

# Clinical Updates for Pre-Exposure Prophylaxis (PrEP) for HIV

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#### **Conflict of Interest Disclosure Statement**

No financial interests to disclose

• The views expressed in this presentation are those of the authors and do not necessarily reflect the official policy or position of the U.S. Department of Health and Human Services, the Indian Health Services, or the U.S. Government

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## **NNHAAD**





#### OUR WHY



#### The two sides of the same coin

- 40 yo male, MSM, recently ended 10 year marriage. Seen by PCP that provides medical services to LGBTQ community. Too embarrassed to ask for PrEP. PCP never offered PrEP.
  - Acquired HIV within 12 months.

- 25 yo male, MSM, recently ended a 4 year monogamous relationship, asked if it would be weird to get HIV prevention services at PIMC since knows many staff members.
  - On PrEP for 2 years and continues to be HIV negative.



#### What We Will Cover

- The evidence for <u>Pre-Exposure Prophylaxis</u> (PrEP)
- Guidelines for determining patient eligibility
- PrEP services currently offered by I/T/U clinicians
- Patient monitoring
- Drug procurement for I/T/U facilities



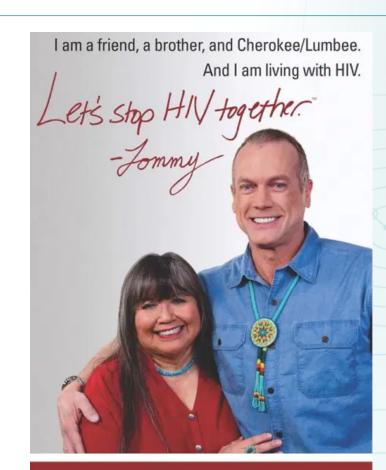
# THE EVIDENCE



#### **HIV** in the United States

1.2 million people living with HIV

- 36,400 new HIV infections in 2018
  - 7% decrease compared with 2014
- Lifetime risk for men who have sex with men 1 in 6 (17%)



Tommy (right) has lived with HIV since 1985.

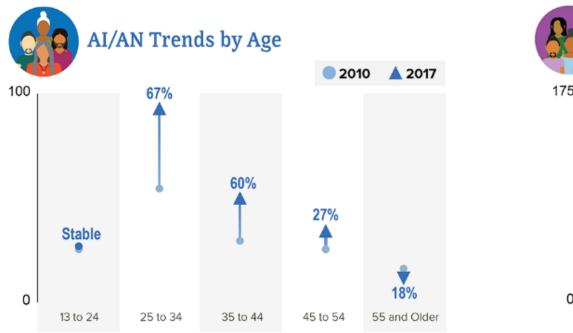


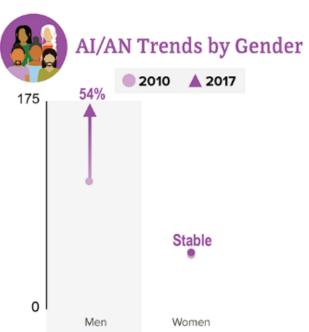






# HIV and American Indians & Alaska Natives





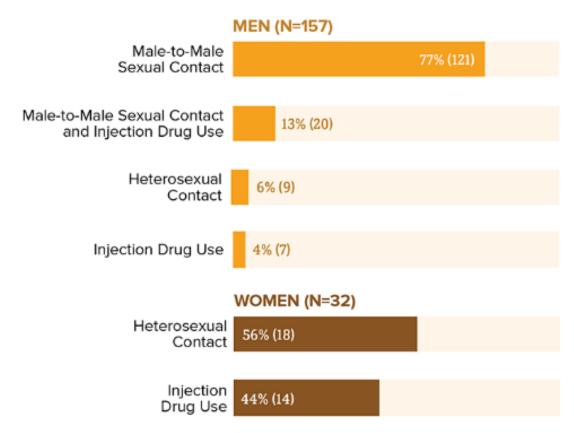
<sup>\*</sup>Changes in populations with fewer HIV diagnoses can lead to a large percentage increase or decrease. Source: CDC. NCHHSTP AtlasPlus. Accessed April 27, 2020.

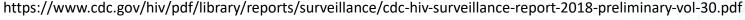


#### HIV and

#### **American Indians & Alaska Natives**

AI/AN represent 1.3% of the U.S. population and are
 ~0.5% of the HIV diagnoses in 2018







# **Ending the HIV Epidemic**

Ending
the
HIV
Epidemic

**GOAL:** 

75%
reduction in new
HIV infections
by 2025
and at least
90%
reduction
by 2030.



www.hiv.gov



# **Ending the HIV Epidemic**



**Diagnose** all people with HIV as early as possible.

**Treat** people with HIV rapidly and effectively to reach sustained viral suppression.





**Prevent** new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

**Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.





# Treatment as Prevention (TasP)



Are U in the Conversation?

