HEPATITIS C SCREENING AND TREATMENT

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DISCLOSURES:

Brian McMahon – None

Lisa Townshend-Bulson - Principal investigator on an ANTHC sponsored hepatitis C treatment study which was funded in part by Gilead Sciences.

OBJECTIVES

To understand why screening for hepatitis C is important

To recognize ways to screen for hepatitis C

To identify hepatitis C treatment options available

To understand hepatitis C treatment in special populations

To identify ways to overcome current challenges to hepatitis C cascade

To discuss what it will take to achieve HCV elimination

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

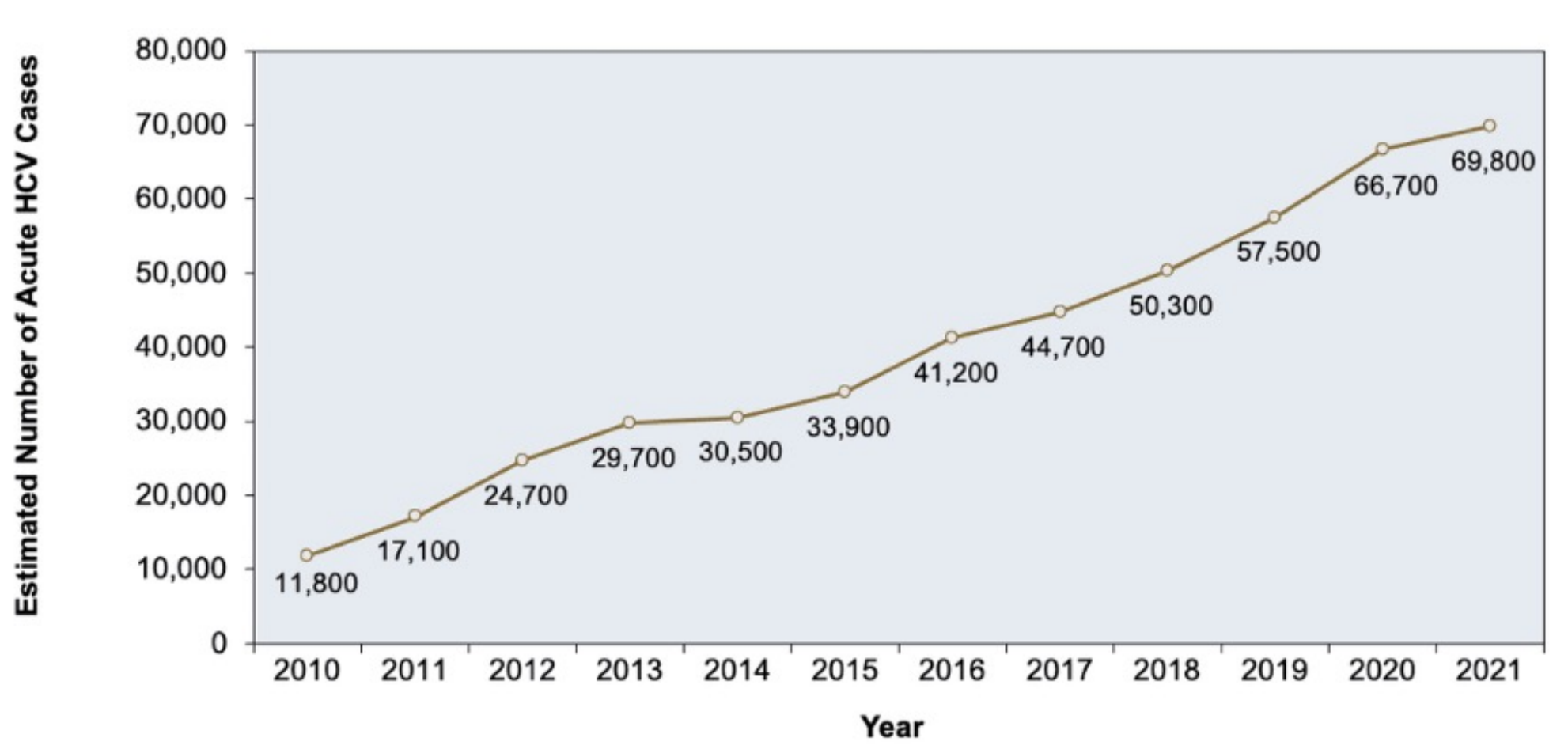
MORE THAN 50,000 ESTIMATED NEW CASES in the U.S. each year since 2018

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.

