PrEP 101
Pre-exposure Prophylaxis

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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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Objectives

- Describe “U=U”
- Recall effectiveness rates of PrEP
- Identify potential barriers & facilitators to PrEP utilization
- Recall factors that increase risk of HIV infection
- Identify patients indicated for PrEP
- Identify resources for PrEP clinical guidance

HIV is PREVENTABLE!

- U = U
  - Undetectable = Untransmittable
  - Treatment as Prevention (TasP)
  - Early initiation of ART associated with more favorable outcomes
- PrEP
  - Up to 99% risk reduction from sexual transmission
  - Up to 74% risk reduction from injection drug use
  - Include: behavioral risk reduction counseling & education, condoms

Indian Country At Risk

- Increased rates of new HIV diagnoses among AI/AN
- “Hot Spots” accounting for >50% of new HIV diagnoses
  - Maricopa County
- Syphilis outbreak
  - New & congenital infections in AI/AN
  - 27% co-infection with HIV
- Reduced PrEP uptake
  - AI/AN MSM, TGW, 13-24 yo, PWID
  - Medically underserved, lower socio eco classes

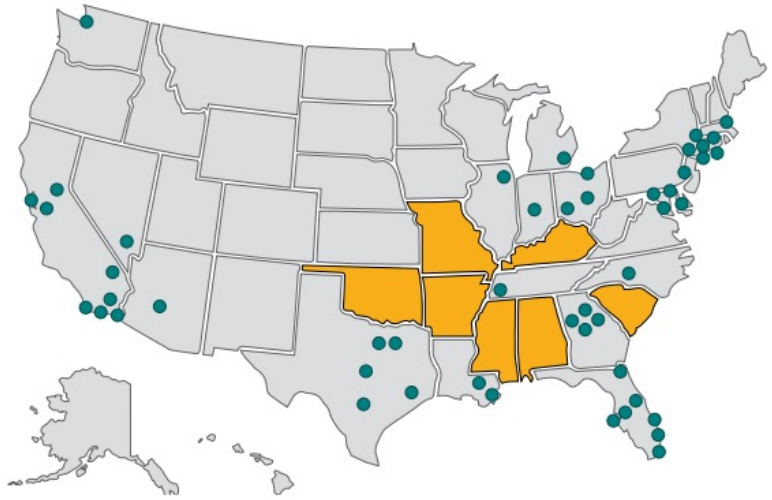
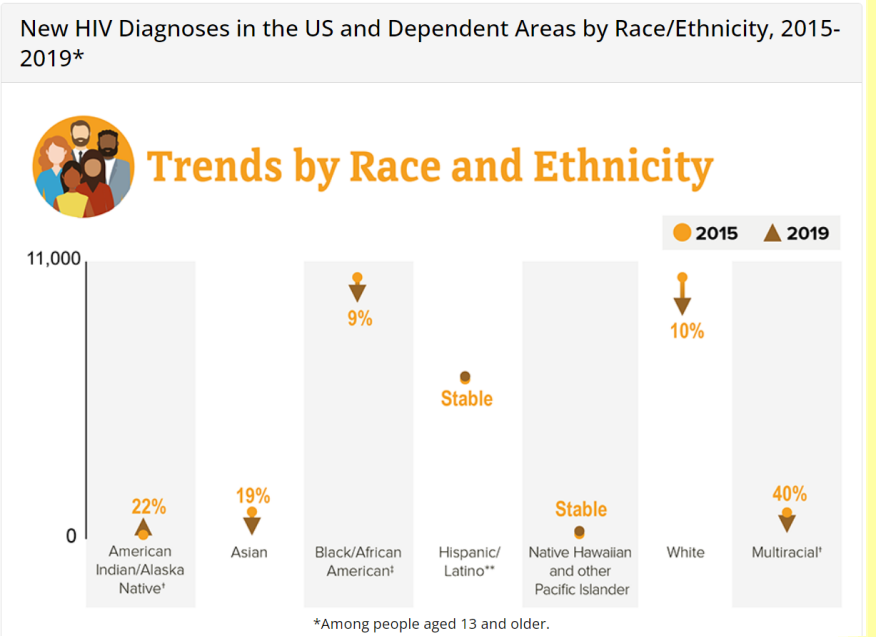
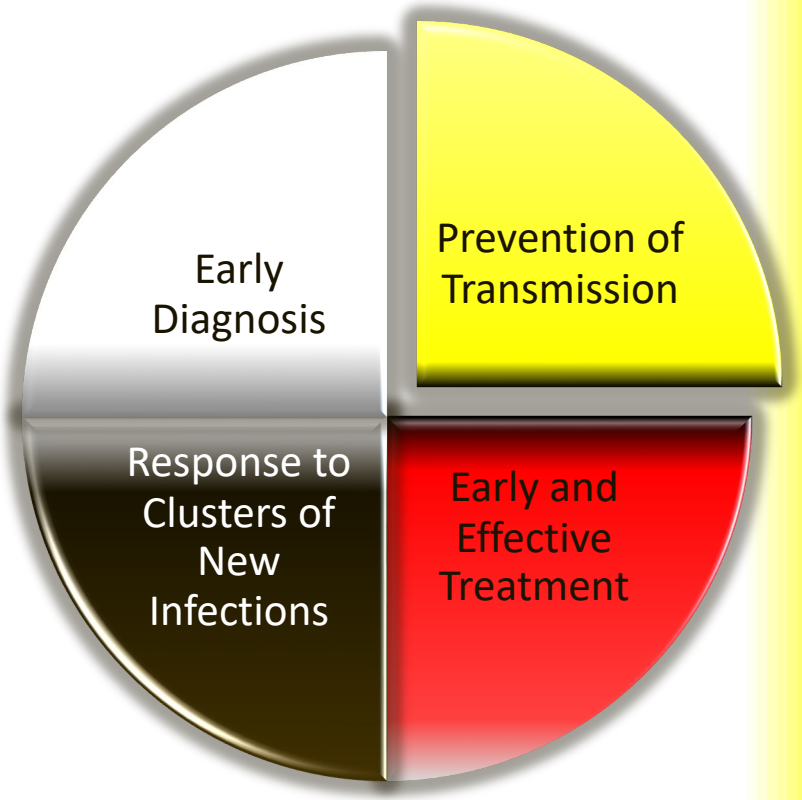


