ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Session 3:
Ending the Syndemic: STI/HIV, presented by Leah Besh, PA-C
Hepatitis C Screening, Treatment and Elimination, presented by Hope McGratty, PA-C, MPH, AAHIVS

These presentations were part of the one-day Fairbanks Syndemic Clinical Training: Addressing the Syndemic of Substance Use Disorders and Related Disease States held on April 9 and April 10, 2025.

AETC AIDS Education & Training Center Program Mountain West

Ending the Syndemic: STI/HIV

Fairbanks, AK - April 9-10, 2025

Leah Besh, PA-C, AAHIVS
Early Intervention Services/HIV Program
Alaska Native Tribal Health Consortium
labesh@anthc.org
(907) 729-2907

I have no conflicts of interest to disclose

MWAETC

Acknowledgement

This Mountain West AIDS Education and Training (MWAETC) program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $3,098,654 with 0% financed with non-governmental sources.

The content of this presentation are those of the author(s) and do not necessarily represent the official views, nor an endorsement, by HRSA, HHS, or the U.S. Government.

MWAETC

What is Sexual Health?

". . . state of physical, emotional, mental and social well-being in relation to sexuality. It is not merely the absence of disease, dysfunction, or infirmity"

World Health Organization. Gender and human rights.

http://www.who.int/reproductivehealth/topics/gender_rights/sexual_health/en/index.html

MWAETC

Objectives

- Understand the Epidemiology of HIV and STIs and how it affects your community (EPI slides have been removed from the PDF.)
- Increase your knowledge and comfort with comprehensive STI screening
- Increase your knowledge and prescribing of PEP and PrEP
- Understand how you can play a part in HIV elimination
- Understand where there are disparities and gaps in care related to HIV/STI prevention

MWAETC

Four Pillars of Ending the HIV Epidemic in the U.S. (EHE)

75% reduction in new HIV diagnoses in 5 years and a **90%** reduction in 10 years.

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 using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

Respond

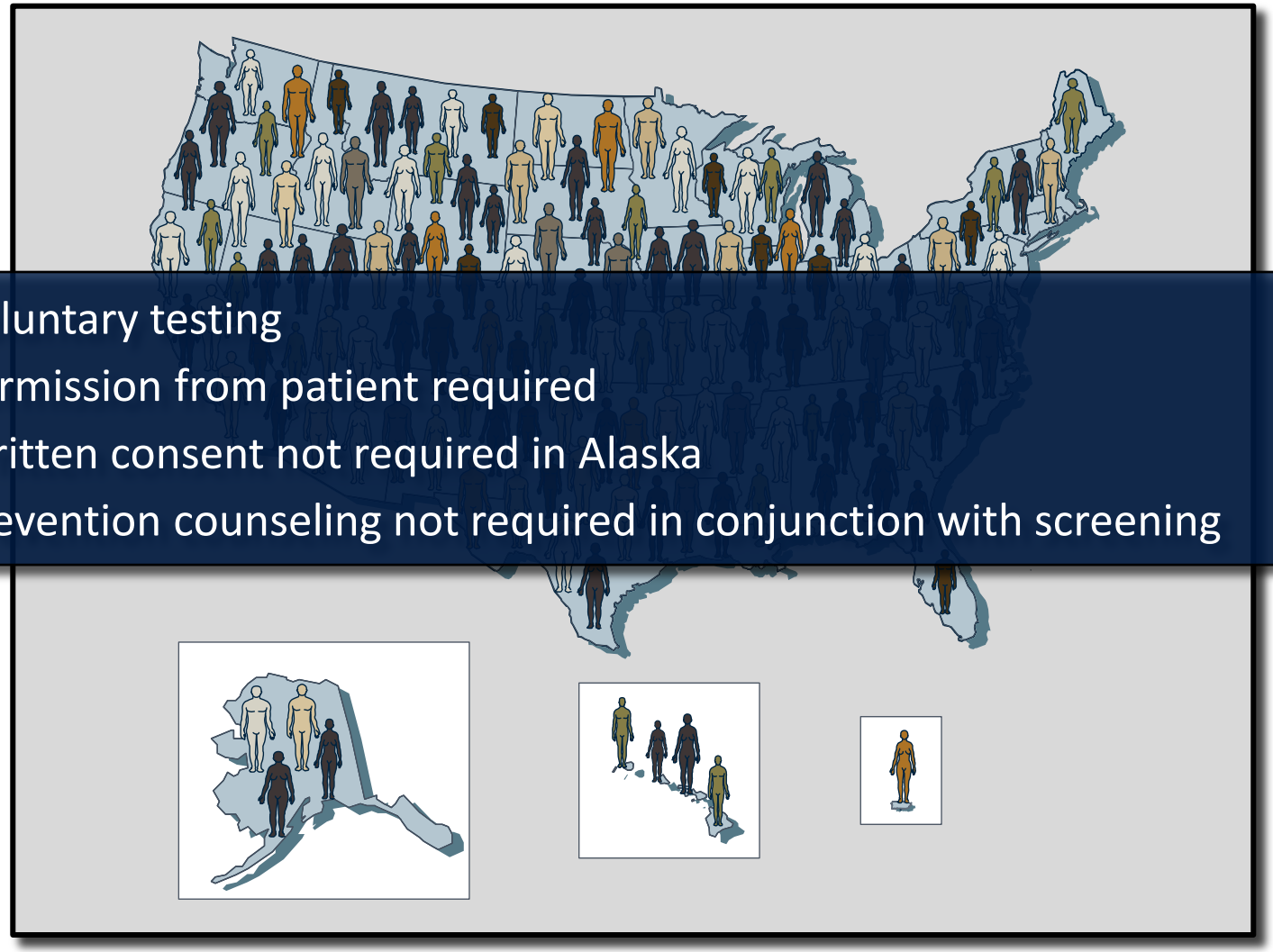
Quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

MWAETC

HIV/STI Screening and Lab Interpretation

Routine Screening for HIV Infection

CDC and USPSTF Grade A recommendation



- Voluntary testing
- Permission from patient required
- Written consent not required in Alaska
- Prevention counseling not required in conjunction with screening

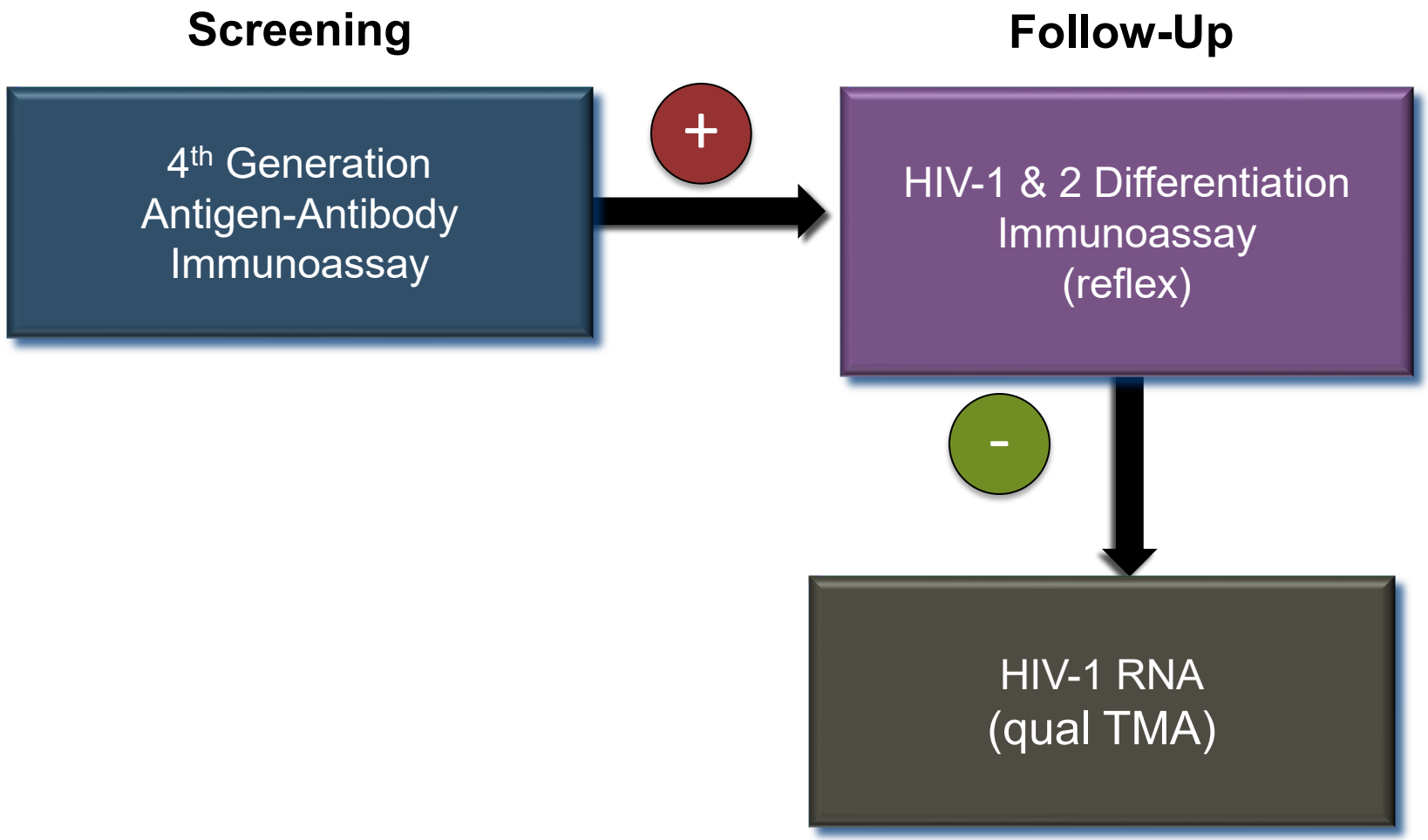
Universal screening:

- At least once in your life
- More frequency per risk
- With each pregnancy

Source: CDC. MMWR 2006;55(no. RR-14):1-17. CDC HIV SCREENING RECOMMENDATIONS

MWAETC

Approach to HIV Screening and Diagnostic Testing



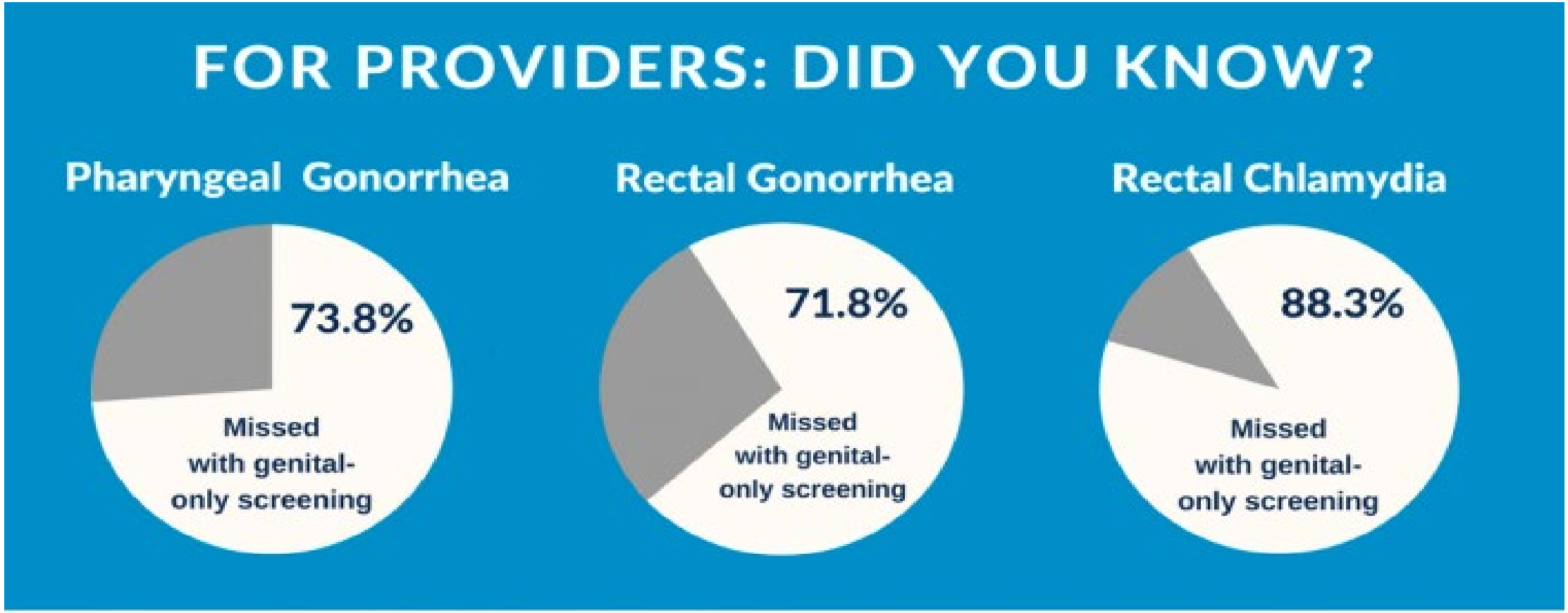
Slides courtesy of David Spach, NWAETC

MWAETC

STI/HIV Complete Screen

Test	Exceptions
HIV Ag/Ab screening	-Add HIV PCR if concerned for acute HIV infection -All positive rapid Ab only HIV testing need confirmatory testing
Syphilis screen	-Start with RPR if Hx of syphilis infection
Chlamydia/Gonorrhea	-Offer testing at all sites people use for sex-ASK, offer all sites anyway -We rarely use urethral swabs, urine is just fine (and clients more likely to return for testing!)
Trichomonas	-Offer with all vaginal aptima swabs -No specific guidelines for non-vaginal testing
Hepatitis C Antibody	-If positive it means patient has been exposed, may not have active infection-confirmation needed -If known Hx of HCV, Screen via HCV PCR (viral load)
Hepatitis B Screening with: HBV surface Antigen, HBV core Antibody, HBV surface antibody	-If there is documentation of full vaccine series, screen may not be indicated unless immunocompromised. -If no infection and not immune-VACCINATE
Hepatitis A total Antibody	Screening recommended for MSM, IDU populations. -I would recommend if there is no documented Hx of HAV vaccination series, and HAV total Ab negative-VACCINATE (if pos they are immune from prior vaccine or prior infection)

Checking Urine Alone Insufficient in MSM



STD Surveillance Network, July 2010- June 2012 ,
STD clinic data for 11 SSuN jurisdictions. Patton, et al. Clin Infect Dis. March 2014.

NASTAD

National Coalition of STD Directors

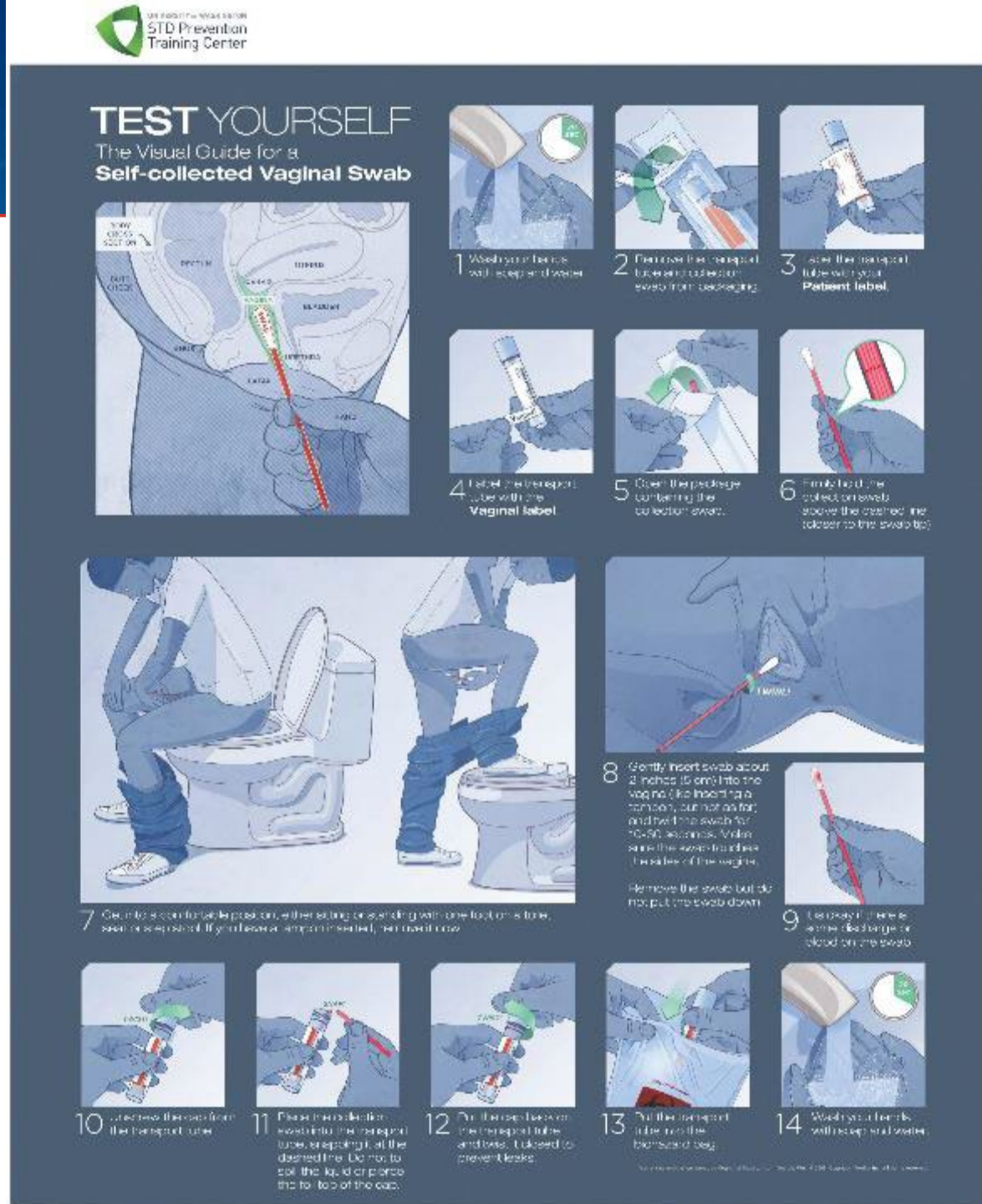
MWAETC

Vaginal Swab Tips and Tricks

- Insert about 2 inches just like a tampon, swirl for 10-30 seconds or whatever they want.
- If giving patients the collection tube, remind them not to poke through the foil top or spill the fluid, consider giving just the wrapper.
- Does not matter if they are on their period or bleeding.