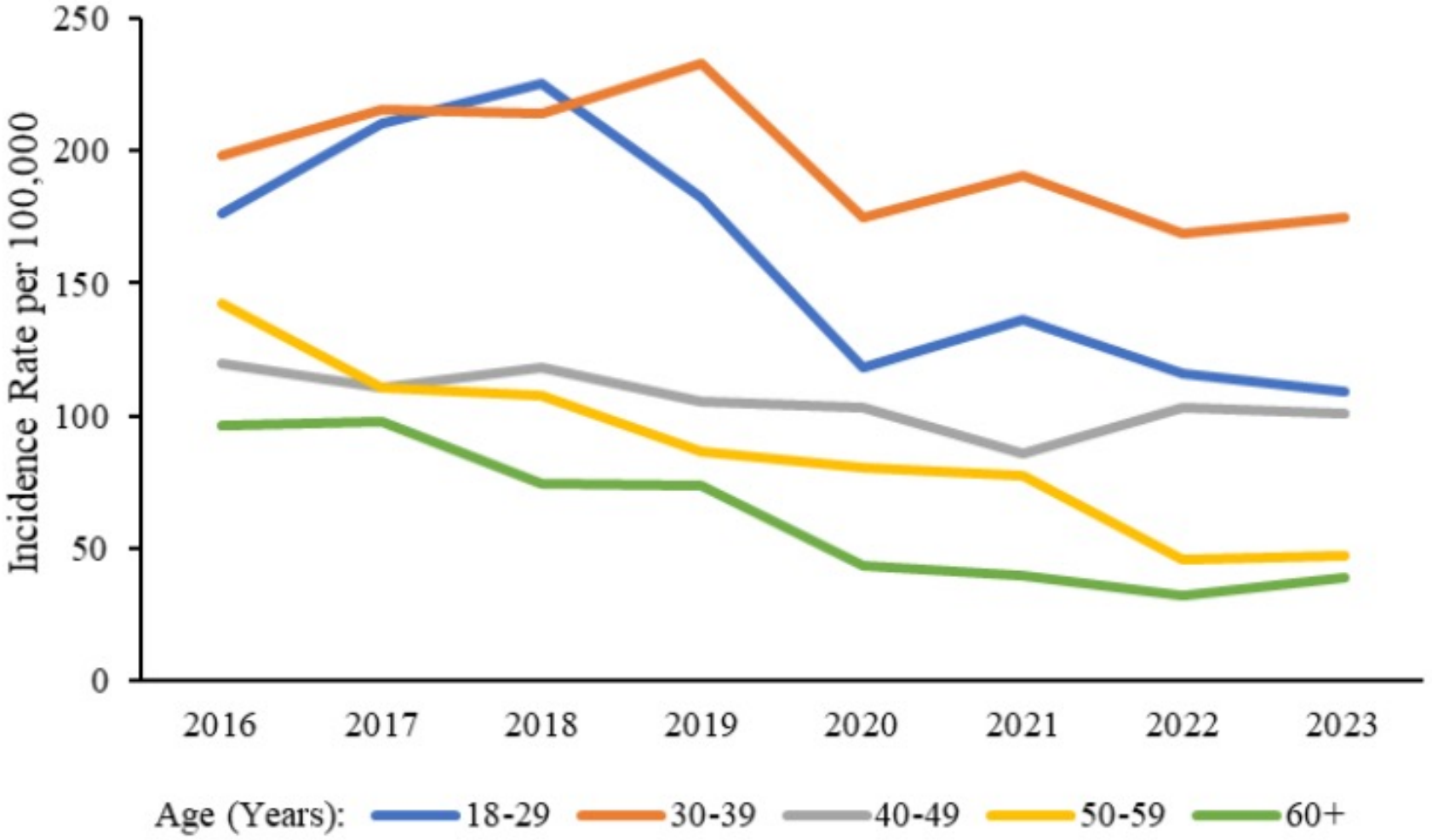
20-39 YEAR OLDS have the highest rate of new hepatitis C cases

ACUTE CASES OF HCV IN U.S.



