Pre-Exposure Prophylaxis for HIV: PrEPing Alaskan Prevention and Care Providers

This webinar will begin shortly.
Webinar Etiquette

- To unmute your phone line
  - Press *7 to unmute.
  - Press *6 to re-mute.

- Verbal Questions
  - There will be dedicated time for questions.
  - Please wait until the Q & A section to ask questions on the phone.
  - Please identify yourself when asking a question or providing a comment.

- Written Questions
  - Participants have the ability to submit written questions during the webinar using the “Chat” function.

PRESENTED BY:

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Overview

- What is PrEP
- The Data Leading to PrEP
- PrEP Research
- Key Points Related to PrEP: Adherence, Side effects and Behavioral Counseling
- CDC PrEP Guidelines
PEP: Isolated HIV Exposure

- HIV Exposure
- HIV Infection

Timeline:
- 0 hr
- 72 hr
- 1 mo
- 5 mo
PEP: Prevents Infection After Isolated Exposure
PrEP: Multiple Exposures

HIV Exposure → HIV Exposure → HIV Infection

0 hr  72 hr  1 mo  6 mo
PrEP: Prevents Infection Before Exposure

HIV Exposure

HIV Exposure

PrEP

0 hr  72 hr  1 mo  6 mo
Evolution of HIV Therapies Related to PrEP

- Highly active antiretroviral therapy (HAART)
Evolution of HIV Therapies Related to PrEP

• Highly active antiretroviral therapy (HAART)
• Prevention of mother-to-child transmission (PMTCT)
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- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
Evolution of HIV Therapies Related to PrEP

- Highly active antiretroviral therapy (HAART)
- Prevention of mother-to-child transmission (PMTCT)
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
- Pre-exposure prophylaxis (PrEP)
Relationship Between HIV Viral Load and HIV Transmission

- HIV viral load is closely associated with HIV transmission.
- The lower the viral load, the less likely HIV is to be transmitted.

SERUM VIRAL LOAD OF PERSON WITH HIV

<table>
<thead>
<tr>
<th>Viral Load</th>
<th>Number (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50,000 copies/ml or more</td>
<td>23.0</td>
</tr>
<tr>
<td>10,000–49,999 copies/ml</td>
<td>14.0</td>
</tr>
<tr>
<td>3,500–9,999 copies/ml</td>
<td>11.0</td>
</tr>
<tr>
<td>&lt;3,500 copies/ml</td>
<td>2.2</td>
</tr>
</tbody>
</table>

NUMBER OF NEW HIV INFECTIONS PER 100 PERSONS IN ONE YEAR
Prevention Science Overview: Biomedical Intervention Efficacy

Modified from Abdool Karim, Lancet, 2011
• Treatment *before* exposure to HIV
iPrEx Study: PrEP in MSM

Among the men with detectable levels of medicine in their blood (meaning they had taken the pill consistently), PrEP reduced the risk of infection by as much as 92%.

Participants who became infected had far less drug in their blood, compared with matched participants who remained uninfected.
Partners PrEP Study: Heterosexual Serodiscordant Couples

Efficacy: 62 – 73%

Among those with detectable levels of medicine in their blood, PrEP reduced the risk of HIV infection by up to 90%.
Bangkok Tenofovir Study: PrEP in Injection Drug Users

For participants who had detectable tenofovir in their blood, PrEP reduced the risk of infection by 74%.
Key points to remember about PrEP:

• Adherence is closely associated with PrEP efficacy
• Though rare, side effects are possible
• Undertake ongoing behavioral risk discussions
Increased Adherence Associated with Increased Efficacy

![Graph showing the correlation between increased adherence and increased efficacy.](image)

*CAPRISA 004 (tenofovir gel, BAT-24 dosing), iPrEx, TDF2, Partners PrEP (TDF), Partners PrEP (TDV/FTC), FEM-PrEP, VOICE (TDF), VOICE (TDF/FTC), VOICE (tenofovir gel, daily dosing)*

*Calculations based on analyses involving a subset of total trial participants. Pearson correlation = 0.86, p=0.003*

Abdool Karim, CAPRISA, 2013
Increased Adherence Associated with Increased Efficacy

Efficacy

84%  100%

Grant, Lancet, 2014
Prevention Science Overview: Biomedical Intervention Efficacy

