Alaska Infectious Disease ECHO

ALASKA NATIVE
TRIBAL HEALTH
CONSORTIUM

NPAIHB
Indian Leadership for Indian Health

HCV-HIV-PrEP-STIs

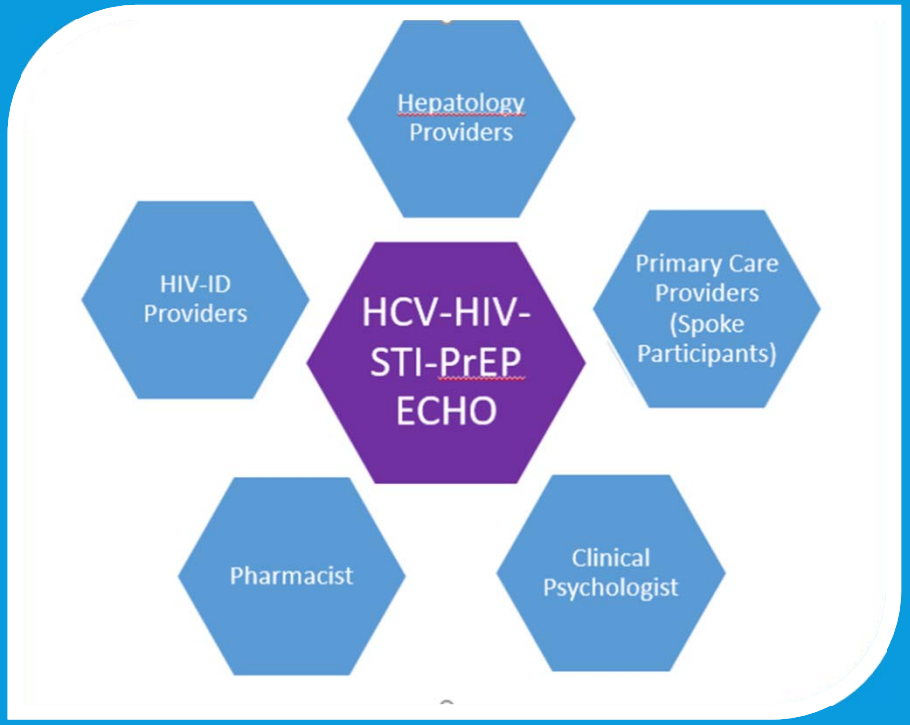
Alaska Native Tribal Health Consortium

WHAT WE DO

- Starting February 2021: **accepting case presentations and questions pertaining to:**
  - HCV
  - HIV
  - PrEP and Preventative Strategies
  - STIs
- Provide Expert Panelists
- Didactic Presentations pertaining to ECHO topics
- Provide CE/CME including pharmacotherapy credits

CONSULTANT TEAM

- Youssef Barbour, MD Hepatologist
- Leah Besh, PA-C HIV/Hepatology Specialist
- Terri Bramel, PA-C HIV Specialist
- Rod Gordon, R.Ph. HIV Pharmacy Specialist
- Lucia Grauman Neander, PhD Clinical Psychologist
- Jacob Gray, MD Infectious Disease Specialist
- Annette Hewitt, ANP Hepatology Specialist
- Brian McMahon, MD Hepatologist
- Lisa Rea, RN HIV Case Manager
- Lisa Townshend, ANP Hepatology Specialist



TENTATIVE SCHEDULE AT A GLANCE

- February 9th: PrEP 101-Pre Exposure Prophylaxis for HIV and exciting new options in the pipeline
- March 9th: 2020 AASLD Update: What's new with HCV Treatment
- April 13th: STI Epidemiology, Screening, Treating: HIV
- May 11th: STI Epidemiology, Screening, Treating: Syphilis
- June 8th: STI Epidemiology, Screening, Treating, Expedited Partner Therapy: Chlamydia/Gonorrhea
- July 13th: How to take an accurate sexual history
- August 10th: PEP-Post Exposure Prophylaxis
- September 14th: STI prevention programs, initiatives, harm reduction resources
- October 12th: Trauma Informed Care
- November 9th: Stigma with patient perspective
- December 14th: HCV Epidemiology, Alaska Elimination Plan

Welcome to Alaska Infectious Diseases ECHO – HCV, HIV, PrEP, STI

Approved Provider Statements:

Alaska Native Tribal Health Consortium (ANTHC) is accredited by the Washington State Medical Association to provide continuing medical education for physicians.

ANTHC is approved as a provider of nursing continuing professional development by the Montana Nurses Association, an accredited approver with distinction by the American Nurses Credentialing Center's Commission on Accreditation.

Contact Hours:

ANTHC designates this live activity for a maximum 12 *AMA PRA Category 1 Credit(s)* ™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ANTHC designates this activity as meeting the criteria for one nursing contact hour credit for each hour of participation up to a maximum 12 hour(s).

Conflict of Interest Disclosures:

Lisa Townshend-Bulson, faculty for this educational event, is the primary investigator in a study funded in part by Gilead Sciences. All of the relevant financial relationships listed for these individuals have been mitigated.

Requirements for Successful Completion:

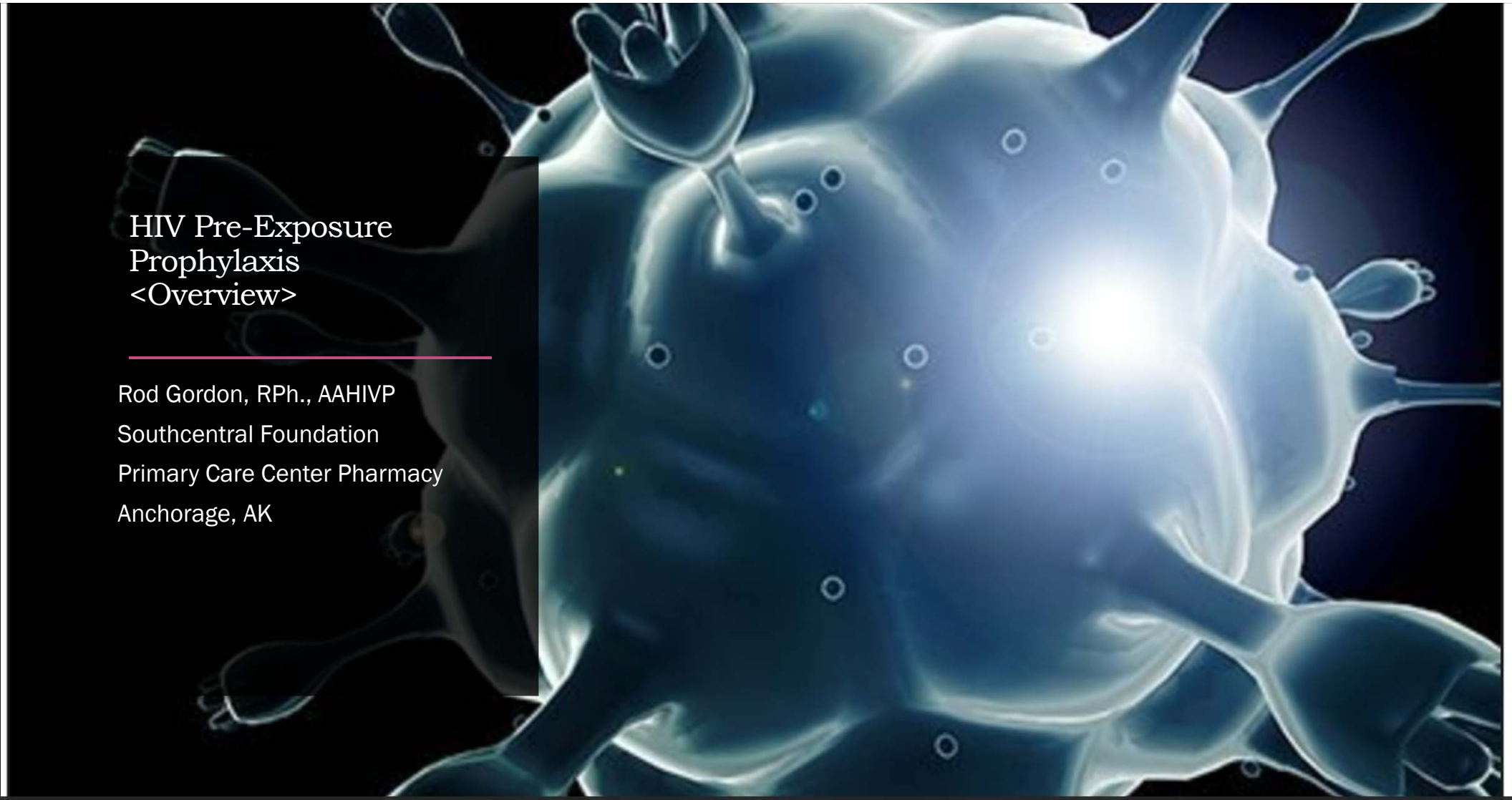
To receive CE credit please make sure you have actively engaged in the entire activity, your attendance is recorded by the facilitator, and complete the course evaluation form found here: https://forms.gle/18t4EgvN2WdnM4P77

For more information contact
jlfielder@anthc.org or (907) 729-1387

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

HIV Pre-Exposure Prophylaxis <Overview>

Rod Gordon, RPh., AAHIVP
Southcentral Foundation
Primary Care Center Pharmacy
Anchorage, AK



Electron Microscopic View of the HIV virus- Medscape, 2021

Objectives -

Participants will gain a better understanding of:

- Current global and US epidemiology of HIV infection
- Current FDA approved products for PrEP
- Evidence of efficacy in select patient populations
- Guidelines for appropriate use of PrEP
- Investigational products on the horizon for PrEP