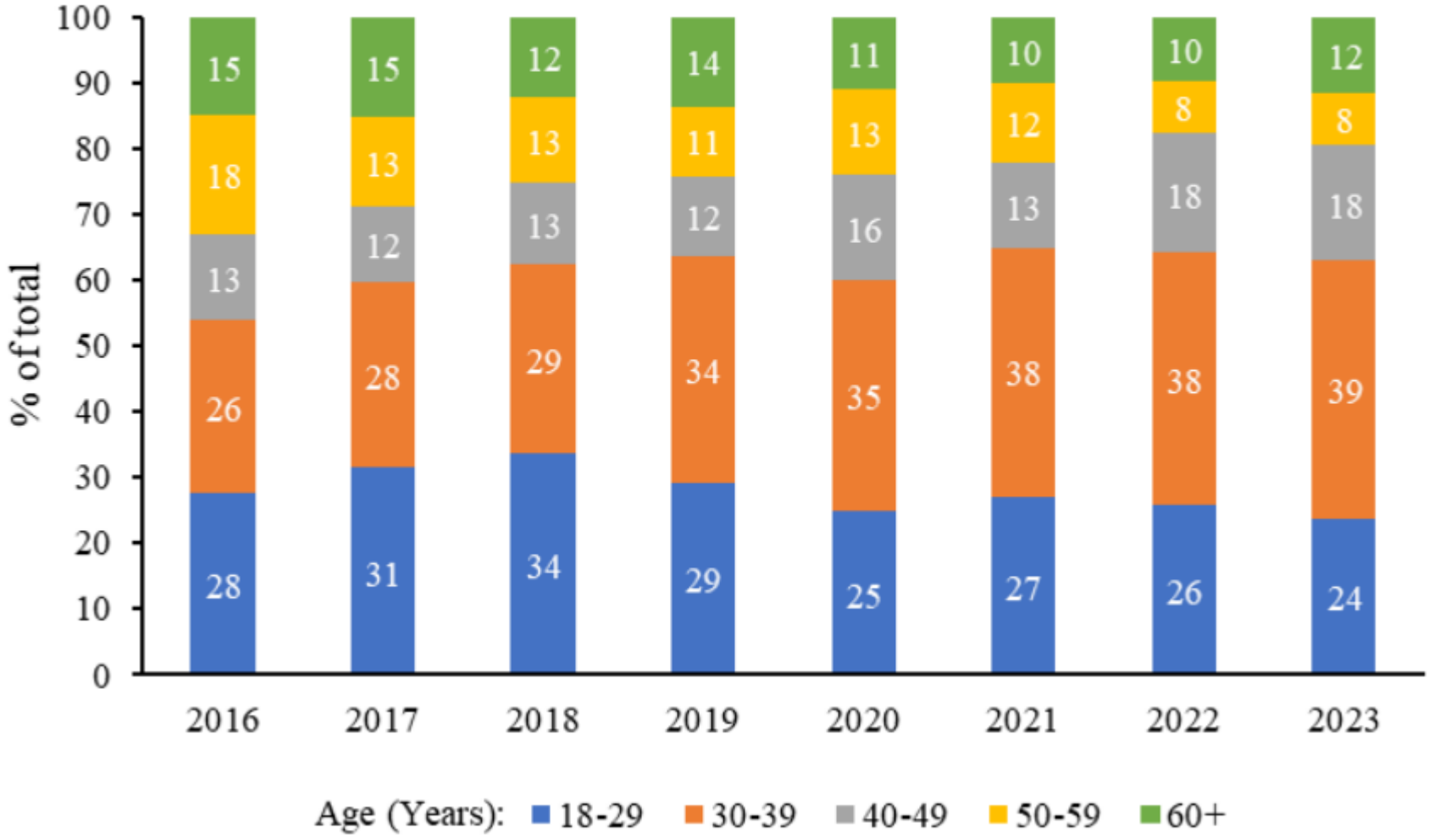
https://www.cdc.gov/hepatitis/statistics/2021surveillance/index.htm