**Effectively zero risk of sexual transmission** 



# **Ending the HIV Epidemic**



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# **Ending the HIV Epidemic**













# Why PrEP?

"An ounce of prevention is worth a pound of cure"

Benjamin Franklin

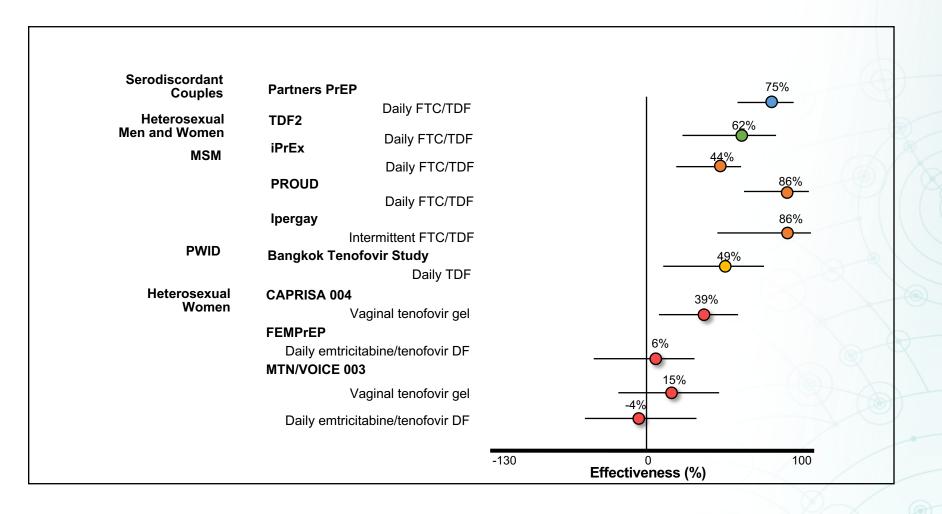


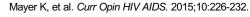
#### **PrEP**

- July 2012
  - FDA approved daily tenofovir disoproxil fumarate/emtricitabine
  - AKA Truvada or TDF/FTC
- October 2019
  - FDA approved daily tenofovir alafenamide/emtricitabine
  - AKA Descovy or TAF/FTC
  - Not indicated in individuals at risk of HIV-1 from receptive vaginal sex



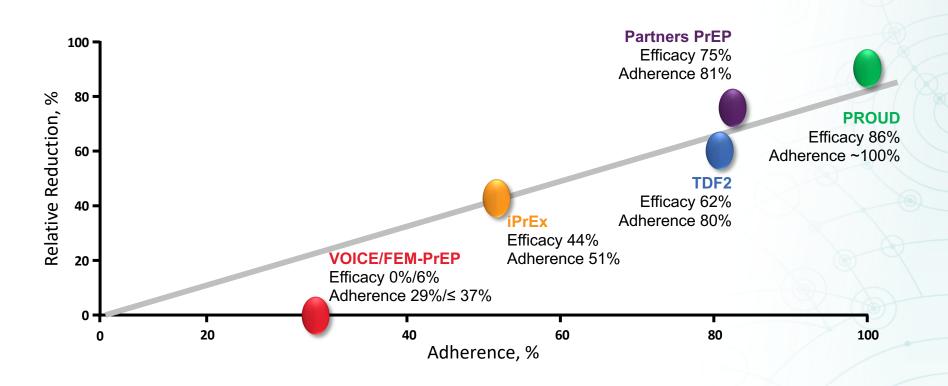
#### **PrEP** is Effective







# Adherence is key for PrEP Success



Grant RM, et al. NEJM 2010. Van Damme L, et al. NEJM. 2012. Thigpen MC, et al. NEJM. 2012. Baeten JM, et al. NEJM. 2012. Marrazzo JM, et al. NEJM. 2015.. McCormack S, et al. Lancet. 2016.



#### GUIDELINES FOR DETERMINING ELIGIBILITY



#### **Indications for PrEP**

#### Behavior

- Sex without condoms
- Sex with partner who has HIV & not on treatment or unknown status
- Sharing of injection equipment

#### History

- STI in the past 6 months
- "High" number of sexual partners

## Epidemiology

- Sexual activity in a high prevalence area or network
- Commercial sex worker

#### **Contraindications for PrEP**

HIV Infection

CrCl <60 for TDF/FTC or CrCl <30 for TAF/FTC

(Special considerations for those with HepB)

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE

A CLINICAL PRACTICE GUIDELINI



#### **CURRENT SERVICES**



#### **Prevention Services**

- Opt-out testing
  - Pregnancy, 1<sup>st</sup> and 3<sup>rd</sup> trimester at PIMC
  - Empaneled patients every 5 years at PIMC
  - Use bundles for STI testing to make sure HIV is included
- Condoms
- Non-occupational post-exposure prophylaxis
- PrEP
- TasP



