Simplified Hepatitis C Treatment Training Course

Provided by the ANTHC Liver Disease & Hepatitis Program

with support from the ANTHC Cancer Prevention Services

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LIVER DISEASE & HEPATITIS PROGRAM

AGENDA	PRESENTER
Overview of Hepatitis C Screening for Hepatitis C Confirmation of HCV	Brian McMahon, MD
Who should be treated Exclusions and Considerations Assessment of patient before treatment Fibrosis assessment using FIB-4, cirrhosis assessment, labs and FibroScan Audit-C, PHQ-9 and when to refer	Lisa Townshend-Bulson, APRN, FNP-C
Treatment options available Choosing appropriate treatment Drug interactions Medication coverage, prior authorization, patient assistance programs Monitoring during treatment Follow up after treatment is completed Checking for SVR, follow up for those with advanced fibrosis, treatment failure, reinfection	Annette Hewitt, APRN, FNP-C
Harm reduction, HIV and Syphilis Case Studies using the Simplified Treatment Algorithm	Leah Besh, PA-C

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Land Acknowledgement

Out of great respect, we acknowledge the Creator of all living things and the original inhabitants upon whose traditional lands we respectively now gather or reside.

Let us, forever, remember the benefits and bounty of the vast resources that stem from these traditional lands, and thank the original inhabitants for their past and present stewardship of the resources (i.e., waters, plants, animals), and the spiritual practices which they cherish on the lands we now call home.

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- Please keep camera and mic off during presentation until Q&A. Type questions and comments in the chat box anytime.
- This live session will be recorded for enduring access
- **Number of contact hours: 1.5**
- Please fill out evaluation form to receive credits. Evaluation form will be emailed at the end of the training. Certificates will be sent out once evaluation form is complete.

Following completion, all participants will receive a kit including:

- notebook
- scroll pen with simplified treatment information
- magnet
- t-shirt (limited supply of sizes).

Expect an email to provide your t-shirt size and mailing address.

Please contact mjwehrli@anthc.org or 907-729-1599 with questions.

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INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Alaska Native Medical Center (ANMC) is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Welcome to the HCV Simplified Treatment Training

Approved Provider Statements:

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CPE Credit will be posted to the online CPE Monitor system within 60 days following completion of each activity when applicable.

Contact Hours:

ANMC designates this activity for a maximum of 1.5 contact hours, including 0.5 total pharmacotherapeutics contact hours.

ENDURING ACCESS FOR CREDIT AVAILABLE UNTIL AND EXPIRES DECEMBER 2, 2022

Financial Disclosures:

Lisa Townsend-Bulson, planner and faculty for this event is the Primary Investigator for a HCV treatment grant sponsored by ANTHC with grant funded in part by Gilead Sciences. None of the additional presenters and planners for this educational activity have any relevant relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Requirements for Successful Completion:

To receive CE credit please make sure your attendance is documented, actively engaged in the entire activity, and completed the course evaluation form.

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

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Current Hepatitis C Treatment Hurdles

Hep C blood test is done – result positive

Patient seen by provider in local clinic

Patient is referred for test for fibrosis assessment

Patient is seen by specialist or specialist is consulted

Eventually, patient is treated by local clinic or the specialist

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Simplified HCV Treatment – Changing Mindset About Hepatitis C

- Sees hepatitis C as an infection that should be treated ASAP
- Removes barriers to HCV treatment
- Recognizes that simple FIB-4 calculation is a valid assessment of liver fibrosis
- Recognizes that hepatitis C treatment is effective and can prevent cirrhosis and liver cancer

Treatment is prevention

Treatment is prevention

Treatment is prevention

Treatment is prevention

Treatment is prevention

Treatment is prevention

Treatment is prevention

Treatment is prevention

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Hepatitis C Infection: Epidemiology and Disease Outcome

Brian J McMahon MD

Medical and Research Director

ANTHC Liver Disease and Hepatitis Program

Conflict of Interest Disclosure Statement

I have nothing to disclose for this presentation.

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The Two Epidemics of Hepatitis C in the USA and Alaska

- Epidemic in the 1960's, 1970's and early 1980's
  - Related to IDU use, unscreened blood transfusions, unregulated tattooing, body piercing and lack of universal precautions before HIV
    - 60%-70% due to IDU
    - 30%-40% due to lack of universal precautions
- Current epidemic since 2010 from recent surge in injection opioid and other drug use
  - Up to 90% of PWIDs will acquire HCV infection within one year of starting

Source:
www.cdc.gov/hepatitis/statistics/surveillanceguidance/HepatitisC.htm

About Hepatitis C

- Hepatitis C is the most common blood-borne pathogen in the U.S.
- More than 3 million Americans are living with HCV with 17,000 new cases identified each year.
- It is the leading cause of complications from chronic liver disease.
- Prior to COVID-19, it was associated with more deaths than the top 60 reportable infectious diseases in the US combined.
- Only 55.6% of adults diagnosed with HCV reported knowing they had hepatitis C.
- The highest rates of chronic HCV are seen in American Indian/Alaska Native people.

Source: www.cdc.gov/hepatitis/hcv/index.htm

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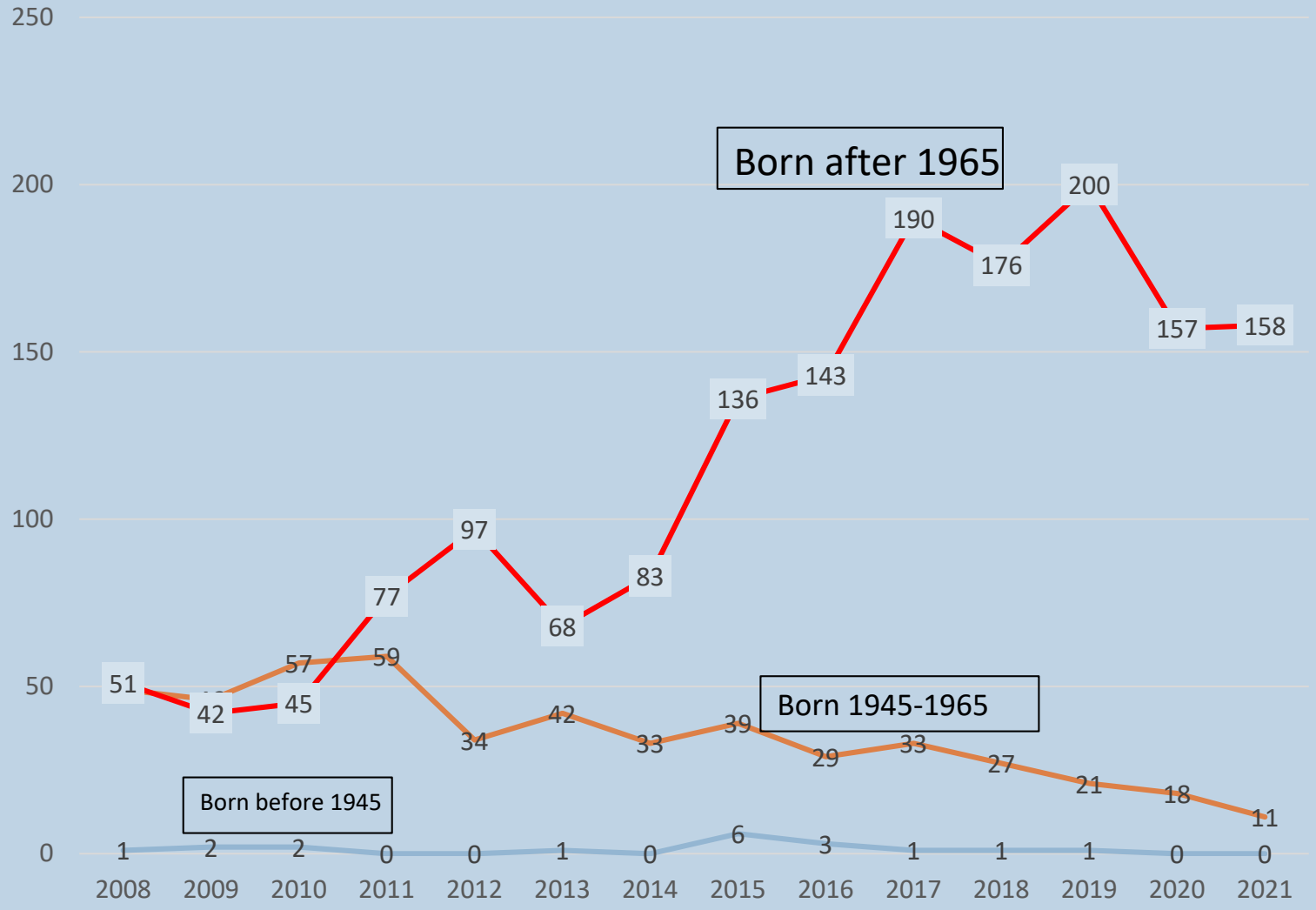
Estimate of HCV Infected Persons in State of Alaska

Due to the opioid epidemic, the influx of persons with new HCV diagnosis far outstrips number of persons with HCV who have been treated and cured

Hepatitis C On the Rise: Data from ANTHC



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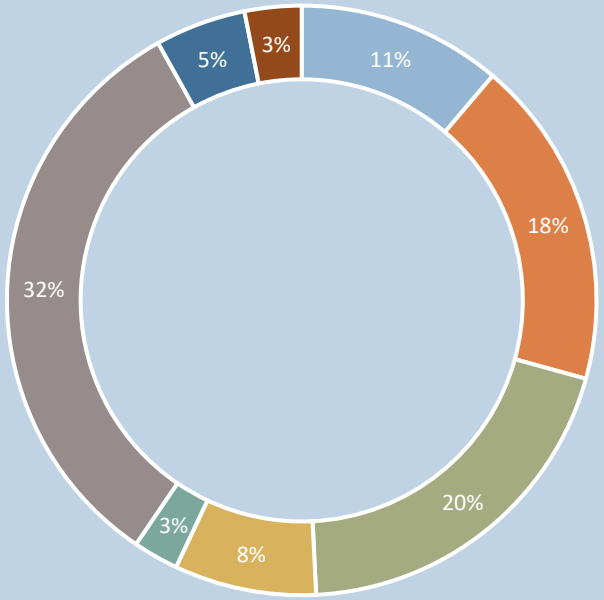
Where is Hepatitis C found in Alaska?

Diagnosed, Untreated HCV in AN/AI Persons Outside Anchorage Area



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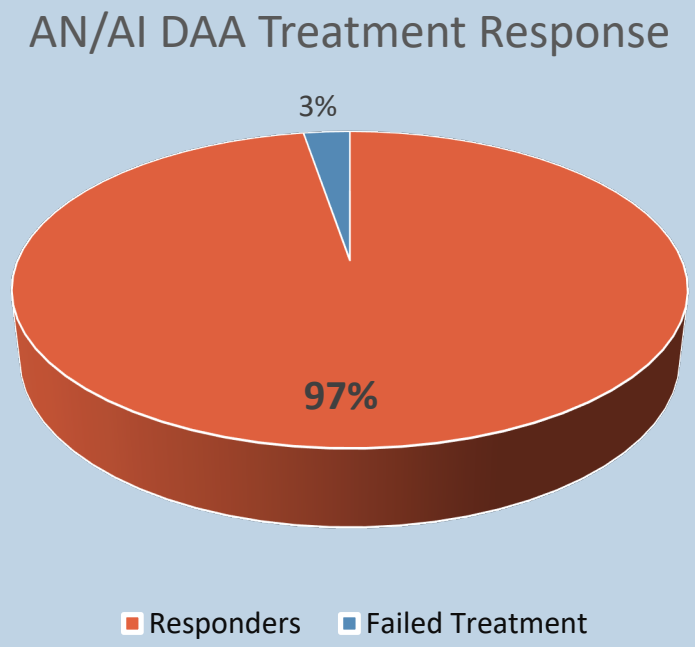
Direct Acting Antiviral HCV Treatment

- 1174 Started on Treatment
- 42 currently on treatment
- 90 pending SVR
- 994 responders
- 20 discontinued but responders
- 12 discontinued and failed tx
- 15 treatment failures/relapse

SVR rate 1014/1042 = 97%

28 known re-infections after completing treatment



Townshend-Bulson, E Roik, Y Barbour, D Bruden et al. The Alaska Native/American Indian Experience of hepatitis C treatment with sofosbuvir-based direct acting antivirals. PLOS One, https://doi.org/10.1371/journal.pone.0260970, 12/2/21.