ALASKA ANNUAL RATES OF NEWLY REPORTED CHRONIC HEPATITIS C CASES PER 100,000 ADULTS, BY AGE GROUP, 2016-2023



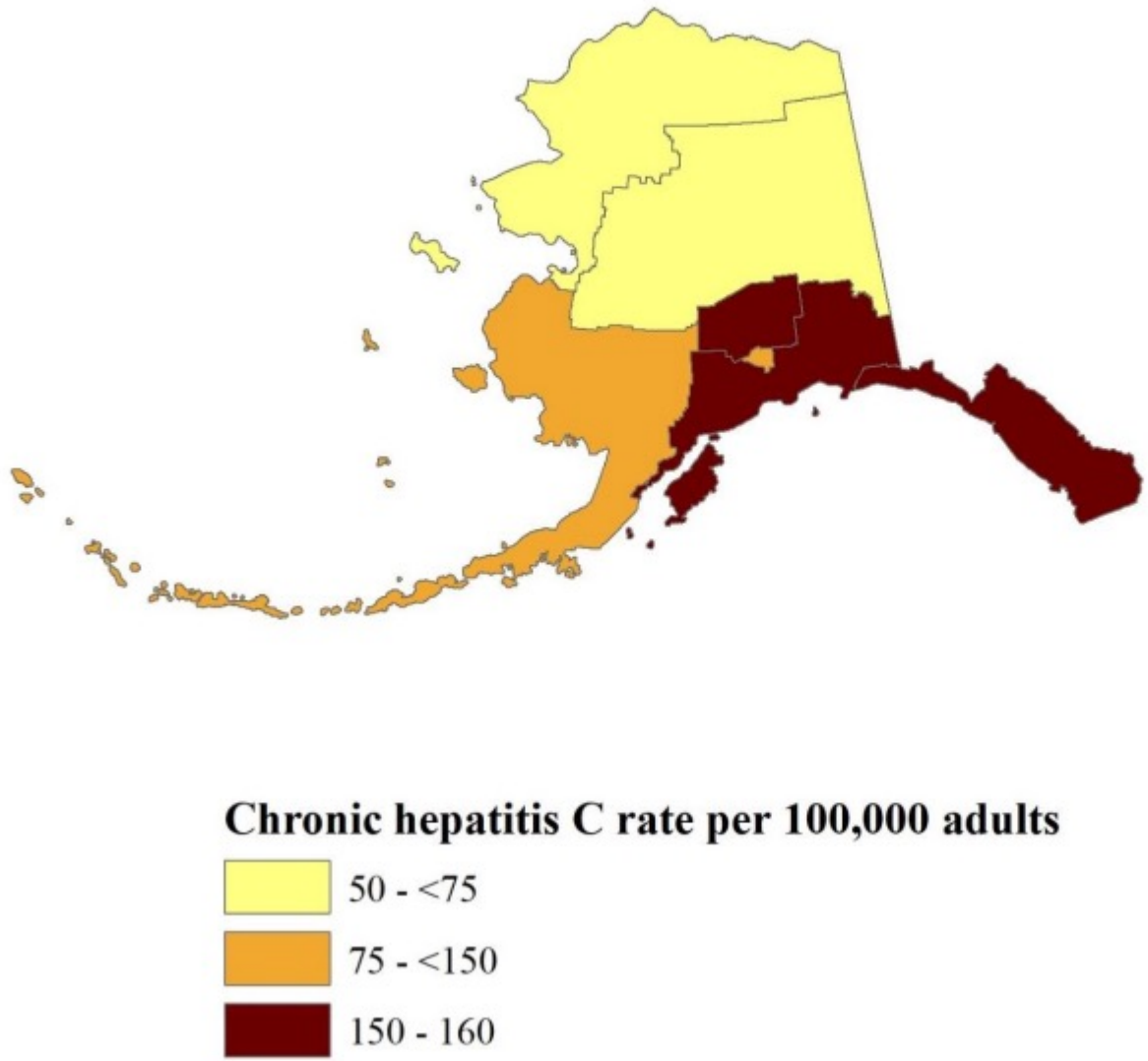
https://epi.alaska.gov/bulletins/docs/rr2024_02.pdf