Posters available, email AlaskaKit@anthc.org

https://www.uwptc.org/self-testing-guides-downloads

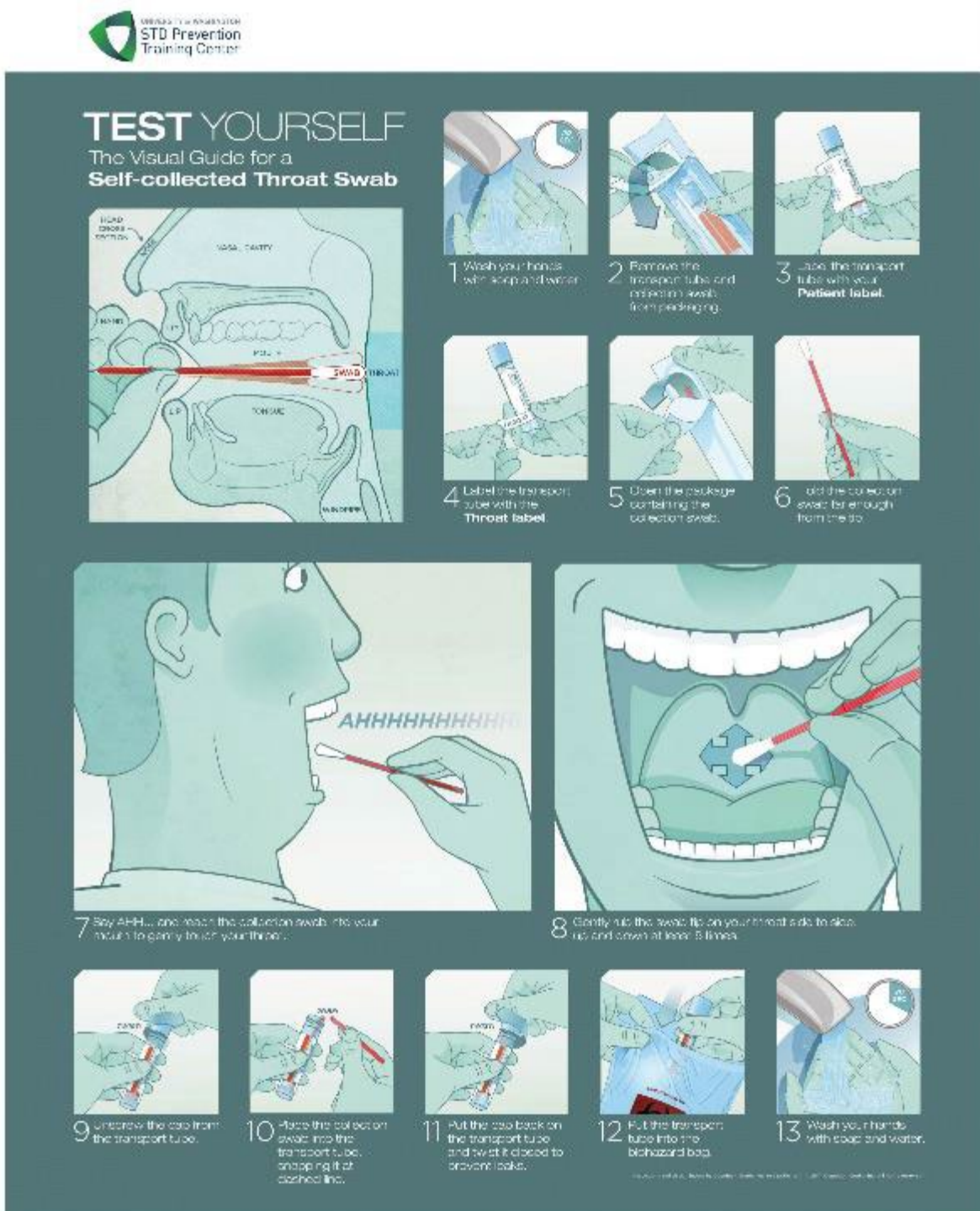


Pharygeal Swab Tips and Tricks

- It's just like a strep swab, no need for stigma!
- The one swab patients often prefer the care team to do due to gag reflex.

Posters available, email AlaskaKit@anthc.org

https://www.uwptc.org/self-testing-guides-downloads



Rectal Swab Tips and Tricks:

- Ask patients to separate their buttocks, spreading out the anal opening allows for less friction while inserting probe
- Can dampen with water, but no lube even if water-based, please.
- You really only need to go in one inch, and swirl 5 times. You do not need to reach the transition zone as in an anal PAP

Posters available, email AlaskaKit@anthc.org

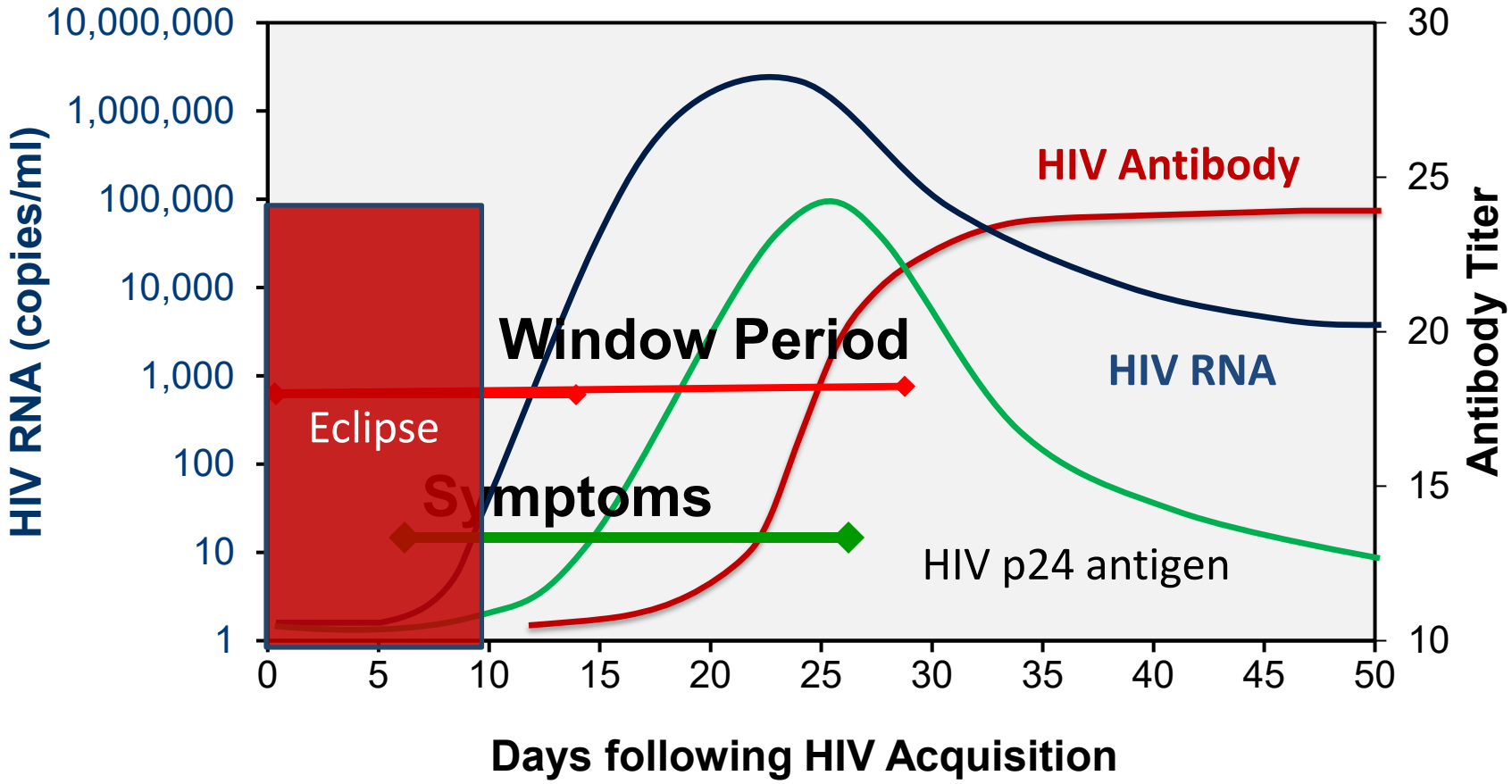
https://www.uwptc.org/self-testing-guides-downloads

HIV Self-Test Kit

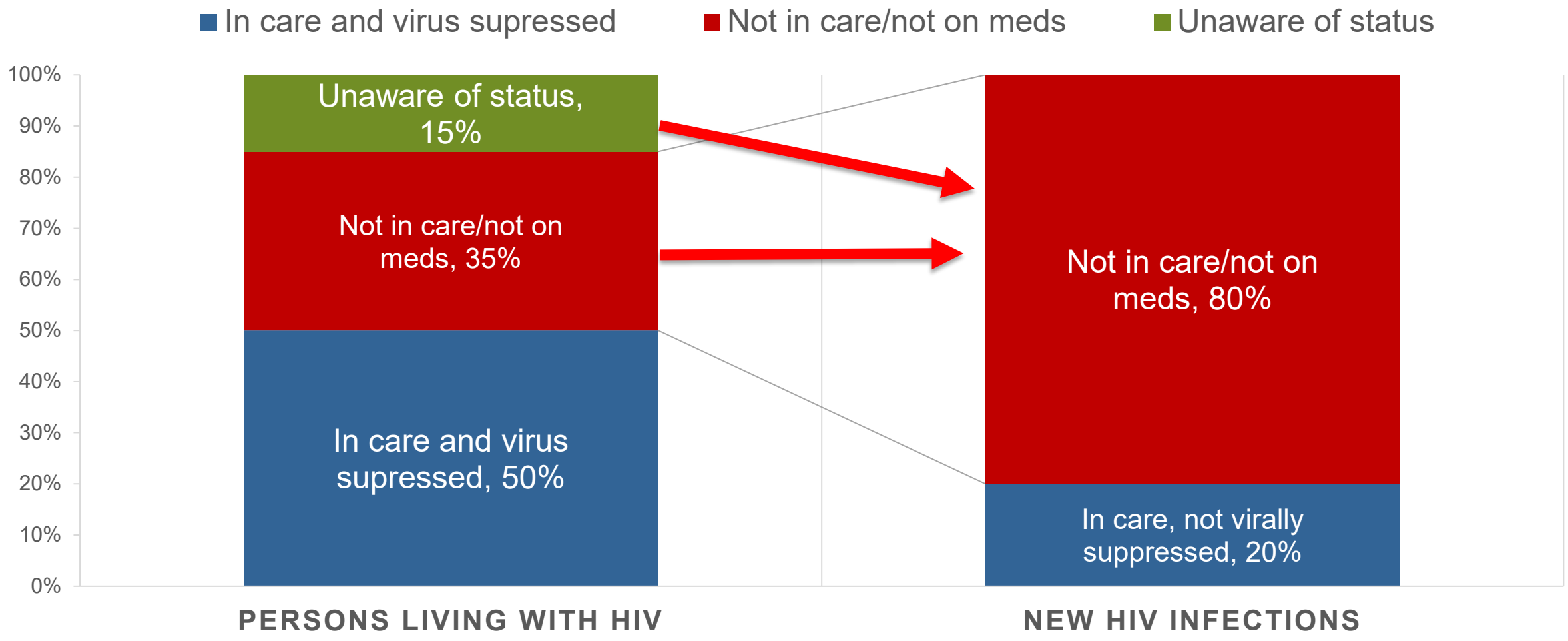
- Mailed to individuals
- OraQuick 24/7 support center available via telephone
- AK-based RN available during business hours

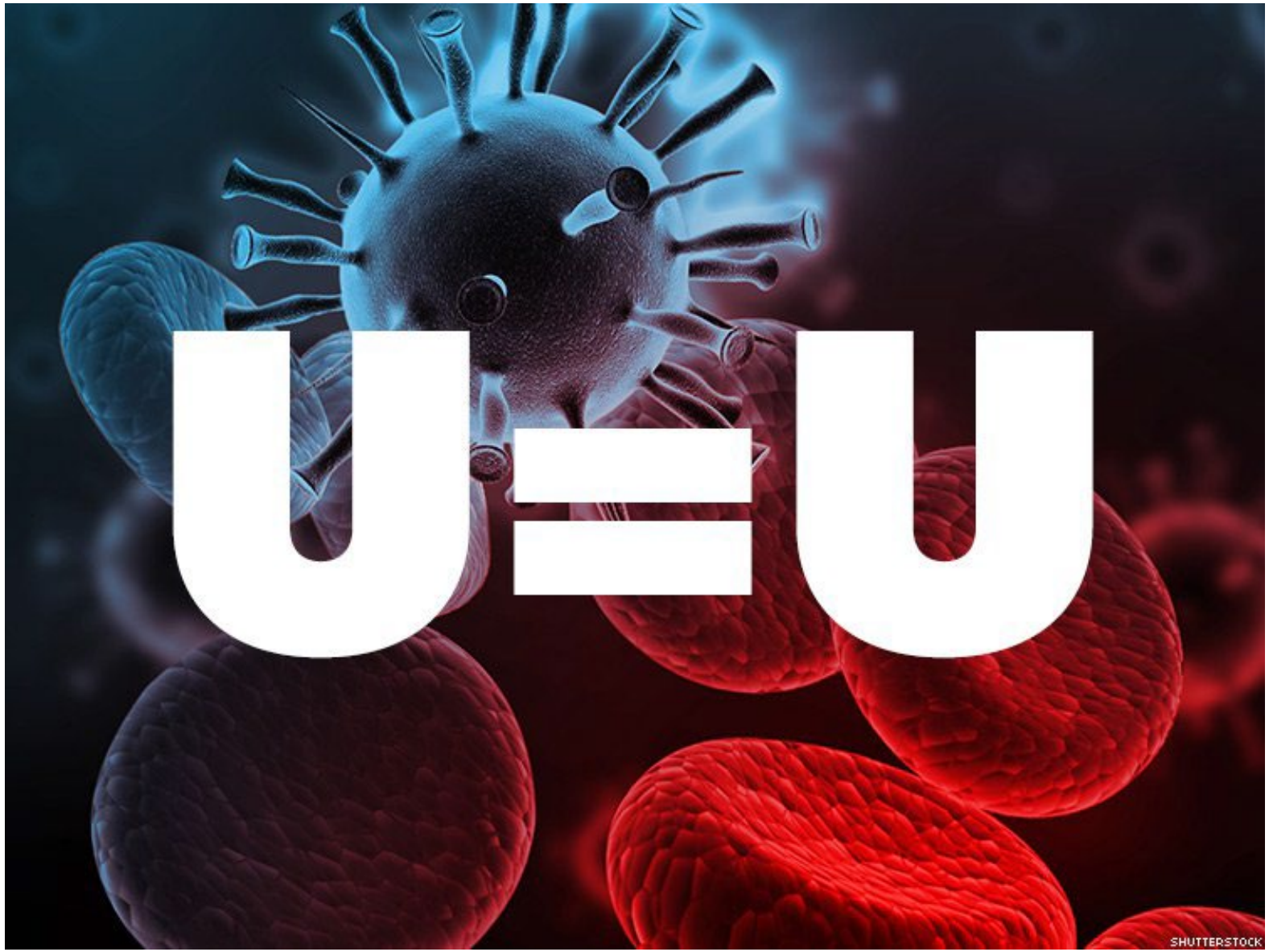
iknowmine.org/shop

Laboratory Diagnosis of Early HIV Infection



PLWHIV not in care transmit most of new infections

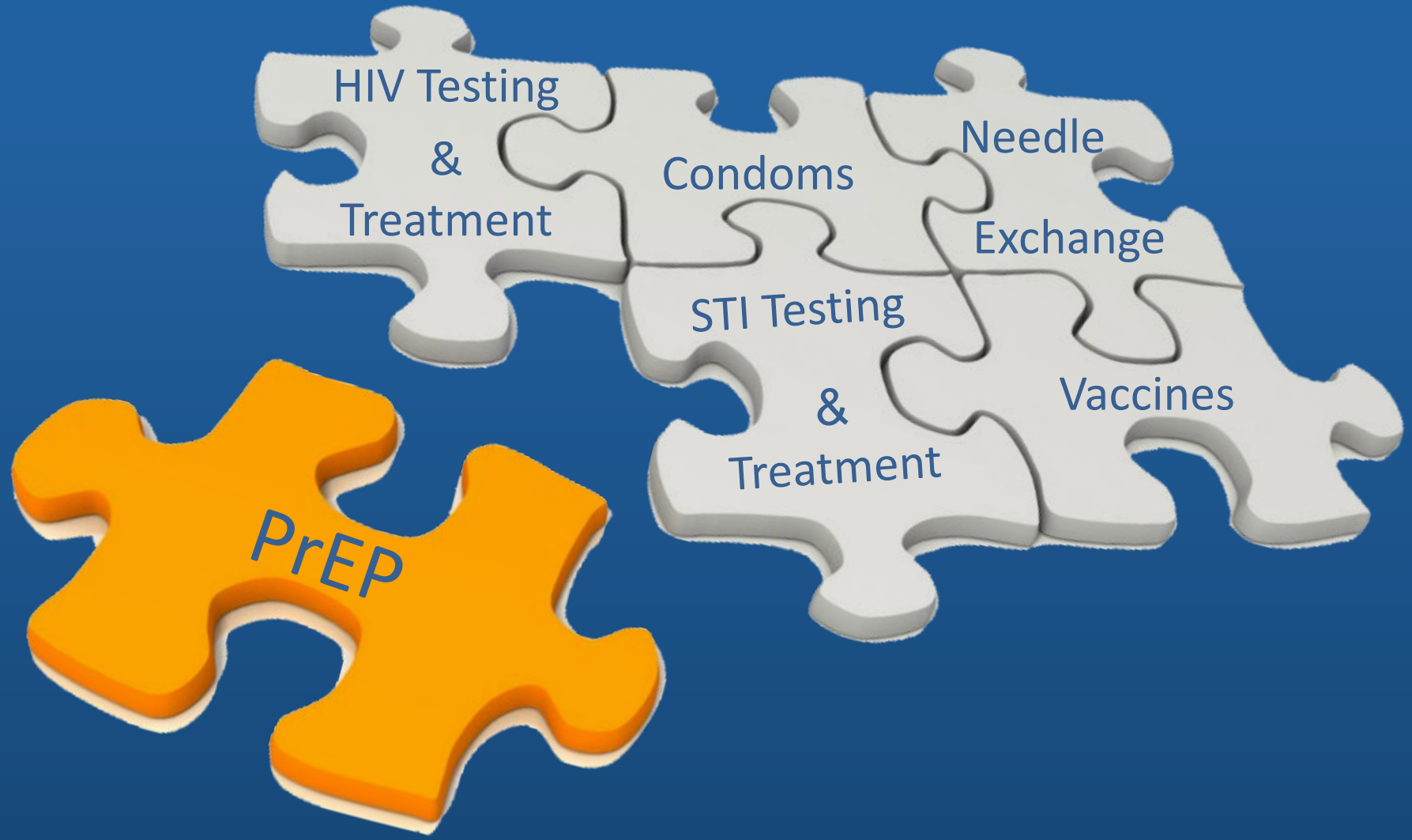



U=U
SHUTTERSTOCK

HIV Prevention
PEP/PrEP

MWAETC

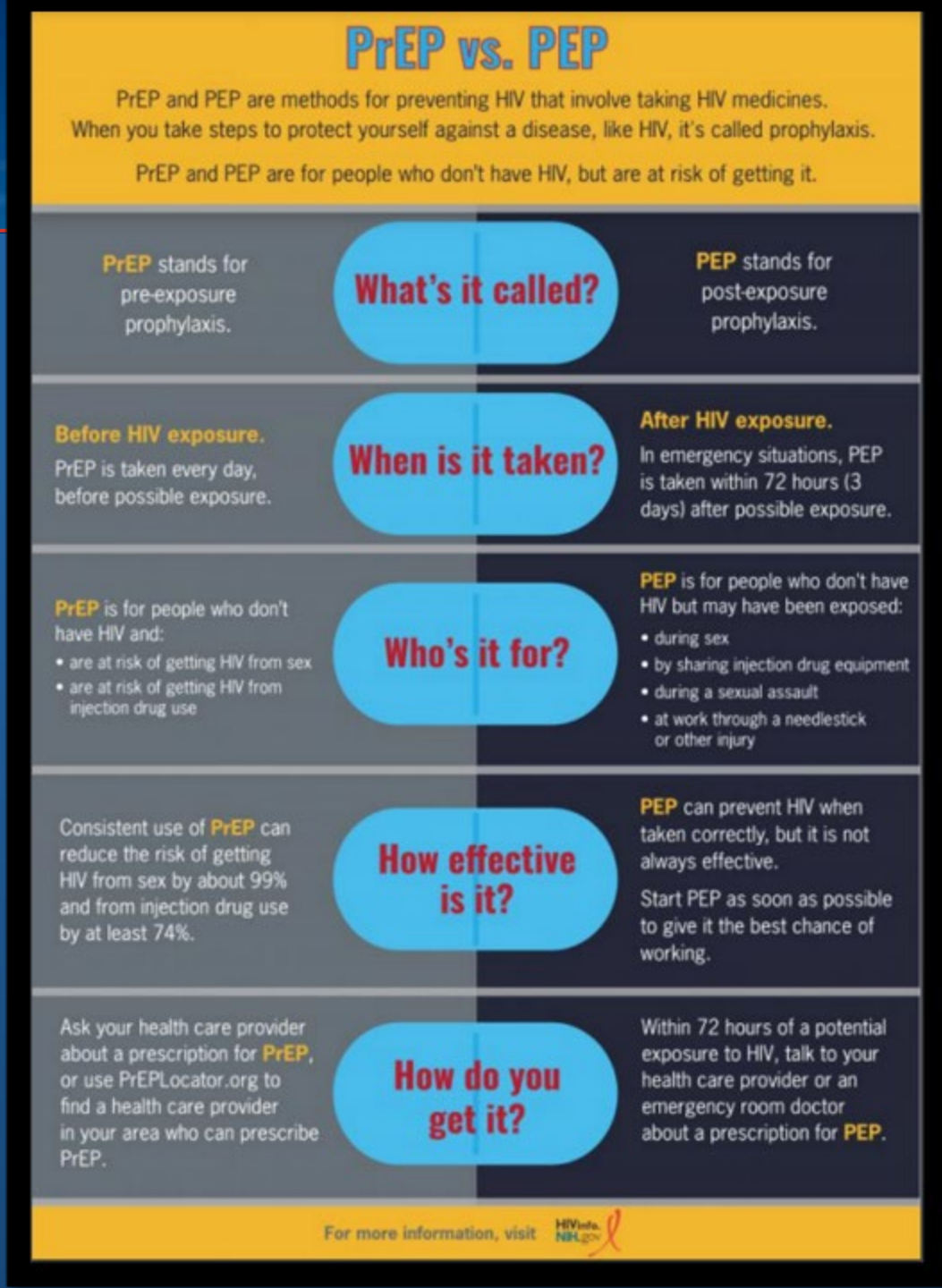
PrEP is One Piece of the HIV Prevention Puzzle



Nonoccupational or Occupational Post-Exposure Prophylaxis is a tool we can use to help prevent HIV infections.