Figure 4. 57 jurisdictions prioritized in Phase 1 of the *Ending the HIV Epidemic* initiative



Call to Action

- Ending the HIV Epidemic (EHE)
  - Reduce new HIV diagnoses by 90% by the year 2030
- HIV Strategic Plan
- Dr. Christensen communication
  - Response to STI in Indian Country



the next generation free from HIV

USPHS Guideline Recommendation

- All sexually-active patients be informed about PrEP and it's role in preventing HIV infection.
- Clinicians should evaluate all adult and adolescent patients who are sexually active or who inject drugs and offer to prescribe PrEP to those at risk for HIV infection. Consider behavior and epidemiologic factors.

The Guidelines – Risk of HIV Infection

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment

Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[3] – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[3] – [vaginal, oral, rectal, urine- as indicated], blood **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels

[1] adolescents weighing at least 35 kg (77 lb)
[2] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated
[3] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs
[4] estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥30 ml/min for F/TAF use

- Also consider alcohol use, non-injection drug use, epidemiological factors
- Guidelines: If a patient requests PrEP but does not report any risk factors, PrEP should be prescribed to those patients (given they are clinically eligible, per the next slide)

Indicated vs. Clinically Eligible

Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications

- HIV test Ag/Ab laboratory test, do not rely on patient report, POC testing that relies on oral fluid, Acute HIV infection, STI infection, Renal Function, Hepatitis, Lipids (Descovy; TAF)

Acute symptoms of HIV

- Tiredness
- Joint or muscle aches
- Sore throat
- Rash
- Fever
- Headache
- Vomiting or diarrhea
- Night sweats
- Enlarged lymph nodes

PIMC & PrEP

- PIMC patients
  - PrEP first prescribed at PIMC 2014
    - Initially limited due to cost, now generic Truvada costs less than birth control
  - Over 300 patients on PrEP for at least one month
  - Currently ~125 patients actively taking PrEP
  - First cabotegravir injectable patient will be starting within a few weeks
- No new HIV acquisitions while actively taking PrEP
  - Number needed to treat is as low as 17 in high risk populations
  - Multiple patients stopped PrEP then acquired HIV, some within 6 months

What limits the use of PrEP?