ALASKA PROPORTION OF NEWLY REPORTED CHRONIC HEPATITIS C CASES AMONG ADULTS AGE ≥ 18Y, BY AGE GROUP AND YEAR



https://epi.alaska.gov/bulletins/docs/rr2024_02.pdf

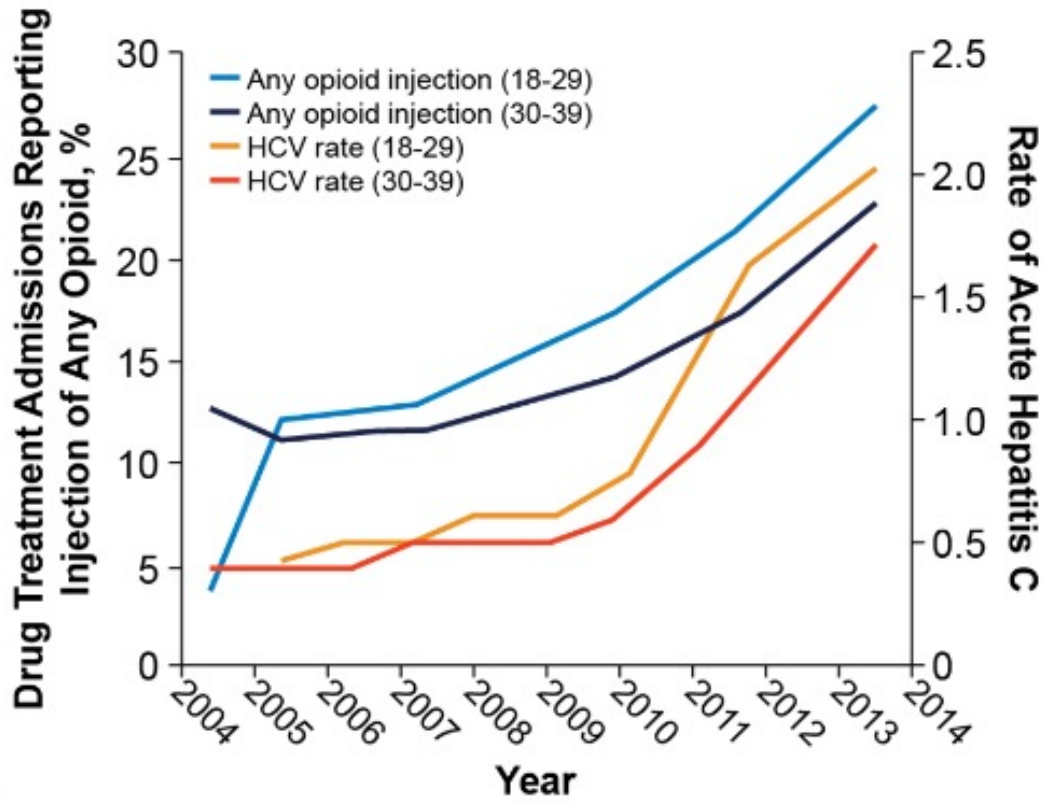
Figure 3. Average Age-Standardized Rate of Newly Reported Chronic Hepatitis C Cases per 100,000 Adults Aged ≥18 years, by Region — Alaska, 2016–2023



https://epi.alaska.gov/bulletins/docs/rr2024_02.pdf

Increase in Hepatitis C Infections Linked to Worsening Opioid Crisis[1]

Hepatitis C and Opioid Injection Rose Dramatically in Younger Americans From 2004-2014



Among people **ages 18-29,** admission for injection opioid use increased by **622%**

HCV incidence increased by **400%** **in the** same cohort

As many as **1 in 2 patients have incomplete testing**[2]

~7% of people who use drugs have received Tx

1. https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection-press-release.html. 2. Feld JJ. *J Infect Dis.* Published online October 13, 2023

Adult Screening

SOURCES: CDC Recommendations for Hepatitis C Screening, MMWR, April 2020
CDC Vital Signs, April 2020