{There will be a pre- and post-test}

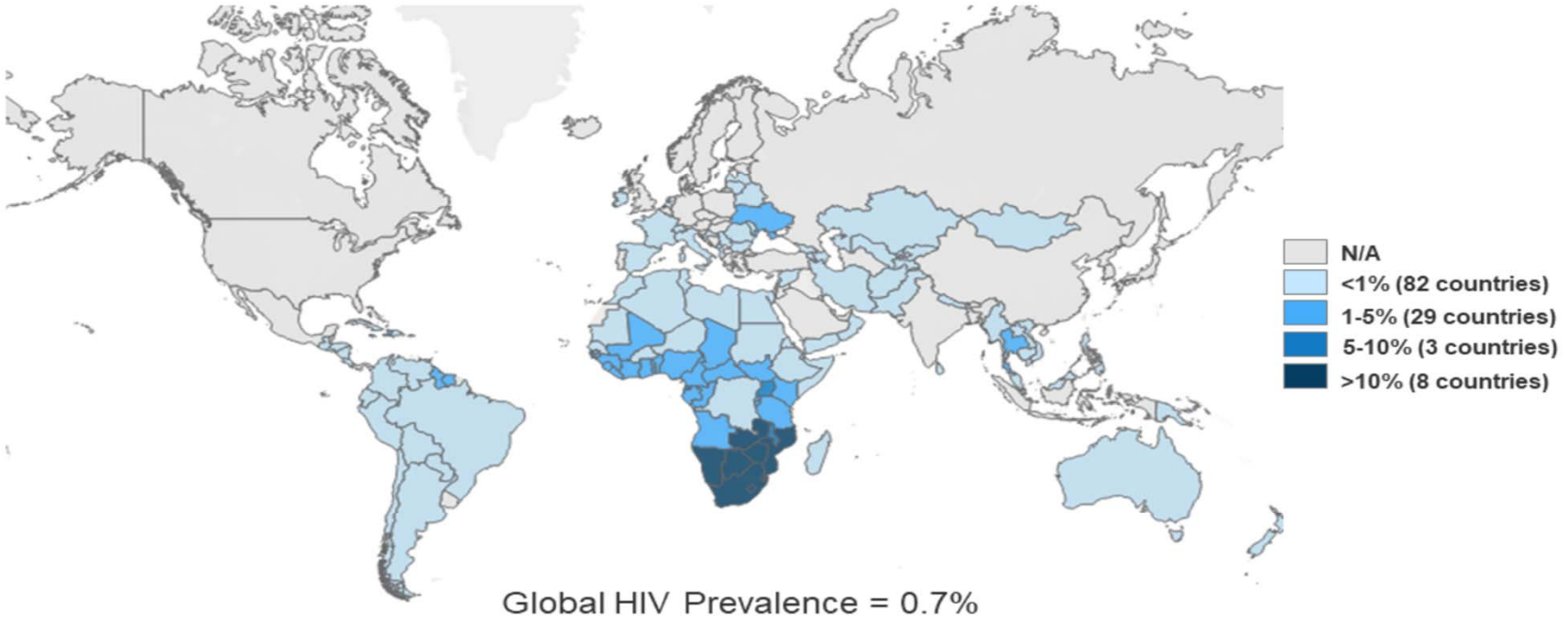
Which of the following recommendations about the initiation of PrEP is accurate?

A. When starting PrEP, a 120-day supply of medication is recommended.
B. If the risk for HIV acquisition is through vaginal sex, tenofovir alafenamide-emtricitabine is indicated to prevent HIV acquisition.
C. If the risk for HIV acquisition is through vaginal sex, it may take approximately 7 days for tenofovir-emtricitabine to reach maximum protection levels in cervicovaginal tissues
D. Current guidelines recommend against the use of PrEP in at-risk individuals who are pregnant or breastfeeding.

Pre-Test:

Figure 1

Adult HIV Prevalence, 2019



Global HIV Prevalence = 0.7%

NOTES: Data are estimates. Prevalence includes adults ages 15-49.
SOURCE: KFF, based on UNAIDS, AIDSinfo, Accessed July 2020.

KFF
HENRY J KAISER FAMILY FOUNDATION

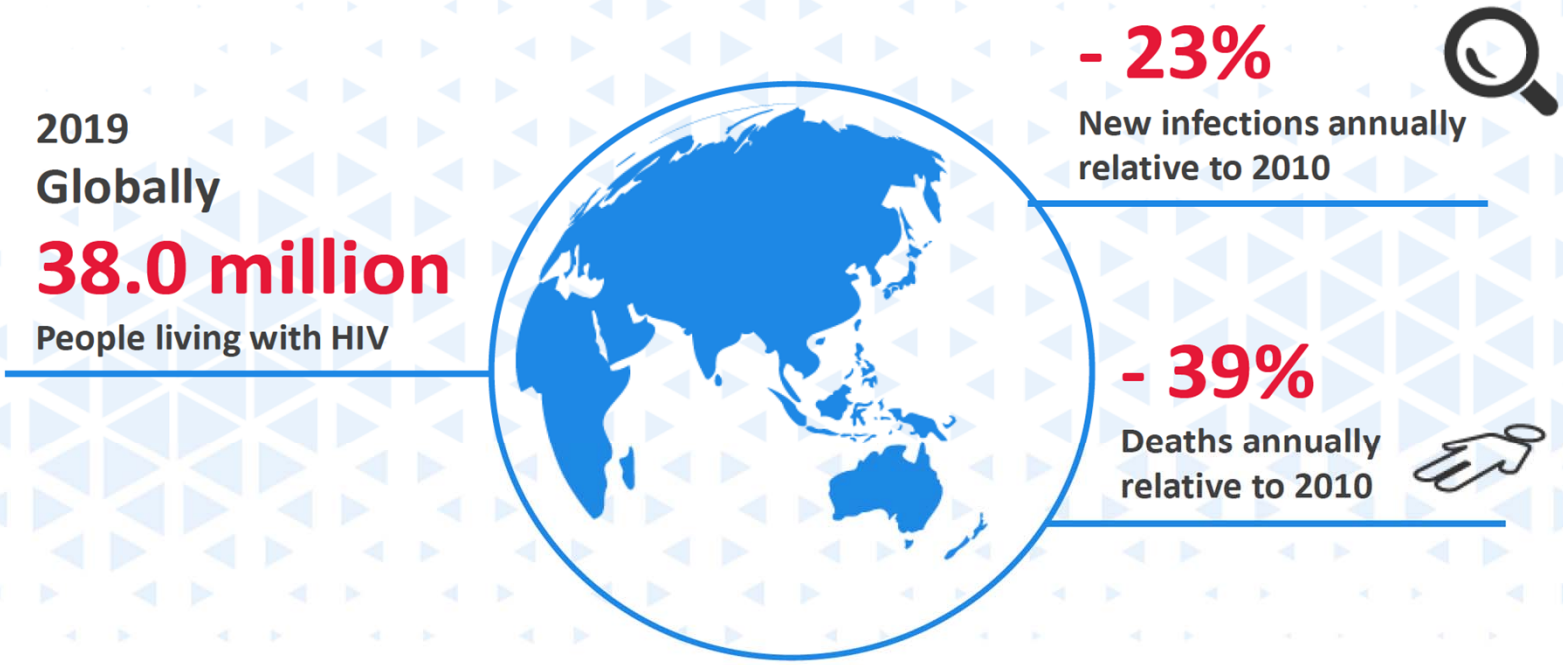
Figure 1: Adult HIV Prevalence, 2019

Incidence & Mortality- 2019

Progress since 2010:

- ↑ ART coverage
- ↑ Prevention Efforts
- ↓ AIDS related morbidity & mortality

Global HIV Epidemic



Source: UNAIDS/WHO estimates

Latest HIV estimates and updates on HIV policies uptake, November 2020

World Health Organization

HIV Prevalence- 2018
1,040,352

Rates of Adults and Adolescents Living with Diagnosed HIV Infection, Year-end 2018

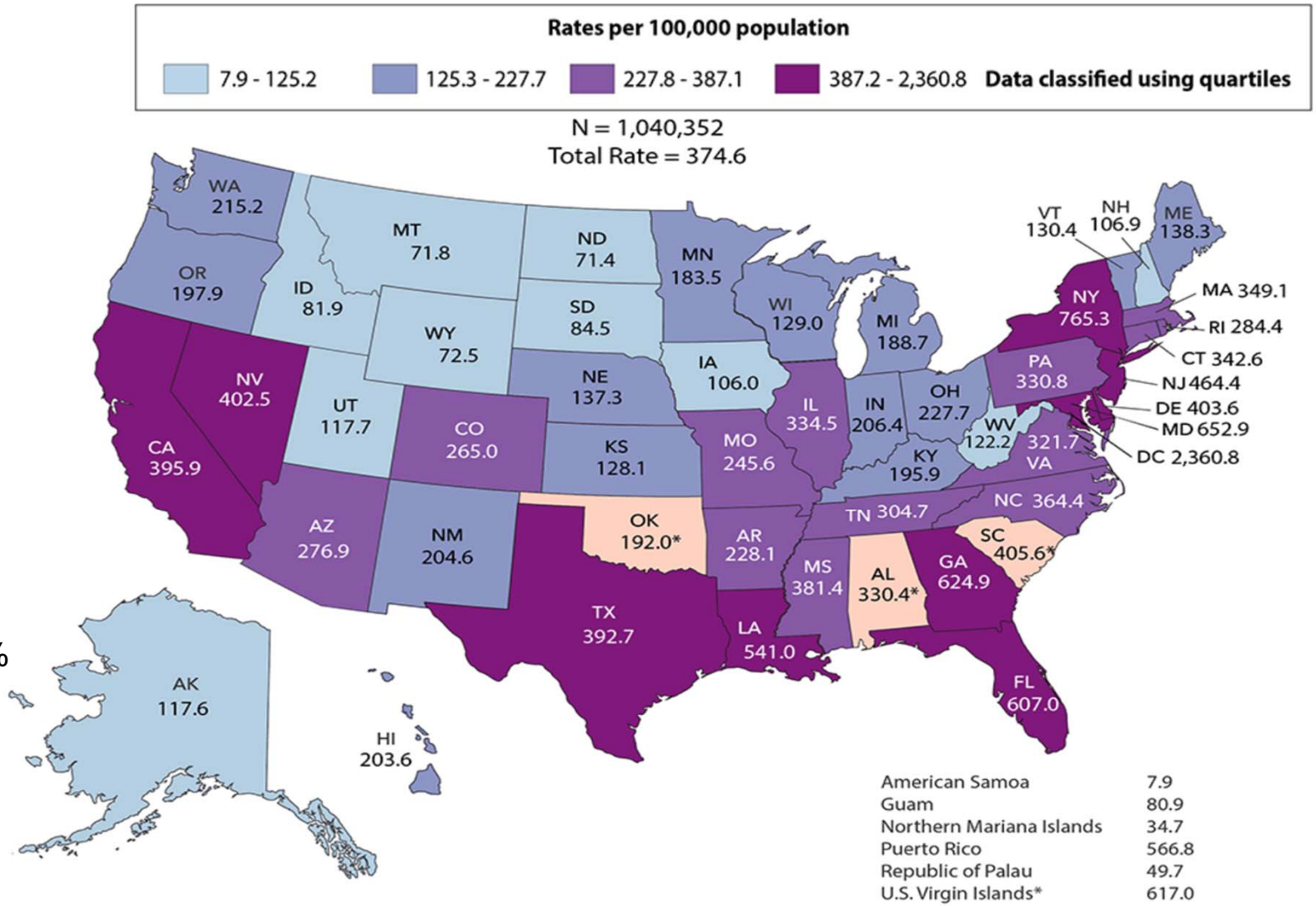
United States and 6 Dependent Areas

US average = 0.4%

Highest:
District of Columbia = 2.4%

Lowest:
North Dakota = 0.07%

Alaska = 0.12%



Data for the year 2018 are preliminary and based on deaths reported to CDC as of December 2019. Data are based on address of residence as of December 31, 2018

