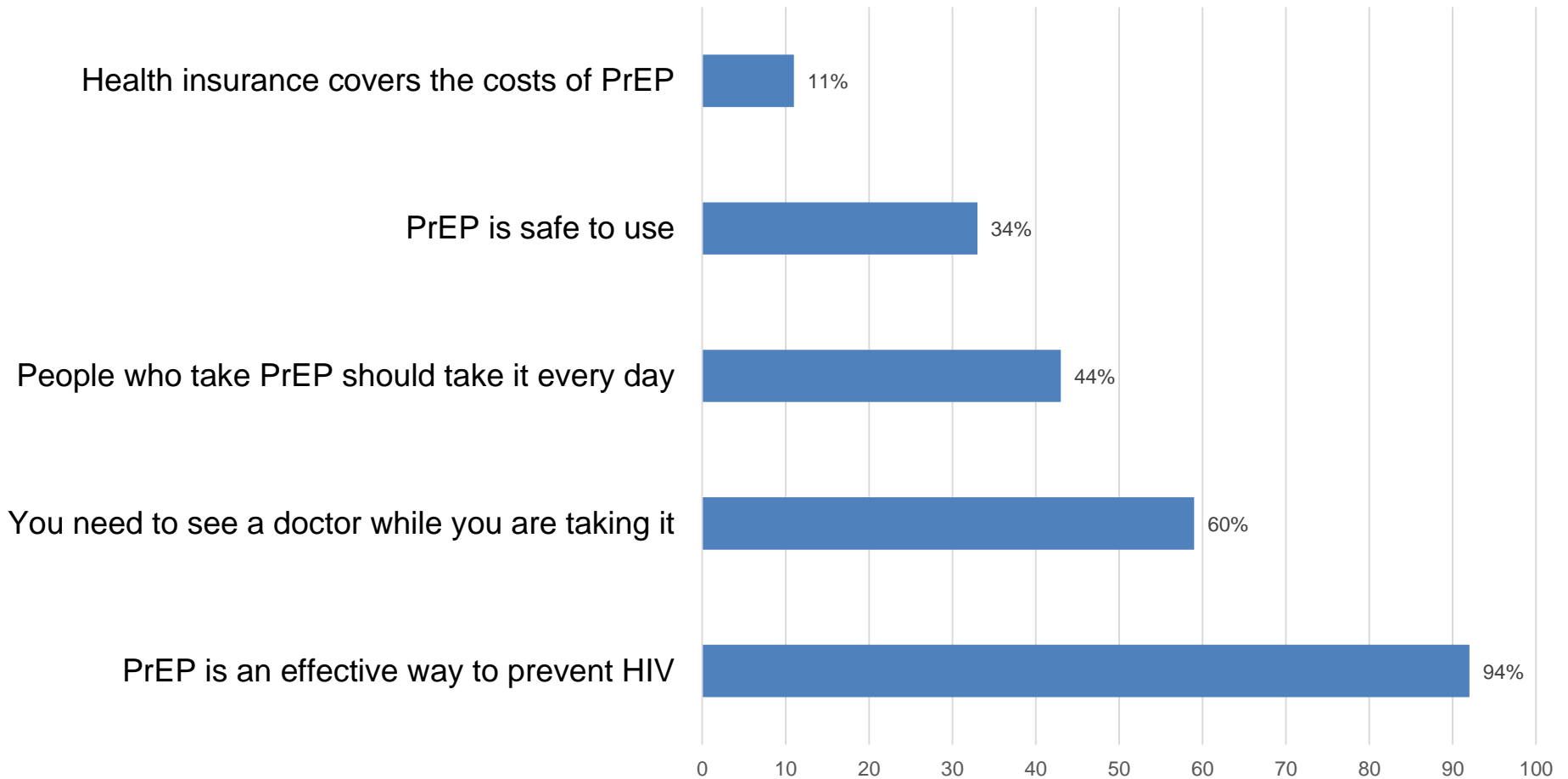
**You can get PrEP at many places in Western Washington. To find out more, email [PrEP@gaycity.org](mailto:PrEP@gaycity.org) or call 206.486.1410.**

# Follow-up Survey (April/May 2017)

- Heard of PrEP = 98 (98%)
- Used PrEP = 21 (21%)
- Using PrEP now = 17 (81%)
- Two most frequently reported concerns:
  - “I don’t think I can afford it” (44%)
  - “I don’t know enough about it” (34%)

# Follow-up Survey: Belief in PrEP Facts

Which of the following do you think are true?