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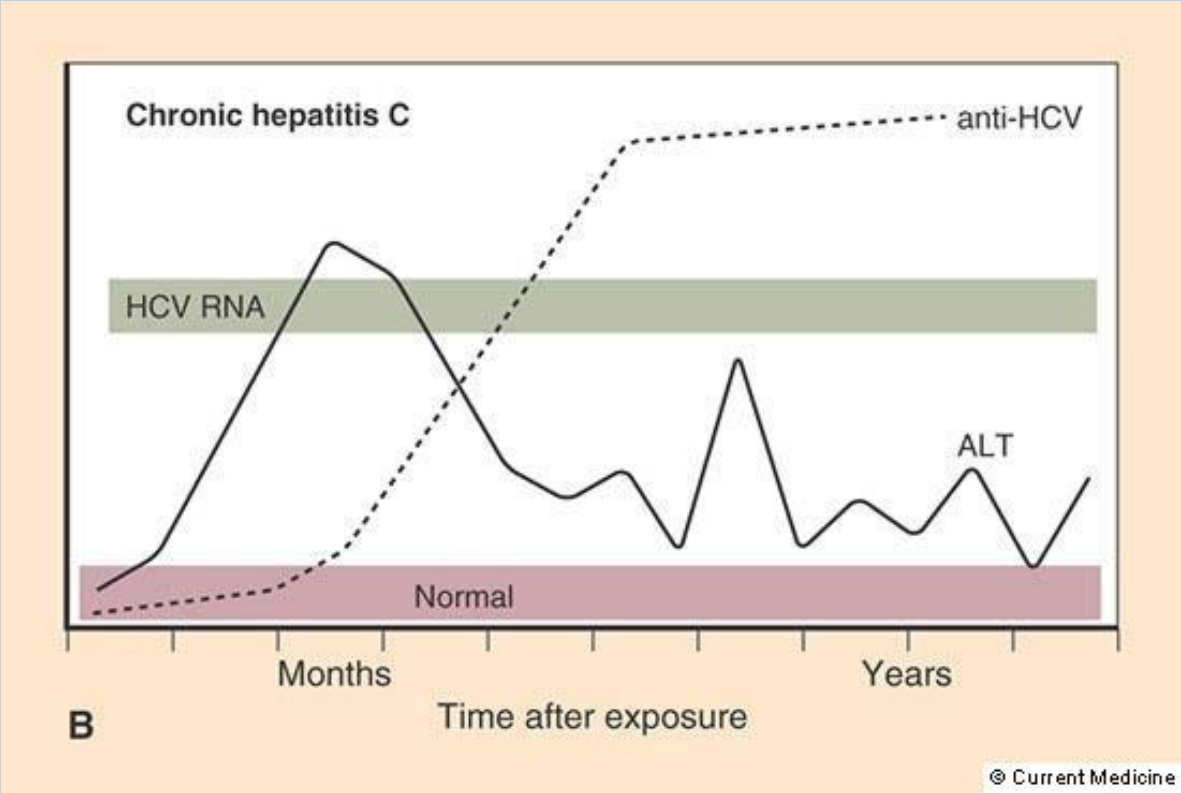
HCV Modes of Transmission & Persons to Screen

- Contaminated Needles:
  - Injection drug use: Accounts for about 60% to 70% in baby boomers and > 90% of new infections in US
  - Unsafe medical procedures: In baby boomers and in developing world
  - Sexual Contact: Low except in persons Rare in monogamous heterosexual couples
- Transfusion/Organ transplant before 1992
- Perinatal: ~ 8 to 10%; 15%-20% with HIV
- Other potential factors: tattooing, snorting cocaine, sharing tooth brushes/razors, body piercing, incarceration, men who have sex with men
- Baby Boomers born 1945-1965 (3.5% have been exposed)

Source: www.cdc.gov/hepatitis/hcv/statisticshcv.htm

Serology and HCV RNA in Acute to Chronic Hepatitis C



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AMERICAN LIVER FOUNDATION®
Your Liver. Your Life.

Hepatitis C Virus Confirmation

OraQuick® Fingerstick test for Hepatitis C Antibody

→ POSITIVE →

Blood Draw Test for HCV RNA

↓

POSITIVE

↓

PERSON HAS ACTIVE HEPATITIS C INFECTION

→ **Connect patient for Treatment**

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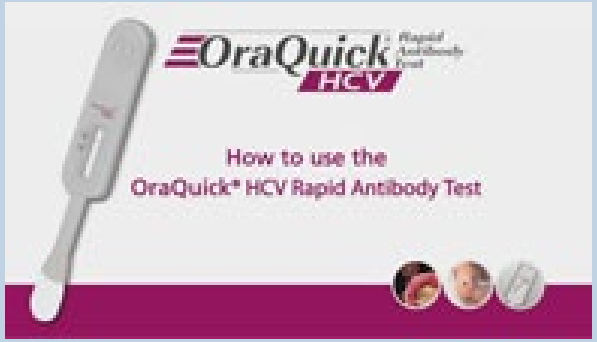
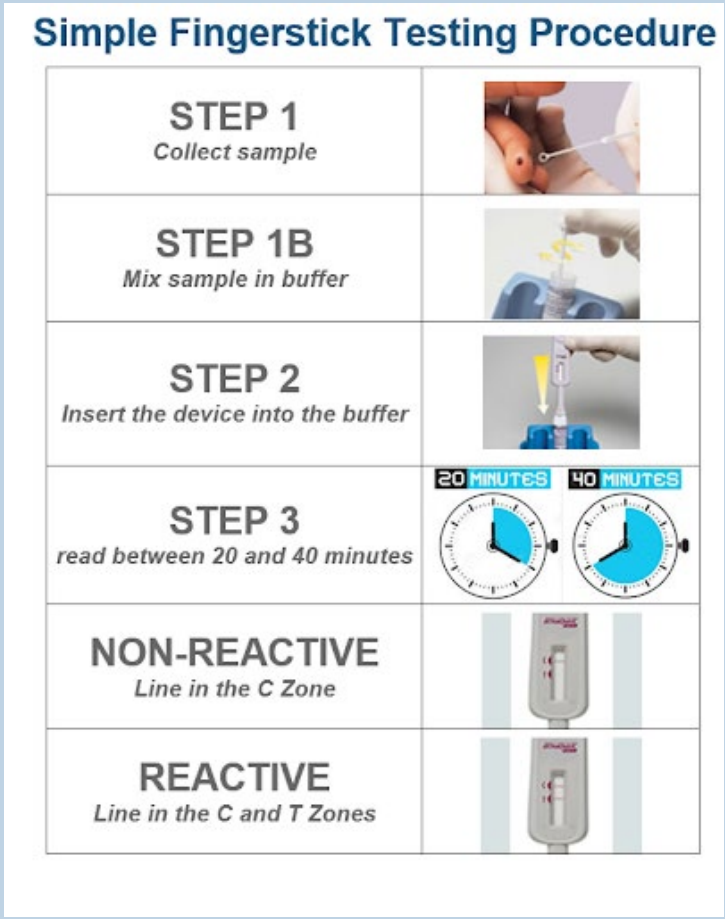
www.anthctoday.org/community/hep/providers
http://www.hcvguidelines.org/full-report-view

Rapid HCV Antibody Test





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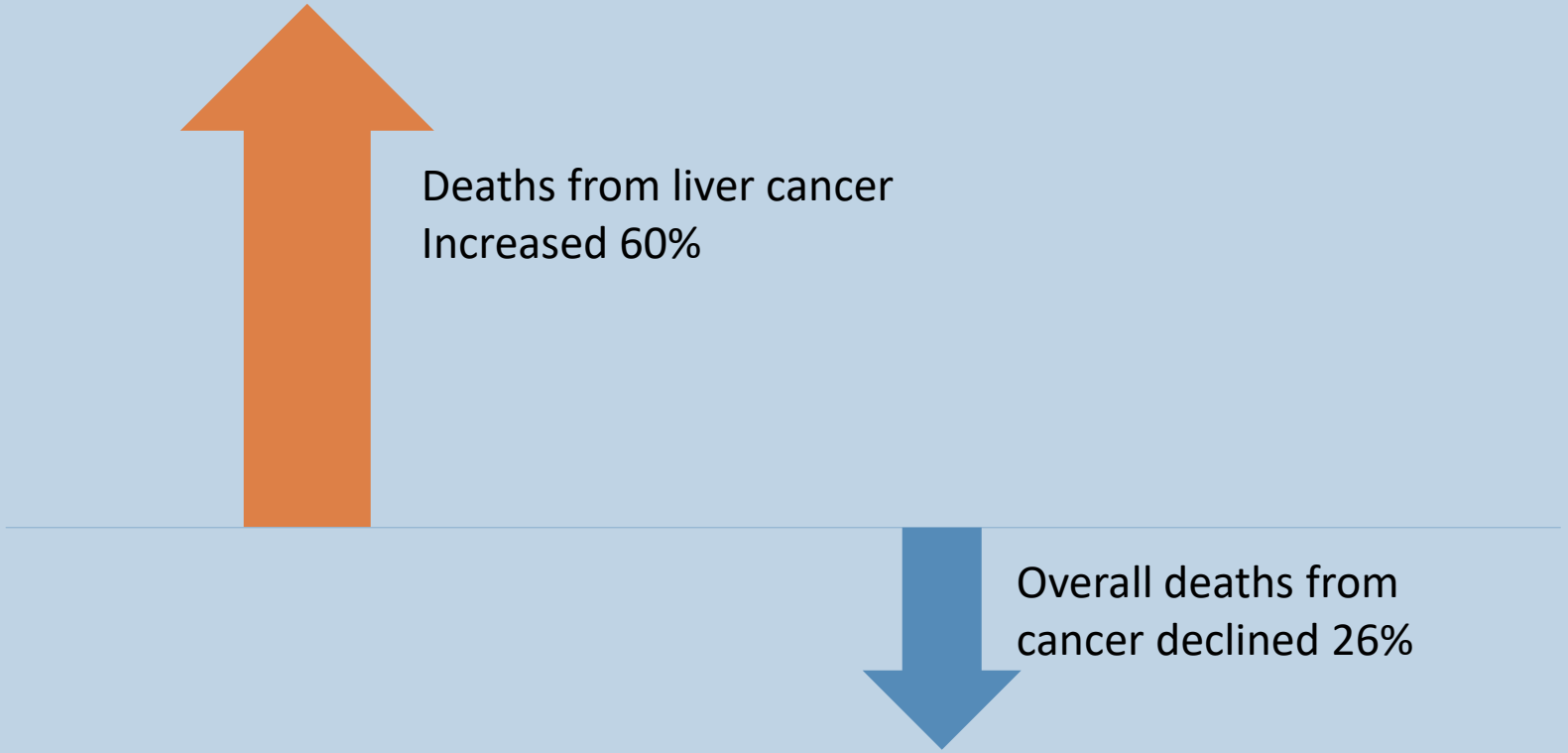
Deaths from Cancer, 1990-2015



Source: www.cdc.gov/cancer/dcpc/data/index.htm

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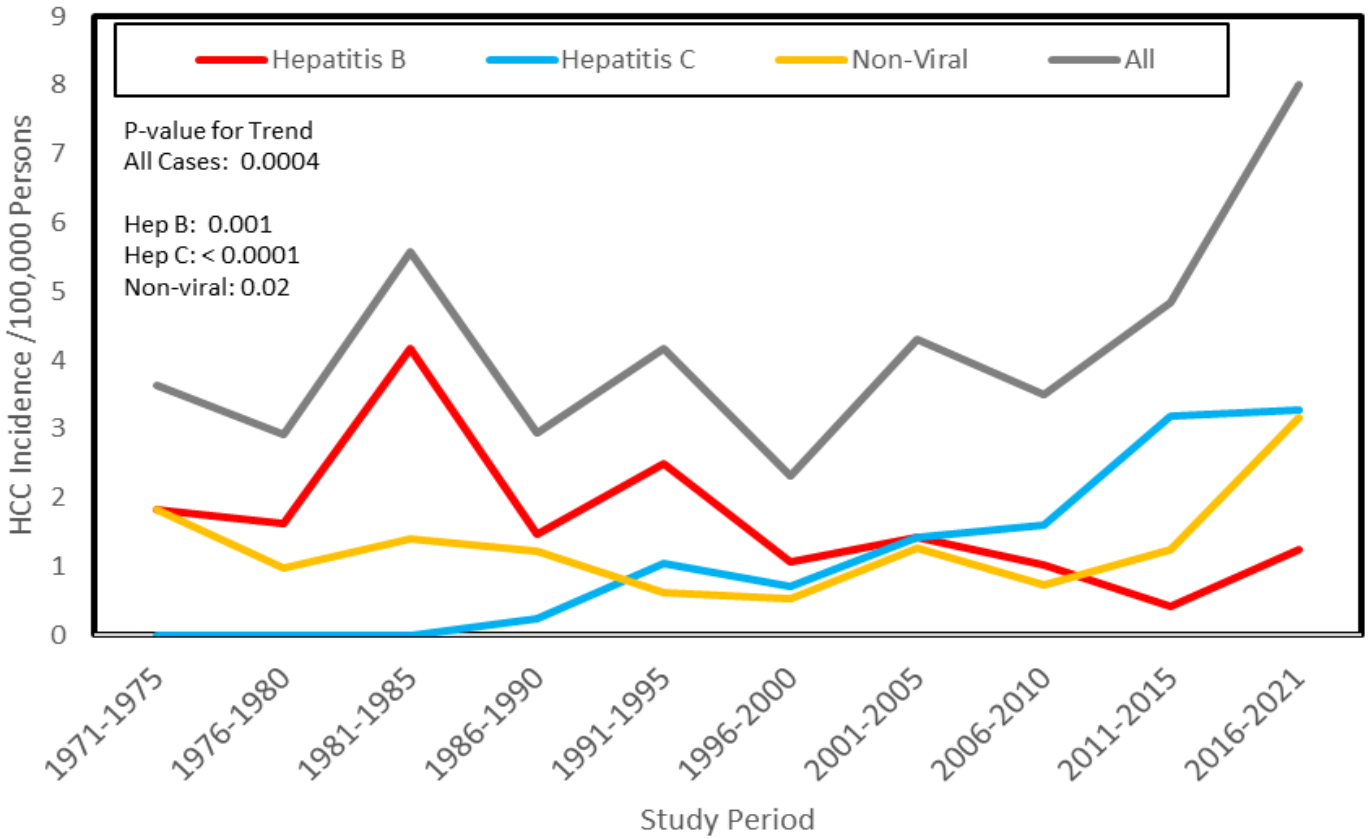
Hepatocellular Carcinoma (HCC) in Alaska Native People: 1997- to 2021