#### **PrEP** services

- Rapid Start
- Initial visits
- Follow-up every 3 months
- Immunizations: HAV, HBV and HPV

- Many different clinic types are utilized
  - PCP versus a specific provider
  - Pharmacist-led clinics
  - Labs plus telemed



#### PATIENT MONITORING



# **Monitoring PrEP patients**

- Initial start
  - Within 3- 6 months: syphilis screening and gonorrhea and chlamydia 3 site testing
  - Within 30 days: Hepatitis B serology, hepatitis C testing, renal function
  - Within 7 days: HIV testing
  - Screen for risk of acute HIV and symptoms
- Recommend 1 month follow-up to assess adherence, side effects, recheck HIV and CMP, and build patient-provider relationship, then 3 month follow-up



# 3 site or alternate testing

- What is 3 site testing?
  - Gonorrhea and Chlamydia "live where you put it" so can be oral, vaginal/urethra, or anal
  - Urine (vaginal & urethra), throat swab, and anal swab
- Who needs 3 site testing?
  - Anyone at risk for an STI and needs screening in all the "parts" they are using for sex
    - DON'T MAKE ASSUMPTIONS ABOUT SEXUAL PRACTICES



# **Ongoing Monitoring**

- Every 3 months
  - Assess adherence, side effects and risk reduction
  - Repeat HIV screening
  - Prescription renewal
- Every 6 months
  - Check creatinine and creatinine clearance
  - Screen for STIs



#### DRUG PROCUREMENT



# **HIV PrEP FDA Approved Medications**

# Tenofovir Disoproxil Fumarate/emtricitabine

- 1 tablet by mouth once a day
- Prescribe for ≤ 90-day supply
- Approved for adolescents & adults > 35kg (77 lb.)\*
- More bone loss and renal issues than TAF
- Approved in females
- Quicker time to full protection

#### Tenofovir alafenamide/ emtricitabine

- 1 tablet my mouth once a day
- Prescribe for ≤ 90-day supply
- Approved for adolescents & adults > 35kg (77 lb.)\*
- Not for patients at risk from receptive vaginal sex or who's risk is through injection drug use
- Longer until full protection
- More weight gain than TDF



# **Paying for PrEP**

- Private Insurance
  - Almost always covered
  - Now generic, may have a co-pay if filled at outside pharmacy
- Medicaid (AZ AHCCCS)
  - PrEP was added to the formulary, still filling brand
- Ready, Set, PrEP program
- National Core Formulary



# Ready, Set, PrEP program

- Advantages
  - Users linked by site
  - Quick enrollment: only requirement is no insurance
  - Requires Brand (DAW)
  - Mail order and delivers to PO Boxes
  - E-scripts

- Disadvantages
  - Annual enrollment/renewal
  - Limited pharmacies

https://getyourprephcp.iassist.com/iassist



# Join Indian Country PrEP ECHO

 The 6 session virtual training curriculum provides comprehensive information for clinicians to end the HIV epidemic and effectively integrate and improve PrEP services in Indian Health Service, Tribal, and Urban Indian clinics. Continuing education credits will be provided.





# Join Indian Country PrEP ECHO

- When: The first PrEP ECHO session will take place April 23<sup>rd</sup> meeting every 2 weeks from 12-1pm MT for 3 months
- The PrEP ECHO program will include topics such as:
  - Rationale, Indications and Contraindications for PrEP
  - How to Start PrEP
  - Monitoring Patients while on PrEP/Addressing Complications
  - Recruiting for PrEP Candidates
- To learn more and register, please visit:
  - https://www.surveymonkey.com/r/PrEPECHO2021



#### References

- AETC National HIV Curriculum <a href="https://aidsetc.org/nhc">https://aidsetc.org/nhc</a>
- HIV Treatment Guidelines https://aidsinfo.nih.gov/guidelines
- HIV Information www.cdc.gov/hiv
- PrEP Guidelines
  - Recommendations for HIV prevention with adults and adolescents with HIV in the United States, 2014: <a href="https://stacks.cdc.gov/view/cdc/44064">https://stacks.cdc.gov/view/cdc/44064</a> AND
  - Preexposure Prophylaxis for the Prevention of HIV in the United States 2017 Update: Clinical Providers' Supplement: <a href="https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf">https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf</a>
- National HIV Curriculum Prevention module <a href="https://www.hiv.uw.edu/go/prevention">https://www.hiv.uw.edu/go/prevention</a>
- Indian Country PrEP ECHO <a href="https://www.indiancountryecho.org/program/prep/">https://www.indiancountryecho.org/program/prep/</a>
- Warmline <a href="https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/">https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/</a>

