Northwest ATTC presents

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

Joanne Stekler, PhD, MPH
Vanessa McMahan, MS, PhDc
Today’s Presenters

**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

Mofenson et al MMWR 2006
Lifetime risk of HIV in U.S.

**Lifetime Risk of HIV Diagnosis by Transmission Group**

- MSM: 1 in 6
- Women Who Inject Drugs: 1 in 23
- Men Who Inject Drugs: 1 in 36
- Heterosexual Women: 1 in 241
- Heterosexual Men: 1 in 473

**Lifetime Risk of HIV Diagnosis by Race/Ethnicity**

- African American Men: 1 in 20
- African American Women: 1 in 48
- Hispanic Men: 1 in 48
- Hispanic Women: 1 in 227
- White Men: 1 in 132
- White Women: 1 in 880

**Lifetime Risk of HIV Diagnosis among MSM by Race/Ethnicity**

- African American MSM: 1 in 2
- Hispanic MSM: 1 in 4
- White MSM: 1 in 11
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
• 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
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.
<table>
<thead>
<tr>
<th>Study</th>
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<th>Study Randomization</th>
<th>HIV Incidence Impact</th>
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<tbody>
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<td>IPrEx (Brazil, Ecuador, South Africa, Thailand, US)</td>
<td>2499 MSM and transgender women</td>
<td>Daily oral TDF-FTC or placebo</td>
<td>TDF-FTC: 44% ↓</td>
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<td>Partners PrEP Study (Kenya, Uganda)</td>
<td>4147 heterosexual HIV discordant couples</td>
<td>Daily oral TDF, TDF-FTC, or placebo</td>
<td>TDF: 67% ↓ TDF-FTC: 75% ↓</td>
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<td>1219 heterosexual men and women</td>
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<td>5029 women</td>
<td>Randomized to daily oral TDF, TDF-FTC, oral placebo, TDF vaginal gel, or gel placebo</td>
<td>TDF: no protection TDF-FTC: no protection TDF gel: no protection</td>
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<td>2413 injection drug users</td>
<td>Randomized to daily oral TDF or placebo</td>
<td>TDF: 49% ↓</td>
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<td>IPERGAY (France, Quebec)</td>
<td>400 MSM</td>
<td>Randomized to “on-demand” TDF-FTC or placebo</td>
<td>TDF-FTC: 86% ↓</td>
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<td>PROUD (United Kingdom)</td>
<td>545 MSM and transgender women</td>
<td>Randomized to daily oral TDF-FTC immediately or delayed</td>
<td>Immediate TDF-FTC: 86% ↓</td>
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### Key HIV PrEP Trials Using Oral Tenofovir (TDF) or Tenofovir-Emtricitabine (TDF-FTC)

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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

Choopanya et al Lancet 2013
Does PrEP Work?
The Relationship Between Adherence and Efficacy

<table>
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<th>PrEP Type</th>
<th>Efficacy in randomized comparison</th>
<th>% of blood samples with tenofovir detected</th>
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<tr>
<td>Partners PrEP</td>
<td>75%</td>
<td>81%</td>
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<td>TDF2</td>
<td>62%</td>
<td>79%</td>
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<td>67%</td>
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</tr>
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<td>29%</td>
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Sources:
- Grant et al. N Engl J Med 2010
- Choopanya et al. Lancet 2013
- Marrazzo et al. CROI 2013 #26LB
Rates of PrEP Utilization, 2016

AIDSVu (aidsvu.org)
PrEP Uptake by Race/Ethnicity


Total FTC/TDF for PrEP Utilization by Race/Ethnicity, Sept 2015, US


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%)

Oldenburg et al AIDS and Behav 2016
McMahan et al CROI 2017
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%
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.
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

**Educational Material Development**

**Focus Group #1**
Knowledge/opinions about PrEP & brainstorm materials

**Focus Group #2**
Knowledge/opinions about PrEP & review materials

**Focus Group #3**
Knowledge/opinions about PrEP & assess impact of materials

**Baseline Survey**
Assessing knowledge & interest in PrEP

**Final Survey**
Assessing knowledge & interest in PrEP & impact of educational materials
ADAI Small Grant: Schematic

Focus Group #1: Knowledge/opinions about PrEP & brainstorm materials
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Educational Material Development