- The three drug antiviral regimen helps by blocking the HIV virus entry into cells, and therefore blocks infection.
- PEP first used in 1990s for healthcare workers
- nPEP guidelines first published by the CDC in 2005, updated in 2016

https://hivinfo.nih.gov/understanding-hiv/infographics/prep-vs-pep



nPEP Considerations

- What is your patient's HIV status?
- Do you know the source patient's HIV status?
  - If they do have HIV, do we know their HIV antiviral history?
- What exposure occurred?
- When did the exposure occur, or when did it last occur?

MWAETC

What is your patient's HIV status

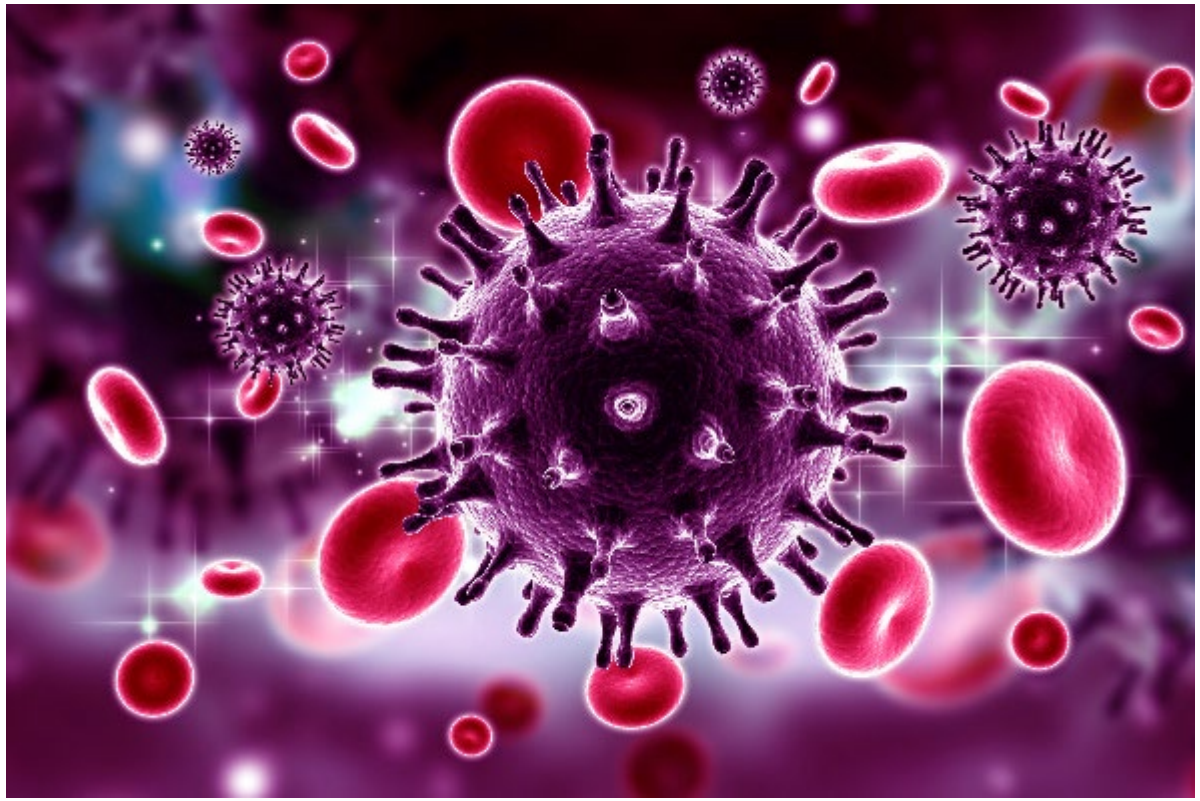
A HIV screen (Antigen/Antibody) screen should be obtained at baseline

- If Screen is positive:
  - Connect patient to services for ongoing HIV management and rapid antiviral therapy start
  - A 28 day of PEP is not useful
- If Screen is negative:
  - Continue to assess PEP indication
  - Are they taking PrEP? If Yes, PEP may not be indicated

MWAETC

Do you know the source patient's HIV Status

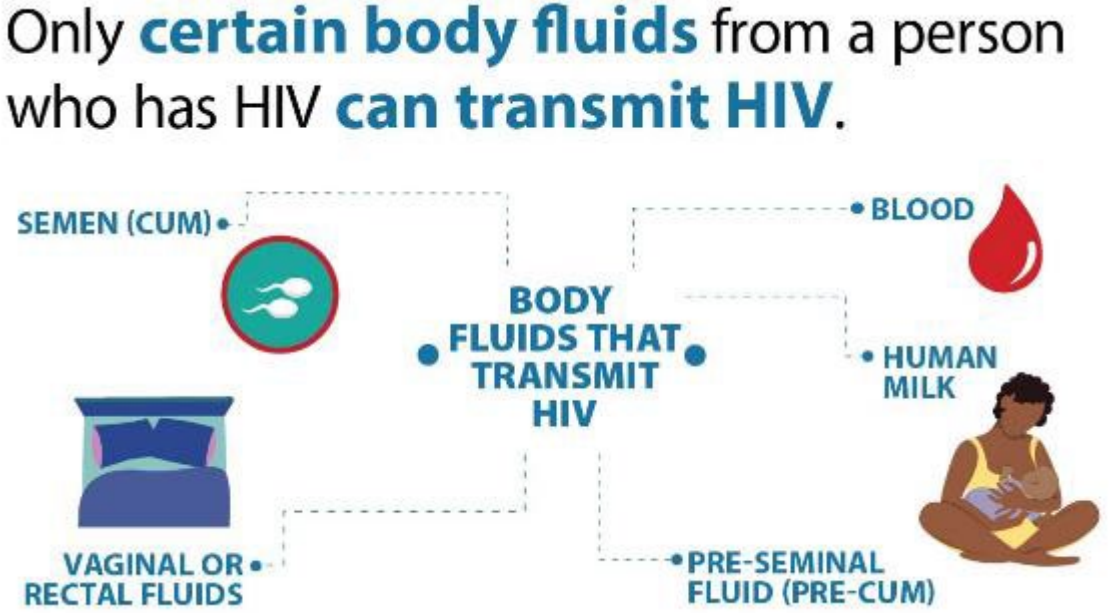
- Often in cases of sexual assault the source patient status will be unknown
- If HIV status positive
  - Are they undetected
  - U=U (undetectable = untransmissible)



MWAETC

What was the exposure

Nonoccupational HIV PEP should only be used in the setting of “substantial risk for HIV acquisition,” defined as contact involving an area of the body known to be associated with HIV acquisition (vagina, rectum, eye, mouth, or other mucous membranes, nonintact skin, or percutaneous needlestick injuries) with an infectious body fluid (e.g., blood, semen, vaginal secretions, rectal secretions, breast milk, or any other body fluid visibly contaminated with blood).



MWAETC

Risk

Table 1.
Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*

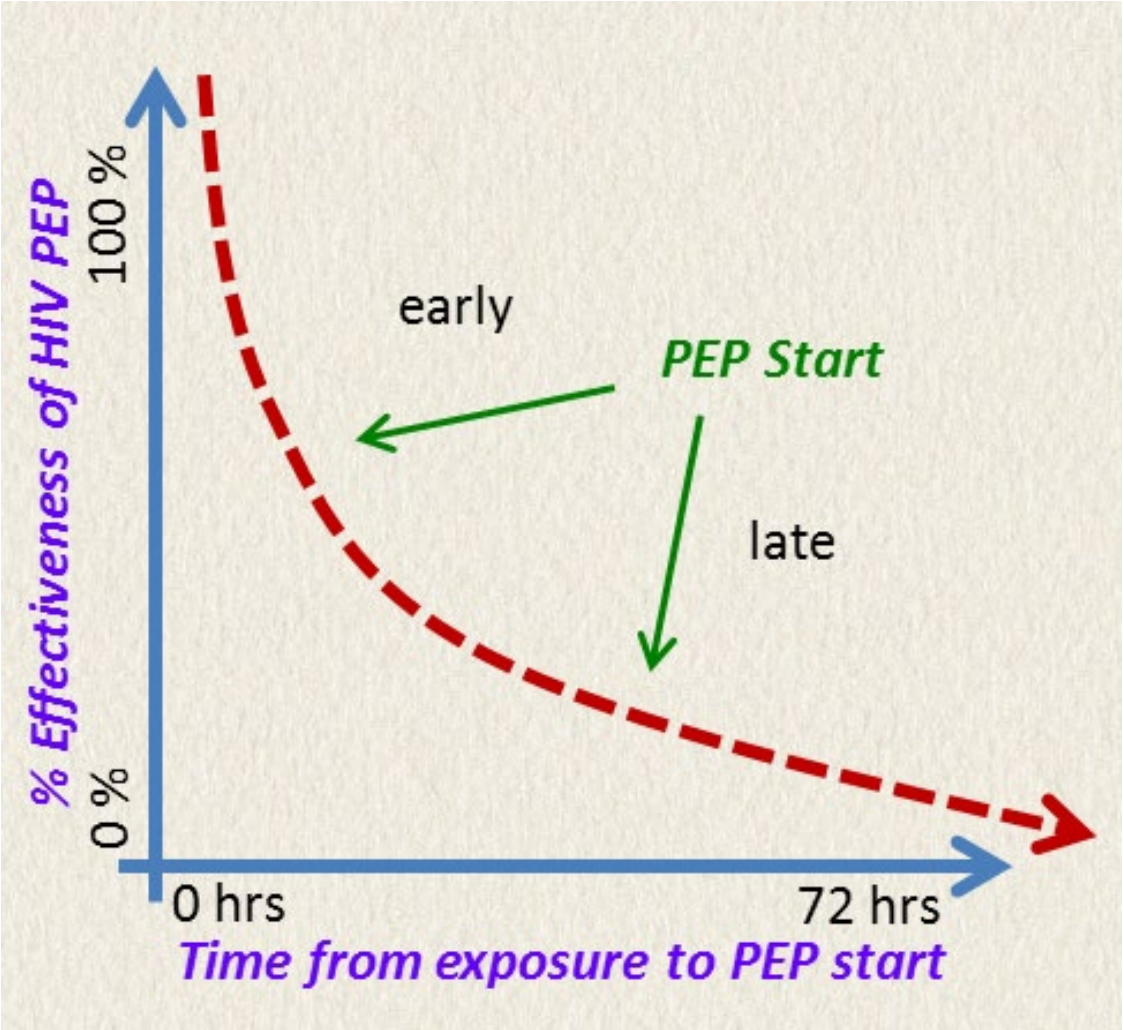
Exposure Type	Rate for HIV Acquisition per 10,000 Exposures
Parenteral	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
Sexual	
Receptive anal intercourse	138
Insertive anal intercourse	11
Receptive penile-vaginal intercourse	8
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
Other^	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible

Centers for Disease Control and Prevention: U.S. Department of Health and Human Services. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, and Other Nonoccupational Exposure to HIV—United States, 2016.

MWAETC

When did it occur

- Multiple studies have demonstrated PEP is only beneficial if started within 72 hrs
  - If multiple exposures, can initiate within 72 hrs after last exposure

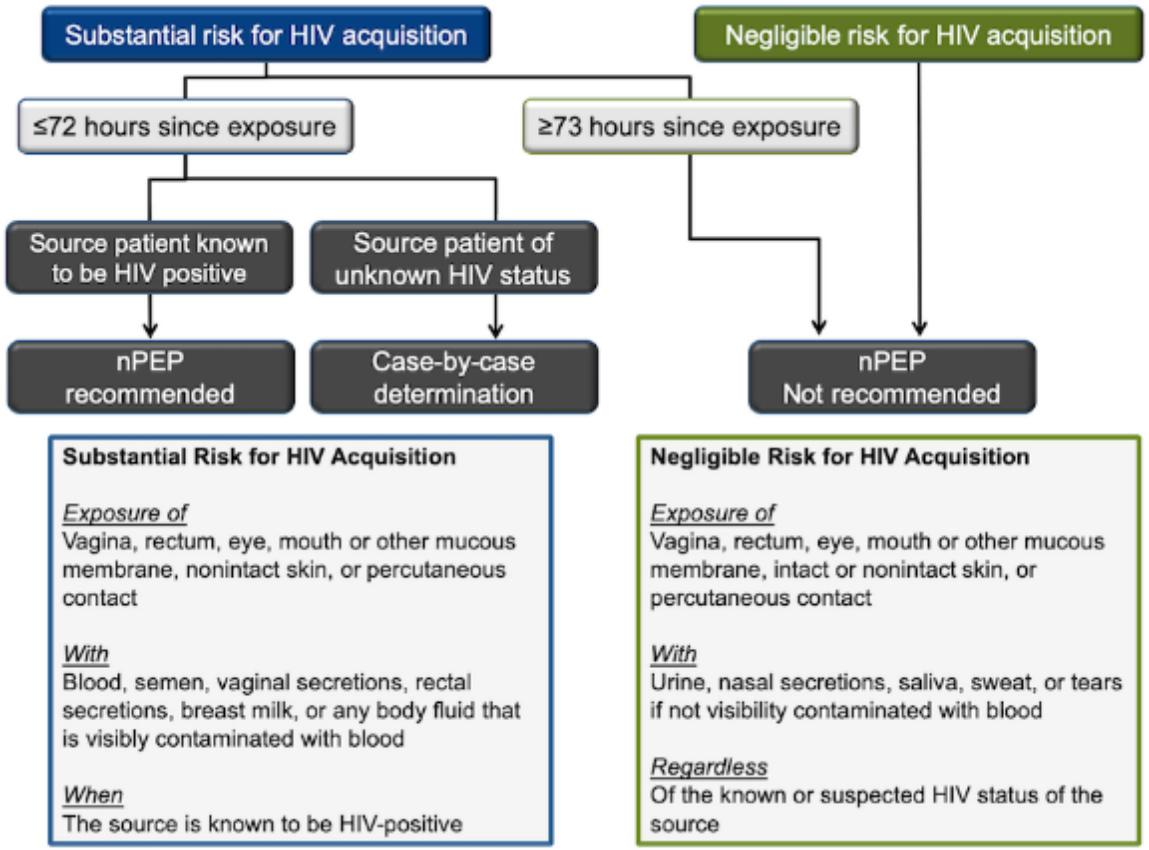


https://calgaryzonehivpep.wordpress.com/community-doctors/start-page/disclaimer/cpepse-qs/no-cpepse-02/

MWAETC

What is nPEP:
nonoccupational Post Exposure Prophylaxis

- TDF/FTC 200/300mg 1qd (Truvada) **plus** Raltegravir 400mg BID or Dolutegravir 50mg 1qd x 28 days
  - Once a day dosing preferred
  - Prescribe all 28 days initially
- *BIC/TAF/FTC (Biktarvy) 1qd x 28 days*
  - *IAS-USA guideline (not yet in CDC guideline)*
- Determine if PEP is necessary
- Start within 72 hours of exposure
- Determine if client should transition from PEP→PrEP
- Ensure follow-up labs occur

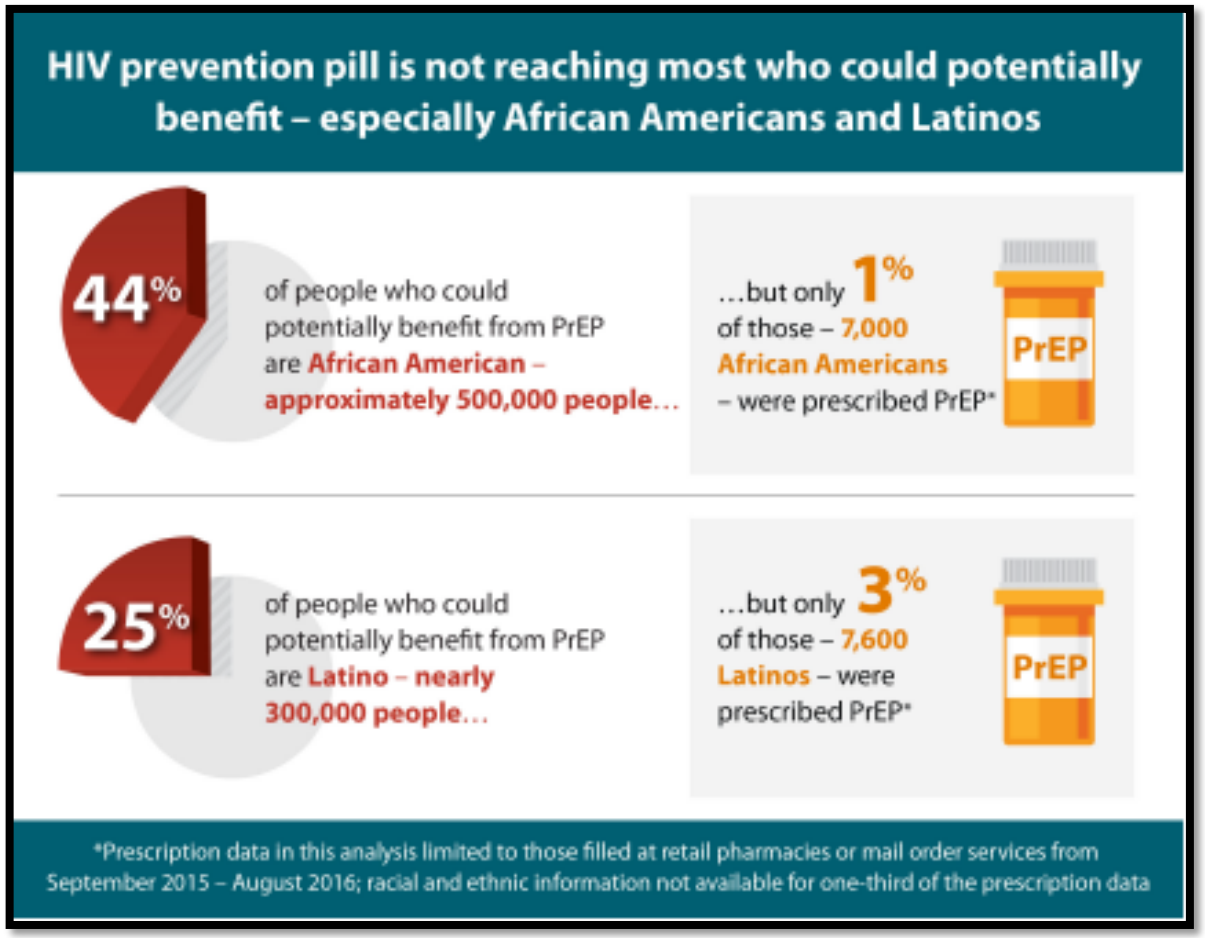


www.hiv.uw.edu/go/prevention/nonoccupational-postexposure-prophylaxis/core-concept/all

MWAETC

What is PrEP?