HIV Incidence- 2018
37,881

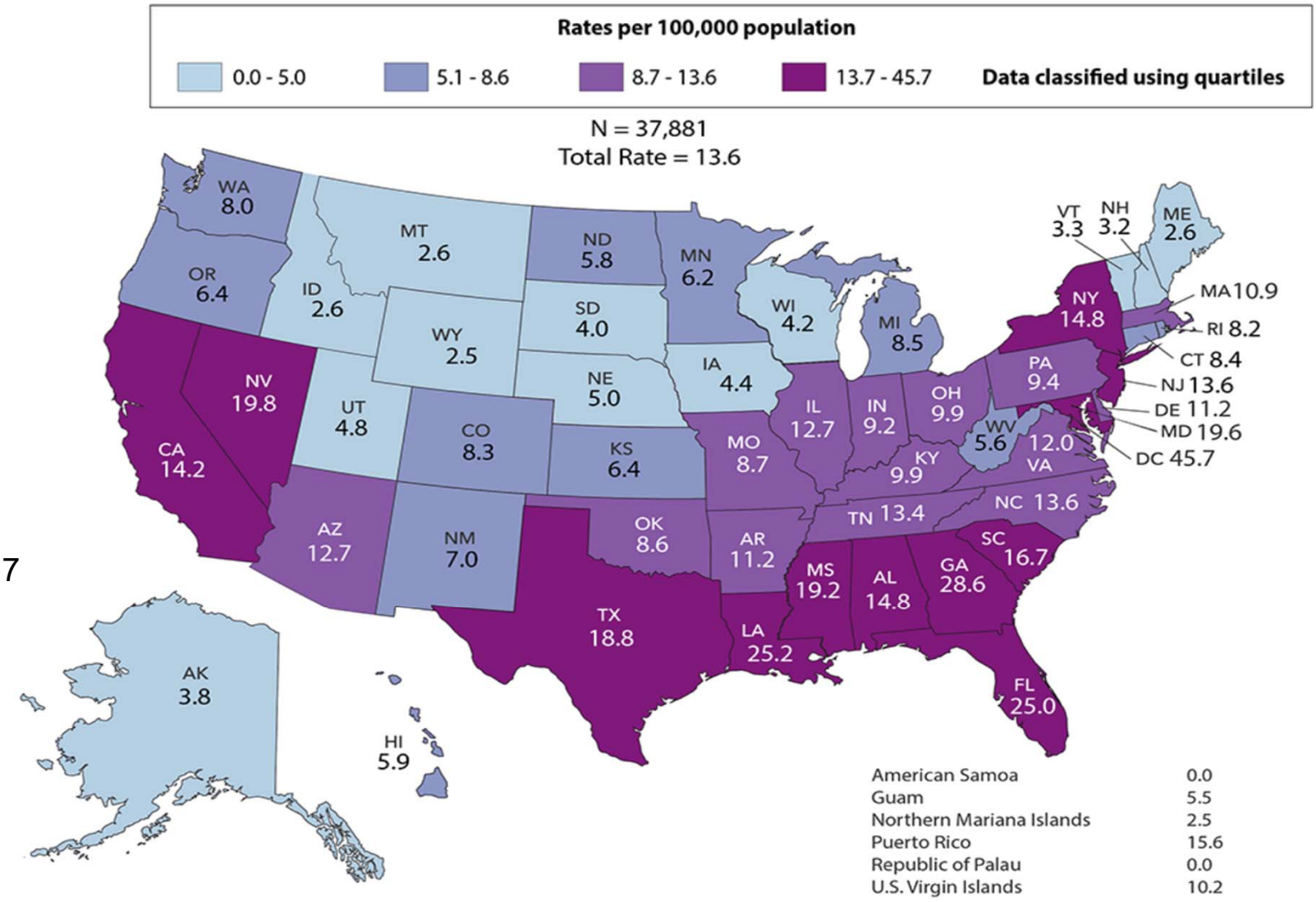
Rates of Diagnoses of HIV Infection among Adults and Adolescents, Year-end -2018

United States and 6 Dependent Areas

Highest:
District of Columbia = 45.7

Lowest:
Wyoming = 2.5

Alaska = 3.8



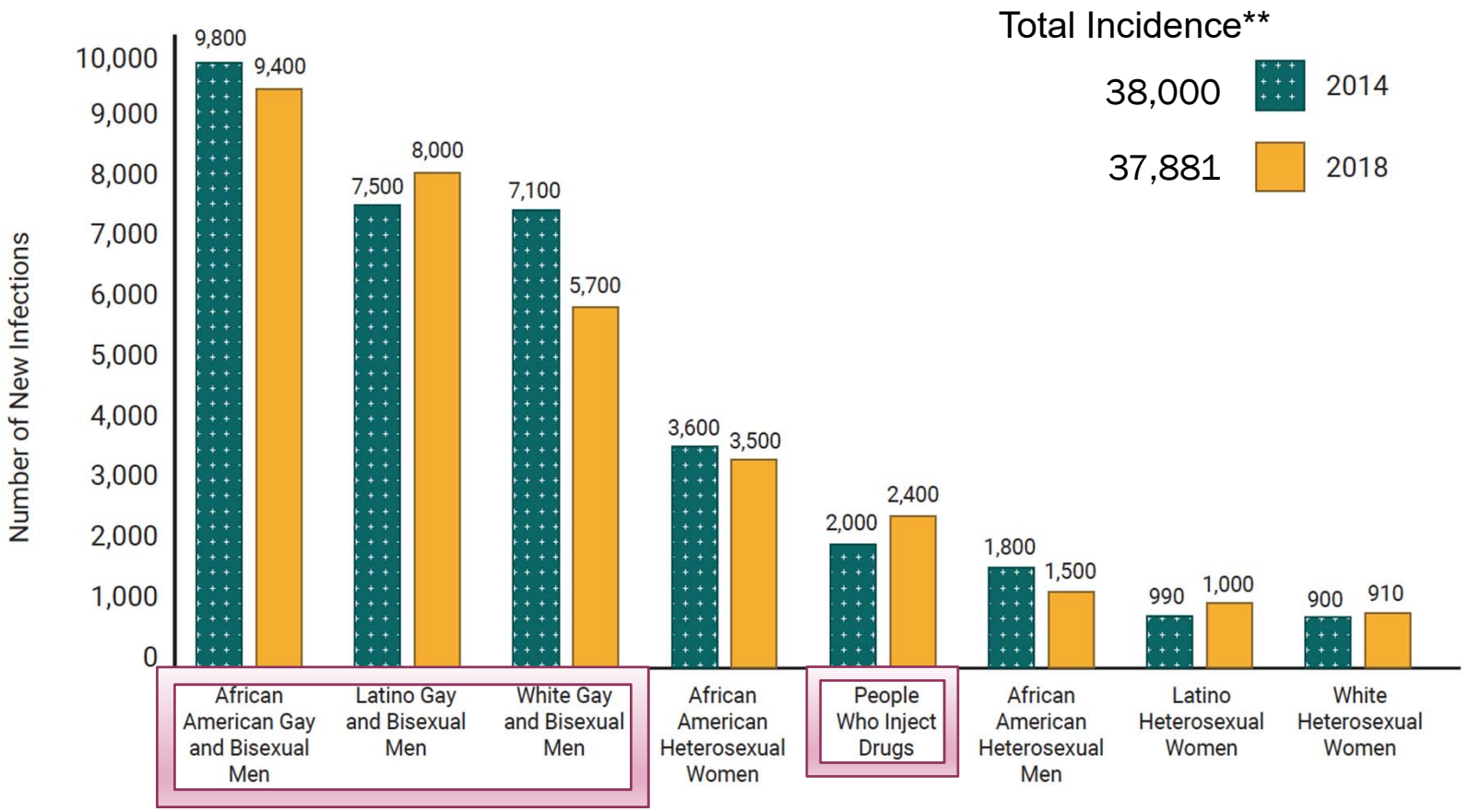
Data for the year 2018 are preliminary and based on deaths reported to CDC as of December 2019. Data are based on address of residence as of December 31, 2018

US HIV Epidemic

Incidence 2014-2018

Modest progress since 2014

Persistence driven by high-risk behaviors common among Gay Bisexual, PWID



**Data for the year 2018 are preliminary and based on deaths reported to CDC as of December 2019. Data are based on address of residence as of December 31, 2018

Alaska Incidence 2019

Alaska HIV Epidemic

Incidence has ranged from a high of 38 cases in 2016 to a low of 22 cases in 2018.

Cases were up slightly in 2019 to 27.

Incidence rate has ranged from 3-5 cases per 100,000 people in Alaska over the last four years.

Highlights, 2019 Newly Diagnosed HIV Cases (n=27)

Of the 69 cases reported to the Alaska Section of Epidemiology in 2019, 27 were newly diagnosed in Alaska. Of those 27:

- 4 (15%) were also diagnosed with AIDS at the time of initial diagnosis
- One is known to have died
- 20 (74%) were male
- 14 (52%) were Men Who Have Sex with Men (MSM); 6 (22%) were heterosexual; 3 (11%) were Injection Drug Users (IDU); 1 (4%) were MSM/IDU
- 12 (44%) were White; 6 (22%) were Alaska Native/American Indian; 5 (19%) were Black; 4 (15%) were Hispanic
- 19 (70%) were 34 years old or younger at the time of diagnosis
- 13 (48%) were living in Anchorage/Mat-Su at the time of diagnosis; 6 (22%) were living in the Interior

State of Alaska, Section of Epidemiology – May 2020

Alaska Division of Public Health

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http://epibulletins.dhss.alaska.gov/Document/Display?DocumentId=2057

Slide courtesy of Leah Besh, PA-C

HIV Ending the HIV Epidemic

National Strategic Plan
A Roadmap to End the Epidemic
for the United States | 2021–2025

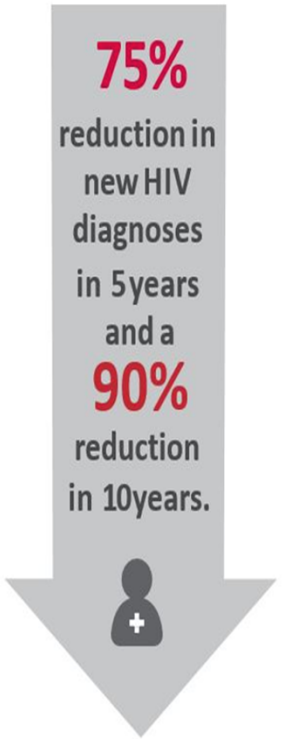
A PLAN FOR AMERICA

Ending the US HIV Epidemic

The **Four Pillars** of "Ending the HIV Epidemic"

Goals:
↓ HIV diagnoses
- By 75% >> 2025
- By 90% >> 2030

PrEP plays major role in achieving these goals; >>Increase PrEP use by at-risk populations to at least 50% by 2025



www.hiv.gov

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.