Source: www.cdc.gov/cancer/uscs/about/data-briefs/no13-liver-cancer-incidence-aian-prcda-2012-2016.htm

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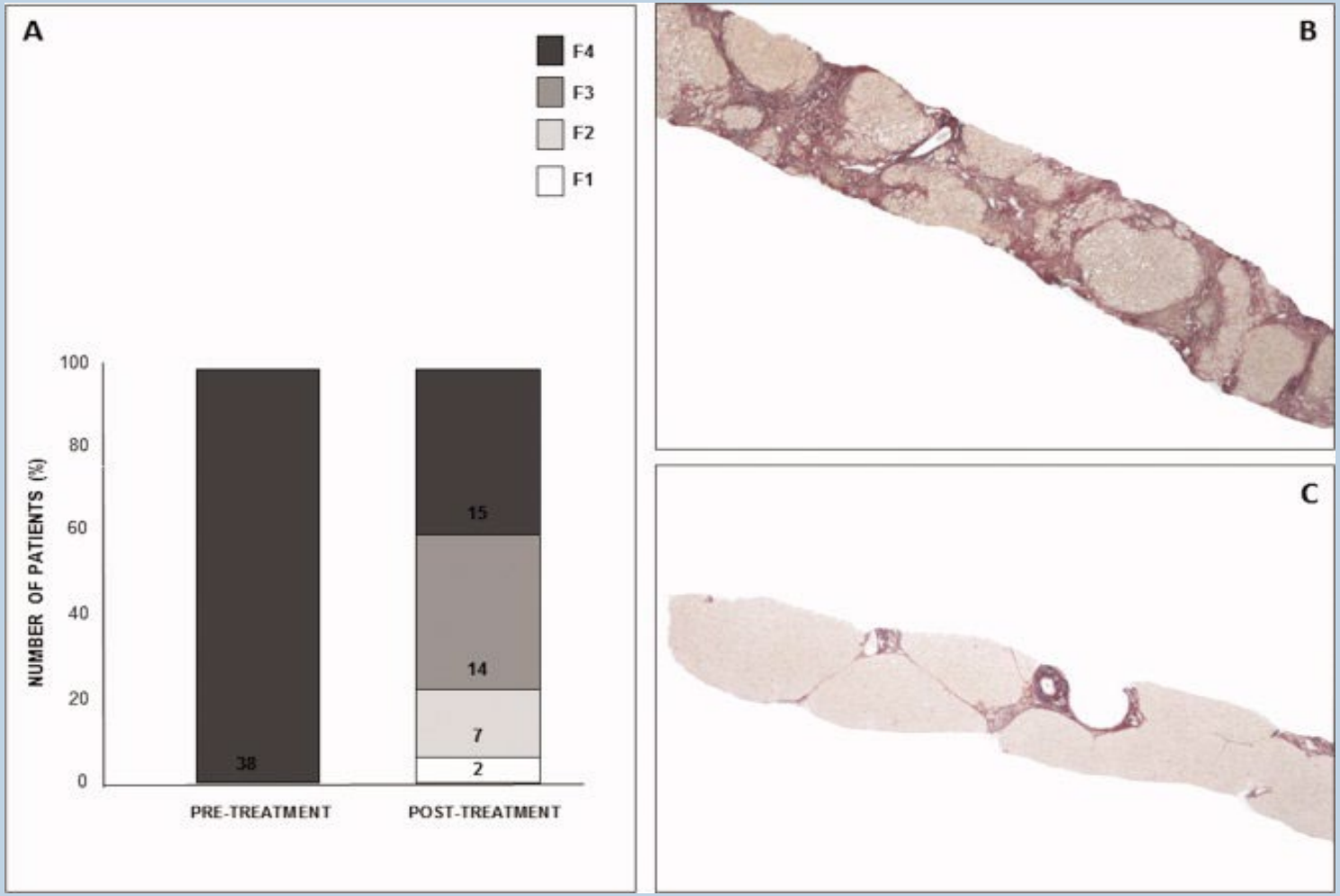
Assessing Fibrosis Stage in Persons with Chronic HCV: Why is this important

- Medicaid and most insurers in Alaska no longer require fibrosis staging
  - Persons actively using drugs or alcohol can be treated
- Fibrosis remains important to identify those persons with advanced fibrosis or cirrhosis (F3-F4)
    - Appearance of HCC may occur in persons in first 1-2 years after they are treated and have an SVR as they may have a pre-existing malignancy present to small to detect
      - Highest risk in persons whose AFP does not fall to normal after SVR
    - In general, in persons cured of HCV by interferon therapy the future risk of HCC does decrease up to 75% over the following 5 to 10 years
    - Extent of reduction in rate of HCC has not been determined after DAA SVR
    - Persons with pre-existing advanced fibrosis or cirrhosis are still at risk and need regular surveillance with AFP and liver US every 6 months

Good News: Early Cirrhosis Can be Completely Reversed!

- Remove the cause of cirrhosis and reversal will take place over about 10 years
- Even 30% to 50% of persons with decompensated cirrhosis will become compensated (look normal clinically and by LFT) after proper treatment

A morphometric and immunohistochemical study to assess the benefit of a sustained virological response in hepatitis C virus patients with cirrhosis



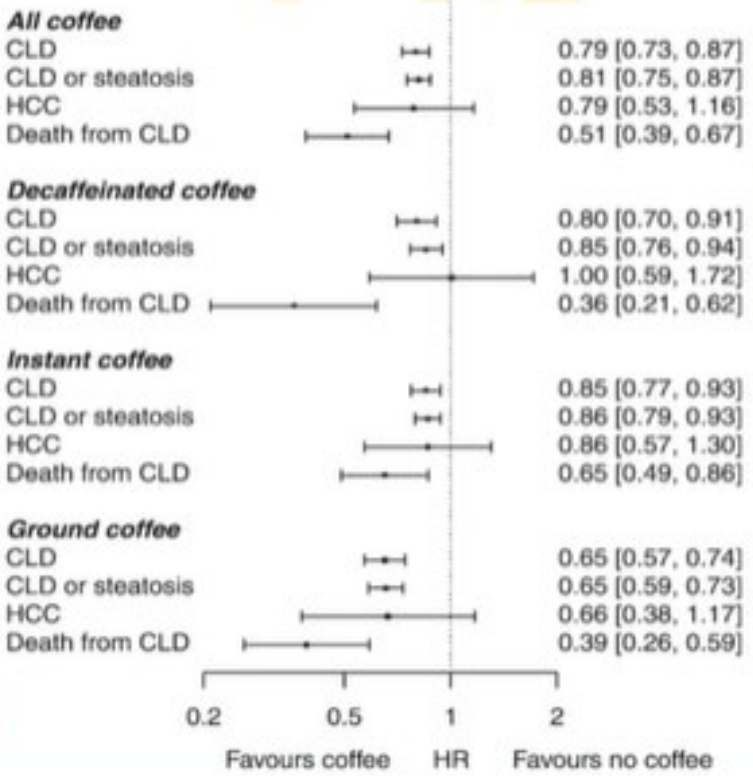
Source: Hepatology Volume 56, Issue 2, pages 532-543, available online: http://onlinelibrary.wiley.com/doi/10.1002/hep.25606/full#fig1

How Can the Incidence and Prevalence of HCV in the US be Reduced in the Near Future? CDC, IHS, AASLD, IDSA and IOM Recommendations

- USPSTF/CDC now recommend universal screening all adults one time ages 18-79 : Insurers will cover
  - Baby boomers: ~50% can have advanced fibrosis/cirrhosis
- Other high risk groups: screen more frequently
  - PWID
  - Persons with a history of incarceration
  - All Pregnant women
- Risk reduction:
  - Counseling and availability of clean needles
  - Alcohol and drug rehabilitation
  - Diet and exercise to avoid or help those with NAFLD
  - Coffee: Both caffeinated and decaf: multiple studies confirm

All coffee types decrease the risk of adverse clinical outcomes in chronic liver disease

- 494,585 UK Biobank participants
- Linkage to hospital, death and cancer records
- Adjusted HRs: age, sex, deprivation, smoking status, diabetes, ethnicity, alcohol frequency and BMI



Kennedy OJ., BMC Public Health 2021

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Screening and Treatment is Cost Saving

- By following USPSTF and CDC recommendations for screening finding persons with HCV infection can save future costs of:
  - Care and hospitalizations for liver failure including Liver Transplant evaluation
  - Care and hospitalizations for hepatocellular carcinoma
- Early detection and treatment will reduce future death rates and save lives!

Conclusions:

- Widespread screening for HCV and treatment of infected persons:
  - Is cost effective
  - Saves lives
  - Prevents liver cancer
  - Saves costs and work of care in the future
  - Creates the most grateful patients you will ever encounter

Patient Assessment – Pre-Treatment Workup

Lisa Townshend-Bulson, MSN, FNP-C

Program Director, ANTHC Liver Disease & Hepatitis Program

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Disclosure

The ANTHC Liver Disease & Hepatitis Program has an investigator-sponsored HCV treatment study which was funded in part by Gilead Sciences.
I am a co-investigator for this study.

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Who Is Eligible for Simplified Treatment*

Adults with hepatitis C (any genotype) who do NOT have cirrhosis or have compensated cirrhosis (CTP score ≤ 6) and persons who have not previously received HCV treatment

*ANTHC Simplified Treatment has been adapted from AASLD/IDSA HCV Guidelines available at: www.hcvguidelines.org/

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Who Is *NOT* Eligible for Simplified Treatment

Patients who have any of the following:

- Prior HCV treatment
- Current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score > 6 or presence of ascites, hepatic encephalopathy, total bilirubin > 2.0mg/dL, albumin $\leq$ 3.5g/dL, or INR $\geq$ 1.7
- HIV positive
- HBsAg positive
- Current pregnancy
- End-stage renal disease (i.e. eGFR <30mL/min/m^2)
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

Simplified Treatment – 3 Easy Steps

1. Determine FIB-4 score (need age, ALT and AST, and platelet count)
2. Get pre-treatment labs
3. Write Prescription

www.anthc.org/hep/hep-c-treatment-information

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Fibrosis-4 (FIB-4) Calculator

Share

The Fibrosis-4 score helps to estimate the amount of scarring in the liver. Enter the required values to calculate the FIB-4 value. It will appear in the oval on the far right (highlighted in yellow).

$$\text{FIB-4} = \frac{\text{Age } (\textit{years}) \times \text{AST Level } (\textit{U/L})}{\text{Platelet Count } (\textit{10}^9/\textit{L}) \times \sqrt{\text{ALT } (\textit{U/L})}} =$$

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

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FIB-4 Calculation for Fibrosis in Hepatitis C

< 1.45 > 3.25

Cutoff ruling out advanced fibrosis/cirrhosis (Metavir F3/F4)	**< 1.45 = No significant fibrosis** Proceed with Simplified Treatment
Negative predictive value of FIB-4 < 1.45 = 90%	
Cutoff for ruling in advanced fibrosis/cirrhosis (Metavir F3/F4)	**> 3.25 = Advanced fibrosis/cirrhosis**
97% specificity and 82.1% positive predictive value for advanced fibrosis/cirrhosis	

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Source: Sterling RK, Lissen E, Clumeck N, et. Al. Development of a simple noninvasive index to predict significant fibrosis patients with HIV/HCV coinfection, Hepatology 2006;43:1317-1325.

Evaluating fibrosis

- Why is it important?
  - Identifies those with advanced disease who will need liver cancer (hepatocellular carcinoma or HCC) screening and additional long term follow up after cure
  - Determines appropriate treatment & duration of treatment

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HCV Simplified Treatment For AK Tribal Health System

www.anthc.org/hep/hep-c-treatment-information

Start here

Calculate FIB-4

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

FIB-4 < 1.45
No Cirrhosis

FIB-4 1.45-3.25
Indeterminate Fibrosis

FIB-4 > 3.25 Cirrhosis
Patient should be referred to Liver Clinic for cirrhosis evaluation and follow up.
Treatment process as identified below:

Obtain FibroScan (Anchorage area) or serum fibrosis test (rural/remote clinics). Follow link in green, then proceed with algorithm as above based on whether patient has **No Cirrhosis** or **Cirrhosis**.

https://anthc.org/wp-content/uploads/2022/03/Fibrosis-Interpretation.pdf

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

CTP ≤ 6

CTP > 6

Proceed with Simplified Treatment Step 2

Liver Clinic will provide treatment recommendations
Note: This can be done by consult. PCP can treat patients with compensated cirrhosis, if comfortable.

Liver Clinic will treat persons with decompensated cirrhosis

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Indeterminate Fibrosis

Fib-4 = 1.45 to 3.25

Send for FibroScan or draw serum fibrosis test

Fibrosis Interpretation

For serum fibrosis tests such as **FibroSure** (Labcorp) or **FibroTest** (Quest), use the following cutoffs:			**FibroScan**			
F0-F2	**F3***	**F4***	**F0-F1**	**F2**	**F3**	**F4**
< 0.48	0.48-0.74	> 0.74	< 8.4	8.4 – 9.5	9.6 – 12.7	≥ 12.8

F0-F3 = Treat as No cirrhosis **F4 = Cirrhosis**

*Those with scores indicating F3-F4 fibrosis prior to treatment (highlighted in yellow) should undergo surveillance for hepatocellular carcinoma with RUQ US and AFP every 6 months. Consult Liver Disease Specialist with any questions.