# Educational Cards: Exposure and Impact

- 53/100 participants saw the cards
- 21 of them called the PrEP clinic number
- Trend between seeing cards and PrEP use ( $p=0.053$ )
- All statements on cards were more likely to be believed by those who saw cards (all  $p<0.05$ )

## R34: Interventions to Improve the HIV PrEP Cascade among Methamphetamine Users

- Aim 1. Conduct a pilot randomized control trial (RCT) to evaluate the acceptability and feasibility of a peer navigation intervention for meth-using MSM/TG
- Aim 2. Evaluate acceptability and impact of two-way text messaging on meth use and PrEP adherence.

# R34: Formative Focus Groups & Interviews

- Focus groups and interviews w/ target community
  - Discuss study aims and approach
  - Review text messages
  - Brainstorm educational messages/recruitment materials



Taken daily, PrEP can prevent HIV,  
but it does NOT prevent other STIs.

FIND OUT MORE:  
[PrEP@Kelley-Ross.com](mailto:PrEP@Kelley-Ross.com)  
206.324.6990  
[PrEP@gaycity.org](mailto:PrEP@gaycity.org)  
206.860.6969

## TIPS

✱ ✱ ✱ ✱ ✱  
Take every day.  
✱ ✱ ✱ ✱ ✱  
Match to a daily routine.  
✱ ✱ ✱ ✱ ✱  
See your doctor EVERY 3 months to check in and renew your PrEP.  
✱ ✱ ✱ ✱ ✱

## R34: Eligibility

- Eligibility criteria:
  - Meets clinic's PrEP criteria
  - $\geq$  18 years old
  - Cisgender man or on trans gender variant spectrum who has sex with cisgender men, trans women, or trans men
  - Reports meth use in past 3 months
  - Has a cell phone that can send/receive texts
  - Intends to remain in area for 6 months

## R34: Randomization & Arms

- Participants are randomized to 1 of 4 arms

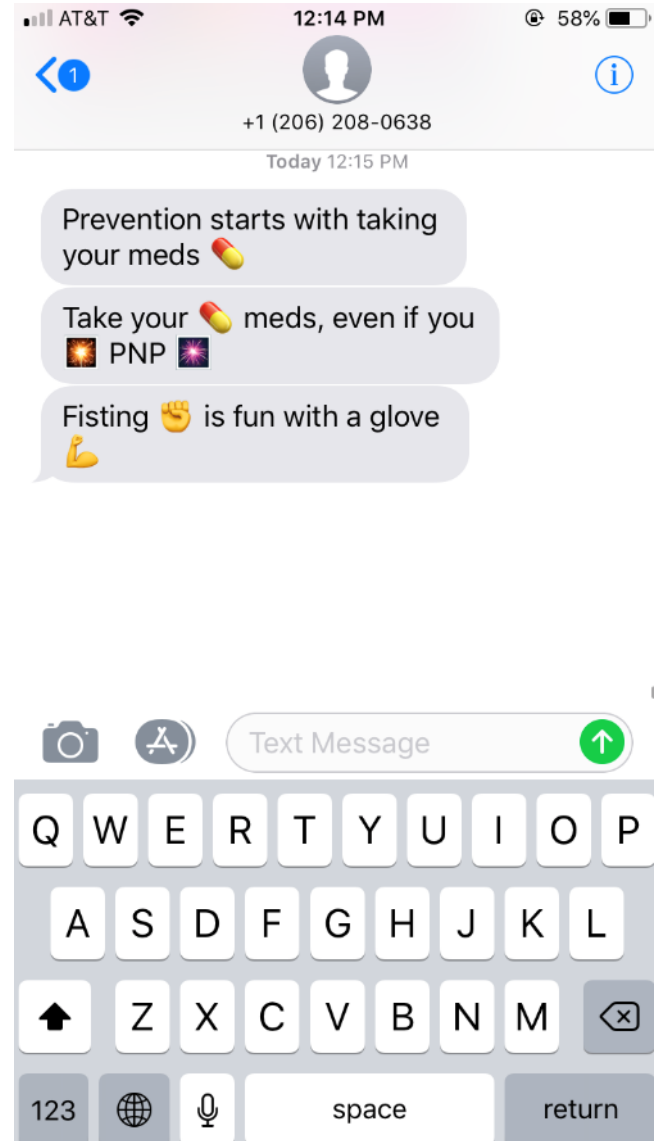
<b>Clinic Standard of Care (SOC) n=10</b>	<b>SOC + Peer Navigation n=10</b>
<b>SOC + Text Messaging n=10</b>	<b>SOC + Text Messaging + Peer Navigation n=10</b>