AASLD/IDSA Guidance:
www.hcvguidelines.org

AASLD/IDSA recommends that PWID, men with HIV who have condomless sex with men, and MSM who are on HIV PrEP are screened annually

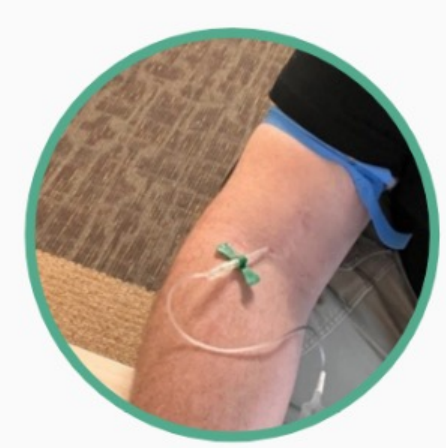
Different Ways to Test for Hepatitis C

Fingerstick HCV Antibody Test (aka Oraquick HCV)

- Results in 20-40 minutes
- Will tell you if HCV antibody is positive (exposure to hepatitis C)
- Must be followed up with HCV RNA venipuncture blood draw to confirm active (current) hepatitis C infection

Fingerstick HCV RNA Test
New: Xpert HCV Viral Load

- Results in < 60 minutes
- Can test adults age 22y+
- Cannot use for monitoring during treatment or SVR testing



Venipuncture blood draw for HCV Antibody (reflexed to HCV RNA if positive)

- Blood is sent to lab for testing
- Reflexed test means HCV RNA test will be done if HCV antibody test is positive
- Results may take 7-10 days

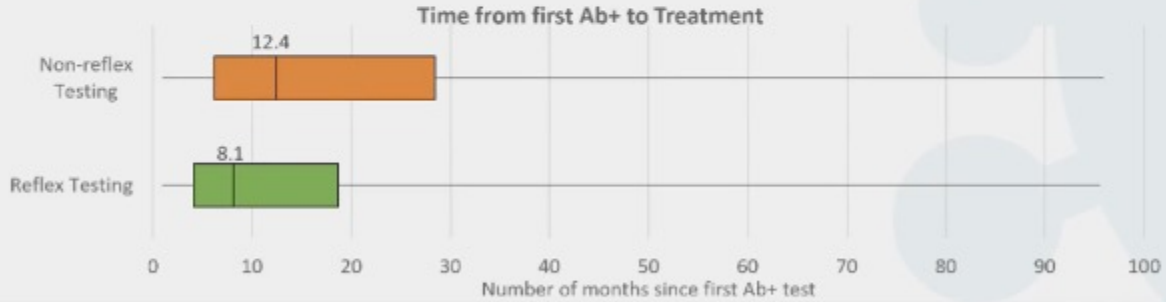
CEPHEID XPERT® HCV VIRAL LOAD TESTING

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

Association of Reflex Testing and Receipt of HCV Treatment, 2014-2021

- Received HCV treatment
  - 30% among persons having reflex HCV RNA testing
  - 8% among persons for whom HCV Ab and RNA testing were ordered separately
- Median time from first HCV Ab+ test to treatment
  - 8.1 mos. median, 14.5 mos. mean among persons having reflex HCV RNA
  - 12.4 mos. median, 19.9 mos. mean HCV Ab and RNA testing ordered separately