HRSA
Ryan White HIV/AIDS Program

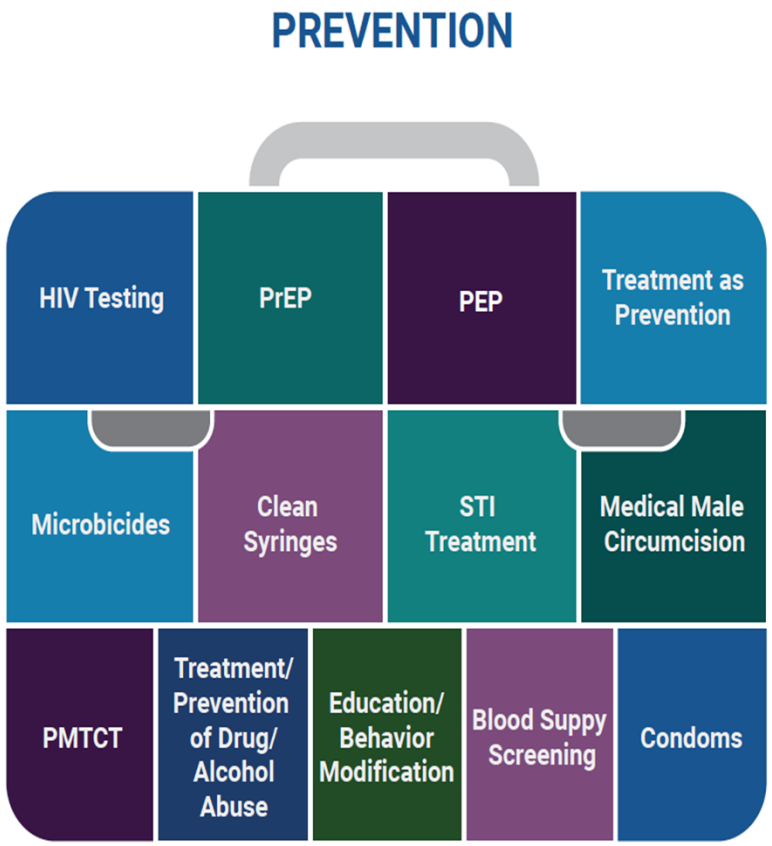
EHE Prevention Pillar- PrEP

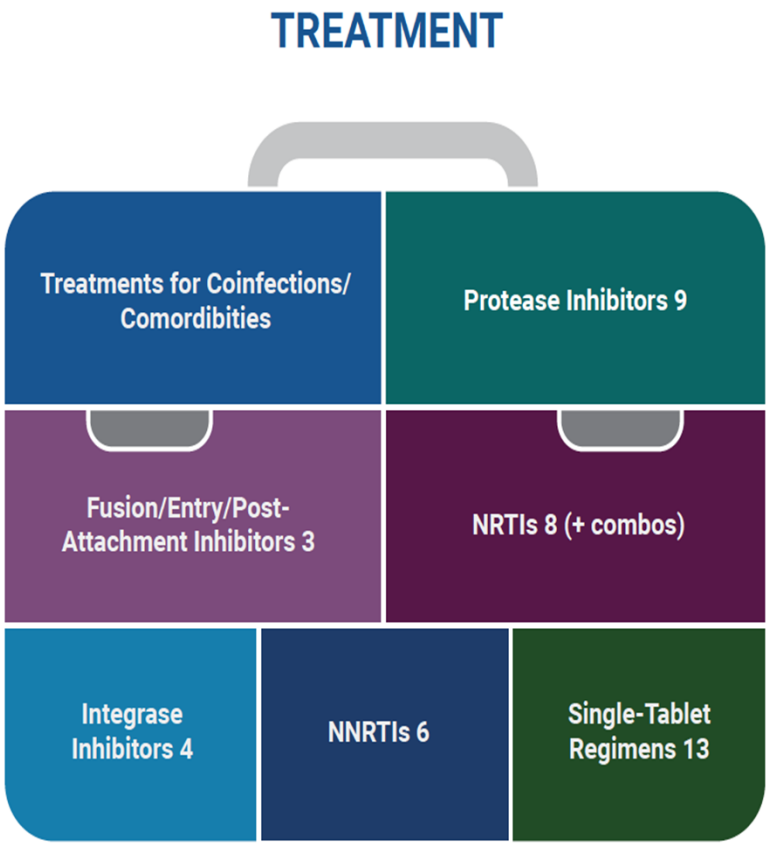
US HIV Epidemic

PrEP is just one biomedical tool for HIV prevention.

Two prevention "Toolboxes"

Treatment is also "prevention".





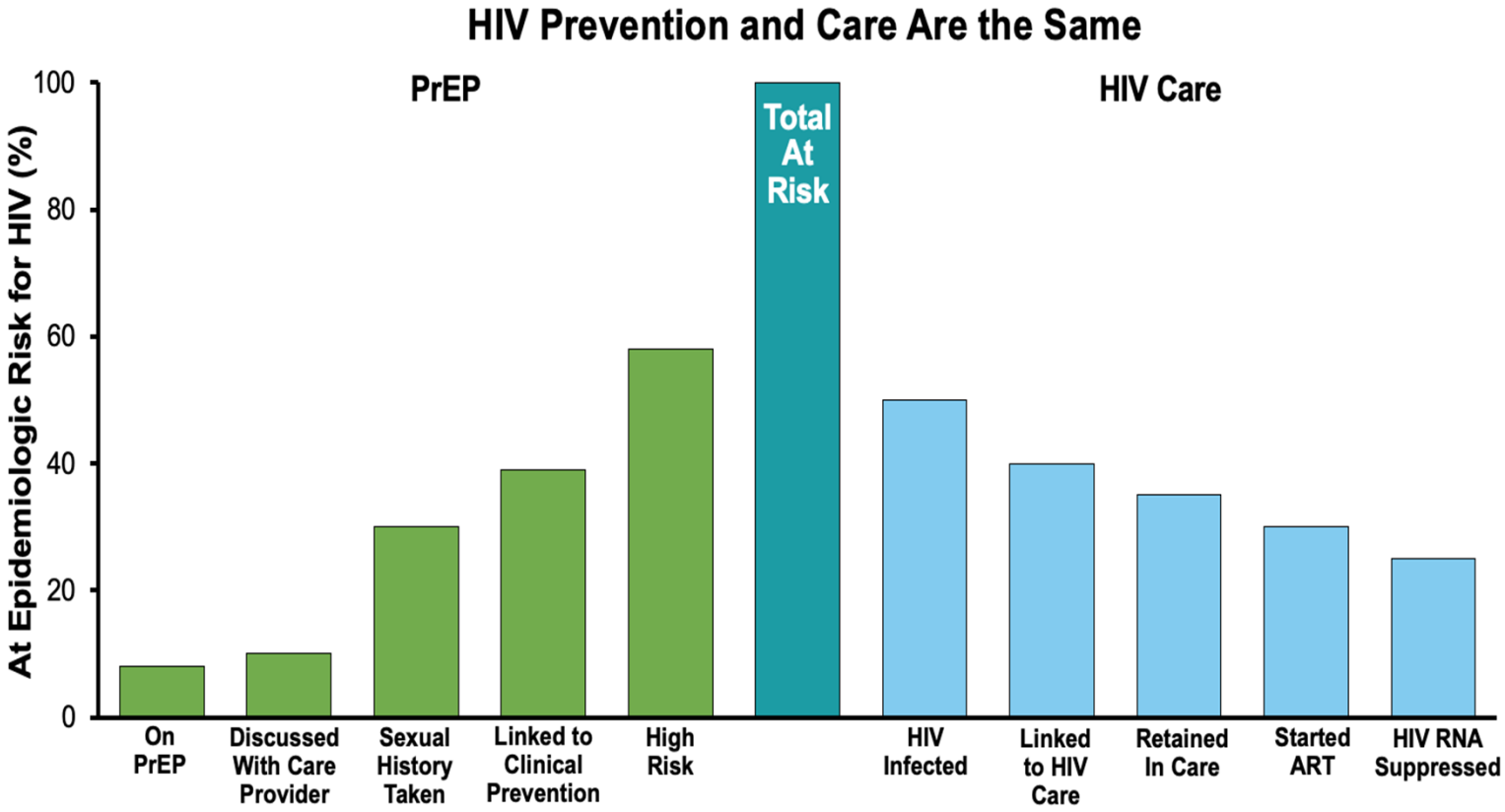
HIV prevention and treatment toolkits. Source: Eisinger et al. Published by Oxford University Press for the Infectious Diseases Society of America 2019. This work is written by U.S. Government employee(s) and is in the public domain in the U.S.

EHE Prevention Pillar- PrEP

US HIV Epidemic

"Status Neutral" means HIV testing serves as an entry point for **all** services.

"Only 18% of the approximately 1.2 million people indicated for PrEP are receiving it; therefore, about 4 in 5 people who could benefit from PrEP are not receiving it."