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Serum Fibrosis Tests

1. HCV FibroSure (LabCorp/Code 550123)
   Negative predictive value85%
2. HCV FibroTest-ActiTest (Quest/Code 92688)

Prep: 8 hour fast recommended

3-5 day turnaround

Sensitivity 75%, specificity 85%

LabCorp — Patient Report

Specimen ID: 350-988-9500-0
Control ID:

SAMPLE REPORT, 550123

Acct #: 90000999 Phone: (336) 436-8645 Rte: 00
LabCorp Test Master
Test Account
5450 Millstream Road
MCLEANSVILLE NC 27301

Patient Details
DOB: 01/01/1960
Age(y/m/d): 059/11/15
Gender: F SSN:
Patient ID:

Specimen Details
Date collected: 12/16/2019 0000 Local
Date received: 12/16/2019
Date entered: 12/16/2019
Date reported: 12/17/2019 0000 ET

Physician Details
Ordering:
Referring:
ID:
NPI:

General Comments & Additional Information
Clinical Info: NORMAL REPORT

Ordered Items
HCV FibroSure

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
HCV FibroSure					
HCV FibroSURE Results:					01
Fibrosis Score	**0.55**	**High**		0.00 - 0.21	01
Fibrosis Stage					01
F2 - Bridging fibrosis with few septa					
Necroinflammat Activity Score					
	0.24	**High**		0.00 - 0.17	01
Necroinflammat Activity Grade					
	A0-A1				01

Interpretations: 01
Quantitative results of 6 biochemical tests are analyzed using a computational algorithm to provide a quantitative surrogate marker (0.0-1.0) for liver fibrosis (METAVIR F0-F4) and for necroinflammatory activity (METAVIR A0-A3).

Fibrosis Scoring: 01
<0.21 = Stage F0 - No fibrosis
0.21 - 0.27 = Stage F0 - F1
0.27 - 0.31 = Stage F1 - Portal fibrosis
0.31 - 0.48 = Stage F1 - F2
0.48 - 0.58 = Stage F2 - Bridging fibrosis with few septa
0.58 - 0.72 = Stage F3 - Bridging fibrosis with many septa
0.72 - 0.74 = Stage F3 - F4
>0.74 = Stage F4 - Cirrhosis

Necroinflamm Activity Scoring: 01
<0.17 = Grade A0 - No Activity

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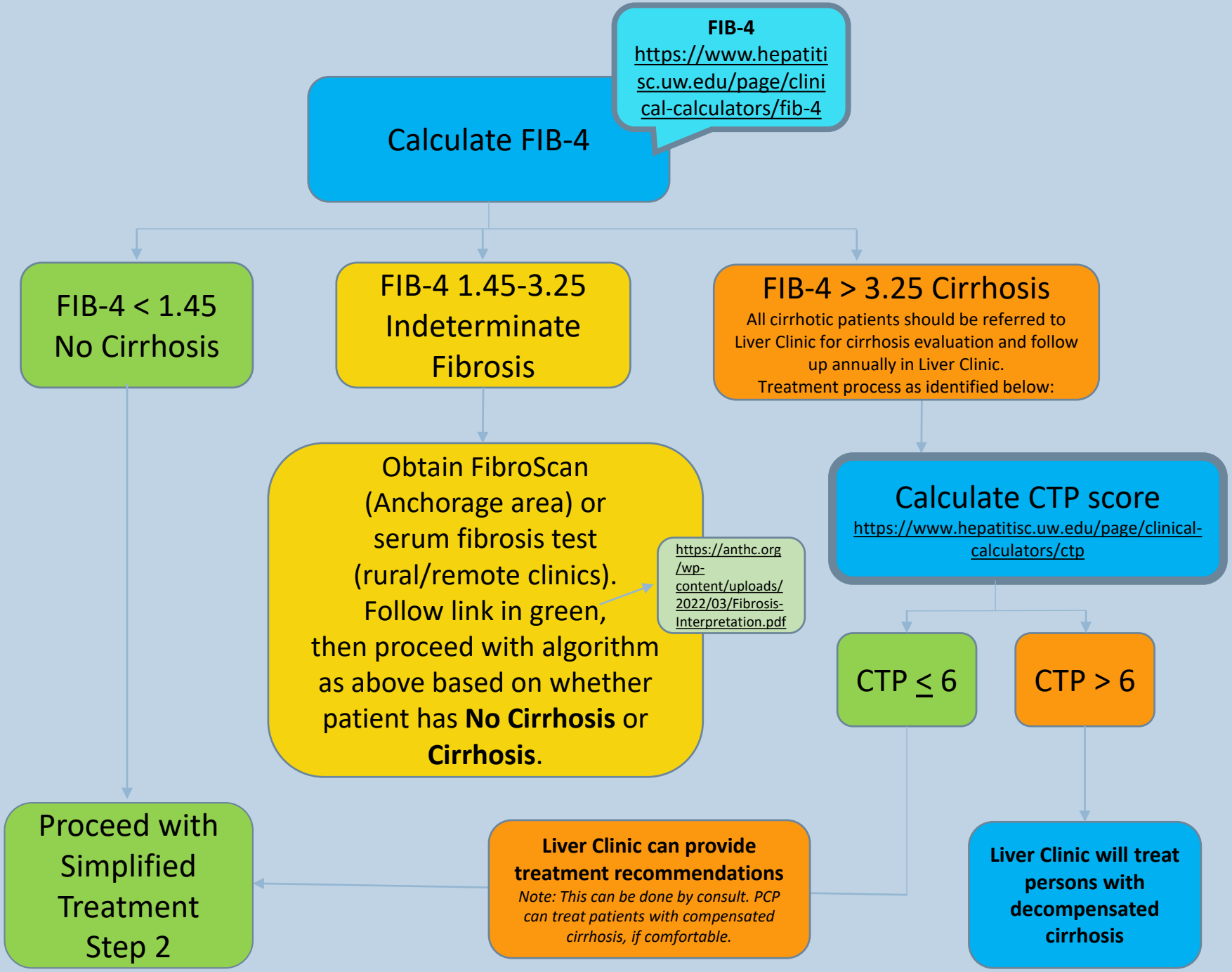
Sources: https://www.labcorp.com/tests/550123/hepatitis-c-virus-hcv-fibrosure, https://testdirectory.questdiagnostics.com/test/test-detail/92688/liver-fibrosis-fibrotest-actitest-panel?cc=MASTER, Baranova, A., Lal, P., Birerdinc, A., and Younossi, Z. Non-Invasive markers for hepatic Fibrosis. BMC Gastroenterology available at: https://bmcgastroenterol.biomedcentral.com/articles/10.1186/1471-230X-11-91

Vibration Controlled Transient Elastography aka FibroScan®

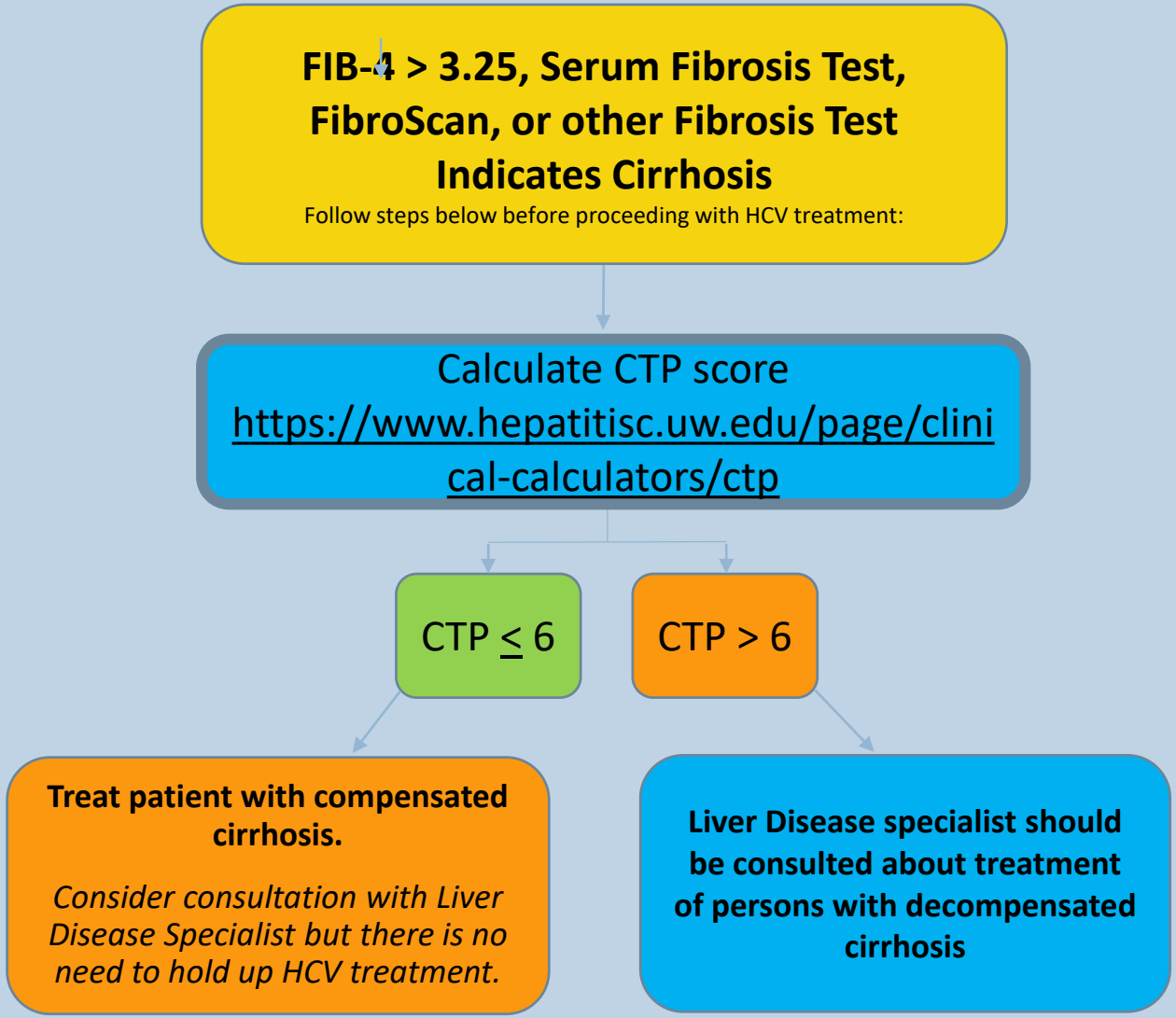
- Noninvasive test using ultrasound waves to measure liver stiffness in kPa which correlates with liver fibrosis
- Includes Controlled Attenuation Parameter (CAP™) expressed in dB/meter which correlates with liver steatosis
- Area probed is 100 times bigger than liver biopsy
- Good performance for excluding advanced stage disease (stage 3-4)
- Can have problems when patient has significant truncal obesity, if patient drank alcohol in excess recently, or if operator is inexperienced
- Negative predictive value of 97.5% for advanced fibrosis at 10.1kPa cutoff

Source:
El-Hariri, M., Megid, A., Ali, T., Hassany, M. Diagnostic value of transient elastography (FibroScan) in evaluation of liver fibrosis in chronic viral hepatitis C: compared to liver biopsy. Egyp Journal of Radiology and Nuclear Medicine, Vol. 48, no. 2, 329-327.

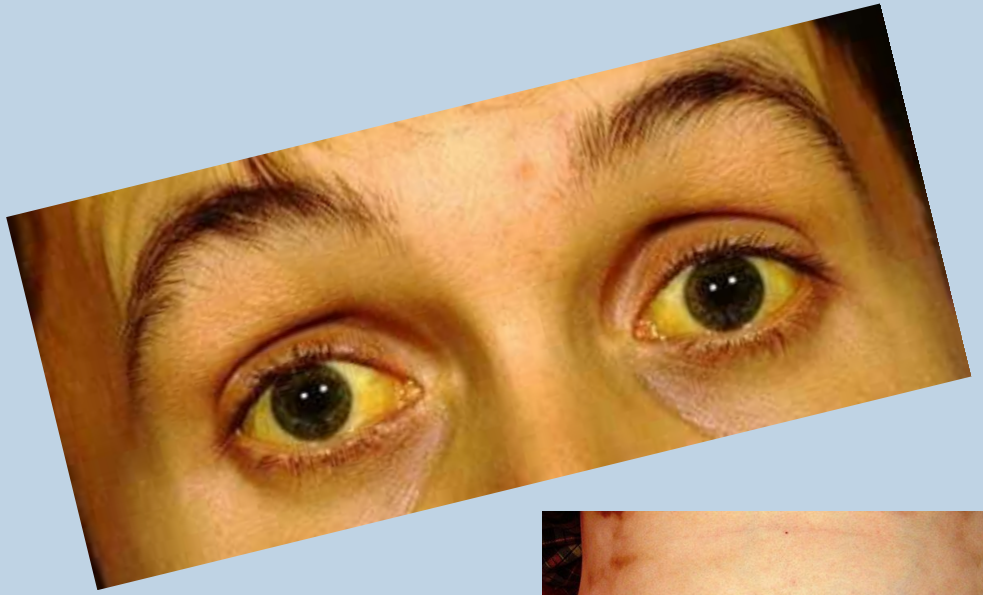
What if fibrosis test indicates cirrhosis?