- Training and comfort level of providers
- Workload- not enough time to ask about sexual health
- Missed opportunities in STI assessment and treatment
- Stigma, hesitancy to discuss detailed sexual history (patient & providers)
- Belief that will lead to more unprotected sex
- Cost
  - Generic Truvada less than $30 acquisition cost for 30 day supply
  - Biktarvy $1800+ for 30 day supply
- Purview Paradox

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

Taking a Sexual History

- Should be done with everyone, infections are occurring in all settings
- Include efforts to assure sexual history is a part of routine care
- Destigmatize
- Ensure confidentiality
- Patients may not offer information that they are not SPECIFICALLY asked about
- Patients may ask for PrEP without eliciting any information that indicates risk, offer PrEP if they ask.

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
- December 2021
  - FDA approved first injectable cabotegravir
  - Indicated for at risk adults and adolescents at least 35 kg

TDF/FTC versus TAF/FTC

Tenofovir Disoproxil Fumarate/emtricitabine	Tenofovir alafenamide/ 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	• 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

Apretude (Cabotegravir)

- Oral lead-in is optional
- First year requires 7 injections
  - Month 0 and Month 1 cabotegravir 200mg/ml
    - Loading dose
  - Month 3, 5, 7, 9, 11: cabotegravir 200mg/ml
    - Ongoing dose
- Flexible dosing: 7 days before or after
- More than 1 week, oral bridge preferred
  - Can bridge for up to 2 months without repeating loading dose
- Side effects: site reactions (12-15%), headaches (2-12%), increased creatine phosphokinase (2-15%)
- Drug interactions: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine and others

See package insert for full prescribing information- information above is abbreviated

PrEP labs

New start

- Hepatitis A total Antibody
- Hepatitis B surface antigen
- HBV surface antibody (total or IgG)
- HBV antibody (total or IgG)
- Hepatitis C
- HIV-1 quantitative PCR (optional)

Restart or regular follow-up

- HIV-1 quantitative PCR

- CMP
- HIV Ag/Ab
- Syphilis with reflex RPR
- Gonorrhea & Chlamydia x 3 sites

Doxy- PEP

- What is it?
  - The morning after pill for STIs
- Who needs it?
  - Recommended: Men who have sex with men (MSM) or transgender women (TGW) who have had ≥1 bacterial STI in the past 12 months
  - Shared decision-making to all non-pregnant individuals at increased risk for bacterial STIs and **to those requesting doxy-PEP**, even if these individuals have not been previously diagnosed with an STI or have not disclosed their risk status.
- Counseling
  - Two tablets once ideally within 24 hours but no later than 72 hours after sexual exposure for infection prevention

Monitoring

- Guidelines include in-person, virtual or phone visits
- Every 3 months
  - HIV testing
  - Assess for signs and symptoms of acute HIV
  - Bacterial STI (MSM, TGW)
  - Assess adherence and risk reduction
- Every 6 months
  - Renal function (people over 50; baseline CrCl <90 mL/min)
  - Bacterial STI all folks as indicated
- Every 12 months
  - Renal function for all folks
  - Chlamydia for heterosexual women and men
  - Lipids and weight for TAF (Descovy)
- As indicated
  - Clean needles, SUD treatment referral/consult
  - Behavioral risk reduction counseling, condoms

Clinical Pearls

- Offer PrEP with every STI treatment
- If they are asking, give it to them
- Expecting abstinence for 2 weeks may not be reasonable
  - Limit to 30 days with no refills
- Patient assistance programs for injectables are good at verifying coverage especially medical billing
- PrEP agreement (contracts)
- PrEP closeout letter
  - nPEP, PrEP, 2-1-1
- E3 Vaccine strategy: HAV, HBV, HPV, Mpox

Clinical tools

- Pocket Guides? Or like lanyard cards/attachements
- Clinical PEPline: 888-448-4911
- https://www.cdc.gov/hiv/clinicians/prevention/prep.html
- https://www.cdc.gov/stophivtogether/clinician-resources/index.html

References

- Project ECHO http://echo.unm.edu
- AETC National HIV Curriculum https://aidsetc.org/nhc
- 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: https://stacks.cdc.gov/view/cdc/44064 AND
  - Preexposure Prophylaxis for the Prevention of HIV in the United States – 2017 Update: Clinical Providers' Supplement: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf

- National HIV Curriculum Prevention module
  - https://www.hiv.uw.edu/go/prevention

- Indian Country PrEP ECHO
  - https://www.indiancountryecho.org/program/prep/

- Warmline
  - https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/