FDA PrEP Approvals

Drugs Approved for PrEP

Truvada [TDF/TFC]
2004 Tx Adults & Peds
2012 + Adults PrEP
2018 +Adolescents PrEP
[Generic available-Teva]

Descovy [TAF/FTC]
2015 Tx Adults & Peds
2019 + Adults and Adolescents PrEP

https://www.gilead.com/~/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf

https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/descovy/descovy_pi.pdf

PrEP Drug Comparisons

Truvada [TDF/TFC]
2004 Tx Adults & Peds
2012 + Adults PrEP
2018 +Adolescents PrEP
[Generic available-Teva]

Descovy [TAF/FTC]
2015 Tx Adults & Peds
2019 + Adults and Adolescents PrEP

*(No data on efficacy for receptive vaginal exposure risks- Discover trial enrolled only MSM, TGW)

Drugs Approved for PrEP

Comparative Feature	Truvada [TDF/FTC]	Descovy [TAF/FTC]
NRTI Combination	Tenofovir Disoproxil Fumarate 300mg/ Emtricitabine 200mg	Tenofovir Alafenamide 25mg / Emtricitabine 200mg
Brand/Generic Status	Generic Available [Oct 2020]	No Generic Available
Standard PrEP Dosing Recommendations	1 tablet daily, with or without food	1 tablet daily, with or without food
Duration of therapy	For period of increased risk	For period of increased risk
Targeted Patients	Adults/Adolescents 12 and older weighing at least 77 lbs	Adults/Adolescents 12 and older weighing at least 77 lbs
Targeted Risk Categories	Sexually active adults and adolescents, or PWID who are at risk of acquiring HIV	Sexually active adults and adolescents, or PWID who are at risk of acquiring HIV **[excludes receptive vaginal]**
General adverse effects	Nausea, vomiting, diarrhea, fatigue, 3-6%;	Nausea, vomiting, diarrhea, fatigue, 2-5%
Bone Safety	Mild ↓BMD over first 2 years, hip, spine; then stabilizes; reversable with short term use;	Less BMD loss compared to TDF, hip and spine.

https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/descovy/descovy_pi.pdf
https://www.gilead.com/~/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf

PrEP Drug Comparisons

Truvada [TDF/TFC]
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Descovy [TAF/FTC]
2015 Tx Adults & Peds
2019 + Adults and Adolescents PrEP

Drugs Approved for PrEP

Renal Safety	Rare Fanconi Syndrome, risk of proximal tubular injury, phosphate, glucose, uric acid wasting, risk for ↑ excretion of B_2 microglobulin & retinol binding protein, ↓ CrCl	Rare Fanconi syndrome, but lower excretion of urinary markers of proximal tubular injury, more preserved CrCl
Renal Dosing	Do not use if CrCl <60 ml/min	OK to use down to 30 ml/min
Effect on Lipids*	Evidence of improved LDL/TC	No protective effect on lipids
Weight**	Some evidence that may prevent weight gain	Some evidence that may increase weight gain
Excretion/Metabolism/PK	Renal/prodrug- hydrolysis to TFV in plasma prior to uptake into lymphoid tissue/PBMCs; generates 90% higher plasma levels of TFV than TAF; / Substrate of transporters P-gp, BCRP; no CYP450 activity	Renal for ~80% of active TPV-DP; /prodrug- hydrolysis in PBMCs, macrophages, hepatocytes/ substrate of transporters: P-gp, BCRP, OATP1B1, OATP1B3; no significant CYP450 activity

https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/descovy/descovy_pi.pdf
https://www.gilead.com/~/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf

*Aribbas, JR et al. J Acquir Immune Defic Syndr 2017;75:211–218
**Opera Cohort: Mallon. AIDS 2020. Abstr OAB0604

Metabolic Distinctions

Drugs Approved for PrEP

Truvada [TDF/TFC]
2012 Adults PrEP
2018 + Adolescents PrEP
[Generic Available- Teva]

Descovy [TAF/FTC]
2019 Adults and Adolescents PrEP

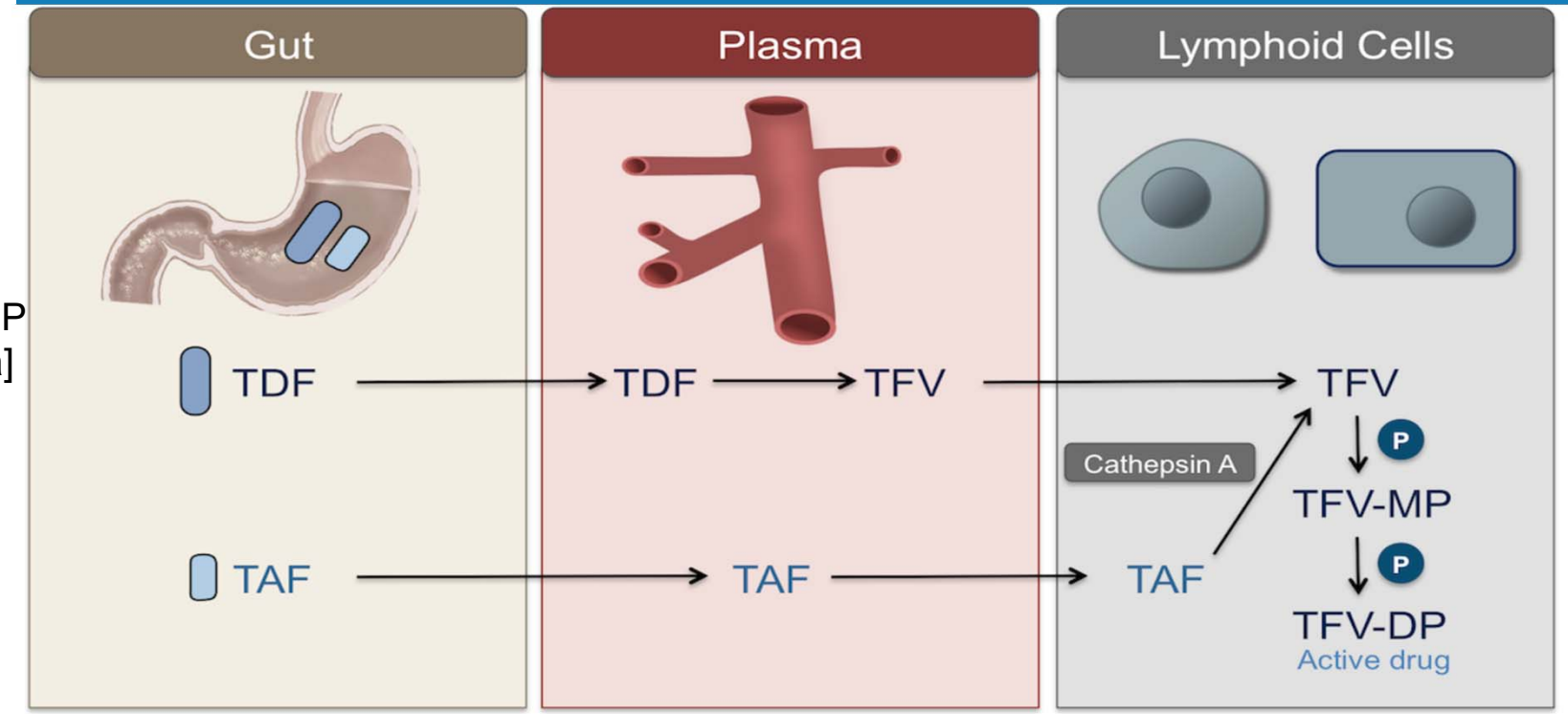
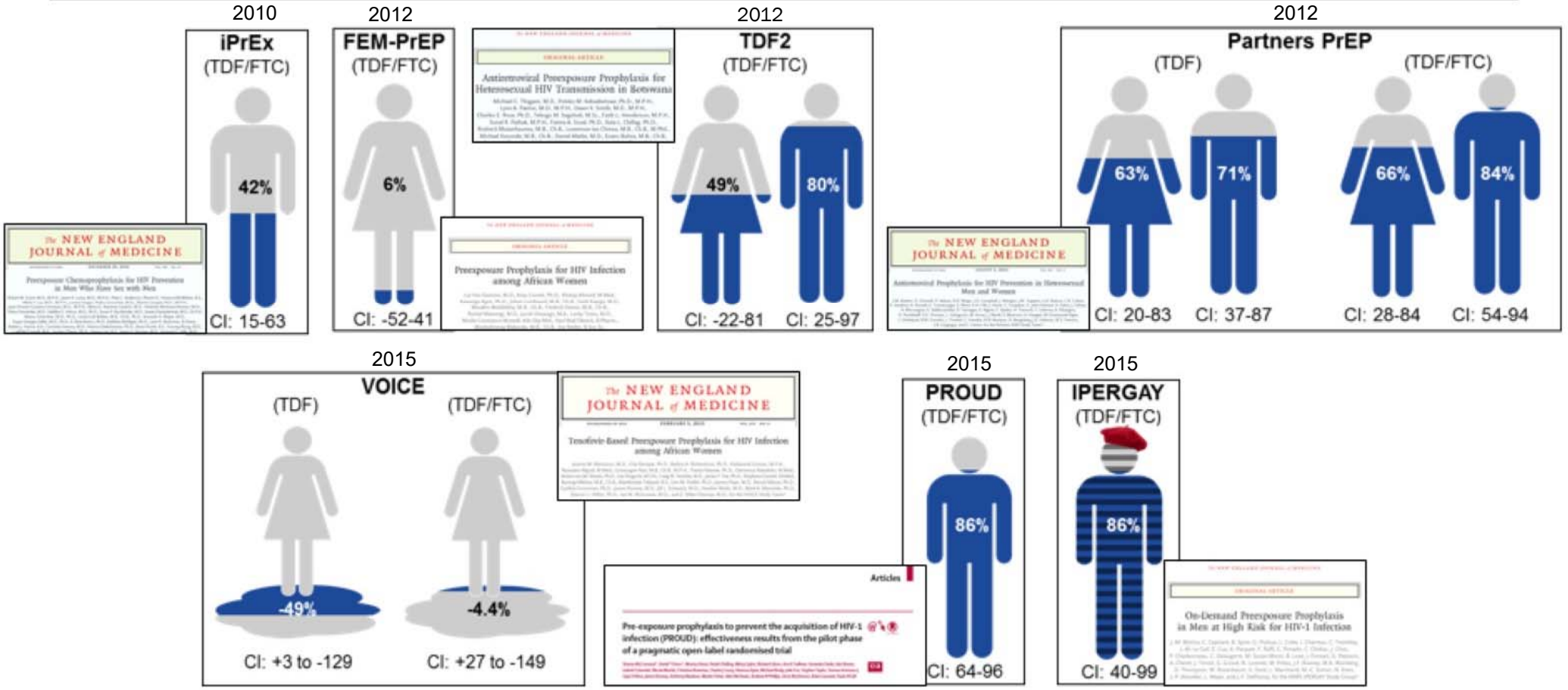


Figure 10 - Metabolism of Tenofovir DF and Tenofovir alafenamide
A 25 mg dose of tenofovir alafenamide has 90% lower circulating plasma tenofovir levels when compared with a 300 mg dose of tenofovir DF.