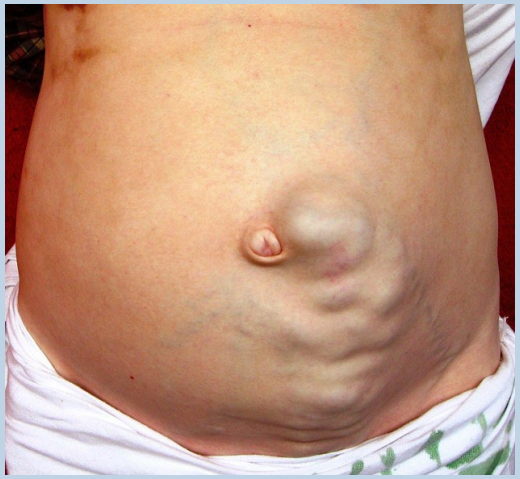


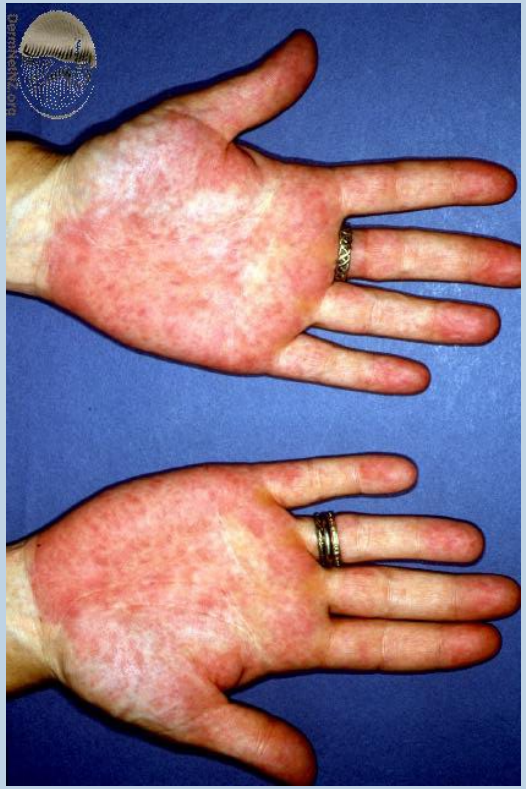
Cirrhosis –
Outside Anchorage or Outside Tribal System

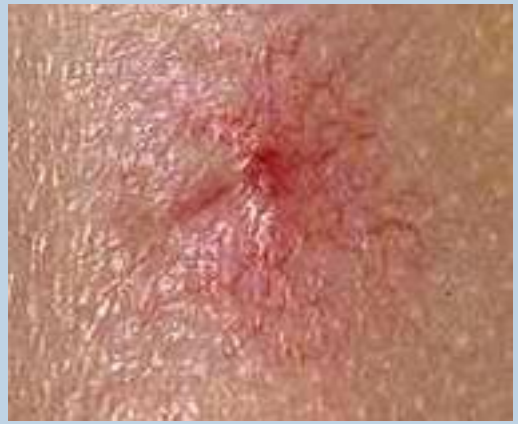


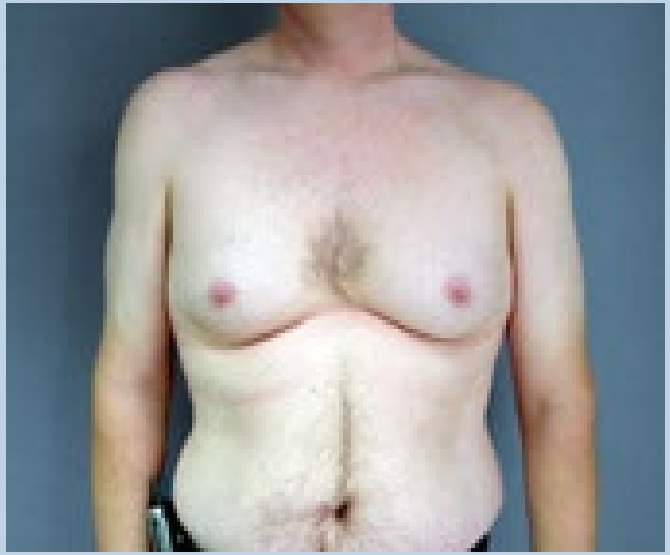
Signs of Advanced Liver Disease











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Health history review for clinical evidence of cirrhosis: liver nodularity and/or splenomegaly on imaging or platelet count < 150,000.

What else should you be aware of?

- Hepatitis C can co-exist with other forms of liver disease:
  - Alcoholic hepatitis
  - Fatty Liver Disease (NAFLD or NASH)
  - Autoimmune hepatitis (AIH)
  - Chronic hepatitis B

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Step 2. Obtain Pre-Treatment Labs

Lab Test	When Needed?
Serum fibrosis test (FibroSure or FibroTest) if FIB-4 is indeterminate (1.45-3.25). FibroScan test can be done in lieu of serum fibrosis test if available (i.e. ANMC)	Complete prior to choosing HCV medication
Pregnancy Test	Immediately prior to treatment start and counsel about pregnancy prevention during treatment
HCV RNA	Acceptable within past 6 months
Hepatic function panel and eGFR	Acceptable within past 6 months
AFP*	Acceptable within past 6 months
CBC (without differential)	Acceptable within 3 months if cirrhosis, 6 months if no cirrhosis
HIV antigen/antibody	Anytime prior
Hepatitis B surface antigen	Anytime prior
PT/INR (only needed in cirrhosis)	Acceptable within 3 months
HCV genotype (only needed if patient has cirrhosis and you are treating with sofosbuvir/velpatasvir)	Anytime prior
Hepatitis A Antibody Total IgG (not IgM)*	Only if unvaccinated against Hep A and no record of immunity

* Recommended by ANTHC Liver Disease & Hepatitis Program

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Pre Treatment Checklist

- ❑ For advanced fibrosis/cirrhosis, complete a physical exam for signs of significant liver disease: icterus, jaundice, ascites, spider angioma, gynecomastia, palmar erythema, asterixis, caput medusa)
- ❑ Determine hepatitis B status (if unknown, draw HBsAg and HBsAb) and vaccinate if all are negative
- ❑ If unvaccinated against hepatitis A and not immune, vaccinate.
- ❑ Assess mental health status, including depression (using questionnaire such as PHQ-9)
- ❑ Screen for active substance use disorder (SUD) and refer to Behavioral Health/Treatment.
- ❑ Screen for alcohol use disorder. Administer Audit-C. Counsel and refer for treatment as appropriate.
- ❑ For those with ongoing injection drug use, connect patient with syringe service program (SSP) for harm reduction/prevent reinfection (SSPs in Alaska: www.alaskanaids.org, www.interioraids.org, or www.iknowmine.org
- ❑ Review drug interactions www.hep-druginteractions.org
- ❑ Counsel re: pregnancy prevention (ethinyl estradiol not recommended with glecaprevir/pibrentasvir (Mavyret®)
- ❑ Review medication-specific information with patient at treatment start

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Thank You!

My Contact Info:
Lisa Townshend-Bulson, FNP-C
ANTHC Liver Disease & Hepatitis Program
ltownshend@anthc.org

Visit our website: **www.anthc.org/hep**
To learn more about liver diseases, tune in to our other CE programs:
LiverConnect (CE program on liver disease – 2nd Tuesdays, 8-9am)
AK ID ECHO (Didactic/Case-based Learning 2nd Tuesdays, 12n-1pm)
AK Liver Disease ECHO (Didactic/Case-based Learning 3rd Thursdays, 12n-1pm)

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HCV Treatment, Monitoring and Follow Up

Annette Hewitt, MSN, FNP-C

ANTHC Liver Disease & Hepatitis Program

Hepatitis C Treatment

Annette Hewitt, ARNP

- Medications
- Drug Interactions
- Medication Coverage
- Monitoring on Treatment
- Follow-up after Treatment

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Appropriate Treatment Regimens

No Cirrhosis

Options

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

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

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Appropriate Treatment Regimens

Compensated Cirrhosis

Options

- Glecaprevir/Pibrentasvir (Mavyret™) 3 tablets daily for 8 weeks
- Sofosbuvir/Velpatasvir (Epclusa®) [1] 1 tablet daily for 12 weeks

[1] Obtain genotype if treating with Epclusa. If genotype 3, obtain NS5A RAS testing and if Y93H RAS is negative, proceed with Epclusa treatment. If Y93H RAS is present, refer to Liver Disease Specialist.

Glecaprevir/Pibrentasvir (Mavyret)

- Glecaprevir 100mg
  - NS3/4A protease inhibitor
- Pibrentasvir 40mg
  - NS5A inhibitor
- Total daily dose 300mg/120mg
- Pangenotypic

(Treats all genotypes 1, 2, 3, 4, 5, & 6)

- Treatment duration 8 weeks for most
- AK Medicaid preferred and no PA needed

https://www.rxabbvie.com/pdf/mavyret_pi.pdf

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Glecaprevir/Pibrentasvir

- Treatment naïve or retreatment
- Not safe in decompensated cirrhosis
- Side effects – headache (18%), fatigue (15%), nausea (12%) and comparable in patients with or without cirrhosis
- Do not co-administer with rifampin, atazanavir
- Not recommended with ethinyl estradiol (most OCP's/NuvaRing) , atorvastatin, lovastatin, simvastatin

Sofosbuvir/Velpatasvir (Epclusa)

First pangenotypic Direct Acting Antiviral (DAA)

- NS5B polymerase inhibitor (sofosbuvir) and NS5A inhibitor (velpatasvir)

Treatment duration 12 weeks

Side effects

- Headache (~22%)
- Fatigue (~16%)
- Nausea (~9%)

1 pill/day

Safe in severe liver disease (decompensated)

Interactions with acid-suppressing medications:

- Omeprazole 20mg/day ok – Take 4 hrs after SOF/VEL
- Famotidine 40mg BID – Take at same time +/or 12 hrs apart
- Separate aluminum, magnesium containing antacids 4 hours apart from SOF/VEL

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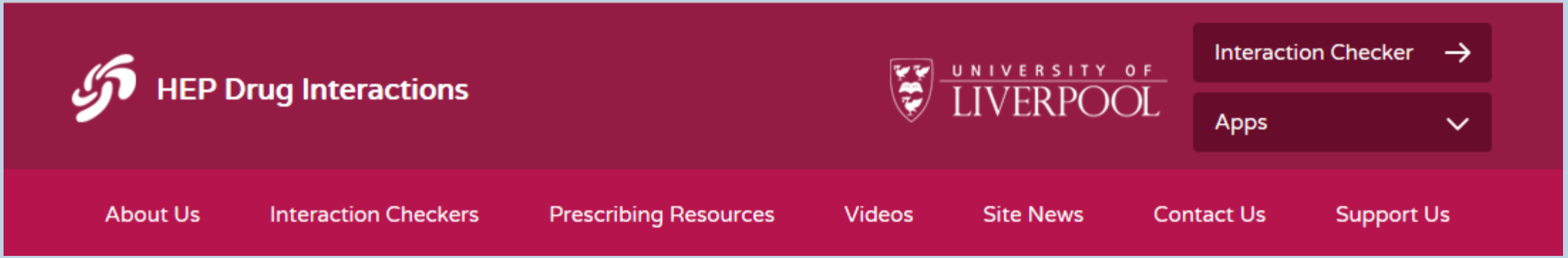
http://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf

Checking Drug Interactions



- https://www.hep-druginteractions.org

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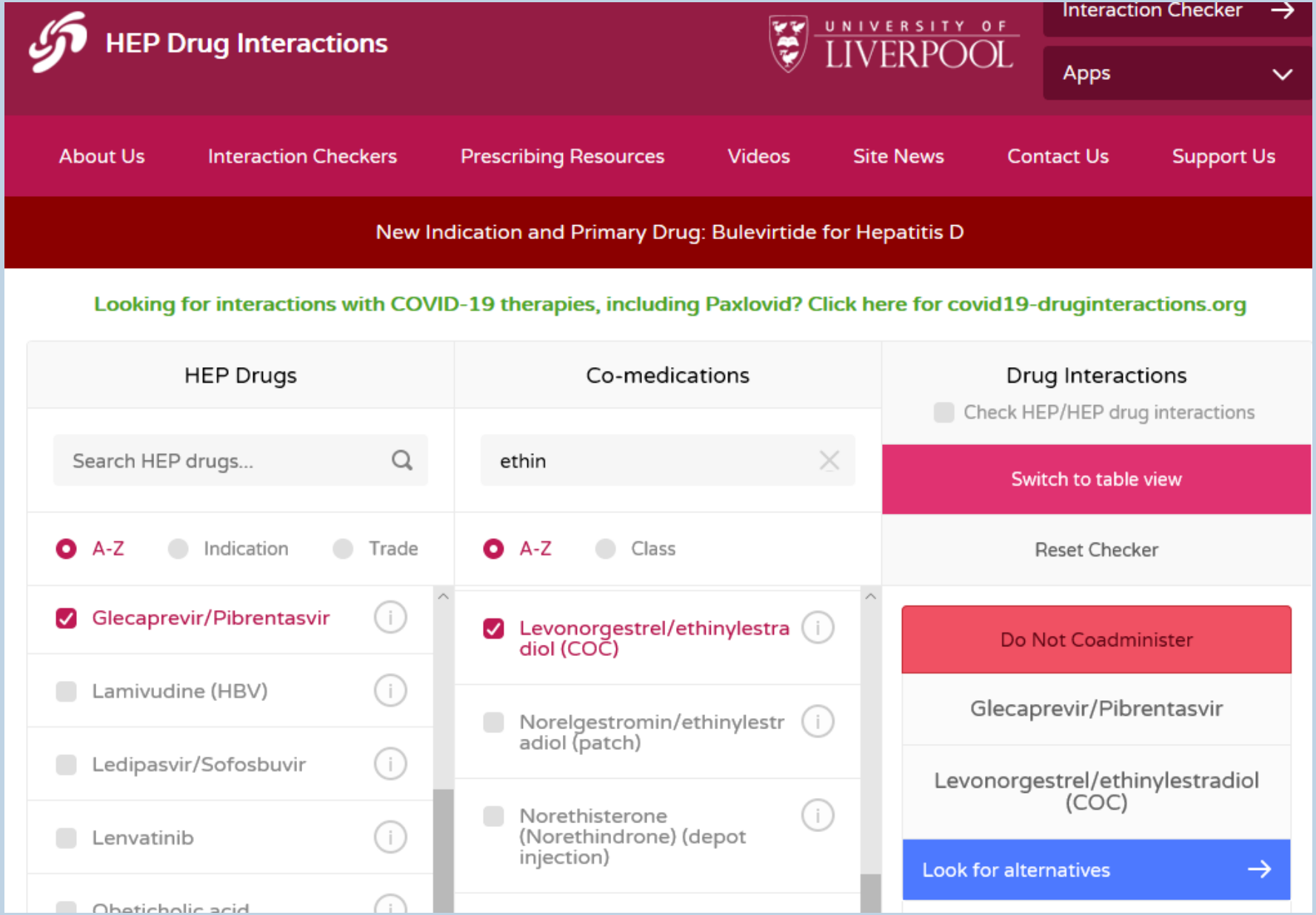
https://www.hep-druginteractions.org/



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Correctly dosing acid suppressing drugs sofosbuvir/velpatasvir (Epclusa)

Acid reducing agents decrease absorption (of sofosbuvir) negatively affecting cure if not dosed correctly.