- A prevention strategy in which an individual takes a medication **regularly** (along with continued behavioral **risk-reduction** strategies) to prevent HIV infection
- Medication first became available in 2012
- United States PrEP guidelines first published in 2014
- U.S. Preventative Task Force classified PrEP as a
- grade A recommendation in June 2019
  - Insurance coverage improved
- First injectable Medication approved January 2022



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

MWAETC

Who May Benefit from PrEP

- Anyone who self-identifies a need for PrEP
- People with partners living with or at-risk for HIV
- People with any of the following risk factors in the past 6 months
  - Bacterial STI (gonorrhea, syphilis, any rectal STI)
  - Condomless anal sex
  - Transactional sex
  - Injection drug use with shared needles and/or shared equipment
- Some populations are at higher risk based on epidemiology and sexual networks

Additional risk factor
If the patient's partners would benefit from PrEP

www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

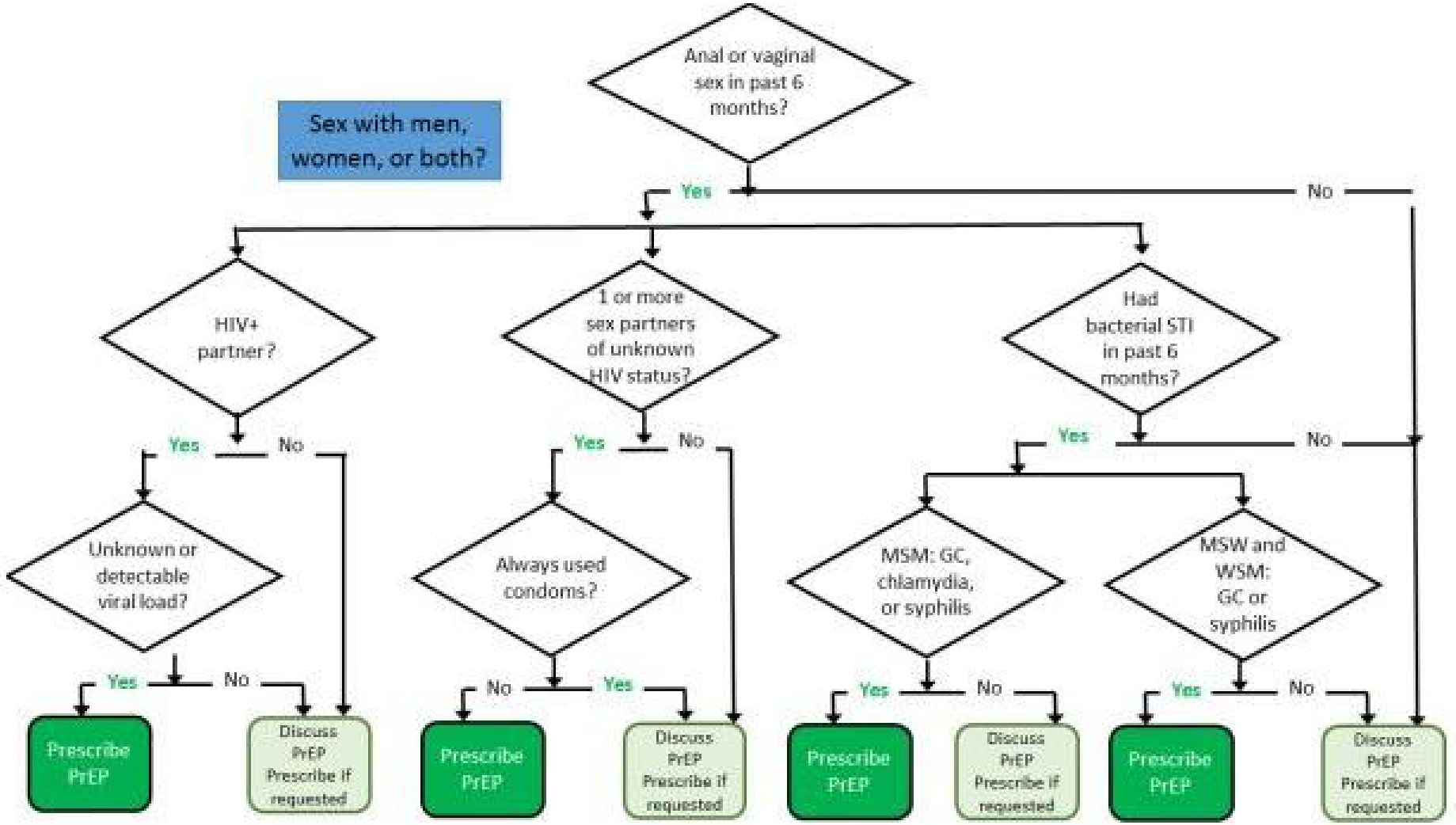
MWAETC

PrEP Medications

- **Tenofovir DF-emtricitabine**: TDF/FTC (Truvada) approved for HIV PrEP by the FDA in July 2012
- **Tenofovir AF-emtricitabine**: TAF/FTC (Descovy) approved for HIV PrEP by FDA October 3, 2019
  - Approved for males and transgender women
  - Not approved for women or on-demand dosing
- Added benefits: some protection against HSV and HBV
- **Long acting Cabotegravir** Injection: CAB (Apretude)
  - Every other month injection (after loading dose)

MWAETC

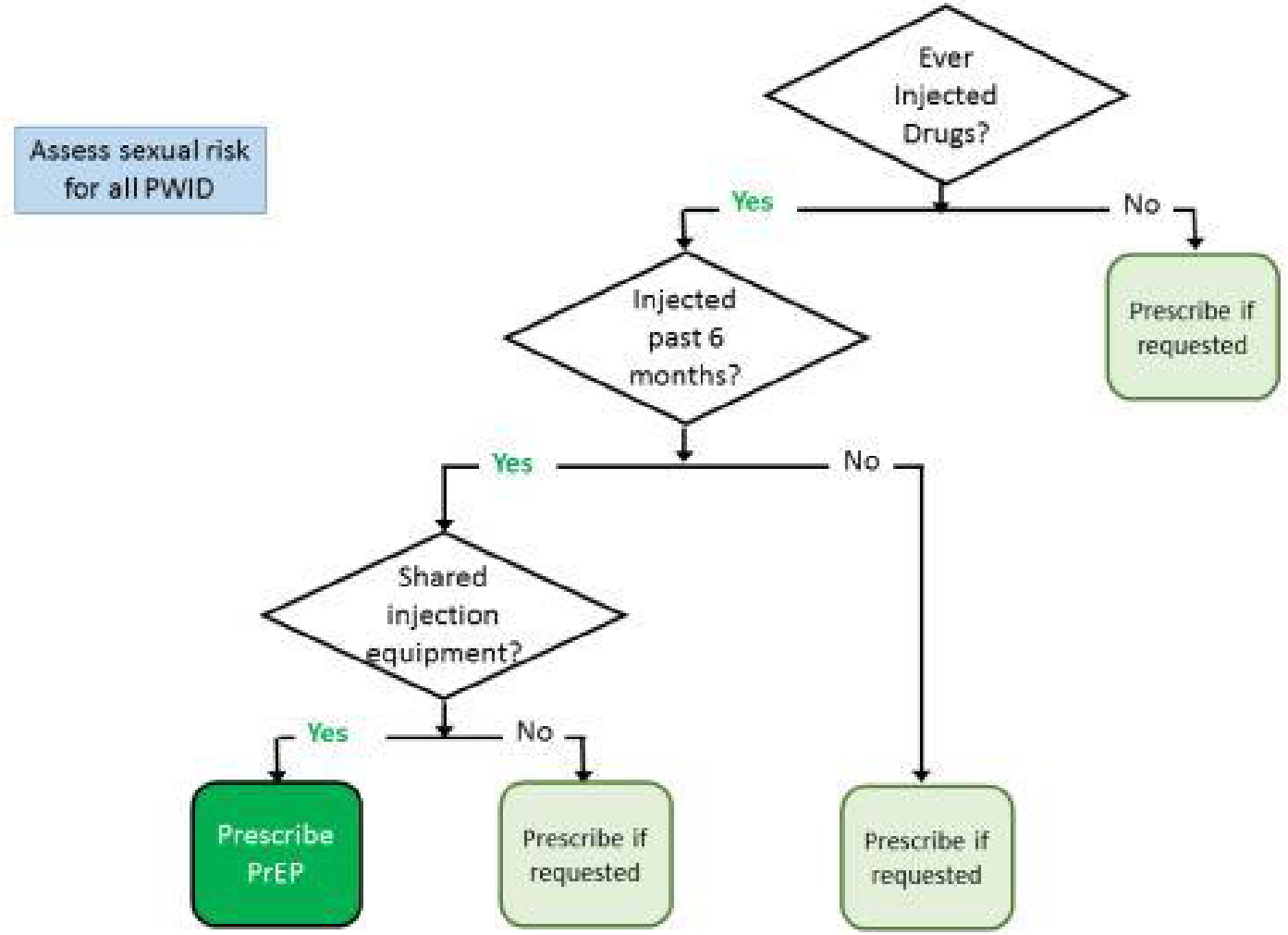
Assessing PrEP indication: Sex Risk



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

MWAETC

Assessing PrEP Indication: IDU



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

MWAETC

PrEP Summary of Recommendations: Oral Meds

- TDF not recommended for CrCl<60
- TAF not recommended for CrCl <30

Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use

	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	

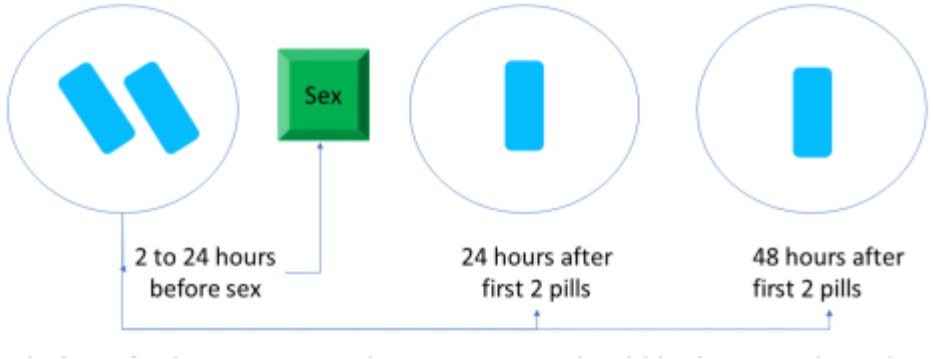
[1] adolescents weighing at least 35 kg (77 lb)
[2] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated
[3] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who 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

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

MWAETC

On Demand/2-1-1 PrEP

- Process of taking PrEP only when engaging in high risk behavior
- No U.S. Guidelines, consideration added to PrEP 2021 update
- Consider in men or transgender women whose risk factor is sexual activity
- TDF/FTC obtains max concentrations in rectal tissue within 7 days of continued use vs 20 days in blood and cervical/vaginal tissue.
- PrEP 2-1-1
  - Take two tablets 2-24 hrs before high risk event, one tablet 24 hrs after, and one tablet 48 hrs after. If High risk events continue, then continue with daily PrEP dosing.

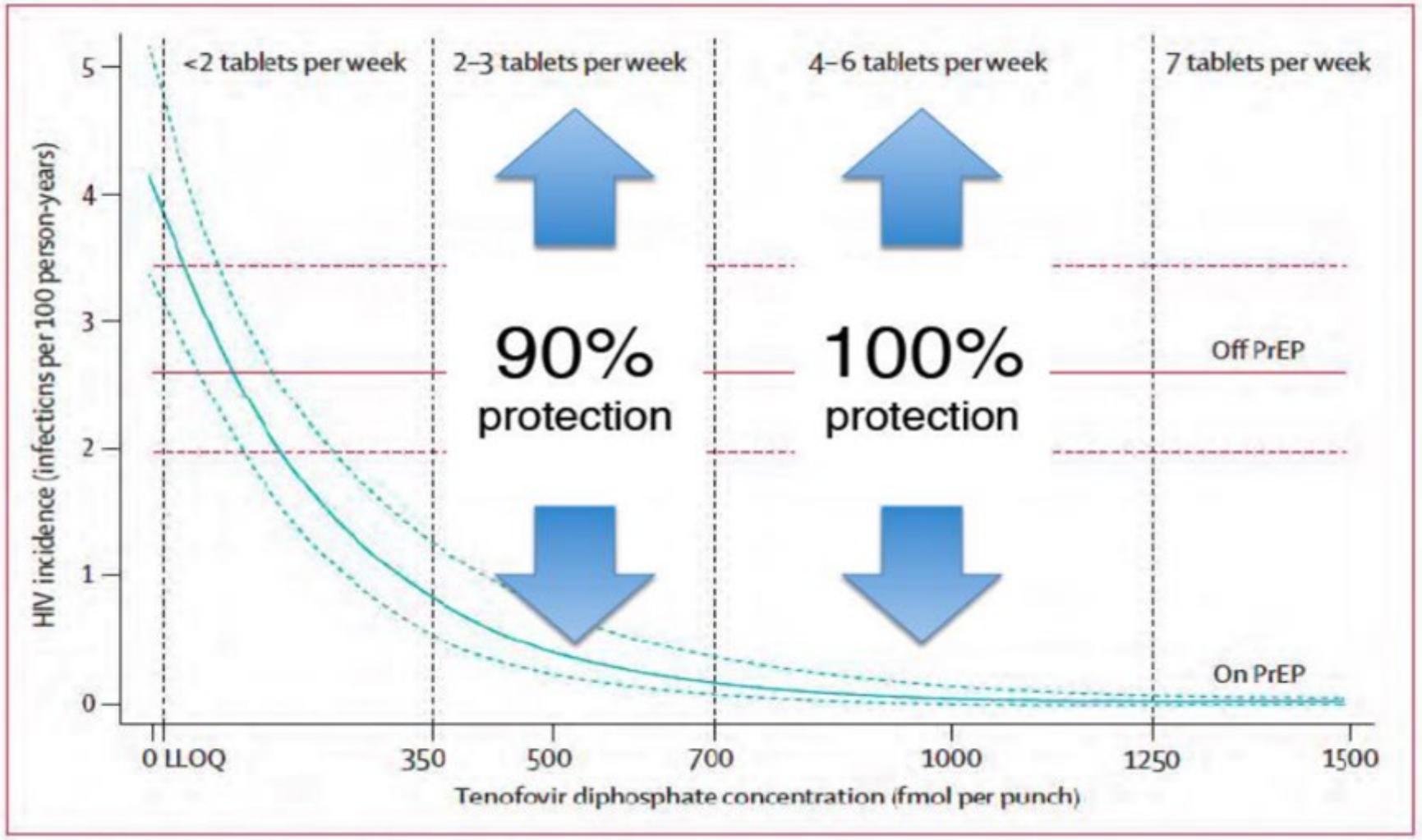


- If next sexual encounter is <7 days after last took pill, restart 1 pill daily
- If next sexual encounter is >7 days after last took pill, restart with 2 pills
- If high risk continues, continue with 1 pill a day
- Prescribe 30 pills at a time

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

MWAETC

iPrEx OLE confirmed prior estimates



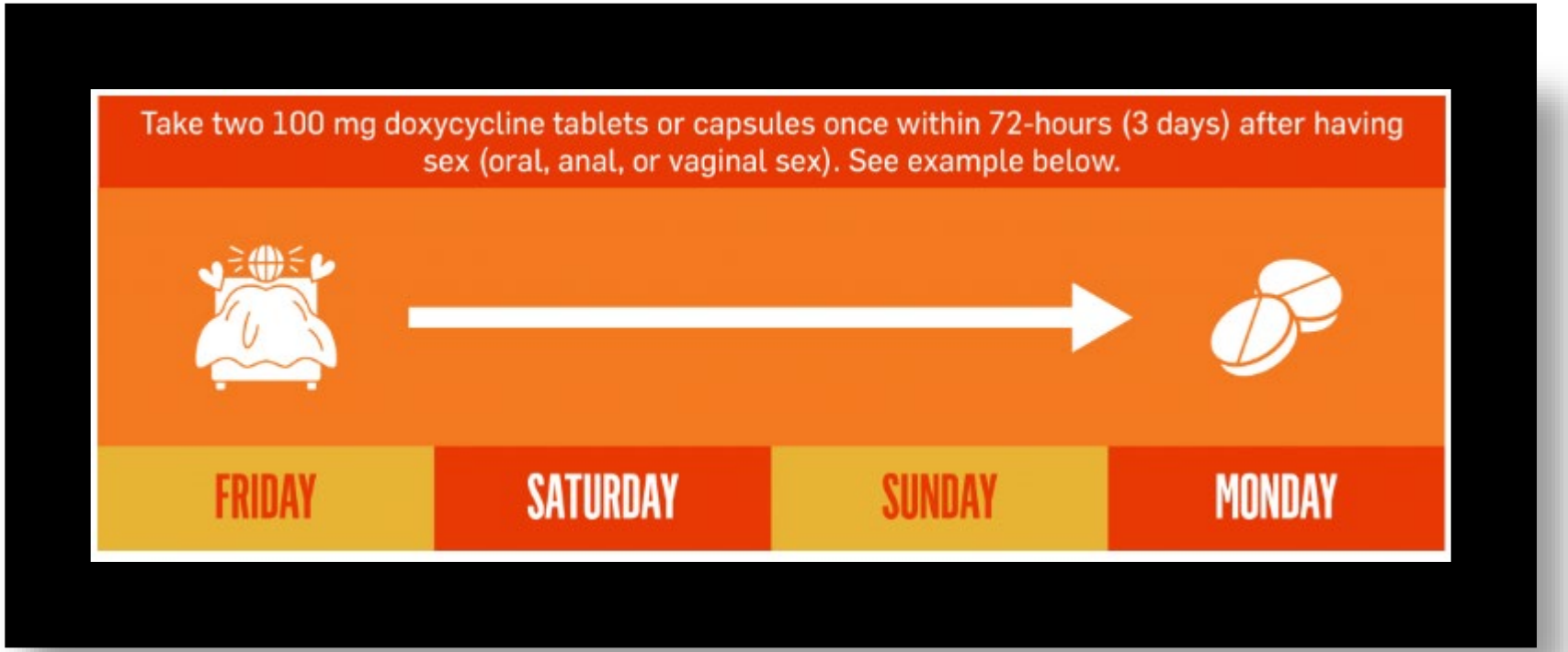
Grant RM, et al. *Lancet Inf Dis.* Sep 2014;14(9):820-9