- Arms developed based on formative findings of possible ways to mitigate meth-specific barriers to adherence
  - The importance of reminders (e.g., when “losing days”)
  - Potential benefit of a peer, including with competing priorities



# R34: Text Message Intervention

- Text messaging intervention (3 / day)
  - 1 PrEP reminder
  - 1 general PrEP message
  - 1 from chosen category(ies)
  - Using emojis is important



# R34: Peer Navigation Intervention

- Peer navigation intervention
  - Schedule an in-person meeting
  - Provide assistance with insurance and other paperwork
  - Provide assistance with refills
  - Send appointment reminders and assist in scheduling
  - Offer to attend appointments and facilitate transportation
  - Check in about adherence
  - Provide referrals as appropriate (e.g., housing, mental health support)



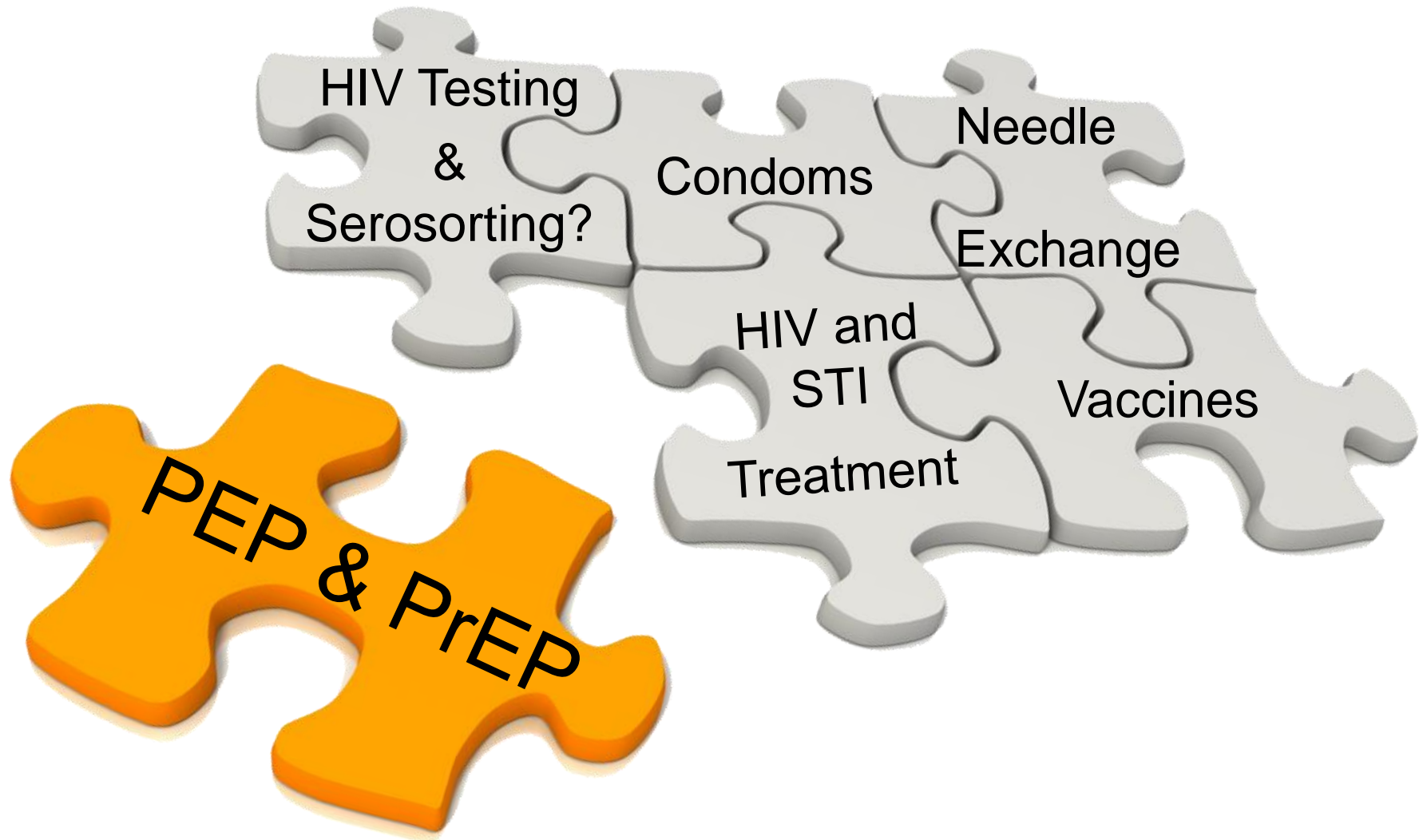
## R34: Follow-up

- Followed for 6 months
- Regular PrEP clinic procedures at months 1, 3 and 6
- Additional research procedures at follow-up visits:
  - Dried blood spots for PrEP adherence
  - Online surveys (months 3 and 6)
- \$20 Amazon gift card for completed surveys
- Qualitative interviews with a subset

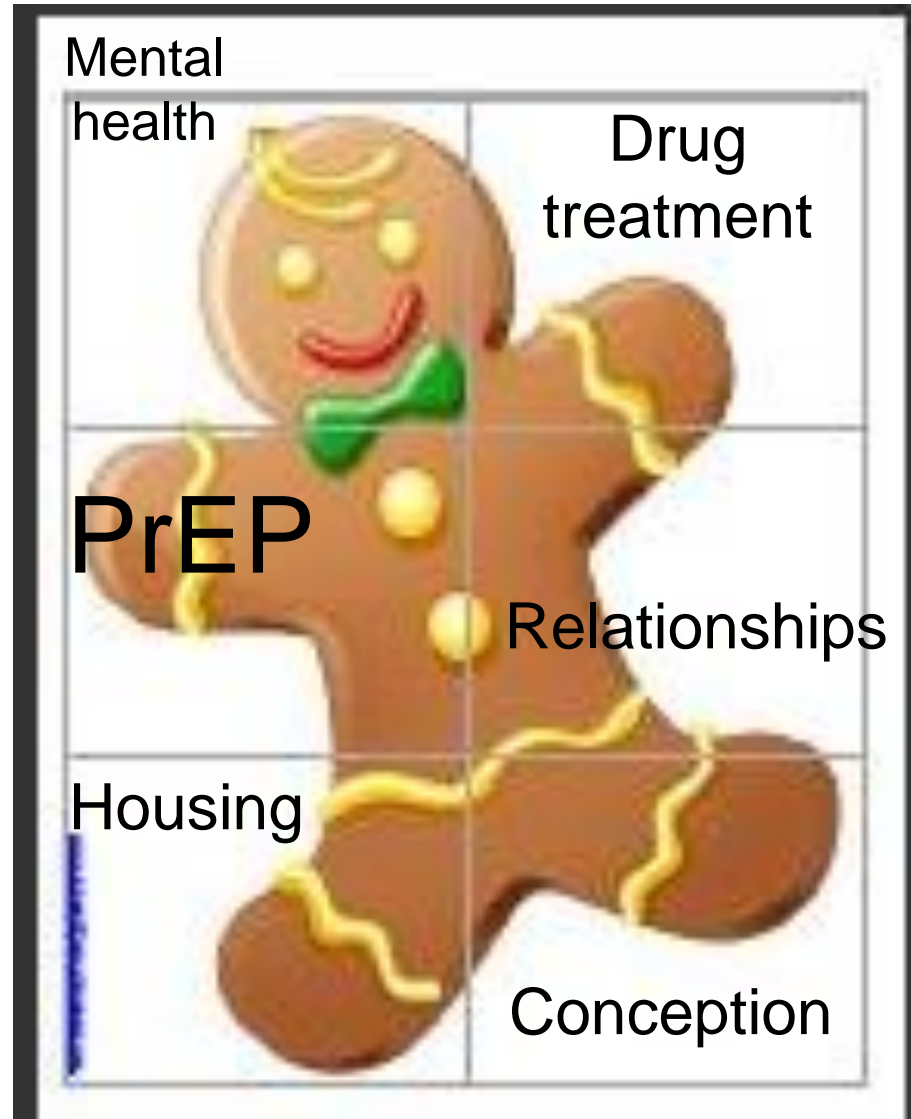
# Conclusions

- PrEP is safe, effective, easy to prescribe, covered by insurance and increasing in both WA and the US.
- Education about PrEP and covering the costs of it remain a priority.
- Cis-MSM/TG who use meth experience stigma as a barrier to PrEP uptake and engagement across the continuum.
- There are meth-specific barriers to PrEP use. Sending reminders and peer support may help with PrEP adherence.