Modified from Abdool Karim, Lancet, 2011
Side Effects

Similar to those seen following years of antiretroviral use in persons living with HIV:

- Diarrhea
- Headache
- Nausea
- Renal dysfunction
- Antiretroviral resistance
- *Bone mineral density loss (has been noted in persons living with HIV, but not yet seen in persons taking PrEP)*
Behavioral Risk Discussions

- PrEP is a biomedical AND a behavioral intervention
- Adherence is closely associated with efficacy
- Behavioral disinhibition – though not seen in the studies – could potentially negate PrEP benefits in real world use settings
- Ongoing risk discussions and risk reduction planning should be an integral component to PrEP
Number of partners actually decreased.
Condom use increased
Federal PrEP Guidelines
## Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>Detecting substantial risk of acquiring HIV infection:</th>
<th>Men Who Have Sex With Men</th>
<th>Heterosexual Women and Men</th>
<th>Injection Drug Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Sexual partner with HIV</td>
<td>- Recent bacterial STD</td>
<td>- Sexual partner with HIV</td>
<td>- HIV-positive injecting partner</td>
</tr>
<tr>
<td>- High number of sex partners</td>
<td>- History of inconsistent or no condom use</td>
<td>- High number of sex partners</td>
<td>- Sharing injection equipment</td>
</tr>
<tr>
<td>- History of inconsistent or no condom use</td>
<td>- Commercial sex work</td>
<td>- History of inconsistent or no condom use</td>
<td>- Recent drug treatment (but currently injecting)</td>
</tr>
<tr>
<td>- Commercial sex work</td>
<td></td>
<td>- Commercial sex work</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Lives in high-prevalence area or network</td>
<td></td>
</tr>
</tbody>
</table>

| Clinically eligible:                                   |                           |                           |                     |
| - Documented negative HIV test before prescribing PrEP |                           |                           |                     |
| - No signs/symptoms of acute HIV infection            |                           |                           |                     |
| - Normal renal function, no contraindicated medications |                           |                           |                     |
| - Documented hepatitis B virus infection and vaccination status |                           |                           |                     |

| Prescription                                           | Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply |
|                                                      |                                                                   |
| Other services:                                        | Do oral/rectal STD testing                                       |
| - Follow-up visits at least every 3 months to provide:| Assess pregnancy intent                                         |
| - HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment | Pregnancy test every 3 months                                  |
| - At 3 months and every 6 months after, assess renal function | Access to clean needles/syringes and drug treatment services |
| - Every 6 months test for bacterial STDs               |                                                                   |


PrEP

• Identifying persons at risk for HIV who might benefit from PrEP
Population versus Individual Risk

Your patient population
Population versus Individual Risk

Your patient population

Population at high-risk for HIV
Population versus Individual Risk

Your patient population

Population at high-risk for HIV

Individuals at high-risk for HIV
Pulling it all together

No need for PrEP

May benefit from PrEP

Offer PrEP
Consider Using an Objective Tool to Assess Risk

MSM Risk Index from the US Public Health Service Clinical Provider’s Supplement to the PrEP Guidelines

<table>
<thead>
<tr>
<th>Question</th>
<th>Scoring Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  How old are you today?</td>
<td>If &lt;18 years, score 0&lt;br&gt; If 18-28 years, score 8&lt;br&gt; If 29-40 years, score 5&lt;br&gt; If 41-48 years, score 2&lt;br&gt; If 49 years or more, score 0</td>
</tr>
<tr>
<td>2  In the last 6 months, how many men have you had sex with?</td>
<td>If &gt;10 male partners, score 7&lt;br&gt; If 6-10 male partners, score 4&lt;br&gt; If 0-5 male partners, score 0</td>
</tr>
<tr>
<td>3  In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?</td>
<td>If 1 or more times, score 10&lt;br&gt; If 0 times, score 0</td>
</tr>
<tr>
<td>4  In the last 6 months, how many of your male sex partners were HIV-positive?</td>
<td>If &gt;1 positive partner, score 8&lt;br&gt; If 1 positive partner, score 4&lt;br&gt; If &lt;1 positive partner, score 0</td>
</tr>
<tr>
<td>5  In the last 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV-positive?</td>
<td>If 5 or more times, score 6&lt;br&gt; If 0 times, score 0</td>
</tr>
<tr>
<td>6  In the last 6 months, have you used methamphetamines such as crystal or speed?</td>
<td>If yes, score 6&lt;br&gt; If no, score 0</td>
</tr>
</tbody>
</table>