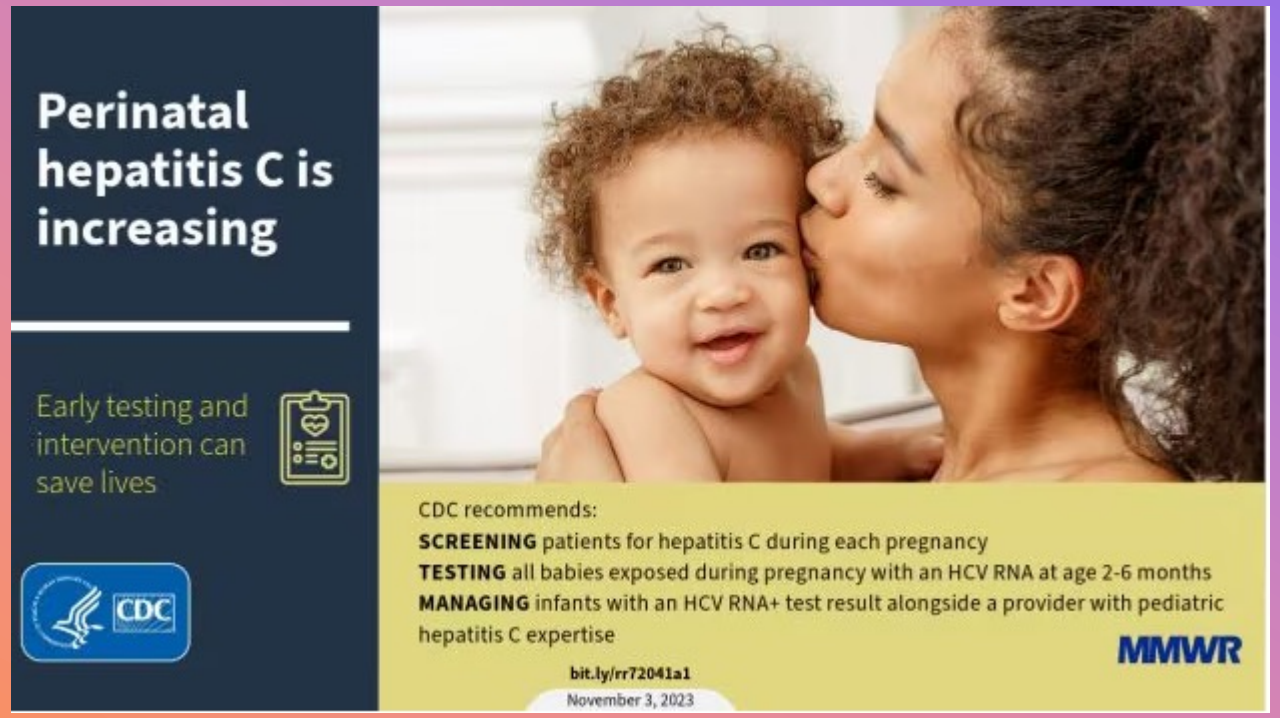


*Percent treated for individuals for whom Ab and RNA testing were ordered separately may be underestimated due to inclusion of those who may not have a confirmed RNA+ test result. Reflex testing (HCV Antibody with reflex to RNA test) was identified by matching the test date (date the specimen was drawn) of the Antibody test with that of the RNA test. Reflex testing analyses are only available with data from one large US national laboratory.
Receipt of treatment was determined based on a viral load decline of at least 1.2 × log10 units since the first positive HCV RNA test, indicating that treatment was initiated in the immediate period prior to the decline. Time to treatment analysis was limited to individuals with an Ab+ test at least 28 days prior to the viral load decline.

GLOBAL HEPATITIS SUMMIT 2023

Hepatitis C Care Cascade and Progress Toward Elimination in the United States, 2021, Ward et al; Global Hepatitis Summit 2023
Slide used with permission.

NEW PEDIATRIC SCREENING RECOMMENDATION



CDC, MMWR, 11/3/23

WOMEN ARE AT HIGHER RISK FOR HCV TRANSMISSION

Women who inject drugs have been shown to have higher incidence of HIV and higher rate of injection-related risk behaviors than men who inject drugs[1]
Higher rates of equipment and syringe sharing in women than men[1] More women using injection equipment after their male partners[1] More women injected by others[1]
More likely than men to have sex partners who inject drugs[2] Overlapping sexual and injection partnerships leads to increased injection risk[2]
Female PWID face stigma; less likely to participate in harm reduction services[1]

[1] Esmaeili A, et al. J Viral Hepat. 2017;24(2): 117-127. https://doi.org/10.1111/jvh.12628
[2] Evans J, et al. J Urban Health. 2003;80(1):137-146. https://doi.org/10.1093/jurban/jtg137