# “Highly Active HIV Prevention”



# PrEP as Part of the Larger Puzzle



# Acknowledgments

## **University of Washington**

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Lauren Violette

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## **Kelley-Ross Pharmacy**

## **Study participants**

## **Project NEON**

Peer counselors

Lindsay Garske

Aleks Martin

Ann McGettigan

## **Research support**

UW ADAI

WA DOH

NIDA

# Surveys

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**Look for our surveys in your  
inbox!**

**We'll send two short surveys:**  
one now, and  
one in a month.



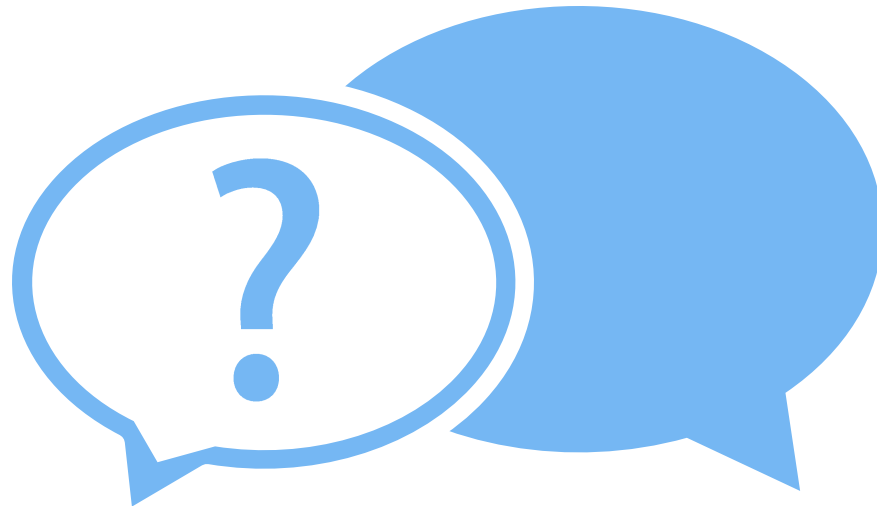
We greatly appreciate your feedback! Every survey we receive helps us to improve and develop our programming.



# Q&A

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Questions? Please type them in  
the chat box!



# Upcoming Events

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**Thank you for coming!**

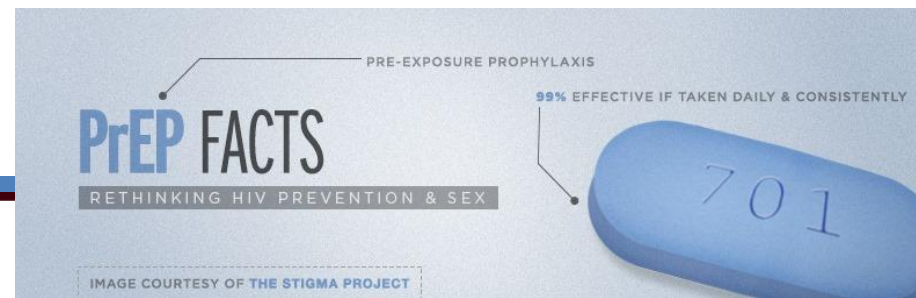
Join us for our next webinar:

**Harm Reduction: An Organizing Framework  
to Address the Opioid Epidemic**

Susan Collins, PhD

October 24, 2018, 12-1pm

# How can I learn more?



## General Information

[www.cdc.gov/hiv/basics/prep.html](http://www.cdc.gov/hiv/basics/prep.html)

[www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf](http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf)

[www.facebook.com/groups/PrEPFacts](https://www.facebook.com/groups/PrEPFacts)

[www.prepfacts.org](http://www.prepfacts.org)