PrEP Discontinuation

- Discontinuation only if:
  - Per patient request/risk decrease
  - Safety concerns related to medication, may consider alternative approved medication
  - Patient becomes HIV positive
  - Continue PrEP for at least 28 days after high risk situation
  - If Patient wishes to Restart PrEP the same pre-treatment eval should be performed
  - Remember to screen for HIV/STIs per risk even after PrEP is stopped

MWAETC

Doxy PEP



https://endinghiv.org.au/blog/what-you-need-to-know-about-doxy-pep/

MWAETC

Implementation

- Who should receive DoxyPEP
    - MSM/TGW on who are a candidate for HIV PrEP or living with HIV
    - If not on HIV PrEP, MSM/TGW with history of STIs within the past 12 months, engages in sex work, has sex under the influence of drugs (chemsex),
- 3-month schedule: Provide enough meds and replenish after HIV/STI screening
- If patient is having signs and symptoms of an STI:
    - Should get immediate testing and treatment; avoid sex x1 week post-treatment
- ICD-10 diagnosis code: Z20.2
  (Contact with and [suspected] exposure to infections with a predominantly sexual mode of transmission)

MWAETC

Prescribing DoxyPEP

- Example:
  - Doxycycline 100 mg tablet, #30 tablets
    - Take 2 tablets PO daily as needed for prophylaxis
  - Doxycycline monohydrate or hyclate can be used
  - Do not take concurrently with antacids or vitamin supplements
  - Possible side effects: photosensitivity, esophageal discomfort

HIV Care: Linkage to Care

MWAETC

Rapid ART Start

- Rapid start of ART (antiretroviral therapy): Starting ART as soon as patient is willing after HIV diagnosis, goal within 1 week.
  - has showed better engagement and retention in care
  - Overtime decreased inflammation within the body, linked to decreased CVD
  - Regimens available that can be started prior to all lab results returning
    - Avoid regimens containing abacavir
    - Should cover HBV unless aware of immune status
  - Patient must be willing, ready and able without contraindications

- Obtain recommended labs at first visit and start ART-do not wait for labs to return to start ART, can modify regimen if needed when resistance results and other labs result.

https://aidsetc.org/resource/rapid-immediate-art-initiation-restart-guide-clinicians

Resources

MWAETC

ANTHC Early Intervention Services/HIV Clinical Team
Program: (907)729-2907 Hospital on-call ID: (907)563-2662

Clinicians

Leah Besh, PA-C, HIV Clinical Specialist labesh@anthc.org
Hope McGratty PA-C, HIV Clinical Specialist hmmcgratty@anthc.org
Jacob Gray, MD, Infectious Disease Specialist
Clifford Schneider, MD, Infectious Disease Specialist
Benjamin Westley, MD Pediatric Infectious Disease Specialist

Patient RN Care Managers

Lisa Rea, RN *ldrea@anthc.org*

Katrina Kearney, RN
Tillie Powers, RN SCF
Claire Lewis, NP YKHC
Sara Malamute, RN TCC

Program Support Team

Linda Hogins, CMA
Minnie Chavez, ACM
Laura Riley, Sr. Program Manager
Jenn Arnold, AETC Coordinator
Jeni Williamson, Rural Navigator, ECHO Coordinator

PrEP Resources: Navigation

please PrEPme.org RESOURCES

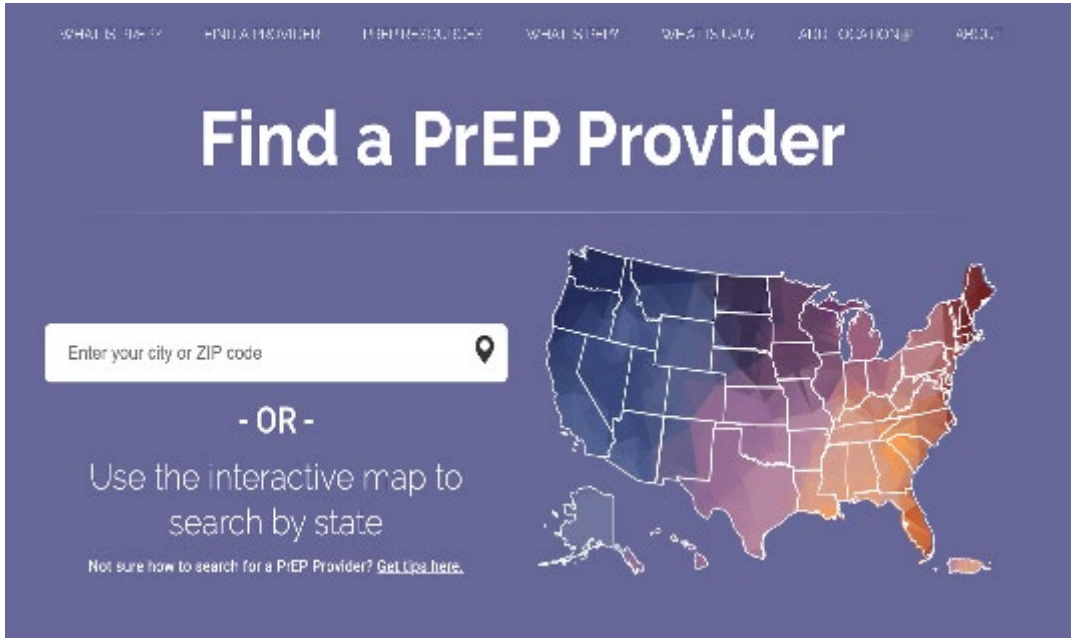
HIV-prevention and payment assistance resources in English and Spanish.

For patients and providers.

please PrEPme.org DIRECTORY

Search for PrEP providers in your area.

In collaboration with NPIN/PrEPLocator.



AETC AIDS Education & Training Center Program South Central

getSFcba

MWAETC

PrEP Resources: Clinical Guidance

National PrEP Line: Free clinician consultations

PrEP: Pre-Exposure Prophylaxis

Clinically supported advice on PrEP for healthcare providers

Up-to-date clinical consultation for PrEP decision-making, from determining when PrEP is an appropriate part of a prevention program to understanding laboratory protocols and follow-up tests.

Call for a Phone Consultation

(855) 448-7737 or **(855) HIV-PrEP**

Monday – Friday, 9 a.m. – 8 p.m. ET

nccc.ucsf.edu

CLINICIAN CONSULTATION CENTER

MWAETC

Alaskan AIDS Education and Training Center (AETC)

- Alaska AIDS Education and Training Centers offers a wide range of training opportunities for health professionals, including lectures, preceptorships, webinars, and conferences.
- Delivers innovative education and training to improve access to care and quality of life for people with or are at increased risk for acquiring HIV.
  - Education and training
  - Clinical consultation
  - Capacity building assistance on prevention, diagnosis, and treatment of HIV and commonly associated co-morbidities
- For more information, please contact AETC@anthc.org

AETC AIDS Education & Training Center Program
Mountain West

National HIV Curriculum

www.hiv.uw.edu

FREE CME, MOC, CNE, Pharmacology CE, and CE

Free, up-to-date website for novice to expert clinicians
to learn about HIV diagnosis, treatment, and prevention

Recertified for CE in fall 2020, six modules with 37 lessons and corresponding question bank topics address:

- Screening and Diagnosis
- Basic HIV Primary Care
- Antiretroviral Therapy
- Co-Occurring Conditions
- Prevention of HIV
- Key Populations

The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services as part of an award totaling $1,000,000 with 0% financed with non-governmental sources.

National HIV PrEP Curriculum

www.hivprep.uw.edu

This free curriculum addresses how to assess, initiate, and monitor HIV PrEP.

- **11 lessons** offer 14 free CME credit, CNE and CE contact hours, 10 pharmacology CE for APNs, and Certificates of Completion
- **HIV PrEP Training Certificate** available in HIV PrEP Fundamentals Module
- **HIV PrEP Tools for Clinicians** app supports interactions with patient from assessment and medication selection to what labs to order
- Experts discuss relevant topics via **Mini-Lectures**, **Panel Discussions**, and **Interviews**
- 4 concise **HIV PrEP Clinical Guides** review HIV PrEP studies, injectable cabotegravir, on-demand dosing, and recommended lab tests
- A learning group tool for healthcare entities & training programs to enroll members, assign units, and track progress

Alaska ID ECHO

Alaska Infectious Disease ECHO: HCV, HIV, PrEP and common STIs

Second Tuesday of every month from noon-1 PM AKST

- Enduring CEs Available
  - HIV Update
  - Syphilis 101
  - Congenital Syphilis
  - PrEP mini-series

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

www.anthc.org/ak-id-echo // akidecho@anthc.org

MWAETC

Questions

Leah Besh PA-C, AAHIVS

Director HIV Clinical Services
Alaska Native Tribal Health Consortium

TigerText for urgent concerns
Email: labesh@anthc.org
aetc@anthc.org-for training inquiries
ANTHC Early Intervention Services
HIV Program: 907-729-2907

MWAETC

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Hepatitis C Screening, Treatment and Elimination

Hope McGratty, PA-C, MPH, AAHIVS
Liver Disease and Hepatitis Program
Early Intervention Services/HIV Program
Alaska Native Tribal Health Consortium
hmmcgratty@anthc.org
(907) 729-1560

Updated April 2025

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

I have no conflicts of interest to disclose

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Objectives

- Understand why screening for hepatitis C (HCV) is important
- Recognize ways to screen for HCV
- Identify HCV treatment options that are available
- Understand HCV treatment in special populations
- Identify ways to overcome current challenges to the HCV cascade
- Discuss what it will take to achieve HCV elimination

Hepatitis C Epidemiology

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Epidemiology

Hepatitis C is the most common bloodborne infection in the United States. These statistics show why there is national concern.

> 50,000 NEW CASES

MORE THAN 50,000 ESTIMATED NEW CASES in the U.S. each year since 2018

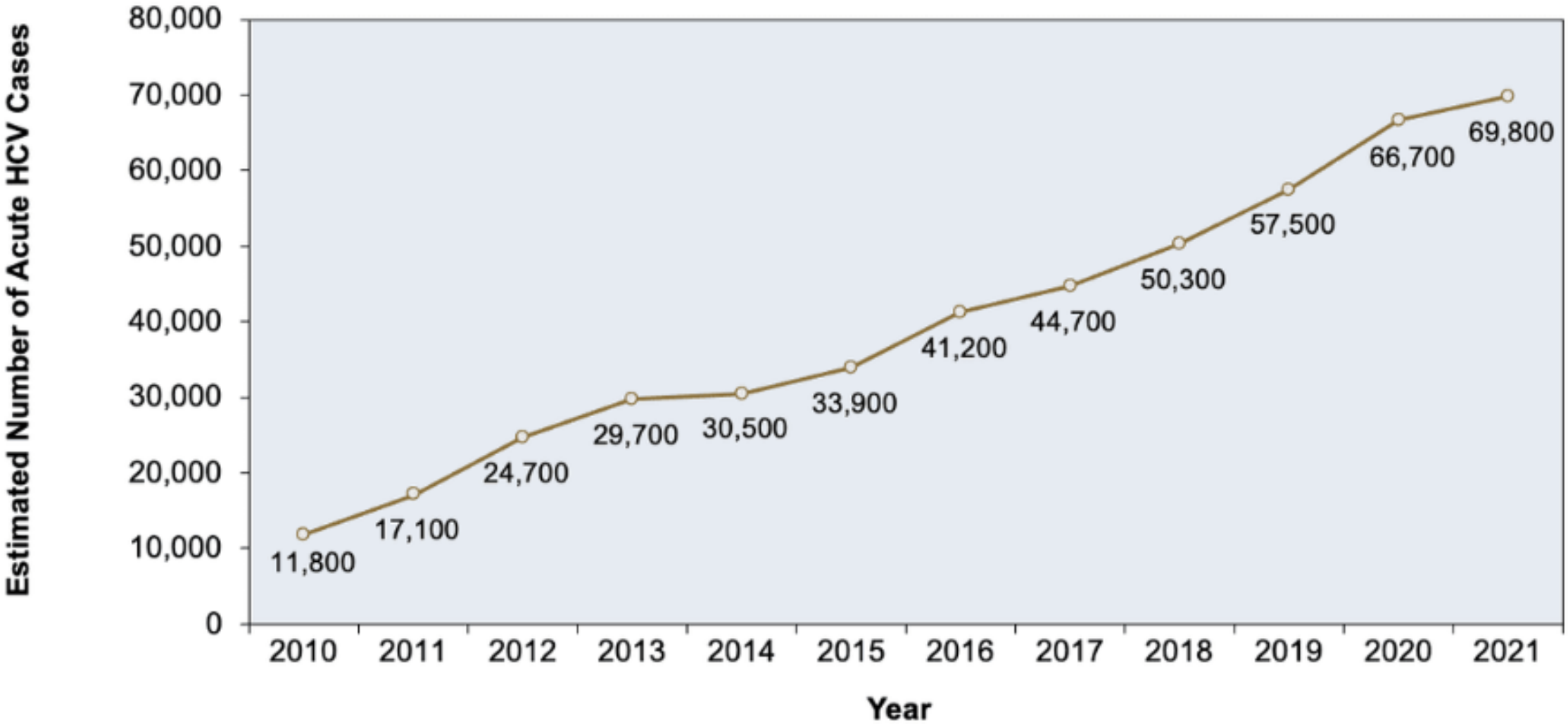
4 OUT OF 10 PEOPLE who have hepatitis C don't know they have it

3-5 MILLION PEOPLE live with active hepatitis C in the U.S.

20-39 YEAR OLDS have the highest rate of new hepatitis C cases

Acute Cases of HCV in the U.S.

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM



ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Alaska Proportion of Newly Reported Chronic HCV Cases Among Adults Age ≥ 18Y, By Age Group and Year

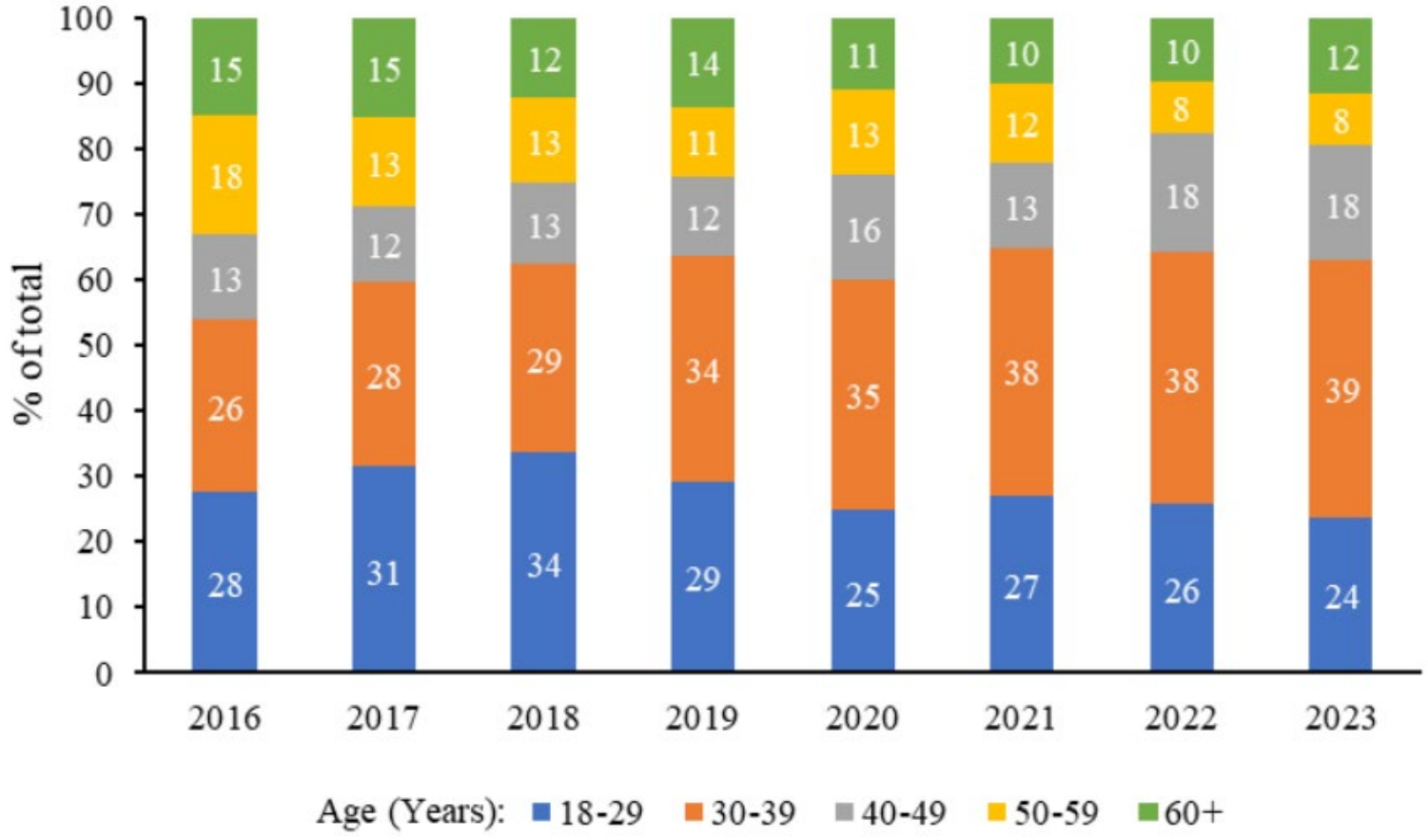
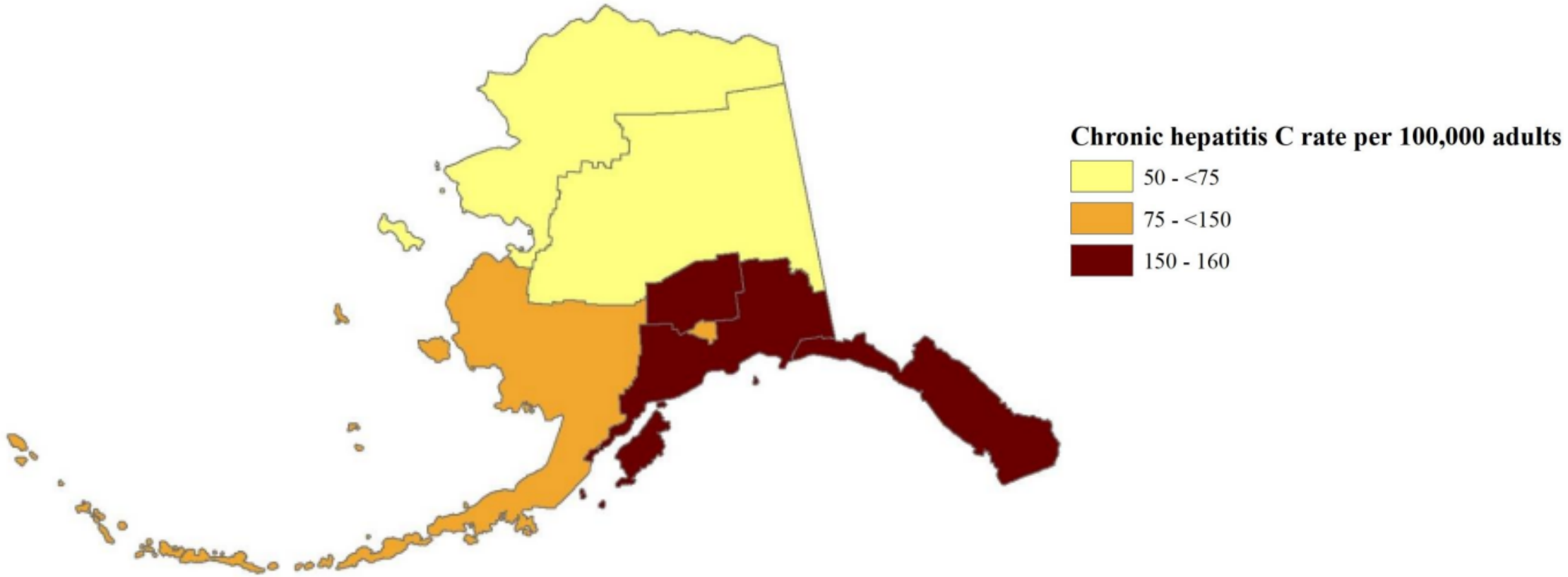