Add down entries in right column to calculate total score

**TOTAL SCORE**

* If score is 10 or greater, evaluate for intensive HIV prevention services including PrEP.
* If score is below 10, provide indicated standard HIV prevention services.
A decision-analytic model of PrEP for MSM.
Tool available online at: https://ictrweb.johnshopkins.edu/ictr/utility/prep.cfm.
Population Cost-Effectiveness Calculator also developed and available at same web address.

**HIV Pre-Exposure Prophylaxis (PrEP) Risk Assessment Tool: Individual Risk Calculator**

1. What percent of the time do you use condoms when having anal sex, including both receptive (bottom) and insertive (top)?  
2. What percent of the time are you the insertive partner (top) when having anal sex?  
3. On average, how many times per month do you have anal sex?  
4. Are you in a monogamous relationship with an HIV positive partner?
HIV Pre-Exposure Prophylaxis (PrEP) Risk Assessment Tool: Individual Risk Calculator

1. What percent of the time do you use condoms when having anal sex, including both receptive (bottom) and insertive (top)?
   - 50%

2. What percent of the time are you the insertive partner (top) when having anal sex?
   - 50%

3. On average, how many times per month do you have anal sex?
   - 6 times

4. Are you in a monogamous relationship with an HIV positive partner?
   - Yes

4b. What is the HIV prevalence in your community?
   - 16%
   (click here for CDC estimates of HIV prevalence among MSM by metropolitan area, age, and race/ethnicity. If left blank, the national average of 19% will be used)

Risk of acquiring HIV this year:

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without PrEP</td>
<td>1 in 44 (2.3%)</td>
</tr>
<tr>
<td>PrEP, expected adherence¹</td>
<td>1 in 77 (1.3%)</td>
</tr>
<tr>
<td>PrEP, expected adherence + increase in risky behavior²</td>
<td>1 in 59 (1.7%)</td>
</tr>
<tr>
<td>PrEP, high adherence³</td>
<td>1 in 538 (0.2%)</td>
</tr>
<tr>
<td>PrEP, high adherence and 100% condom use</td>
<td>1 in 1614 (0.1%)</td>
</tr>
</tbody>
</table>
Ask about STDs: HIV Incidence Increased Following Rectal Bacterial Infections in MSM

Ask about STDs: HIV Incidence Increased in MSM with Prior Syphilis

• Results from the iPrEx study of PrEP in MSM:
  o 2.8 cases of HIV per 100 person-years follow up for those with *no incident syphilis*
  o 8.0 cases of HIV per 100 person-years follow up for those with *incident syphilis*

• Hazard ratio of 2.6 for acquiring HIV for those with syphilis
Syphilis is up

2012 = 19 cases
2013 = 31 cases
2014 = 39 cases (10/31)
72% in MSM

Cases of Newly Diagnosed Syphilis— Alaska, November 2013 – October 2014
HIV is up

2013 = 24 cases
2014 = 38 cases (10/31)
58% in MSM
Prescribing PrEP

- Rule out chronic and acute HIV infection
- Rule out renal insufficiency
- Screen for STDs
- Screen for Hepatitis
Prescribing PrEP

Prescribe up to 3 months worth of PrEP

• The only regimen approved by the FDA and recommended for PrEP with all populations specified in the guideline is the co-formulated tenofovir 300 mg/entircitibine 200 mg (Truvada). (IA)
• Tenofovir alone has shown efficacy and safety in heterosexuals and IDU (but not MSM) and can be considered for these populations. (IC)
• The use of other medications in place or in addition to TDF/FTC or TDF alone is not recommended. (IIIA)
• Prescribing PrEP for coitally-timed or other noncontinuous daily use is not recommended. (IIIA)
Reinforcing Adherence

Adherence counseling

- Establish trust and bidirectional communication
- Provide simple explanations and education
- Support adherence
- Monitor medication adherence in a nonjudgmental manner
Reinforcing Safe Behaviors

Behavioral risk-reduction counseling

- Establish trust and bidirectional communication
- Provide feedback on HIV risk factors identified during sexual and substance use history taking
- Support risk reduction efforts
- Monitor behavioral adherence in a nonjudgmental manner
Follow-up Visits

Every 3 months

• Repeat HIV testing and assess for signs/symptoms of acute infection to document that patients are still HIV-negative. (IA)

• Repeat pregnancy testing for women who may become pregnant.