- Antacids – [Al(OH)3 and Mg(OH)3] separate dosing from Epclusa by 4 hours
- H_2-receptor antagonists (famotidine) admin simultaneously with or 12 hours apart. Dose not to exceed equivalent to famotidine 40mg bid
- PPI's (equivalent to omeprazole 20mg)
  - Not rec, but if necessary admin. 4 hours after Epclusa and take Epclusa w/food

What about Statins?

- Watch interaction w/DAA's due to increased concentration of the statin.
  - Monitor for increased statin side effects
  - Consider lowering dose or holding.
  - Glecaprevir/Pibrentasvir (Mavyret)
    - Do not use atorvastatin, lovastatin, simvastatin
    - Caution with rosuvastatin, pravastatin, pitavistatin, fluvastatin
  - Sofosbuvir/Velpatasvir (Epclusa)
    - Caution with all statins except pravastatin

https://hep-druginteractions.org/checker

When writing prescription, identify insurer and determine if prior authorization (PA) needed

Medicaid

- Glecaprevir/Pibrentasvir (Mavyret) and Sofosbuvir/Velpatasvir (Epclusa) are both on the Alaska Medicaid Preferred Drug List - No prior authorization required.
- Any other HCV medications require PA

Medicare Part D – Prescription Drug Coverage

- Determine plan and identify preferred HCV medication on formulary
- At this time, plans require PA

Private Insurance

- Identify HCV treatment on formulary
- Obtain PA

Prescription Assistance for Uninsured or Underinsured

Non-pharmaceutical Sponsored Program

Pan Foundation

- Call 1-866-316-7263 or online www.panfoundation.org/hepatitis

Pharmaceutical Sponsored Patient Assistance Programs

myAbbvie Assist (Mavyret)

- Call 1-877-628-9738 or online www.abbvie.com

Gilead Support Path (Harvoni, Epclusa)

- Call 1-855-769-7284 or online www.mysupportpath.com

Set patient up for treatment success:

Address any issues with taking medicines:

- Allergies
- Trouble swallowing
- Remembering to take medicine

Ways to keep treatment schedule on track:

- Identify support person to remind them to take meds
- Using alerts on phone
- Using a calendar to keep track of treatment schedule
- Giving patient medication alert card

Monitoring During Treatment

- ❑No specific lab monitoring required but can be considered if clinically indicated.
- ❑In-person or telehealth/phone visit may be scheduled for patient support, assessment of symptoms, and/or new medications
- ❑Instruct patients taking diabetes medications to monitor for hypoglycemia
- ❑Inform patients taking warfarin of potential changes in their anticoagulation status. Monitoring INR for sub-therapeutic anticoagulation is recommended.
- ❑Refer to Liver Disease Specialist, any patient with worsening liver blood tests (e.g. bilirubin, AST, ALT); jaundice, ascites, or encephalopathy; or new liver-related symptoms.

Assessment of Cure (SVR)
Very Important!!!

- ❑ HCV RNA and LFT 12 weeks or more after completing HCV medication
- ❑ If ALT/AST are elevated after SVR, assess for other causes of liver disease, see Elevated LFTs Algorithm
- ❑ https://www.anthc.org/wp-content/uploads/2022/05/Elevated-LFTs-Algorithm-Workup.pdf

Follow-Up After Achieving Cure

- ❑ No liver specific follow-up necessary for patients with no-moderate fibrosis (F0-F2) who have achieved cure and have no other concurrent liver condition.
- ❑ For patients with advanced fibrosis/cirrhosis (F3/4 fibrosis), RUQ US and AFP is recommended every 6 months to screen for hepatocellular carcinoma.
- ❑ Yearly labs to assess for liver disease progression: CBC, LFTs (and AFP) for those with advanced fibrosis; CBC, CMP, PT/INR (and AFP) for those with cirrhosis.
- ❑ Counsel persons with risk for HCV infection (ongoing IVDU, MSM having condomless sex) about risk reduction and obtain HCV RNA yearly and whenever ALT, AST, or bilirubin are elevated to test for reinfection
- ❑ Counsel patients to avoid excess alcohol use. For those with cirrhosis, counsel abstinence from alcohol use.

Follow-Up for Patients Who Do Not Achieve a Cure

- ❑ Refer patient to Hepatology or other specialist for evaluation for re-treatment
- ❑ If unable to retreat, assess for liver disease progression every 6-12 months with LFT, CBC and INR
- ❑ For those with active hepatitis C, abstinence from alcohol is recommended.

Harm Reduction, HIV and STIs

Leah Besh PA-C

ANTHC Early Intervention Services and

Liver Disease & Hepatitis Program

Harm Reduction

A comprehensive prevention strategy, harm reduction is part of the continuum of care. Harm reduction approaches have proven to prevent death, injury, disease, overdose, and prevent substance misuse or disorder. Harm reduction is an effective approach to addressing the public health epidemic involving substance use as well as infectious disease and other harms associated with drug use.

https://www.samhsa.gov/find-help/harm-reduction

Harm Reduction Activities and Intended Outcomes

Incorporating harm reduction can reduce negative effects on health and social wellbeing due to use of alcohol, other drugs, and related behaviors.

Prevention Goals	Related Harm Reduction Activities*
• Reduce the spread of sexually transmitted and other blood-borne infections, including HIV and viral hepatitis • Increase knowledge around safer sex and sexual health	• Access to PrEP • Access to HIV and viral hepatitis testing and treatment • Access to condoms • Comprehensive sex education
• Reduce overdose deaths and other early deaths among people who use substances, including alcohol • Increase knowledge around safer substance use	• Syringe service programs • Fentanyl test strips • Naloxone and overdose education kits
• Reduce sharing of substance use equipment • Improve physical health • Reduce the spread of infectious diseases	• Sterile syringes and other injection equipment to prevent and control the spread of infectious diseases • Syringe Service Programs • Safe smoking supplies • Medical care including wound care • Use of masks, social distancing, and vaccines
• Reduce stigma and increase access to health services • Increase referrals to support programs and health and social services (including treatment and recovery support services)	• Counseling • Motivational interviewing • Low threshold medication for opioid use disorder • Fentanyl test strips • Naloxone and overdose education kits • Peer support specialists • Case managers

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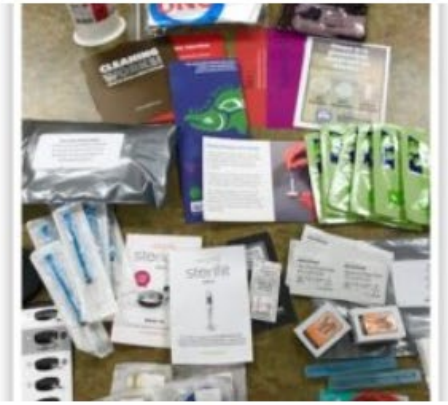
Safer Substance Use

SAFE MEDICINE DISPOSAL SYSTEMS

OVERDOSE RESPONSE | NARCAN® KIT



HARM REDUCTION KIT

FENTANYL TEST STRIPS

SAFER SUBSTANCE USE SUPPLIES

SUBSTANCE USE EDUCATION

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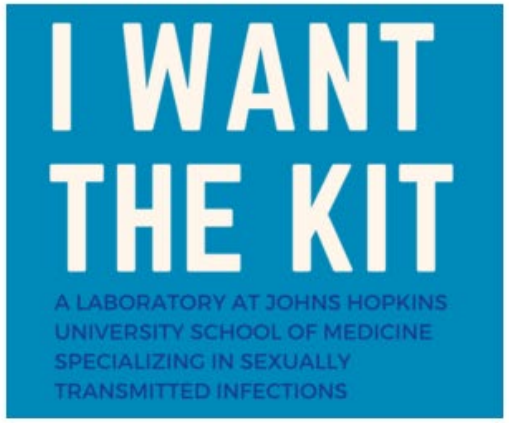
Sexual Health & Wellness

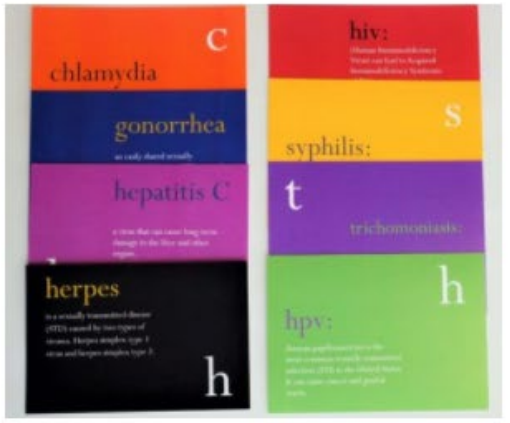
CONDOMS FOR INDIVIDUALS

CONDOMS FOR ORGANIZATIONS

HIV SELF-TEST KIT



STI SELF-TEST KIT



STI CARDS

SEXUAL HEALTH PRINTED MATERIALS

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Syringe Services Across Alaska

- Four A's: Alaskan AIDS Assistance Association
  - https://www.alaskanaids.org/prevention/syringe-exchange
- IAA: Interior AIDS Association
  - https://www.interioraids.org/what-we-do/hiv-prevention/saferdruguseandsupplies.html
- Homer Syringe Exchange
  - https://www.sphosp.org/mc-events/the-exchange/
  - Iknowmine.org/shop

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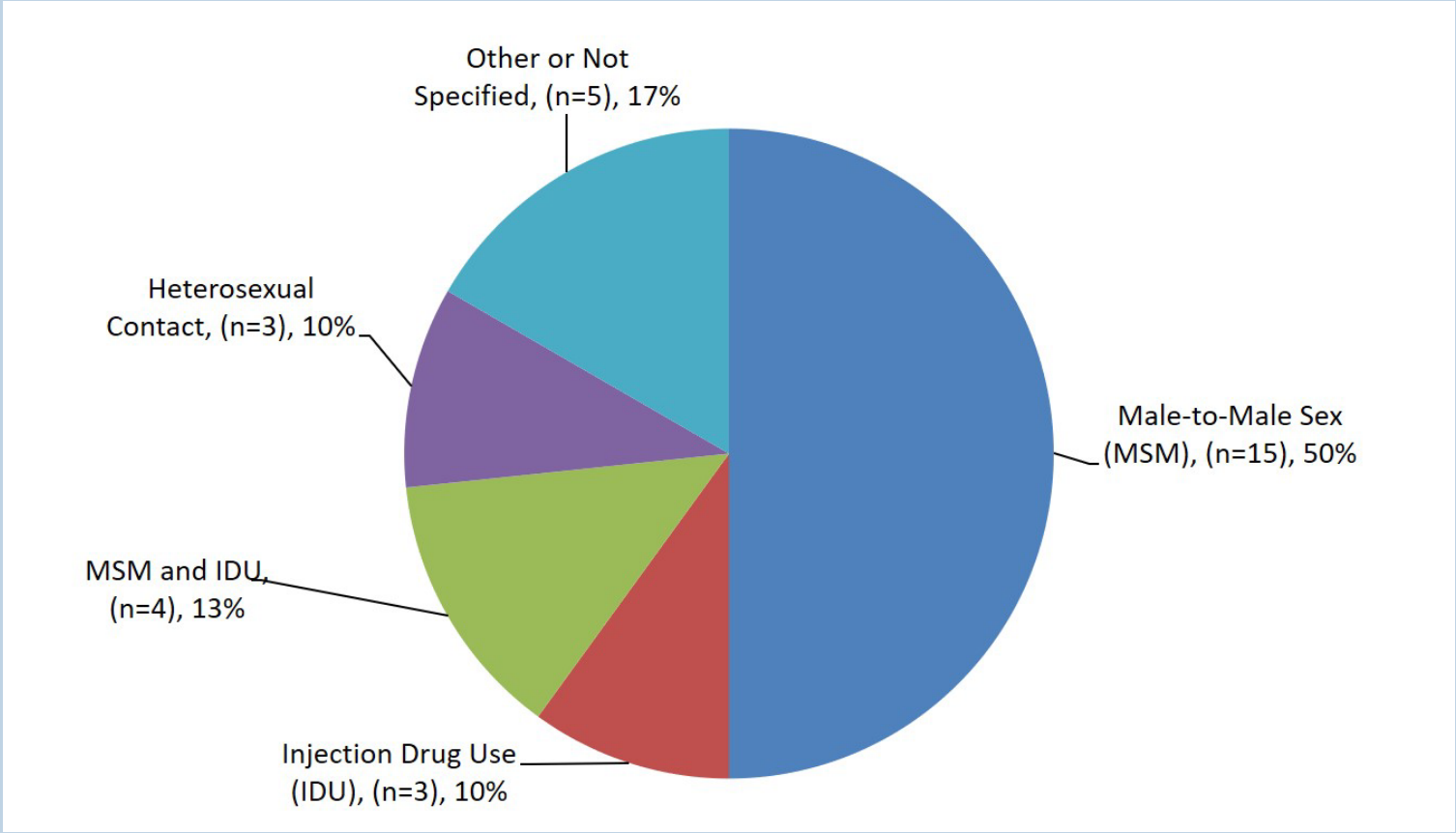
HIV/STI Epidemiology in Alaska