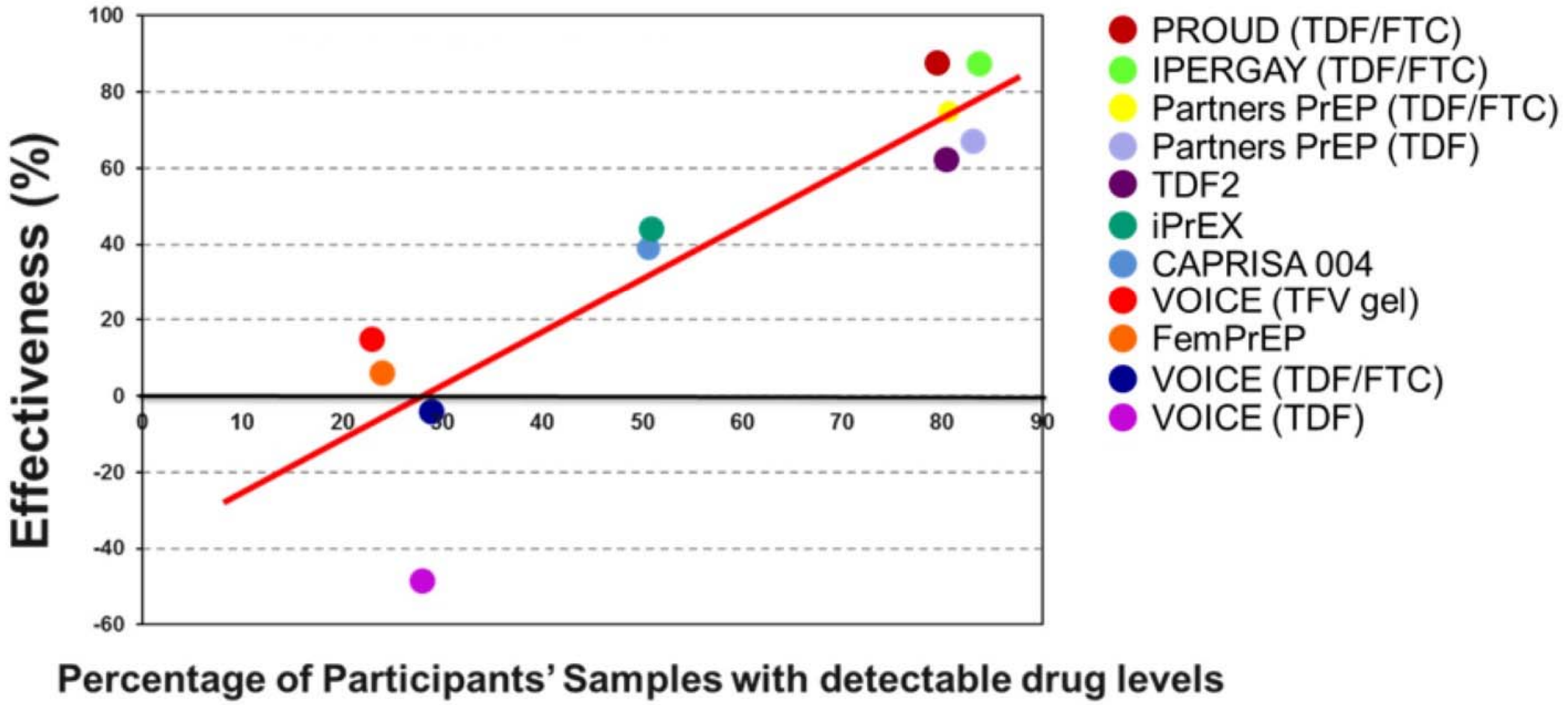
National HIV Curriculum, https://www.hiv.uw.edu/ accessed January 2021

Effectiveness of Daily TDF/FTC in Clinical Trials



"PrEP 2.0 and Beyond" IAS-USA Webinar June 2019: https://www.youtube.com/watch?v=4m4mNrzKCZk&list=PLYmlZPoGuP9BqKAzJTLAEXe0u2WqgcShf&index=10&ab_channel=IAS-USA

Effectiveness of Daily TDF/FTC in Clinical Trials



"PrEP 2.0 and Beyond" IAS-USA Webinar June 2019: https://www.youtube.com/watch?v=4m4mNrzKCZk&list=PLYmlZPoGuP9BqKAzJTLAEXe0u2WqgcShf&index=10&ab_channel=IAS-USA

PrEP Effectiveness

An Open Label Extension Cohort Study of participants from ATN 082, iPrEx, and US Safety Study by Grant, et al. in 2014, compared tenofovir levels in dried blood spots with efficacy.

Results suggest a minimum average weekly administration of 4 tablets required to prevent HIV infection In MSM

PrEP Adherence vs Effectiveness

	BLQ	LLOQ to < 350 fmol/punch	350-699 fmol/punch	700-1249 fmol/punch	≥ 1250 fmol/punch
Estimated dosage, tablets/wk	0	< 2	2-3	4-6	7
Follow-up visits, %	25	26	12	21	12
HIV infections, n	18	9	1	0	0
Person-yrs/infection	384	399	179	316	181
HIV incidence, n (95% CI)	4.70 (2.99-7.76)	2.25 (1.19-4.79)	0.56 (0-2.50)	0 (0-0.61)	0 (0-1.06)
HR vs previous placebo (95% CI)	1.55 (0.88-2.56)	0.69 (0.32-1.32)	0.19 (0.01-0.88)	0 (0-0.25)	0 (0-0.43)
HR vs concurrent off PrEP (95% CI)	1.25 (0.60-2.64)	0.56 (0.23-1.31)	0.16 (0.01-0.79)	0 (0-0.21)	0 (0-0.43)

BLQ, below limit of quantification; LLOQ, lower limit of quantification.

Grant RM, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. Lancet Infect Dis. 2014 Sep;14(9):820-9.

PrEP Effectiveness

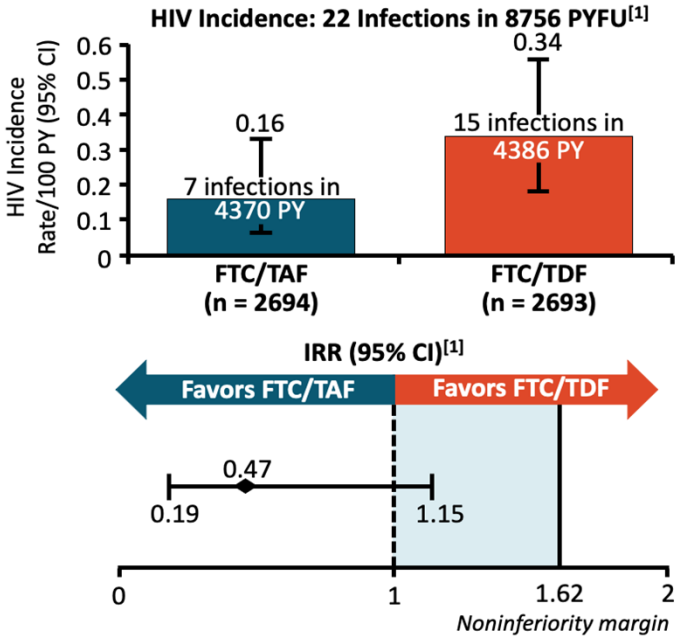
TAF vs TDF for PrEP

Large international, randomized, double-blind, active-controlled phase III study involving 5387 HBV-negative cis-MSM and TGW at high risk of HIV with eGFR ≥ 60 mL/min

HIV incidence rate ratio of 0.47 (95% CI: 0.19-1.15) favoring TAF

Demonstrated TAF non-inferior to TDF

DISCOVER: FTC/TAF Noninferior to FTC/TDF for HIV Prevention



- Primary analysis conducted when 100% completed Wk 48, 50% completed Wk 96[1]
- Noninferiority of FTC/TAF maintained:
  - In sensitivity analysis excluding 5 suspected baseline infections[1]
    - IRR: 0.55 (95% CI: 0.20-1.48)
  - Through Wk 96 analysis[2]
    - IRR: 0.54 (95% CI: 0.23-1.26)

1. Mayer. Lancet. 2020;396:239. 2. Ruane. EACS 2019. Abstr PE3/16.

Slide credit: clinicaloptions.com

Mayer KH, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. Lancet. 2020 Jul 25;396(10246):239-254.

Authoritative PrEP Guidelines

Guidelines for Appropriate Use

IAS-USA Specific Recs	Common "PrEP Drug Tx" Recommendations	CDC Specific Recs
• TAF/FTC for MSM at risk for or with renal dysfunction, osteopenia or osteoporosis • Injectable CAB IM q 8 wks (pending FDA approval) for Cis-Men, TGW who have sex with men	• TDF/FTC 1 tablet daily as PrEP for all risk categories	• TDF 1 tablet daily is rec for PWID and sexually active heterosexual men and women • Do not use any other ARVs for PrEP
IAS-USA Specific Recs	**Common "At-Risk Populations" Recs**	**CDC Specific Recs**
• MSM, MSM&W, and Transgender individuals • Individuals from or whose partners are from any location where HIV prevalence is >/= 3% • Individuals who have been or their partners have been incarcerated	• Individuals who have many sex partners • Individuals who have had a STI • Individuals who trade sex for money, goods or services • Individuals who inject drugs and share injection equipment • Individuals who inconsistently or do not use condoms	• MSM or hetero M or W with an HIV+ sex partner • Hetero M or W in high prevalence area or network.

IAS-USA Guidelines- JAMA. doi:10.1001/jama.2020.17025

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

Authoritative PrEP Guidelines

Guidelines for Appropriate Use

IAS-USA Specific Recs	Common "Prior to Tx" Recommendations	CDC Specific Recs
• HIV negative test within 7 days of starting • POC test must be Ag/Ab • Confirmatory lab test must include HIV RNA level if suspect acute HIV • May start fully suppressive ART while waiting for lab results if highly suspect HIV infection • Hep C IgG Ab (if not known to be positive, if known positive, get RNA) • Hep A IgG Ab for MSM and PWID • Genital and extragenital GC, CT, trachomatis tests by NAAT	• Need documented HIV negative test result before prescribing PrEP • Need for POC test result to be confirmed by sending blood sample to lab for confirmatory Ag/Ab test • Need assurance patient has no signs or symptoms of acute HIV infection • Need baseline Sr Creatinine to calculate renal function • Need Hep B serology and vaccination status • Need syphilis testing	• POC HIV test can be Ab only [third generation] • No contraindicated meds • Hep C Serology only for MSM and PWID • GC testing of all sexually active adults • CT testing for sexually active MSM • No CT testing in sexually active women, unless engaged in anal receptive sex

IAS-USA Guidelines- JAMA. doi:10.1001/jama.2020.17025

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

Authoritative PrEP Guidelines

Guidelines for Appropriate Use

IAS-USA Specific Recs	Common "PrEP Initiation" Recommendations	CDC Specific Recs
• Prescribe only a 30-day supply initially, and schedule first F/U appt in 30 days to repeat Ag/Ab test • If recent high-risk exposure reported within past 72 hours, start PEP x 30 days followed by transition to PrEP, getting Ag/Ab test at end of PEP to confirm HIV negative status before starting PrEP	• Prescribe at least a 30-day supply initially • Prescribe up to 90-day supply thereafter	• May prescribe up to 90-day supply initially to allow patient follow up every 3 months • May want to see patient in 30 days to confirm HIV negative status, assess side effects and adherence.