Figure 2. Proportion of Newly Reported Chronic Hepatitis C Cases Among Adults Aged ≥18 years, by Age group and Year — Alaska, 2016–2023

Chronic HCV Rate per 100,000 Adults

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Figure 3. Average Age-Standardized Rate of Newly Reported Chronic Hepatitis C Cases per 100,000 Adults Aged ≥18 years, by Region — Alaska, 2016–2023

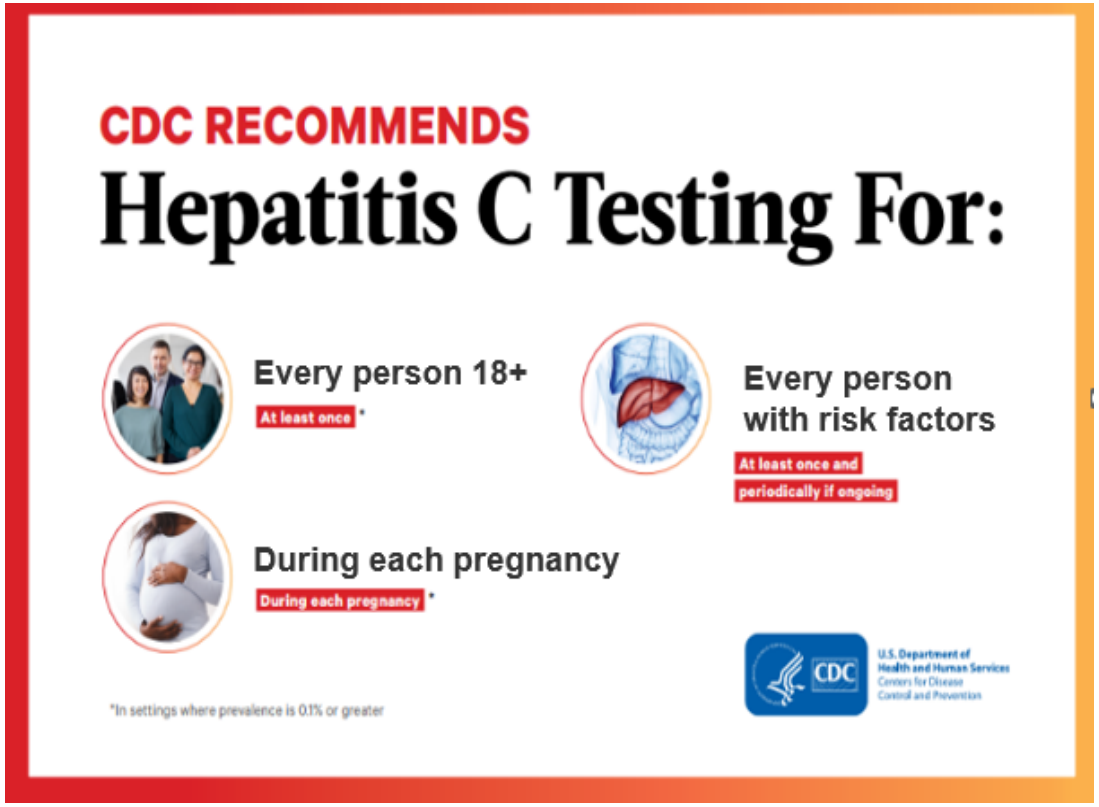


ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Adult Screening

- Initial screening lab
  - HCV Antibody with reflex to HCV RNA
- If known previous HCV infection/exposure
  - HCV Viral Load

  (RNA Qualitative or Quantitative Lab)



New Pediatric Screening Recommendation

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Prevalence of HCV in Children and Adolescents in the United States

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Statistical model using prevalence rates among women, given the assumption that most HCV cases in children are vertically transmitted (2001-2017)

Maternal HCV

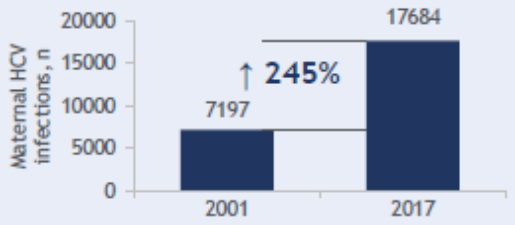
Total Cases

154,016

% of Total Live Births

0.24%

Number of Maternal HCV Infections Over Time



Pediatric HCV

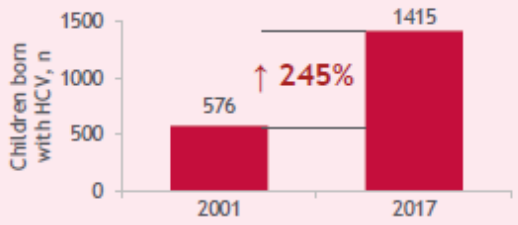
Total Born with HCV

8,649

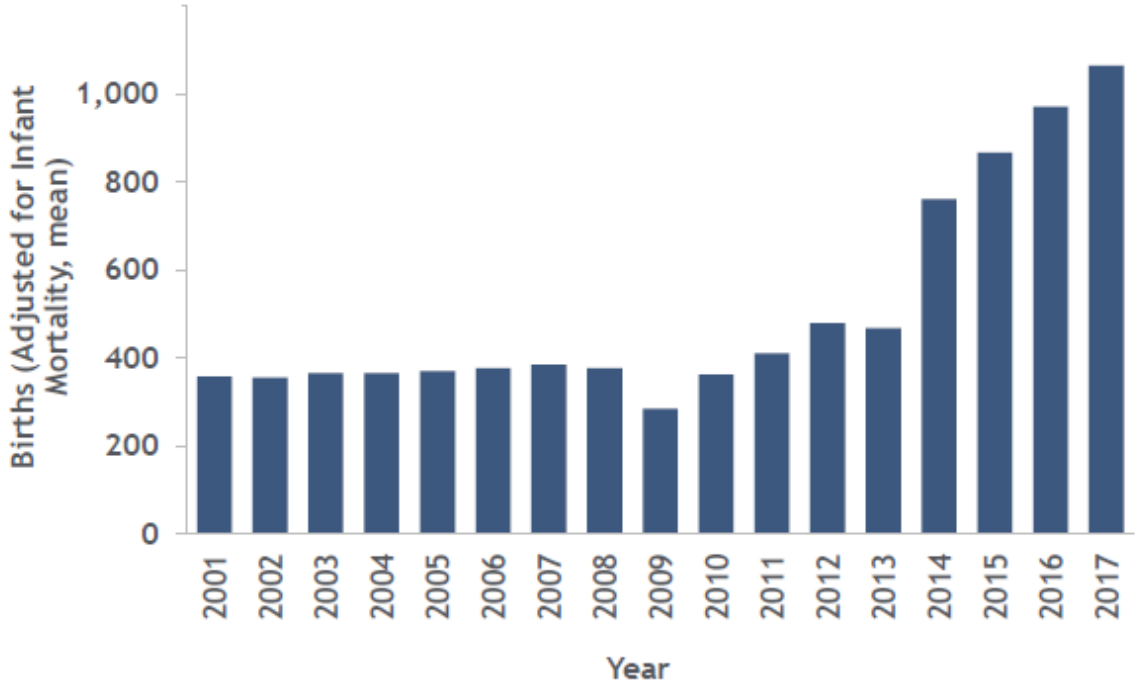
% of Total Live Births

0.01%

Number of Children with HCV Over Time



Births Affected by HCV (Attributed to Vertical Transmission)



The number of HCV-infected women of childbearing age is increasing, resulting in an increase in the number of infants born with HCV infection

Rahal H, et al. Poster presented at: AASLD 2020. P958

History of HCV Therapy

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

- **1989**: Non-A, non-B hepatitis is identified and named Hepatitis C.
- **1991–2011**: Interferon with the addition of ribavirin are the only treatments available.
- **2011**: FDA approved the first two protease inhibitors to be added to interferon and ribavirin for genotype 1, increasing cure rates to 66-79%.
- **2013**: Direct acting antivirals (DAAs) simprevir and sofosbuvir approved to be added to ribavirin +/- interferon for therapy increasing cure rates to > 80%.
- **2014**: FDA approval of sofosbuvir/ledipasvir (Harvoni) for genotype 1. First interferon and ribavirin free, single tablet/single dose per day therapy.
- **2016**: sofosbuvir/velpatasvir (Epclusa) approved and is the first pan-genotypic medication.
- **2017**: glecaprevir/pibrentasvir (Mavyret) approved (pan-genotypic) and sofosbuvir/velpatasvir/voxilaprevir (Vosevi) approved (previous DAA failures)

Simplified Treatment Medications

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

No Cirrhosis or Compensated Cirrhosis

Options

Glecaprevir/Pibrentasvir (Mavyret®) 3 tablets daily for 8 weeks

Not safe in decompensated cirrhosis

Sofosbuvir/Velpatasvir (Epclusa®) 1 tablet daily for 12 weeks

Safe in decompensated cirrhosis

Both Drugs:
No Prior Authorization Needed for Alaska Medicaid
Side Effects: Headache, fatigue, nausea

Hepatitis C Treatment Efficacy

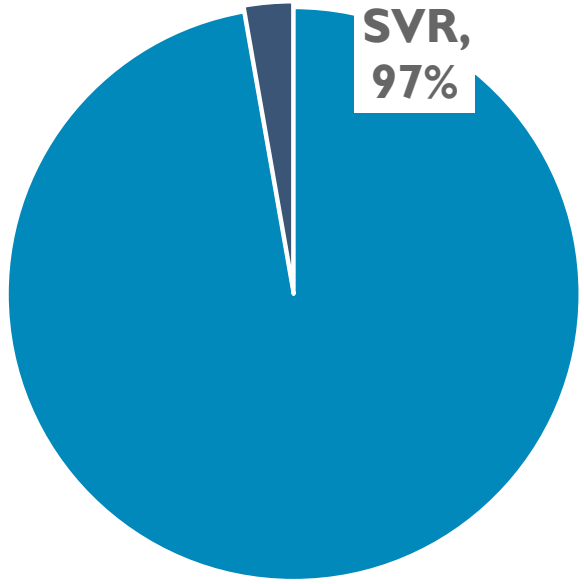
ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Global Data

Efficacy Overview of Recommended Regimens for Most People With HCV[1-6]

Sofosbuvir/Velpatasvir	Glecaprevir/Pibrentasvir
In pivotal clinical trials **98% overall cure rate** in GT 1-6 TN/TE NC/CC adult patients (n = 1,015/1,035; ASTRAL-1, -2, -3 studies)	**Overall treatment-naïve efficacy** Proven 8-week efficacy in treatment-naïve patients without cirrhosis or with compensated cirrhosis **98% cure rate** (SVR12) based on integrated pooled analysis of GT 1-6 TN, NC, and CC patients across 8 clinical trials that included US study locations (n = 1,218/1,248, ITT)
Real-world integrated analysis **99% overall cure rate** in effectiveness population in GT 1-6 TN/TE NC/CC patients (n = 5,141/5,196; pooled analysis of 12 clinical cohorts and studies in Canada, Europe, and the USA, PP)	**8-week real-world evidence** Results from two TRIO Health Network studies **99% cure rate** in per protocol population In GT 1-4 and 6, TN, NC (n = 537/540) and TN, CC (n = 70/71) patients treated for 8 weeks

AN/AI Treatment in Alaska

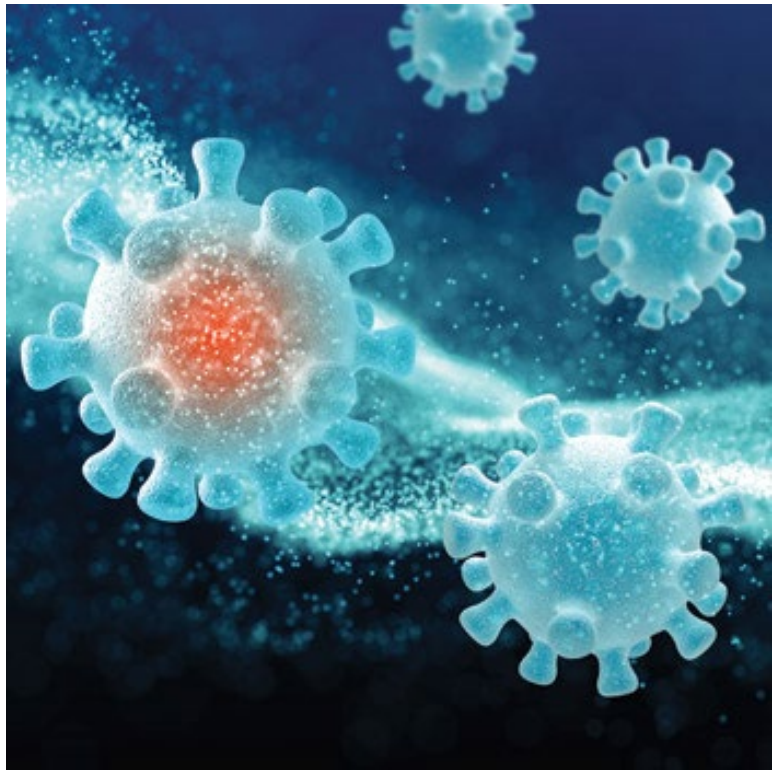


In 1266 ATHS patients who were tested for SVR

Simplified HCV Treatment

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

- Eligibility: Adults with HCV (any genotype) who do **not** have decompensated cirrhosis and have **not** previously been treated.
- Who is not eligible for simplified HCV therapy:
  - HBsAg positive, current pregnancy, known or suspected HCC, prior liver transplantation, end-stage renal disease (eGFR <30)
  - Current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score =/>7 (ascites, hepatic encephalopathy, total bilirubin =/>2.0, albumin >3.5 g/dL, or INR =/>1.7)



ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Simplified HCV Treatment – 3 Steps

1. Pre-treatment labs and assessment

2. Check FIB-4 and assess for cirrhosis.

3. Write prescription and start treatment.

Step 1: Complete Pretreatment Labs & Assessment

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Labs	
Before beginning treatment:	❑ Pregnancy Test and counseling about pregnancy risk of HCV medication should be offered to women of childbearing age.
Acceptable within 6 mos if no cirrhosis or 3 months if cirrhosis:	❑ CBC ❑ Hepatic function panel and eGFR ❑ PT/INR (only needed if cirrhosis)
Acceptable within 6 months:	❑ AFP (recommended for Alaska Native patients with HCV due to higher rates of liver cancer)
Anytime prior:	❑ Quantitative HCV RNA ❑ HIV antigen/antibody ❑ Hepatitis B surface antigen[1] ❑ Syphilis screening ❑ Genotype (only needed if patient has cirrhosis and planning to treat with Sofobuvir/velpatasvir (Epclusa)

❑ Assess for drug-drug interactions at: www.hep-druginteractions.org

❑ Persons with ongoing substance use issues SHOULD be treated for hepatitis C. Do not delay. You can use Audit-C & PHQ-9 or other mental health screening tools to determine if patient would benefit from referral to Behavioral Health/Substance Use Treatment Program; however, there is no HCV treatment contraindication if someone is drinking alcohol or using substances.

HCV Simplified Treatment for Alaska Tribal Health System

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Once you have labs:

Calculate FIB-4
https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4

and

Assess for Cirrhosis:
- FIB-4 > 3.25 or any of the following:
- Transient elastography (e.g. FibroScan stiffness > 12.5 kPa
- Noninvasive serologic tests above proprietary cutoffs for cirrhosis (e.g. FibroSure, FibroTest)
- Clinical evidence of cirrhosis (lover nodularity and/or splenomegaly on imaging, platelet count < 150,000
- Prior liver biopsy showing cirrhosis

FIB-4 < 3.25 and no clinical signs of cirrhosis

FIB-4 > 3.25 or clinical signs of cirrhosis

Calculate CTP score
https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp

CTP ≤ 6

CTP > 6

Proceed with Simplified Treatment Step 2

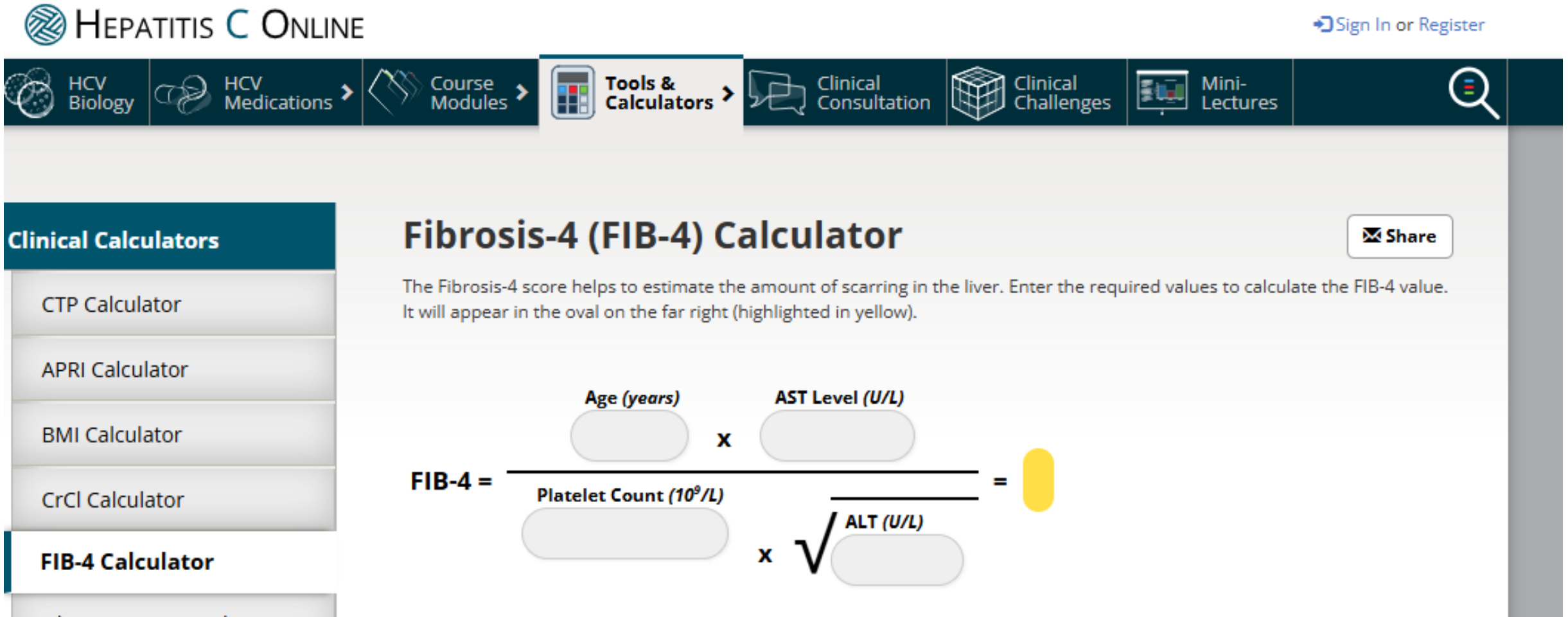
Note: Patients with compensated cirrhosis can be treated in Primary Care setting. For questions about cirrhosis and treatment, please consult Liver Clinic or refer for evaluation. Persons with cirrhosis should have annual follow up with Liver Disease specialist.