## UCSF Clinician Consultation Center

1-855-HIV-PrEP (1-855-448-7737), M-F 11-6 EST

## How to Pay for PrEP

- Gilead's Medication Assistance Program

<http://www.gilead.com/responsibility/us-patient-access/us%20advancing%20access>

- Washington PrEP DAP (also has list of PrEP providers by county)

[www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP](http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP)

# Paying for PrEP

## ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



projectinform.org/prep-chart  
800-822-7422

### YES

(employer, private, insurance marketplace, COBRA, Medicare, Medicaid)

1

#### Gilead Advancing Access Co-pay Card

gileadcopay.com  
877-505-6986

- \$3,600 max/calendar year
- No income restrictions
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
- US resident
- Not available for persons with Medicaid, Medicare, VA or other state/federal prescription drug programs

If pharmacy is unable to process Gilead's Co-pay Card, keep sales and pharmacy receipts. Call number on back of co-pay card. Submit paperwork for reimbursement for all refills. Some restrictions apply: terms, conditions at [gileadcopay.com](http://gileadcopay.com).

2

#### Patient Access Network Foundation

panfoundation.org/hiv-treatment-and-prevention  
866-316-7263

- \$8,000 max/year, re-apply
- Income <500% FPL (\$60,300)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAN Foundation directly

*These programs may be subject to funding shortfalls, which may limit enrollment.*

3

#### Patient Advocate Foundation (PAF)

<https://www.copays.org/diseases/hiv-aids-and-prevention>

- \$7,500 max/year, re-apply
- Income <400% FPL (\$48,240)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help resolve medical cost issues (800-532-5274)

#### FSA (flexible spending account)

If employer offers an FSA, it can help cover up to \$2,550 of out-of-pocket costs.

#### On Medicaid?

Medicaid should cover medical costs related to PrEP. If you encounter barriers to coverage, consult a legal advocate.

### NO

U.S. RESIDENT?

What's the date?

NOV 1 – JAN 31

#### Enroll in an insurance marketplace

[obamacarefacts.com/state-health-insurance-exchange/](http://obamacarefacts.com/state-health-insurance-exchange/)

Avoid Bronze plans if you can: they generally have higher costs. Silver plans will offer lower costs for people earning up to 250% FPL (\$30,150). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

#### Special enrollment

You can get insurance during the rest of the year for "qualifying life events" such as: pregnancy, loss or change of job, change in household size, change in income, recent move, change in citizenship.

FEB 1 – OCT 31

below 138% FPL / yr (< \$16,643)

above 138% FPL / yr (> \$16,643)

Check if you're eligible for your state Medicaid plan.

What's your income?

below

Enroll in the Gilead MAP.  
[www.truvada.com/truvada-patient-assistance](http://www.truvada.com/truvada-patient-assistance)

60,300

500% FPL (2017 FPL: \$12,060 taxable income + \$4,180 per dependent, higher FPL in Alaska and Hawaii, 1040 tax form line 7, 1040 EZ line 1)  
~ only drug costs ~  
<https://tinyurl.com/FPLIncomes>

above

Retail cost of Truvada

NON-RESIDENT/  
UNDOCUMENTED?

To get care, find a public clinic (FQHC) that serves undocumented patients. ([findahealthcenter.hrsa.gov](http://findahealthcenter.hrsa.gov))

Check if you can get an insurance plan through marketplace/employer.

IF NO

UPDATED AS OF  
FEBRUARY 10, 2017

#### If you're a resident, these state plans may also help:

- COLORADO: <https://tinyurl.com/COprepFAP>
- ILLINOIS: <https://tinyurl.com/ILprepAP>
- MASSACHUSETTS: <https://tinyurl.com/MAprepDAP> (cost of drug, services)
- WASHINGTON: <http://tinyurl.com/WAprepDAP> (cost of drug)
- NEW YORK: <http://tinyurl.com/NYprepAP> (cost of services)

# PrEP Side Effects and Safety

## “Startup Syndrome”

- Nausea, headache, or fatigue may occur in first 2-4 weeks

## Renal Safety

- Monitoring at least every 6 months recommended

## Bone Effects

- TDF-FTC associated with small change (~1%) in bone density
- No increase in fractures seen

# Possible Future PrEP Products



Tenofovir-containing pills are not feasible for everyone. There is an encouraging pipeline of new PrEP prevention products that will deliver additional options.

However, we would be naïve to imagine that any one of these will work or be workable for every person.

*What is wanted = prevention options.*