Piloting Educational Materials

Baseline Survey: Assessing knowledge & interest in PrEP
Final Survey: Assessing knowledge & interest in PrEP & impact of educational materials
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

- No concerns (n=125)
- I am not sure it would prevent HIV (n=42)
- Meth might make PrEP not work as well (n=28)
- It wouldn't be safe while I use meth (n=27)
- I am not risky enough (n=7)
- I would have to go to a doctor/clinic (n=8)
- Taking a pill every day (n=18)
- People would think I am a Truvada whore (n=2)
- I would have to get an HIV test to start it (n=3)
- Other (n=2)
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- I am not risky enough (n=7)
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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)
It’s OK if you are tweaking. We aren’t here to judge your drug use.

**PnP + PrEP**

You can use crystal meth while you take your PrEP.

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**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.

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**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 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?

- Health insurance covers the costs of PrEP: 11%
- PrEP is safe to use: 34%
- People who take PrEP should take it every day: 44%
- You need to see a doctor while you are taking it: 60%
- PrEP is an effective way to prevent HIV: 94%
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
R34: Eligibility

• Eligibility criteria:
  - Meets clinic’s PrEP criteria
  - >= 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

<table>
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<tr>
<th>Clinic Standard of Care (SOC)</th>
<th>SOC + Peer Navigation</th>
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<tr>
<td>n=10</td>
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<th>SOC + Text Messaging</th>
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- 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”

- HIV Testing & Serosorting?
- Condoms
- Needle Exchange
- HIV and STI Treatment
- Vaccines
- PEP & PrEP
PrEP as Part of the Larger Puzzle

- Mental health
- Drug treatment
- PrEP
- Relationships
- Housing
- Conception
Acknowledgments

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Ann McGettigan

Gay City

Kelley-Ross Pharmacy

Research support
UW ADAI
WA DOH
NIDA

Study participants
Surveys

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.
Questions? Please type them in the chat box!
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  
www.facebook.com/groups/PrEPFacts  
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
Paying for PrEP

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

YES

1. Gilead Advancing Access Co-pay Card
   gileadcopay.com
   877-505-6996
   - $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 receipts. Some restrictions apply: terms, conditions at gileadcopay.com

2. Patient Access Network Foundation (PAN)
   panfoundation.org/hiv-treatment-and-prevention
   866-316-7263
   - $8,000 max/year, re-applies
   - Income <500% FPL ($58,300)
   - Based on yearly 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

3. Patient Advocate Foundation (PAF)
   https://www.copays.org/diseases/hiv-aids-and-prevention
   - $7,500 max/year, re-applies
   - Income <400% FPL ($56,240)
   - 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)

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

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

FSA (flexible spending account)
If employer offers an FSA, it can help cover up to $2,500 of out-of-pocket costs.

UPDATE AS OF FEBRUARY 10, 2017

NO

U.S. RESIDENT?

- What’s the date?
  - NOV 1 – JAN 31
  - FEB 1 – OCT 31

- What’s your income?
  - below 138% FPL/yr ($21,445)
  - above 138% FPL/yr ($21,445)

- Enroll in the insurance marketplace
  - 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 coming up to 250% FPL ($58,150). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

IF NO

- Enroll in the Gilead MAP
  - www.medicaid.com/truvada-patient-assistance

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

IF NON-RESIDENT/UNDOCUMENTED?

To get care, find a public clinic (HHS.gov) that serves undocumented patients.

IF NO

- Check if you’re eligible for your state Medicaid plan.
- Check if you can get an insurance plan through marketplace/employer.

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

IF NO

- Enroll in the Gilead MAP
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If you’re a resident, these state plans may also help:
- COLORADO: https://www.colorado.gov/CorrMAP
- ILLINOIS: https://dhril.chi.gov/ILPrEP
- MASSACHUSETTS: https://www.mass.gov/MAssPrEP (cost of drugs, services)
- NEW YORK: http://www.ny.gov/NYPrEP (cost of services)

Project Inform: www.projectinform.org
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

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.