Refer to ANTHC Liver Clinic or a medical practitioner with expertise in liver disease

Updated 8/2024
For more information, visit:
www.anthc.org/hep/hep-c-treatment-information

Hepatitis C Online: www.hepatitis.uw.edu

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM



ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Assess for Cirrhosis

FIB-4 > 3.25 or any of the following:

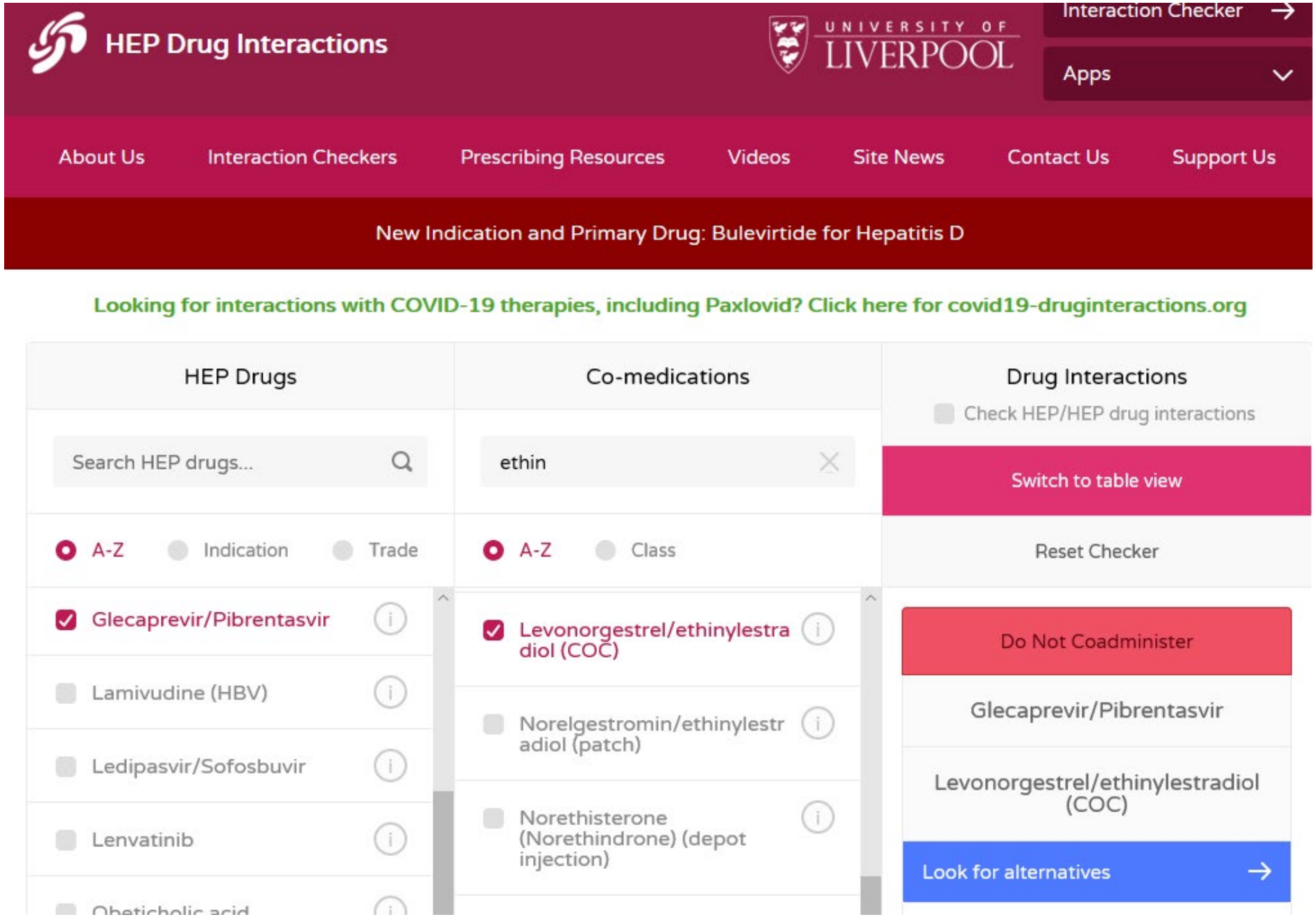
- Transient elastography (e.g. FibroScan stiffness > 12.5 kPa
- Noninvasive serologic tests above proprietary cutoffs for cirrhosis (e.g. FibroSure, FibroTest)
- Clinical evidence of cirrhosis (liver nodularity and/or splenomegaly on imaging), platelet count < 150,000
- Prior liver biopsy showing cirrhosis
- Physical exam – icterus, jaundice, spider angioma, ascites, asterixis

Be Aware of Potential Drug Interactions

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Common ones (NOT ALL INCLUSIVE):

- Glecaprevir/pibrentasvir (Mavyret) specific – Ethinyl estradiol in doses >20mcg (ALT elevation)
- Sofosbuvir/velpatasvir (Epclusa) specific - PPIs (take Epclusa 4 hours before PPI), H2 agonists (take simultaneously or 12h apart)
- Either drug: amiodarone, TB meds – rifas, anti-seizure meds (except levetiracetam), St. John's wort, and digoxin
  - CHECK SPECIFIC DDIs (statins)



https://www.hep-druginteractions.org

Step 3: Write Prescriptions / Start Treatment

- Educate patient about how to take medications, importance of adherence and prevention of reinfection
- Link patients who have ongoing substance use issues with harm reduction supplies & treatment services

www.anthc.org/what-we-do/clinical-and-research-services/hep/hep-c-treatment-information/

No Cirrhosis

Cirrhosis

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

On Treatment Monitoring and Follow-up

- No on-treatment monitoring required
- Check for SVR (sustained virologic response) after treatment
- Persons with cirrhosis need hepatocellular carcinoma screening q6months (RUQ US and AFP)
- Provide alcohol counseling; those with advanced fibrosis and cirrhosis(F2-F4) should abstain completely from alcohol and avoid hepatotoxins
- Work up LFT elevations that continue
- Persons who fail treatment need re-treatment

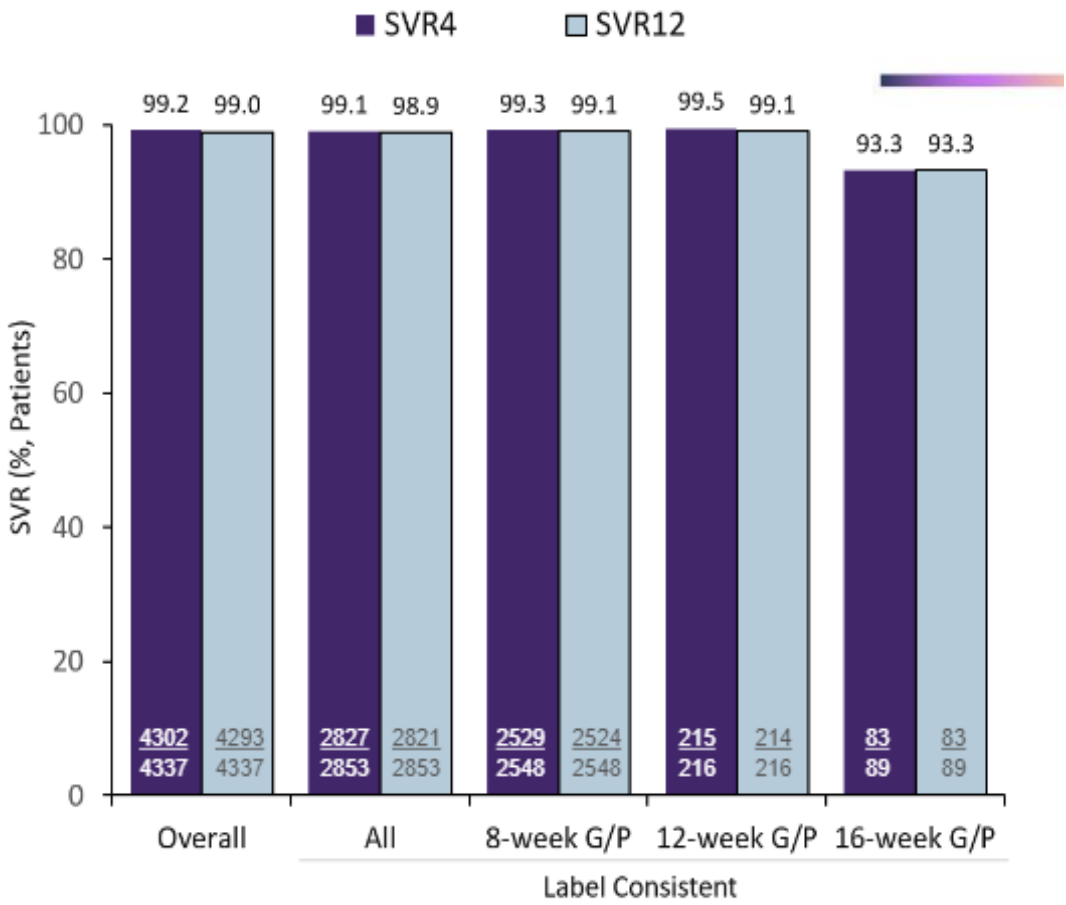
https://www.anthc.org/wp-content/uploads/2024/09/Simplified-Treatment-Checklist.pdf

Positive Predictive Value of SVR4 for SVR12 in Pts treated with G/P

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

- Patients receiving G/P in clinical trials
- >99% of patients that achieved SVR4 achieved SVR12
- All patients that did not achieve SVR4 did not achieve SVR12 (NPV=100%; sensitivity=100%)
- Specificity was 79.5%, indicating the majority of patients relapsing do so by post-treatment week 4

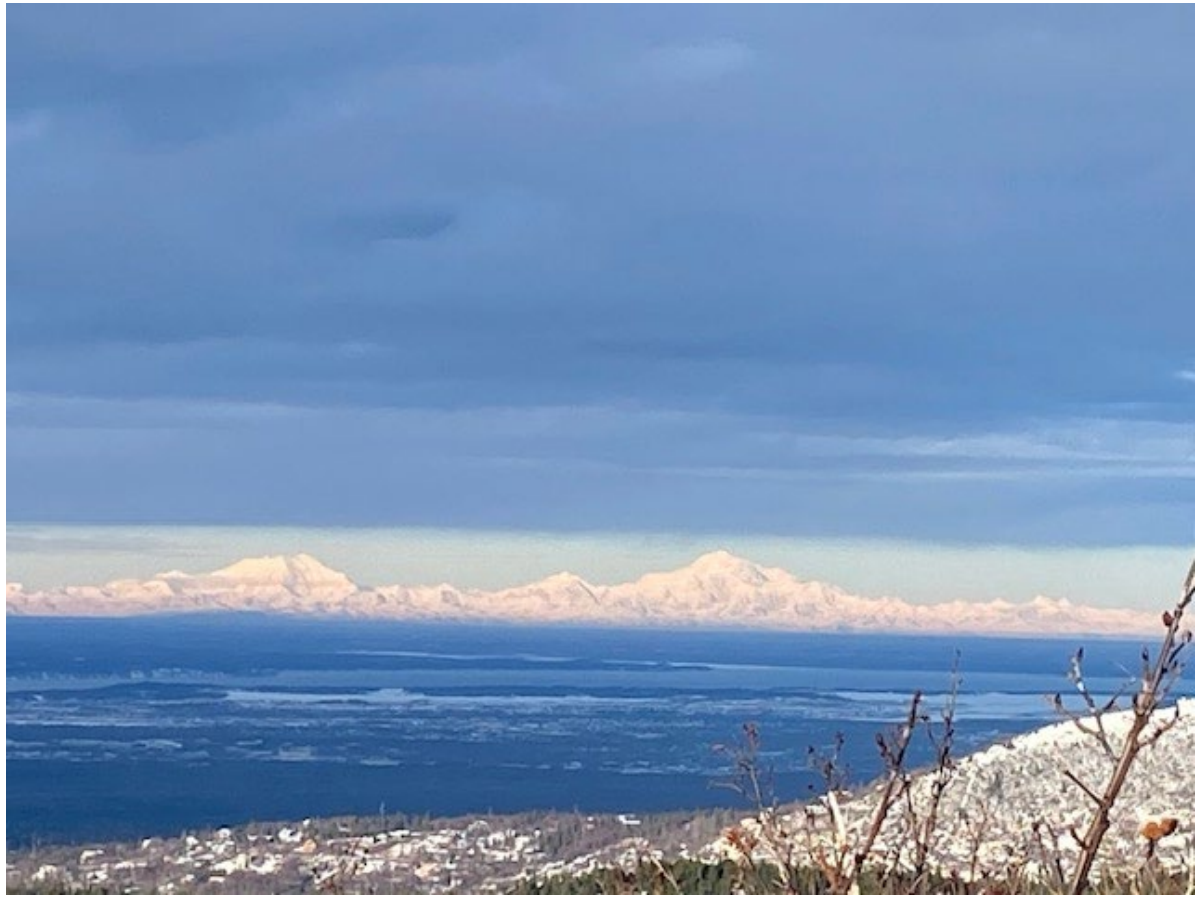
	Overall	All	8-wk G/P	12-wk G/P	16-wk G/P
PPV	99.8	99.8	99.8	99.5	100.0
NPV	100.0	100.0	100.0	100.0	100.0
Sensitivity	100.0	100.0	100.0	100.0	100.0
Specificity	79.5	81.3	79.2	50.0	100.0



ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Lesser Discussed HCV Treatment Scenarios

- DAA treatment discontinuation
- HCV reinfection
- Pregnancy
- Breast/chest feeding
- Pediatrics



ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

DAA Treatment Discontinuation

- Large real-life NAVIGATORE-Lombardia study of 365 patients in Italy[1], SVR rate was 50% for those who took less than 4 weeks of treatment.
- In the ATHS, 42 patients who discontinued treatment, # of prescription fills was known
  - 17/29 (59%) who took < 4 weeks achieved SVR
  - 12/13 (92%) who took > 4 weeks of treatment achieved SVR
- To prevent discontinuation:
  - Consider providing all doses at start of treatment
  - Follow up to see that refills are picked up or mailed
  - Link to SUD treatment and harm reduction

- [1]Massimiliano, F., Lombardi, A., Colaneri, M. et al. High rates of SVR despite premature Discontinuation of DAAs in HCV-infected patients treated in real-life setting. J Viral Hepatology2021; 28:558-568.

Hepatitis C Reinfection after Successful Antiviral Treatment Among People who Inject Drugs: A Meta-analysis

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

- Thirty-six studies were included (6,311 person-years of follow-up)
- **Overall rate of HCV reinfection was 5.9/100 person-years (95% CI 4.1 – 8.5) among people with recent drug use (injecting or non-injecting)**
- 6.2/100 person-years (95% CI 4.3 – 9.0) among people recently injecting drugs
- 3.8/100 person years (95% CI 2.5 – 5.8) among those receiving OAT

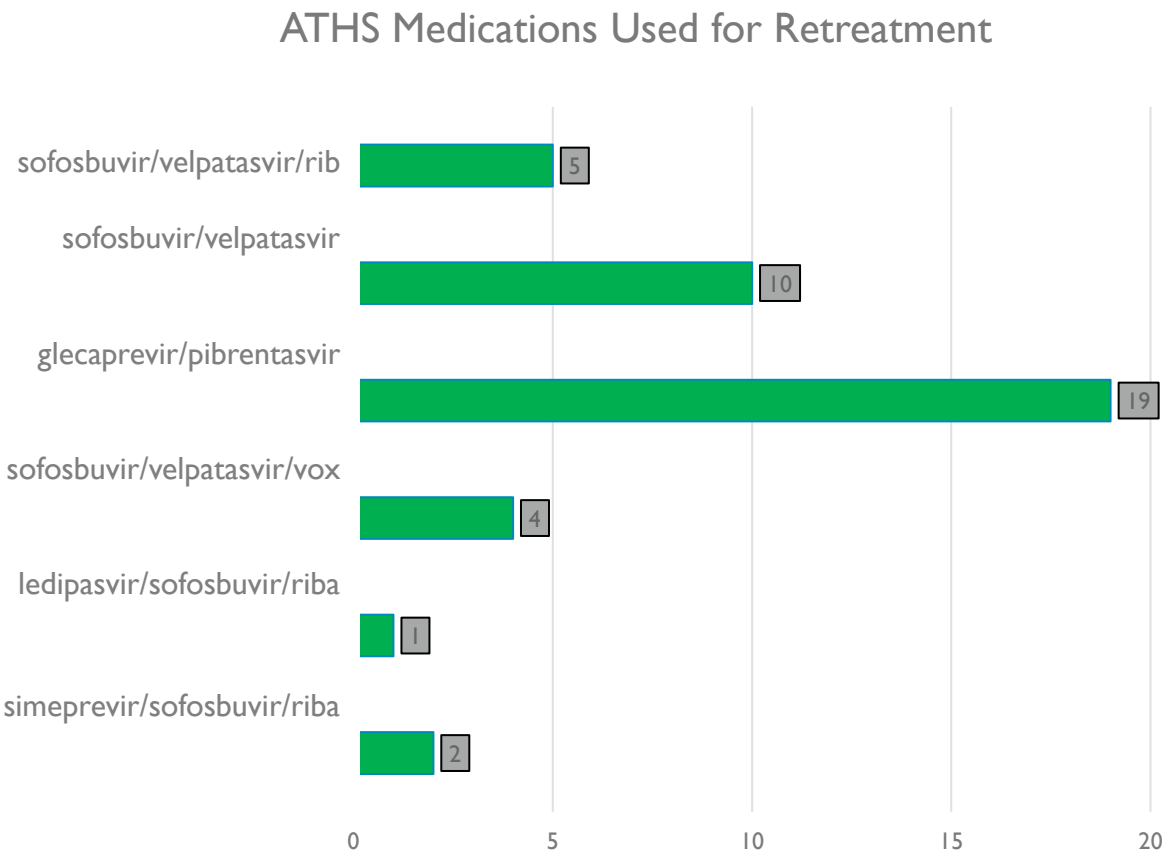
Stratified analysis

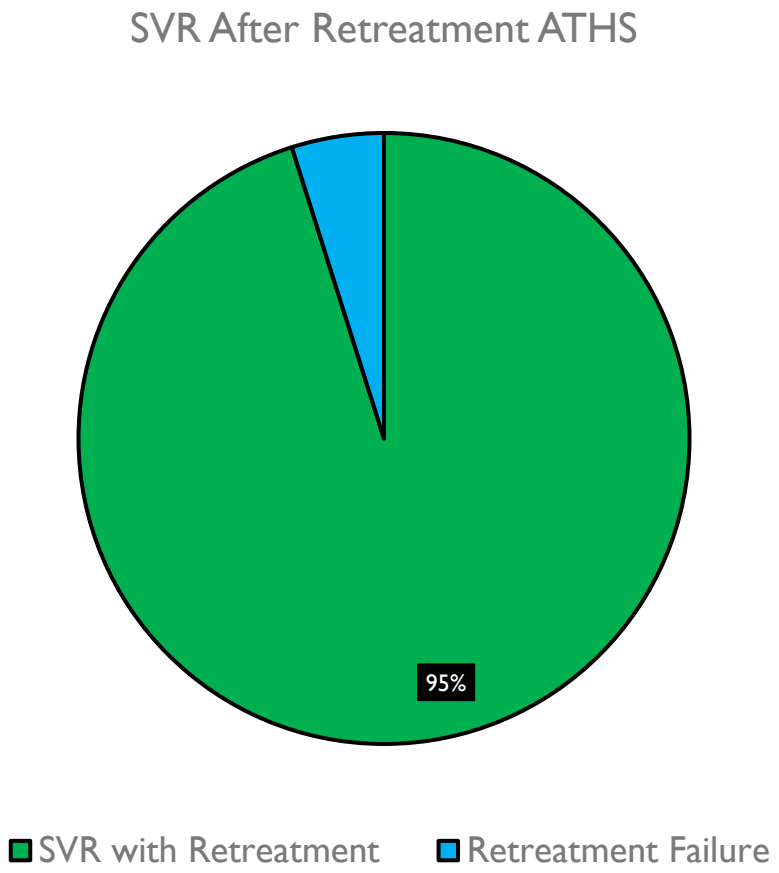
- 1.4/100 person-years (95% CI 0.8 – 2.6) among people receiving OAT with no recent drug use
- 5.9/100 person-years (95% CI 4.0 – 8.6) among people receiving OAT with recent drug use
- 6.6/100 person-years (95% CI 3.4 – 12.7) among people with recent drug use not receiving OAT

Hajarizadeh B, et al. J Hepatol. 2020 Apr;72(4):643-657. doj: 10-1016/j.hep.2019.11.012

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Retreatment After Treatment Failure or Reinfection





Retreatment guidance available: https://www.hcvguidelines.org/treatment-experienced

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Preventing Reinfection

- Preventing reinfection starts with treatment
- Persons who are actively injecting drugs should be high priority to treat
- Educate patients undergoing treatment about reinfection risk
- Provide harm reduction supplies or refer to harm reduction services
- Treat patients as well as partners, inner circle

One untreated person with hep C who is actively injecting drugs will infect 20 people within 3 years[1,2]

[1]NIH National Institute on Drug Abuse. Updated June 2021. Accessed November 2, 2021. https://www.drugabuse.gov/download/37596/heroin-research-report.pdf

[2]NIH National Institute on Drug Abuse. Updated August 3, 2020. Accessed November 9, 2021. https://www.drugabuse.gov/drug-topics/viral-hepatitis-very-real-consequence-substance-use

HCV Treatment in Pregnancy

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

- No large-scale clinical trials on the safety of direct-acting antivirals (DAAs) in pregnancy.
- Small study on ledipasvir/sofosbuvir in pregnancy: 100% SVR12, no safety concerns.
- International case series: 100% SVR12, no early safety concerns for parents or infants.
- No data on pan-genotypic regimes during pregnancy.
- Treatment during pregnancy is not formally recommended.
- Individualized treatment may be considered after patient-clinician discussions on risks and benefits.