IAS-USA Guidelines- JAMA. doi:10.1001/jama.2020.17025

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

Authoritative PrEP Guidelines

Guidelines for Appropriate Use

IAS-USA Specific Recs	Common "Monitoring" Recommendations	CDC Specific Recs
• At 1-month, combined Ag/Ab HIV testing • Quarterly Ag/Ab HIV testing • At 1st quarterly visit, get Sr Cr to estimate renal function, then annually thereafter unless at risk for kidney injury [over 50 y.o., CrCl <90 before starting PrEP, has comorbidities (HTN, DM)] then Sr Cr every 3-6 months.	• Quarterly HIV testing • Quarterly pregnancy testing for women of childbearing potential • Quarterly STI testing	Quarterly tasks: • Repeat HIV testing • Assess for signs and symptoms of HIV infection, document patient is still negative • Assess for side effects, adherence, and HIV acquisition risk behaviors • Provide support for adherence and risk reduction behaviors. • Respond to questions and provide info about PrEP

IAS-USA Guidelines- JAMA. doi:10.1001/jama.2020.17025 https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

Authoritative PrEP Guidelines

Guidelines for Appropriate Use

IAS-USA Specific Recs	Common "Monitoring" Recommendations	CDC Specific Recs
• Hep C IgG Ab annually [every 3-6 months in PWID and MSM who use drug while engaging in sex] • Quarterly genital and non-genital GC, CT, NAAT testing and syphilis testing [may adjust based on individual risk status] • During COVID, may use home-based tests for STIs and HIV, if travel to clinic not possible. • May extend PrEP tx to 6 months if in person and remote lab assessments not available.	Monitoring Guidelines, courtesy Dr. Brian Wood, MWAETC *D. Lab Monitoring* • Every 3 month HIV test • Every 3-6 month STI screening, more frequent per risk • Renal function at 3 months, then every 3-6 months	• STI testing for symptomatic patients • STI testing for MSM who are asymptomatic and have a hx of STIs or multiple sex partners Every 6 months: • Check Sr Cr to assess renal function [unless clinical status warrants more frequent monitoring] • STI testing for all sexually active adolescents and adults even if asymptomatic. [syphilis and GC for men and women, plus CT for MSM]

IAS-USA Guidelines- JAMA. doi:10.1001/jama.2020.17025

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

Authoritative PrEP Guidelines

Guidelines for Appropriate Use

IAS-USA Specific Recs	"Time to Achieve Protection"-Common Recs	CDC Specific Recs
• For MSM, 2 tablets of TDF/FTC reduce time to maximal protection to 24 hours. [must continue for 2 days after last at-risk exposure] • For others, maximum protection is likely achieved in 7 days after initiation of daily TDF/FTC. [Must continue for 7 days after last at-risk exposure]	• No recommendations in common Additional IAS-USA Guidance: • 2-1-1 dosing only for MSM and only using TDF/FTC [not TAF/FTC] • Substantial non-adherence = • Fewer than 4 of 7 doses per week in MSM & TGW • Fewer than 6 of 7 doses per week in Cis-gender women, PWID, and hetero men. • TDF/FTC is recommended for at-risk individuals who are pregnant or breastfeeding.	• Technically "unknown" • No consensus on what intracellular conc of TFV-DP is protective. • PK studies suggest max intracellular conc of TFV-DP is achieved in: • 20 days in blood • 20 days in cervicovaginal tissue • 7 days in rectal tissue

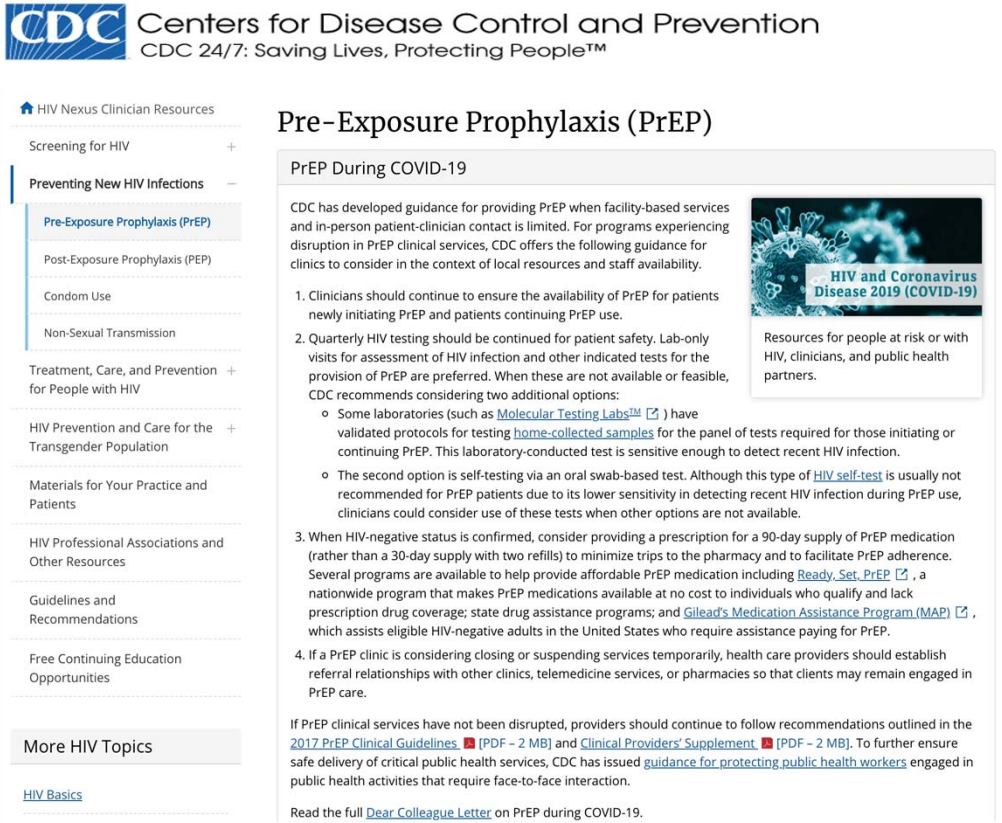
IAS-USA Guidelines- JAMA. doi:10.1001/jama.2020.17025

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

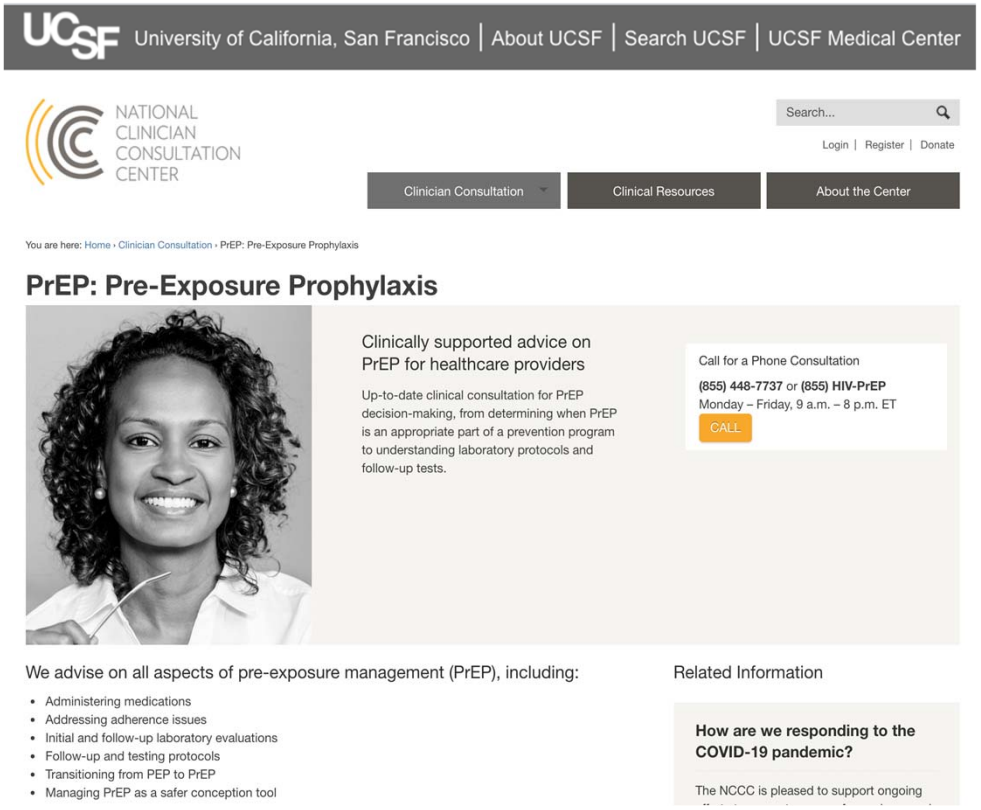
Clinician Resources

Where to turn for “Expert Guidance”

https://www.cdc.gov/hiv/clinicians/prevention/prep.html



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



PrEP Research

Future PrEP Options

CAB LA 600 mg IM Q2M[†] +
PBO PO QD for ≈3 years

FTC/TDF PO QD +
PBO IM Q2M[†‡] for ≈3 years

HIV-uninfected MSM and TGW aged ≥ 18 years at high risk of HIV infection*; no HBV/HCV infection, contraindication to gluteal injection, seizures, or gluteal tattoos/skin conditions (N = 4566)

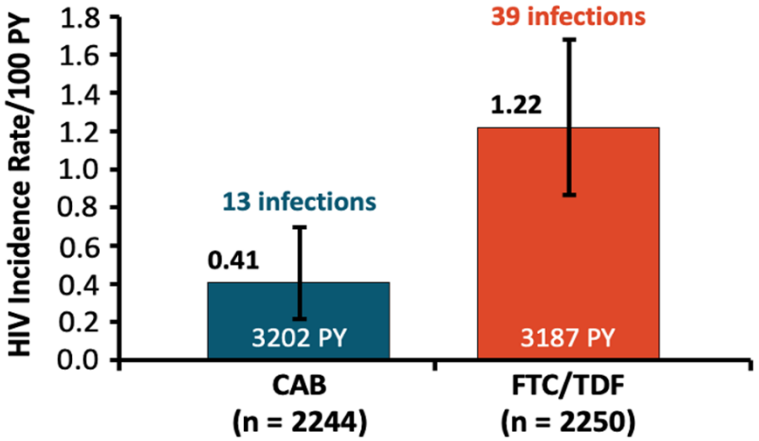
At Interim analysis on May 14, 2020, with 25% of endpoints accrued, DSMB recommended termination of blinded study due to crossing of prespecified O'Brien-Fleming stopping bound.