Highlights, Cumulative HIV Cases, 1982-2020 (N=2,026)

- 1,283 (63%) ever had a diagnosis of AIDS
- 704 (35%) are known to have died
- 1,638 (81%) were male
- 1,227 (61%) were men who have sex with men (MSM), including 171 (8%) MSM/IDU; 372 (18%) were heterosexual (Hetero) and 223 (11%) were IDU
- 1,031 (51%) were White; 399 (20%) were Alaska Native/American Indian; 286 (14%) were Black
- 1,294 (64%) had an initial diagnosis in Alaska, with 883 (68%) residing in Anchorage/Mat-Su at the time of diagnosis

2020 Reported Cases of HIV First Diagnosed in Alaska, by Transmission Category (n=30)



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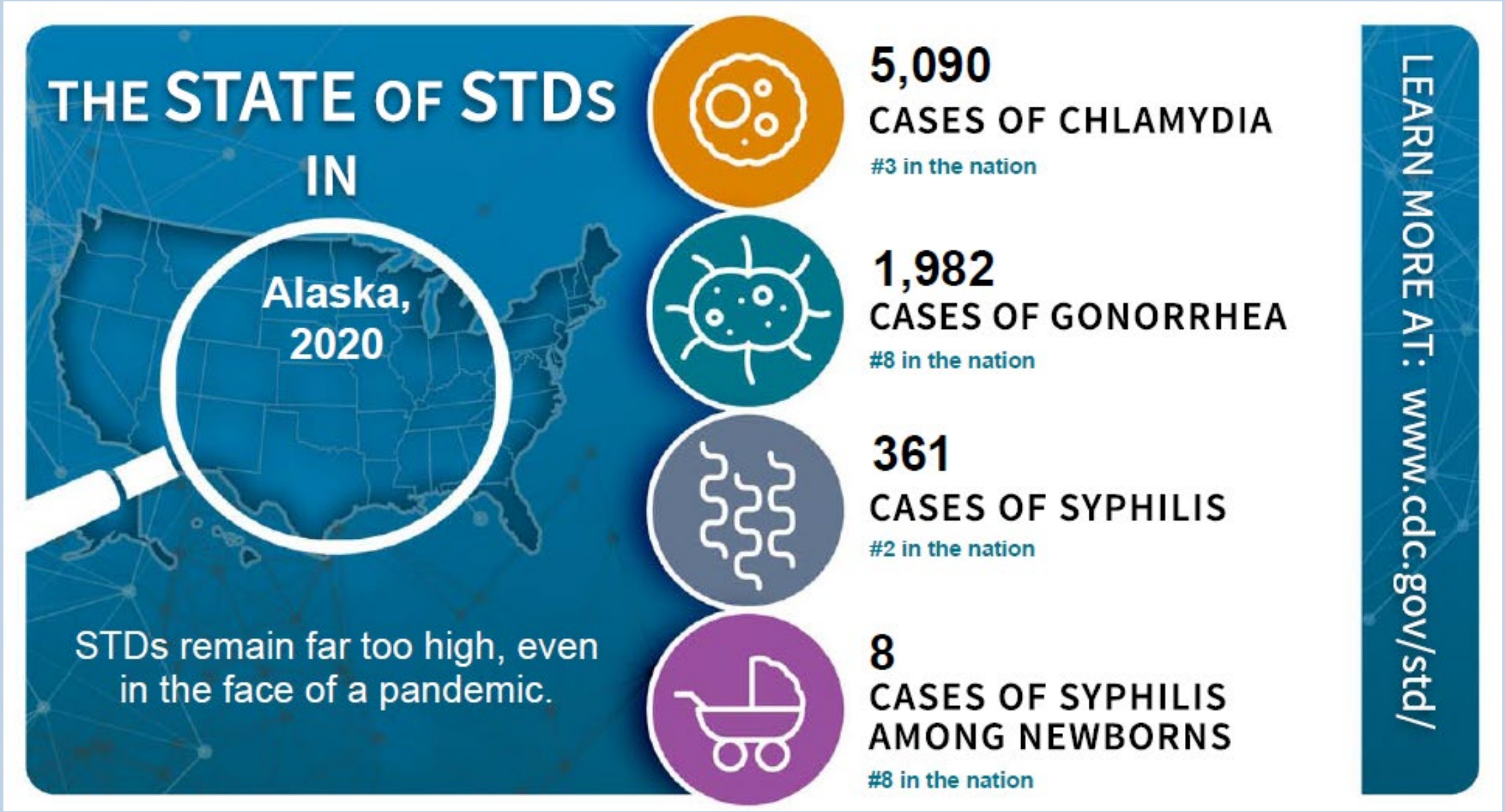
State of Alaska, Section of Epidemiology – May 2021



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US Preventive Services Task Force Recommendations for Routine HIV Screening[1]

Recommendation	Grade
Health care providers should screen for HIV in adolescents and adults aged 15–65 years. Younger adolescents and older adults who are at increased risk should also be screened	A
Health care providers should screen all pregnant people for HIV, including those who present in labor who are untested and whose HIV status is unknown	A

CDC Recommendations for Routine testing[2]:

- Ages 13-64: at least once
- Tuberculosis: when initiating treatment for TB
- STIs: with each STI treatment
- Pregnancy: part of prenatal panel every time
- New relationship: prior to engaging in sexual activity

U.S. Preventive Services TASK FORCE

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1Moyer VA. Screening for HIV: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2013;159:52.
2Branson B, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Morb Mortal Wkly Rep*. 2006;55:1-17. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

CDC Recommendations for Repeat Testing

Repeat HIV testing should be performed for patients at risk at least annually:[1,2]

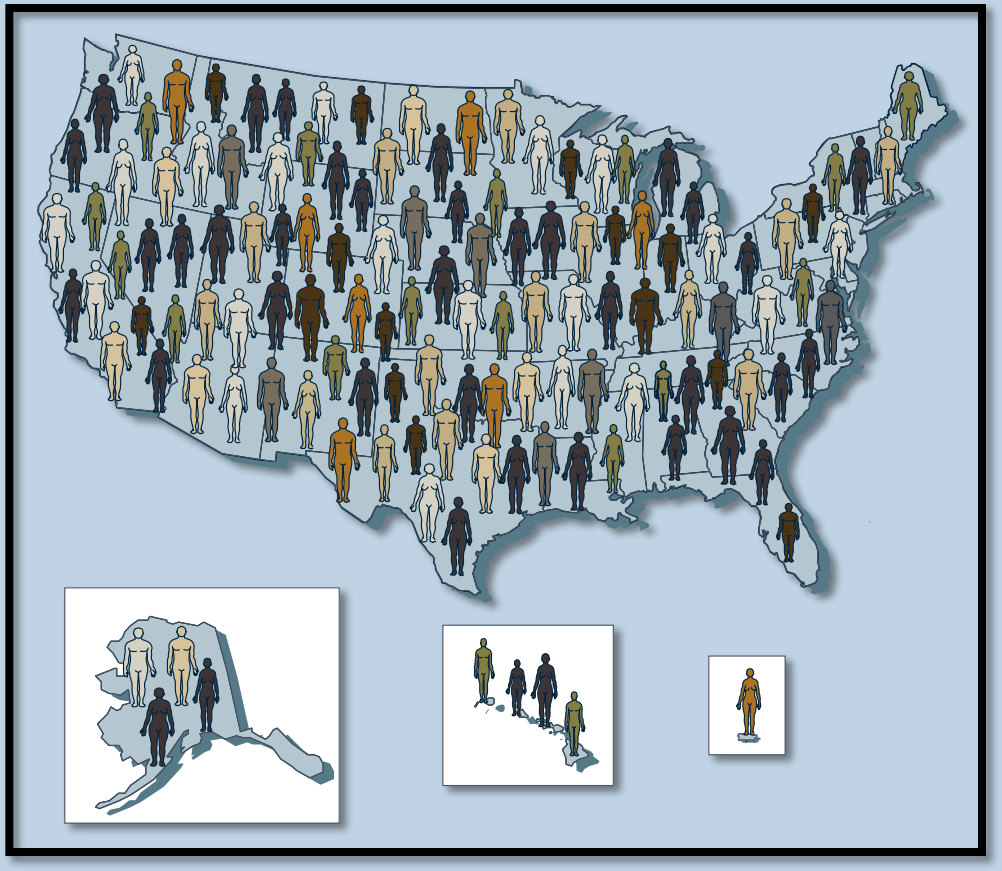
- People who inject drugs and their sex partners
- People who exchange sex for money or drugs
- Sex partners of people with HIV
- Men who have sex with men*
- Heterosexual people who themselves or whose sex partners have had ≥1 sex partner since their most recent HIV test

*More frequent testing (every 3–6 months) can be considered for asymptomatic, sexually active men who have sex with men, based on their individual risk factors, local HIV epidemiology, and local policies[2]

[1] Branson B, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Morb Mortal Wkly Rep.* 2006;55:1-17. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

[2] DiNenno EA, Prejean J, Irwin K, et al. Recommendations for HIV screening of gay, bisexual, and other men who have sex with men — United States, 2017. *MMWR Morb Mortal Wkly Rep.* 2017;66:831. https://www.cdc.gov/mmwr/volumes/66/wr/mm6631a3.htm

CDC Recommendations for Opt-Out Testing



- Patients are notified that an HIV test is a routine part of the encounter
- There is no requirement for formalized counseling or separate written informed consent
- Patients must specifically decline testing, either orally or in writing, to be exempt from having an HIV test

Branson B, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Morb Mortal Wkly Rep*. 2006;55:1-17. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

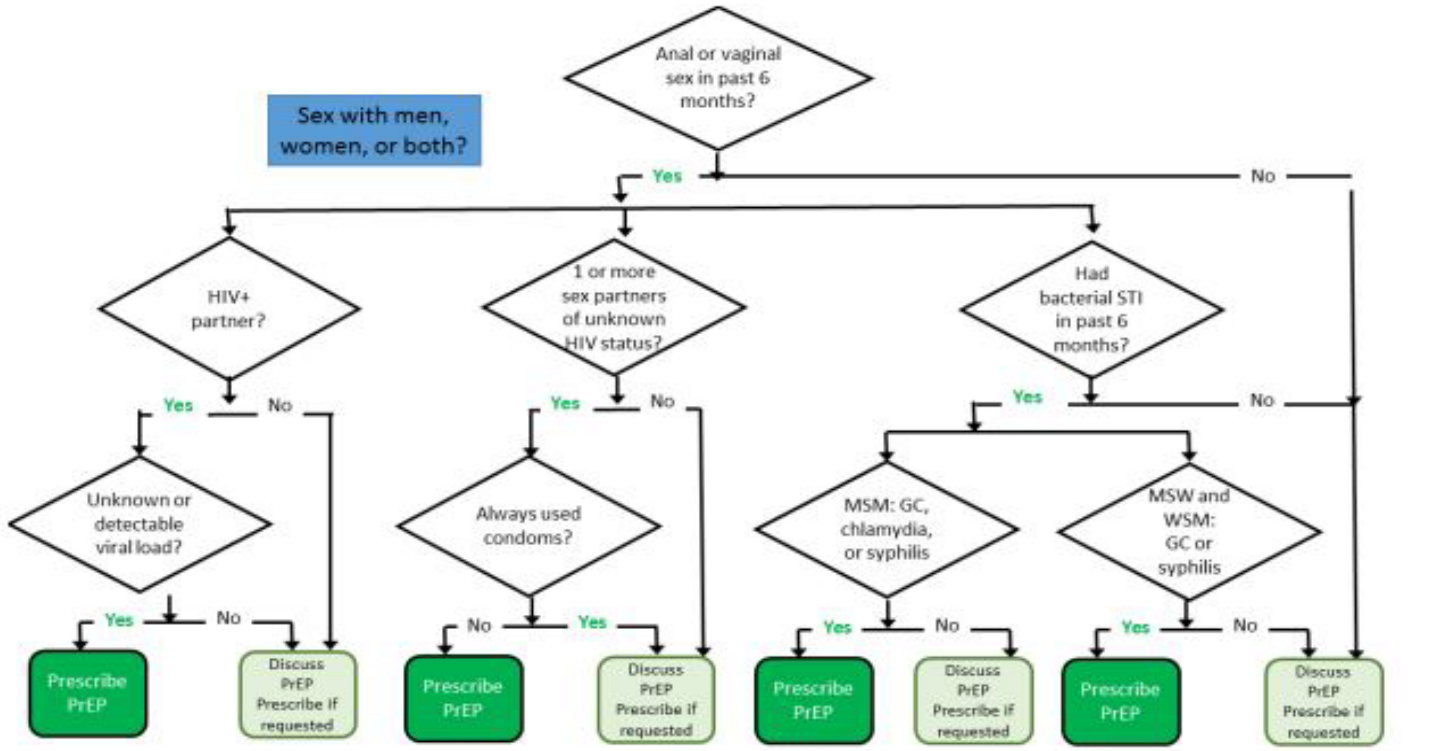
What is PrEP: Pre-Exposure Prophylaxis

- A prevention strategy in which a **high-risk** 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
  - Medications:
    - Truvada (tenofovir disoproxil fumarate/emtricitabine) 1 tablet once daily
    - Descovy (tenofovir alafenamide/entricitabine) 1 tablet once daily
    - Apretude (long acting injectable cabotegravir) 1 injection every 1-2 months