Recommendation Regarding HCV Treatment and Pregnancy	
RECOMMENDED	RATING
For women of reproductive age with known HCV infection, antiviral therapy is recommended **before** considering pregnancy, whenever practical and feasible, to reduce the risk of HCV transmission to future offspring.	I, B

https://www.hcvguidelines.org/unique-populations/pregnancy

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Weighing the Pros/Cons of Hepatitis C Treatment During Pregnancy

Pros

- Person cured while engaged in pregnancy care
- Potential decrease in vertical transmission of HCV
- Person treated while covered by insurance
- Decrease in community transmission
- Potential decrease in HCV-associated adverse effects

Cons

- Human safety in pregnancy is not established
- Safety during breast/chest feeding not established
- More established data available for treatment prior to pregnancy or for children age 3y+
- Difficulty in accessing DAA therapy in time (prior to delivery)
- Cost effectiveness not established

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Hepatitis C and Breast/Chest Feeding

Recommendations Regarding Breastfeeding and Postpartum Care for HCV-Infected Women	
RECOMMENDED	RATING
Breastfeeding is not contraindicated in women with HCV infection, except when the mother has cracked, damaged, or bleeding nipples, or in the context of HIV coinfection.	I, B
Women with HCV infection should have their HCV RNA reevaluated after delivery to assess for spontaneous clearance.	I, B

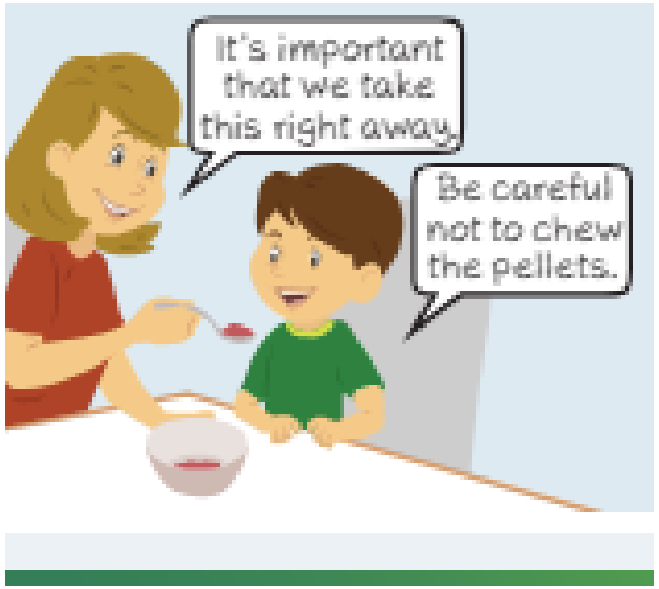
https://www.hcvguidelines.org/unique-populations/pregnancy

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Pediatric HCV Therapy

Treatment is available for children ages 3y+

- Confirm current infection with HCV RNA prior to treatment start
- Medication Options:
  - Genotypes 1,4,5, 6 - Ledipasvir/sofosbuvir (Harvoni) x 12 weeks[1]
  - Sofosbuvir/velpatasvir (Epclusa) x 12 weeks[2]
  - Glecaprevir/pibrentasvir (Mavyret) x 8 weeks[3]
- Weight-based
- Pellets placed in food must be swallowed right away and should not be chewed

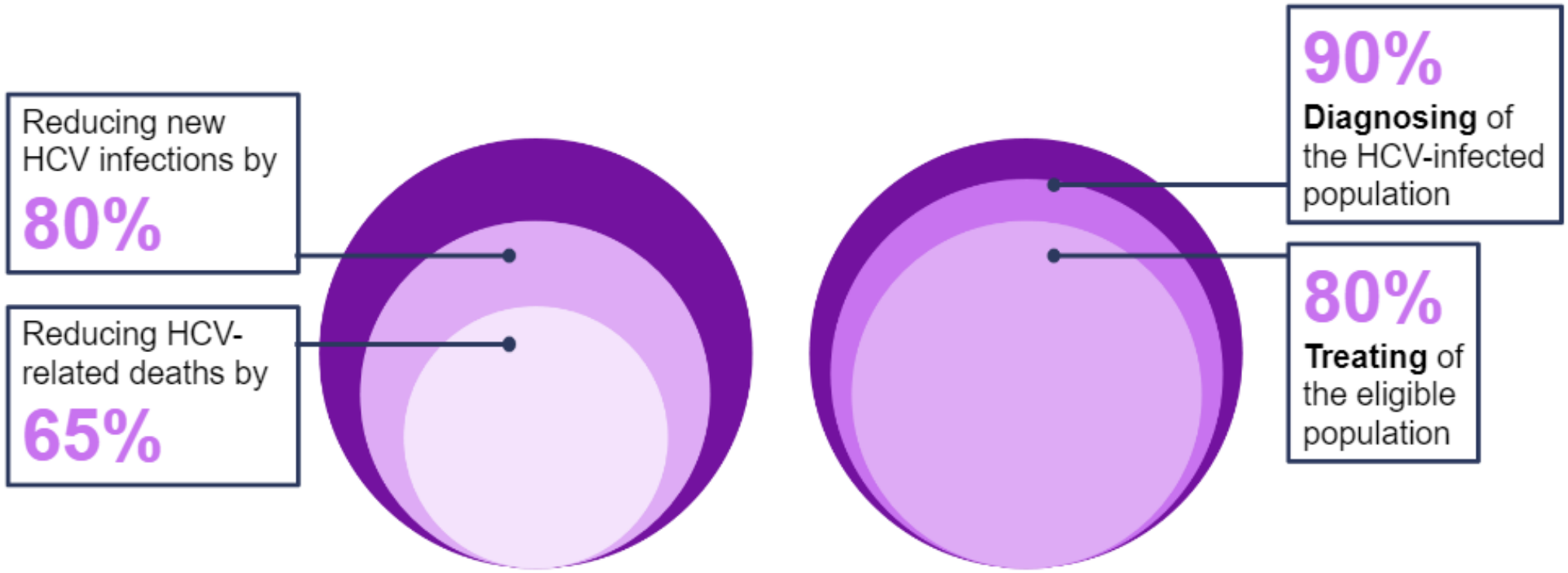


Achieving HCV Elimination

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

WHO Elimination Target

The WHO has developed set targets relative to 2015 benchmark levels with the goal of eliminating HCV as a public threat by 2030:



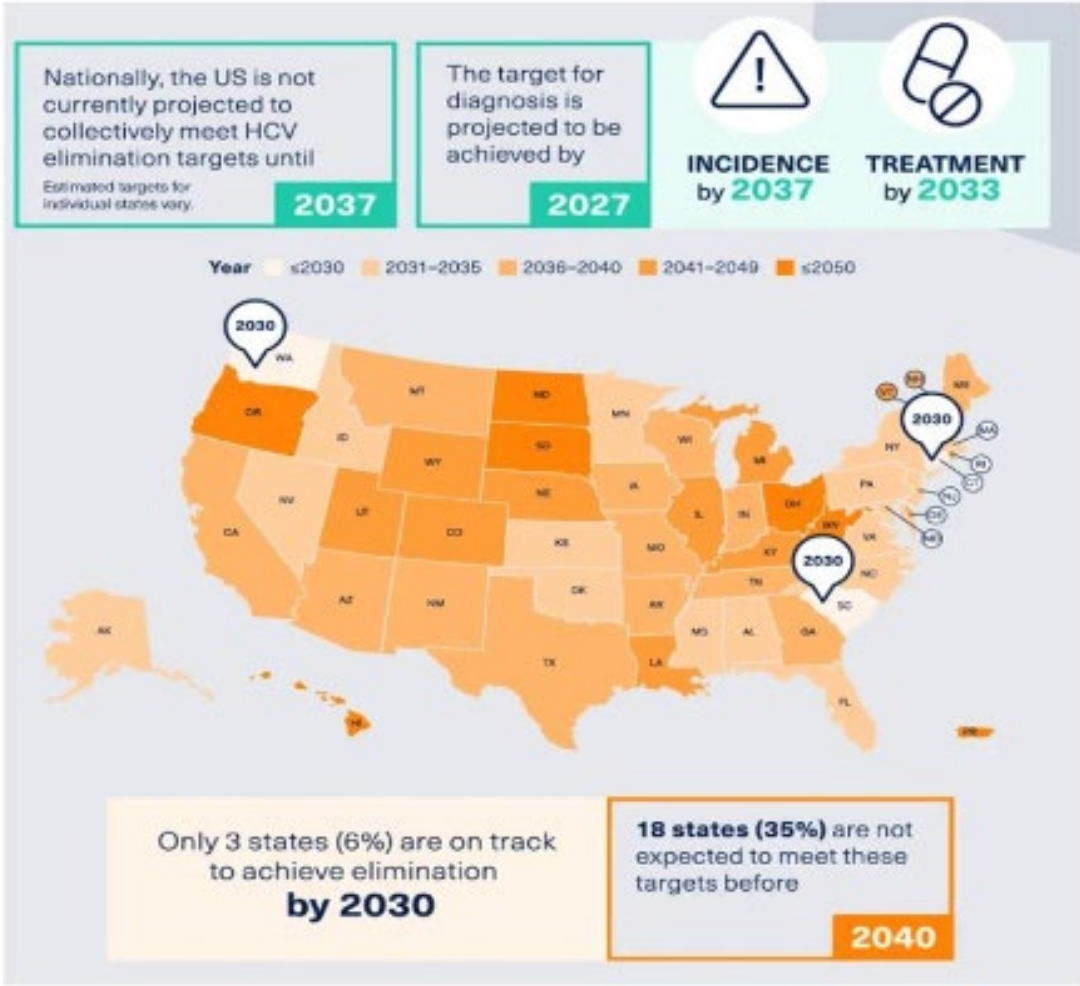
World Health Organization. Global health sector strategy on viral hepatitis, 2016–2020. WHO REFERENCE NUMBER: WHO/HIV/2016.06

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Progress Toward HCV Elimination in the United States

Elimination progress held back by:

- Sobriety Restrictions
- Prescriber Restrictions
- Retreatment Restrictions
- Need for Prior Authorizations
- Patient readiness models of care
- Stigma



Sulkowski,M., Cheng, WH., Marx, S. et al. Estimating the Year Each State in the United States will Achieve the World Health Organization's Elimination Targets for Hepatitis C.

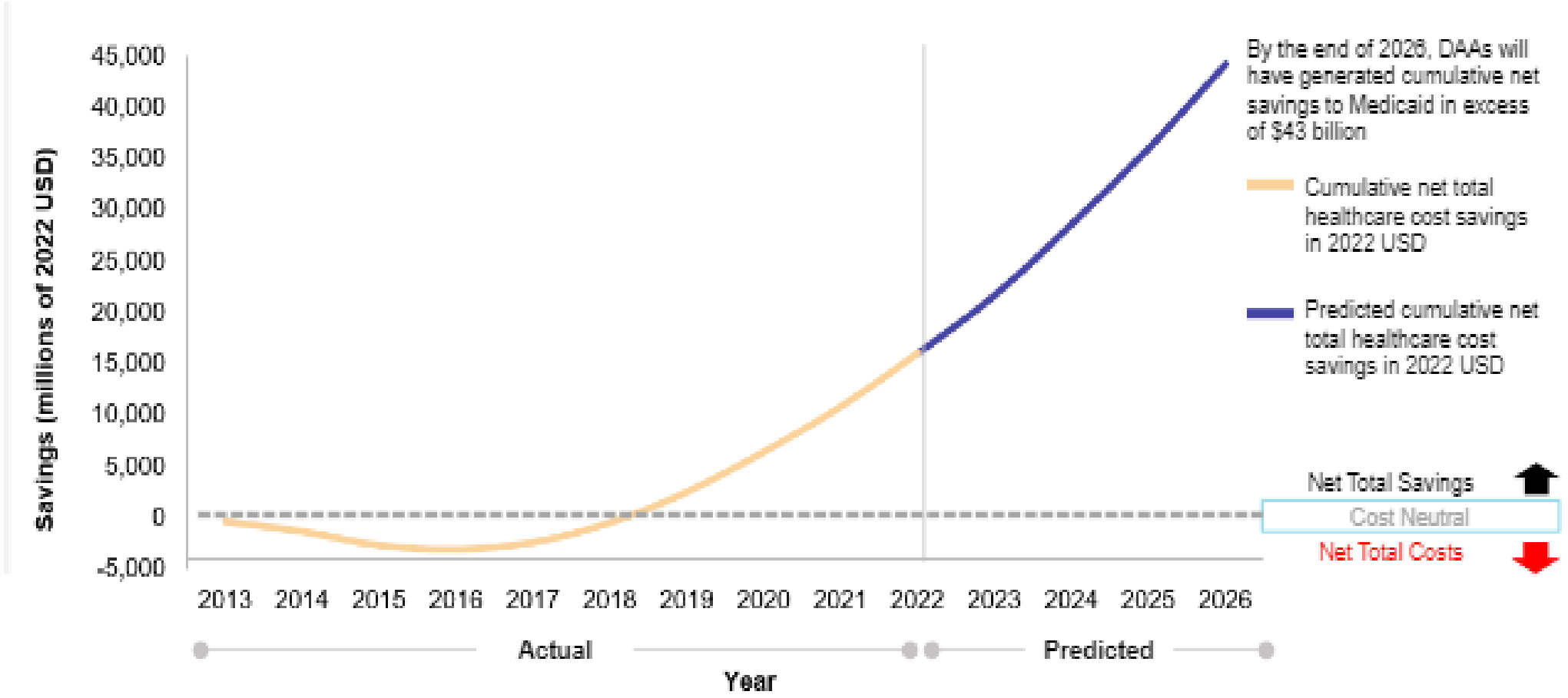
Adults Diagnosed and Cured of Hepatitis C in the U.S. 2013 - 2022

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

- Source: CDC

Impact of DAA Use on Cumulative Net Total Healthcare Savings in Medicaid, 2013 - 2026

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM



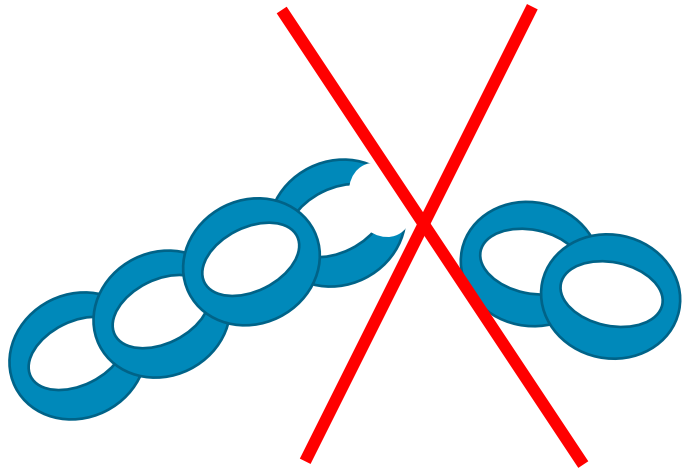
Within a decade of introduction, DAAs provided Medicaid with a cumulative net total healthcare savings* of more than $15 billion and projected to increase up to $43 billion by 2026.

*16 states – Alabama, California, Connecticut, Florida, Illinois, Indiana, Louisiana, Michigan, New Hampshire, New Mexico, New York, Ohio, Oregon, Pennsylvania, Virginia, Washington

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Current Missed Opportunities

- Missed opportunities for screening
- Persons who test positive for hepatitis C aren't linked immediately to care/treatment
- Hepatitis C treatment rarely offered outside of traditional healthcare settings
- Stigma, stigma, stigma



Every broken link decreases the chances of someone getting treated and increases the risk for spreading infection and the progression of liver disease

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Where are We Headed?

- Same day test and treat model with POC HCV viral load testing
- Cepheid Xpert

11.5W x 18"H x 16" D
Weighs about 40 lbs.

CLIA waived POC test
Positive predictive value 93.4%
Negative predictive value 99.8%
Can collect in tubes and run within 4 hrs
Approved for ages 22y+
Not approved in pregnancy

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Conclusions

- Screen WIDELY for hepatitis C
- Speed up time from screening to treatment
- Move from patient readiness model to one of provider readiness
- Be flexible - one size does not fit all for treatment
- Link those with ongoing SUD to addiction services but do not delay HCV treatment
- Be sure to link patients with ongoing SUD to harm reduction and support services

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM

Thank you!

Hope McGratty, PA-C, MPH, AAHIVS
hmmcgratty@anthc.org // 907-729-1560

www.anthc.org/hep

ANTHC Resources

- ANTHC Liver Disease and Hepatitis Program
  - anthc.org/hep
  - 907-729-1560

- AK ID ECHO: HCV, HIV, PrEP and common STIs
  - Second Tuesday of each month from 12:00-1:00 PM AKST
  - akidecho@anthc.org // anthc.org/ak-id-echo

- LiverConnect ECHO
  - Fourth Tuesday of each month from 8:00-9:00 AM AKST
  - liverconnect@anthc.org // anthc.org/hep

- ANTHC AETC Program
  - AETC@anthc.org
  - 907-729-2907