HPTN 083: Efficacy and Safety of LA Injectable CAB vs Daily Oral FTC/TDF for PrEP in MSM and TGW

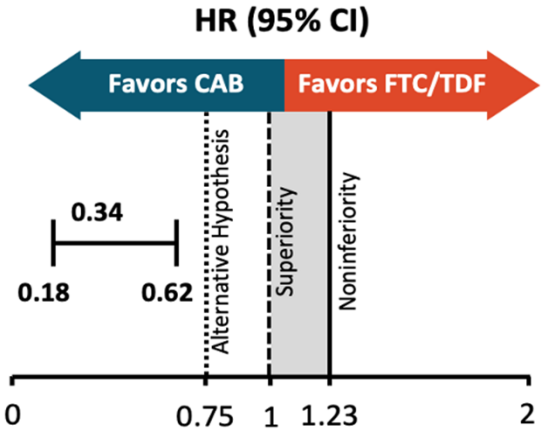
- International, randomized, double-blind phase IIb/III study

(95% CI: 0.61-1.07)

– 52 HIV infections in 6389 PYFU



(HR: 0.75) and demonstrated statistically significant superiority vs FTC/TDF



Median follow-up per participant: 1.4 years (IQR: 0.8-1.9).

DSMB recommended that study be unblinded early due to CAB superiority

Landovitz. AIDS 2020. Abstr OAXLB0101.

Slide credit: clinicaloptions.com

PrEP Research

Future PrEP Options

CAB LA 600 mg IM Q8W*
+ PBO QD

PBO IM Q8W*
+ TDF/FTC QD

Characteristic	CAB (n = 1614)	TDF/FTC (n = 1610)	Pooled (n = 3224)
HIV infections, n	4	36	40
Person-yrs	1953	1939	3892
HIV incidence per 100 person-yrs (95% CI)	0.2 (0.06-0.52)	1.86 (1.30-2.57)	1.03 (0.73-1.4)

- 89% lower risk of HIV infection for women in CAB group vs TDF/FTC group (*P* = .000027)
- 4 incident HIV infections in CAB arm
  - 2 observed despite CAB injections
  - 2 observed in the absence of CAB exposure

Delany-Moretlwe. HIVR4P 2021. Abstr HY01-02.

Slide credit: clinicaloptions.com

HPTN 084 enrolled 3,224 women 18 to 45 years old in sub-Saharan Africa who were at risk for acquiring HIV.

"ViiV Healthcare announces investigational injectable cabotegravir is superior to oral standard of care for HIV prevention in women."

London, 9 November 2020 – ViiV Healthcare, the global specialist HIV company majority owned by GlaxoSmithKline plc ("GSK"), with Pfizer Inc. and Shionogi Limited as shareholders, today announced that an independent data safety monitoring board (DSMB) recommended the early unblinding of the HIV Prevention Trials Network (HPTN) 084 study evaluating the safety and efficacy of investigational, long-acting, injectable cabotegravir for HIV prevention in women. Following a pre-specified interim analysis, the DSMB indicated that cabotegravir met the primary objective of demonstrating superiority when compared to the current standard of care for women, daily oral emtricitabine/tenofovir disoproxil fumarate 200 mg and 300 mg (FTC/TDF) tablets. The study showed cabotegravir was 89% more effective than daily oral FTC/TDF for pre-exposure prophylaxis (PrEP).

https://viivhealthcare.com/en-us/us-news/us-articles/2020/viiv-healthcare-announces-investigational-injectable-cabotegravir-is-superior-to-oral-standard-of-care-for-hiv-prevention-in-women/

Which of the following recommendations about the initiation of PrEP is accurate?

A. When starting PrEP, a 120-day supply of medication is recommended.
B. If the risk for HIV acquisition is through vaginal sex, tenofovir alafenamide-emtricitabine is indicated to prevent HIV acquisition.
C. If the risk for HIV acquisition is through vaginal sex, it may take approximately 7 days for tenofovir-emtricitabine to reach maximum protection levels in cervicovaginal tissues
D. Current guidelines recommend against the use of PrEP in at-risk individuals who are pregnant or breastfeeding.

Post-Test:

Best online HIV continuing education websites:

Clinical Care Options-HIV
https://www.clinicaloptions.com/hiv?q&sortBy&sortOrder=asc&page=1

International Antiretroviral Society-USA
https://www.iasusa.org/

PracticePoint CME
https://www.practicepointcme.com/CMEHome/PID/1337/SearchID/1338/cfs/True/cblcid_31_11/11/cblcid_32_20/20

National HIV Curriculum
https://www.hiv.uw.edu/

Mountain West AETC and AIDS Clinical Conferences
https://mwaetc.org/

Who to consider for PrEP

- Individuals with **“substantial risk”** for HIV

- Examples:
  - Man or woman in relationship with an HIV-positive partner (not reliably virally suppressed)
  - Gay or bisexual man not in a mutually monogamous relationship & not using condoms 100%
  - Man or woman with recent STI or frequent testing of STIs
  - Man or woman sexually active with high-risk individuals
  - Man or woman who uses injection drugs
  - Those engaging in transactional sex

Slide Courtesy of Brian Wood, MD University of Washington HIV ECHO Panelist

PrEP Guidelines:

A. Determine Eligibility

- Substantial ongoing risk for HIV
- Able to take a pill every day and return every 3 months
- Screen for HIV and consider need for HIV RNA (viral load) if sx of acute HIV (flu/mono/COVID like Sx/new rash)
- Check hepatitis B virus panel and renal function, other STIs as indicated.
- Not a requirement to hold PrEP until labs come back, just have plan for patient follow-up if labs return abnormal.

B. Prescribe PrEP

- TDF-FTC or TAF-FTC 1 tab PO daily
- No more than 90 days at a time
- Emphasize importance of adherence

Slide Courtesy of Brian Wood

PrEP Guidelines:

C. Continue Counseling

- Continue risk-reduction counseling and other preventive measures (condoms, clean needles, etc)
- Remember PrEP is not a stand-alone strategy
- Rescreen for HIV if needed

D. Lab Monitoring

- Every 3 month HIV test
- Every 3-6 month STI screening, more frequent per risk
- Renal function at 3 months, then every 3-6 months

Slide Courtesy of Brian Wood

Summary of Recommended Laboratory Evaluation
Baseline and Routine Monitoring for Patients taking PrEP

Recommended Laboratory Testing and Frequency for Patients Taking PrEP				
Laboratory test	**Baseline**	**At least every 3 months**	**At least every 6 months**	**Notes**
HIV screening assay	✓	✓		Consider need for HIV RNA PCR
HBV (panel#) and HCV antibody	✓			Offer HBV vaccination if not immune
Serum creatinine	✓		✓	^CrCl decrease may require stopping PrEP
STI testing	✓	✓	✓	Include oral/rectal screen for MSM if risk
Pregnancy test for women*	✓	✓		Safety of PrEP in pregnancy not known

Abbreviations: eCrCl = estimated creatinine clearance; STI = sexually transmitted infections

#Includes HBsAg, anti-HBc, and anti-HBs

^Do not start tenofovir DF-emtricitabine if CrCl <60 mL/min; do not start tenofovir alafenamide-emtricitabine if CrCl <30 mL/min

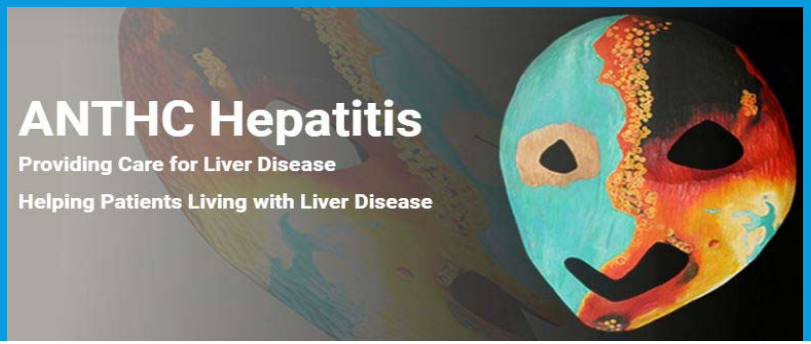
*For women who may become pregnant

Source: US Public Health Service. Clinical practice guidelines for PrEP. May 2014.

National HIV Curriculum

ADDITIONAL LEARNING OPPORTUNITIES

- ANTHC Liver Disease ECHO: Kickoff February 18th!
  - The 3rd Thursday of every month from 12:00-1:00PM Alaska Standard Time
    - 1CE/CME offered per session
  - anthc.org/hep
- ANTHC LiverConnect
  - Second Tuesday of every month 8:00-9:00AM Alaska Standard Time
    - Didactic topics on liver related disease with 1CE/CME offered
  - anthc.org/what-we-do/clinical-and-research-services/hep/liverconnect/



ID ECHO: HCV-HIV-STI-PREP TEAM CONTACTS

- Leah Besh PA-C Program Director
  - labesh@anthc.org
- Jeni Williamson Program Coordinator
  - jjwilliamson@anthc.org
  - **Please email Jeni if you would like to be added to the ECHO list serve**
- Lisa Rea RN Case Manager
  - ldrea@anthc.org
- ANTHC Liver Disease and Hepatitis Program: 907-729-1560
- ANTHC Early Intervention Services/HIV Program: 907-729-2907
- Northwest Portland Area Indian Health Board
  - David Stephens: Director Indian Country ECHO dstephens@npaihb.org
  - Jessica Leston: Clinical Programs Director jleston@npaihb.org

ALASKA NATIVE
TRIBAL HEALTH
CONSORTIUM