• Provide a prescription or refill authorization of daily TDF/FTC for no more than 90 days (until the next HIV test).

• Assess side effects, adherence, and HIV risk behaviors.

• Provide support for medication adherence and risk-reduction behaviors.

• Respond to new questions and provide any new information about PrEP use.
Follow-up Visits

Every 6 months

- Monitor creatinine clearance. (IIIA)
- Conduct STI testing recommended for sexually active adolescents and adults (i.e. syphilis, gonorrhea, chlamydia).
Follow-up Visits

Discontinuing PrEP

- Document HIV status
- Understand reason for discontinuing PrEP
- Counsel based on recent adherence and risk behaviors
NACCHO’s Webcast Series on PrEP and Local Health Departments

Module 1

• PrEP for HIV Prevention: An Introduction
• Beyond the Basics: The Science of PrEP
• US Public Health Service Clinical Practice Guidelines for PrEP

Module 2

• Who Might Benefit from PrEP: Population-level Risk Assessments
• Who Might Benefit from PrEP: Individual-level Risk Assessments

Module 3

• Increasing PrEP Awareness and Knowledge in Your Jurisdiction
• Incorporating PrEP into Comprehensive HIV Prevention Programs

NACCHO’s educational series about PrEP was supported by funding from Gilead Sciences, Inc.
PrEP Poses Many Questions

After watching the webcasts in Modules 1 and 2, join us for a live webinar discussion on Friday, November 21, 2014 from 1:00-2:00 PM ET.

Register at http://www.naccho.org/topics/HPDP/hivsti/prep.cfm

The webinar will be archived and made available via naccho.org.
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• Monday - Friday  |  7 AM - 5 PM MT  |  8 AM - 6 PM CT •
Alaska Native Tribal Health Consortium
HIV/AIDS Clinical Services

HRSA Ryan White Part C Early Intervention Services
Northwest AIDS Education and Training Center-Alaska
State of Alaska CDC/Prevention

State of Alaska PrEP Webinar
11/20/2014
What Do We Do?

- Clinical Care
  - ANTHC
  - ICHC Fairbanks

- Collaboration/Co-management

- Intensive Case Management

- Consultation
  - Northwest AIDS Education and Training Center (NWAETC) Local Performance site
Available for treatment, case management and medical consultation for providers caring for all HIV+ Alaskans

(907) 729-2907
(888) 855-8006 #2
Future Trainings?

Northwest AIDS Education and Training Center, Alaska Local Performance Site

Training coordinator: Joe Cantil

(907) 729-3956
• **ANTHC HIV Clinical Team**
  • Beth Saltonstall, MD
    • Medical director
  • Terri Bramel, PA-C
    • Clinical Specialist

Patient Care Managers:
• Lisa Rea, RN
• Julie Witmer, RN
• SCF- Thor Brendtro, RN
  • (907) 729-4209
ANMC resources

• Infectious Disease Specialists
  - Jake Gray, MD
  - Ben Westley, MD
  - Cliff Schneider, MD

Call ANMC and ask for ID consult on call

(907) 563-2662
Community Resources

Ben Westley, MD
Infectious Disease
(907) 563-3929

Rod Gordon, PharmD
Greatland Infusion Pharmacy
(907) 561-2421
State of Alaska Epi

Melissa Boyette
HIV Surveillance and Disease Intervention
269-8057

Jessica Harvill
HIV Prevention
269-5221
800 478-2437
263-2050

Serving all Alaska except Fairbanks region. Anchorage and Juneau offices

RW Part B funding
Medical case management
Housing assistance
Statewide ADAP Provider
Rapid HIV and HCV Testing
Syringe exchange
Web-based Sexual Health Education
Questions

- **Verbal Questions**
  - Press *7 to unmute
  - Press *6 to re-mute
  - Please identify yourself

- **Written Questions**
  - Submit using chat

- If you have questions regarding this webinar, please contact Jillian Casey at jccasey@NASTAD.org