Assessing PrEP indication: Sex Risk

Figure 2 Assessing Indications for PrEP in Sexually Active Persons



Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline
Page 23 of 108

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

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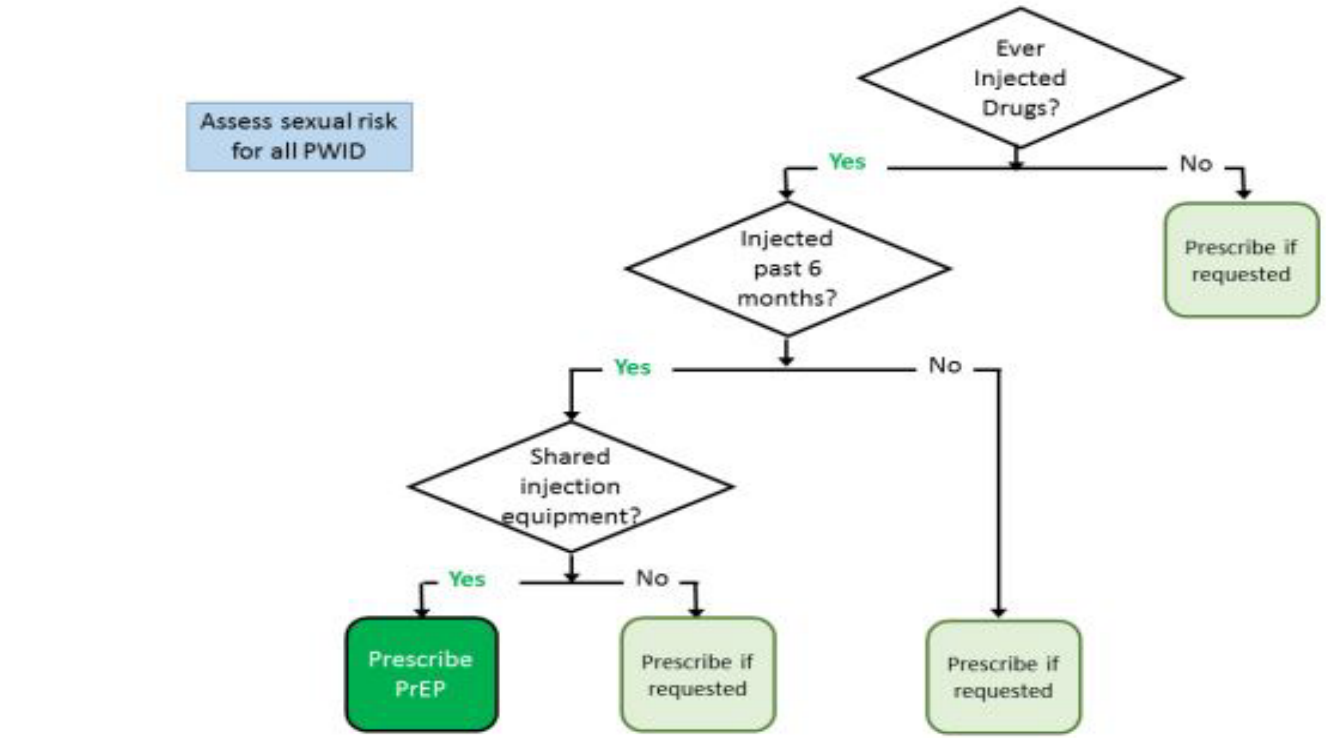
Assessing PrEP Indication: IDU

Figure 3 Assessing Indications for PrEP in Persons Who Inject Drugs



Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline
Page 27 of 108

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

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Simplified Treatment Cases

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Case #1

Katy is a 22 year old female, diagnosed at age 18 with HCV, GT 2a. She has a history of IVDU. She just returned from treatment (not using drugs and alcohol for 4 months), working in landscaping and is living with an older sibling. She has no health care coverage. She made today's appointment to discuss hepatitis C treatment.

Chart review shows she's fully vaccinated against Hepatitis A and B. Hep B surface antigen negative.

Medications: ethinyl estradiol/norethindrone OCP, St. John's wort

You get pretreatment labs…

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Pre treatment Lab Review

HCV RNA - 1,003,458 iu/ml
CBC- WNL, Plt 340
ALT - 49, AST 34, Alk 69, Alb 4.6, t. bili 0.4
eGFR - 112
HIV – negative
HBsAg - negative

FIB-4: 0.31 (no or mild fibrosis)

What are her treatment options ?

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Simplified Treatment

- Apply for Medicaid and if not eligible apply to patient assistance program for free medication
- Mavyret 3 tabs daily for 8 weeks
  - no prior authorization needed if Medicaid
  - switch to a different birth control – barrier or progesterone only contraception is ok
- Epclusa 1 tablet daily for 12 weeks
  - prior authorization required if Medicaid
- Assist with harm reduction, post treatment support program
- 12 weeks or more after treatment obtain HCV RNA and LFTs to test for cure

Case #2

Paul is a 59 year old male found to be HCV antibody reactive on screening labs done during a physical. He was notified of results and returned for confirmatory testing:

HCV RNA was 8,987,654 Iu/mL. (confirming active infection)

He returns to clinic today to review the results and wants to begin HCV treatment. He has AK Medicaid coverage

You review his most recent labs and consult the simplified treatment algorithm.

No history of hepatitis A or B vaccinations.

Medications – Lisinopril 10mg daily, atorvastatin 20mg daily

Lab Results

HCV RNA (viral count): 8,987,654 iu/mL. (confirms active infection)

CBC: Hgb 13.2, plt 160

CMP: ALT 68, AST 75, bili 0.9, alk phos 110, albumin 3.9, eGFR >60

HIV screen: negative

HBsAg: negative, HBsAb: neg, HBcAb: neg

HAV Total antibody: negative

FIB-4: 3.35 (cirrhosis)

Does he need additional tests?

- RUQ US (and AFP) now and every 6 months for life
- PT/INR - 1.1 (within 3 months)
- CTP score - 5 (Class A/compensated)
  - Use online calculator
  - Treat/consider consultation with Liver Disease Specialist about his cirrhosis
- Genotype?
  - Not needed with glecaprevir/pibrentasvir (Mavyret)
  - Sofosbuvir/velpatasvir (Epclusa) – If genotype 3 will need to get NS3 lab, if Y93 positive refer to hepatology for treatment (ribavirin will be needed)

Simplified Treatment – Compensated Cirrhosis (CPT≤ 6)

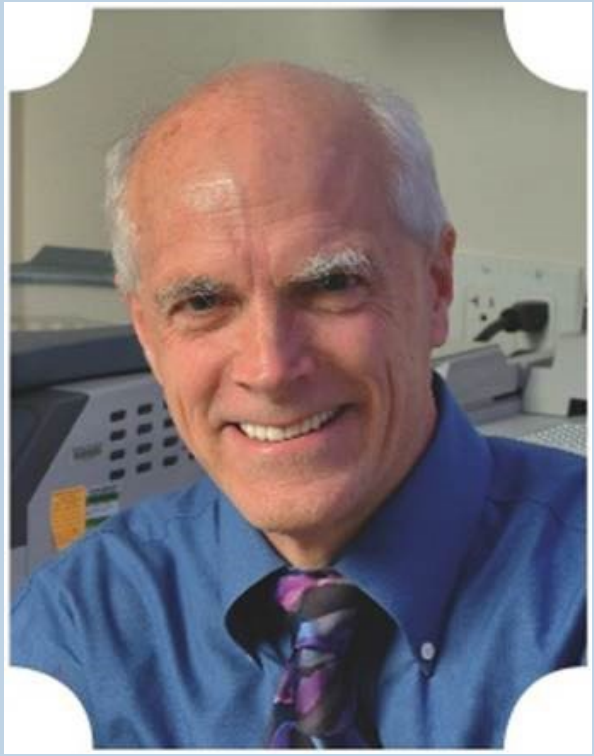
- Mavyret 3 tabs daily for 8 weeks
  - no prior authorization needed
  - hold atorvastatin during treatment or switch to a different statin (rosuvastatin)
- Epclusa 1 tablet daily for 12 weeks
  - prior authorization required
  - If GT 3 and Y93 positive – refer to hepatology for treatment
- Vaccinate against hepatitis A and B – do not delay treatment start for vaccines
- 12 weeks or more after treatment obtain HCV RNA and LFTs to test for cure

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM
LIVER DISEASE & HEPATITIS PROGRAM

Presenters

Brian McMahon, MD

Dr. McMahon has been with the Liver Disease and Hepatitis Program (LDHP) since 1983 serving as the Program Director and currently as the Medical and Scientific Director. He has practiced medicine in Alaska for over 40 years and has served as Principal Investigator on a majority of LDHP's funded research projects. He has authored/co-authored over 150 peer-reviewed publications on viral hepatitis and liver disease and is a widely recognized expert in Hepatology and a coauthor of the American Association for the Study of Liver Disease, Hepatitis B Practice Guidelines.



Annette Hewitt, APRN FNP-C

Annette Hewitt is a family nurse practitioner specializing in the treatment of patients with hepatitis C. She earned a Bachelor and Master of Science in Nursing from UAA. Ms. Hewitt worked in a primary care private practice in Anchorage until relocating her practice to the Liver Disease & Hepatitis Program at ANTHC in February 2014. She provides direct patient care to persons living with all liver diseases and HCV education for health care providers. Annette is a member of the faculty team for AK ID and AK Liver Disease ECHO's. She is a member of the American Academy of Nurse Practitioners and the Alaska Nurse Practitioner Association.

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Leah Besh, PA-C

Leah Besh is a physician assistant who has been treating hepatitis patients since 2016. She graduated from University of Utah's Physician Assistant Program but knew Alaska was always her home. She started her career working at Anchorage Neighborhood Health Center (ANHC) where she participated in University of Washington and Alaska Native Tribal Health Consortium's (ANTHC) ECHO programs for HCV and was able to expand ANHC's HCV treatment program through improved access, patient coordination, and provider mentorship. She joined ANTHC; jointly work with the hepatitis and HIV departments in January of 2019. She enjoys spending time with patients to empower higher quality of life, harm reduction and disease elimination! In her free time she can be found playing in the mountains or on the trails around Alaska on foot, skis or bike.

Lisa Townshend-Bulson, APRN FNP-C

Lisa Townshend-Bulson is the Director of the Alaska Native Tribal Health Consortium (ANTHC) Liver Disease & Hepatitis Program where she practices as a nurse practitioner, is a clinical investigator in liver disease research, and provides program management. She has authored/coauthored several peer-review publications on viral hepatitis. She participates in the American Association for the Study of Liver Diseases (AASLD) Hepatitis B Special Interest Group (SIG), and in the past, participated on the AASLD Public Policy and AASLD Hepatology Associates Committees. Ms. Townshend-Bulson also participated in the Hepatitis C Virus Birth Cohort Testing Work Group for the development of the 2012 CDC guidelines for the screening of baby boomers for hepatitis C. For the past decade, she has been leading efforts in providing continuing education to healthcare providers through the LiverConnect CE program, and more recently for the Liver Disease and AK ID ECHO programs and she leads efforts to maintain up-to-date hepatitis C treatment and other liver disease information for the ANTHC liver disease website www.anthc.org/hep. She holds a Master's Degree in Nursing/Family Nurse Practitioner and is certified as a Family Nurse Practitioner by the American Association of Nurse Practitioners. She is a member of the American Association for the Study of Liver Diseases and the American Academy of Nurse Practitioners.

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM
LIVER DISEASE & HEPATITIS PROGRAM

Thank You!!!

Visit our website: www.anthc.org/hep

AASLD/IDSA Guidelines are available at: www.hcvguidelines.org/

Join us for:

Liver Disease ECHO
3rd Thursdays 12-1pm (AK time)
Liver Disease didactic and cases (CEs)

AK Infectious Disease (ID) ECHO
2nd Tuesdays 12-1pm (AK time)
HCV, HIV, STI, PrEP, PEP didactic and cases (CEs)

LiverConnect – 1 hour didactic program (CEs) on liver disease 2nd Tuesdays 8-9am AK time

Info for all of 3 CE programs is available at: www.anthc.org/hep/liverconnect

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