Prevalence of HCV in Children and Adolescents in the United States

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

Maternal HCV

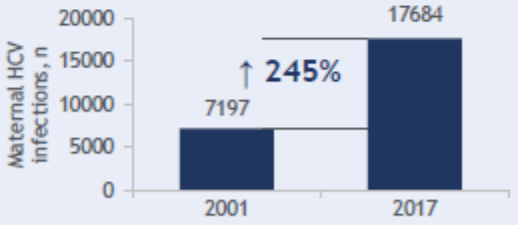
Total Cases

154,016

% of Total Live Births

0.24%

Number of Maternal HCV Infections Over Time



Pediatric HCV

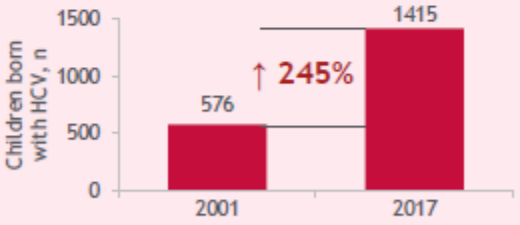
Total Born with HCV

8,649

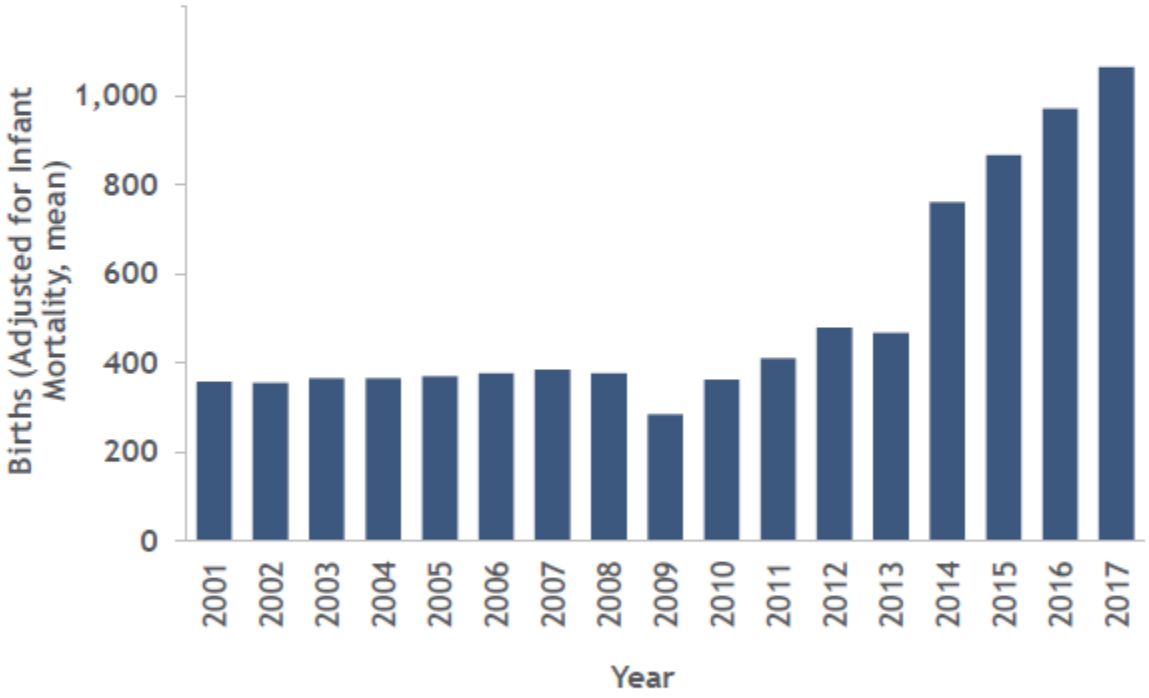
% of Total Live Births

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., Boutros, S., Farhat, M., Kullar, R., Rahal, K., & Saab, S. (2020). Estimating paediatric hepatitis C prevalence in the United States. *Journal of Viral Hepatitis*, *27*(12), 1455–1461. https://doi.org/10.1111/jvh.13377

HEPATITIS C TREATMENT

HEPATITIS C TREATMENT EFFICACY

GLOBAL DATA

Sofosbuvir/Velpatasvir

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)

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)

Glecaprevir/Pibrentasvir

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)

8-week real-world evidence
Results from two TRIO Health Network studies

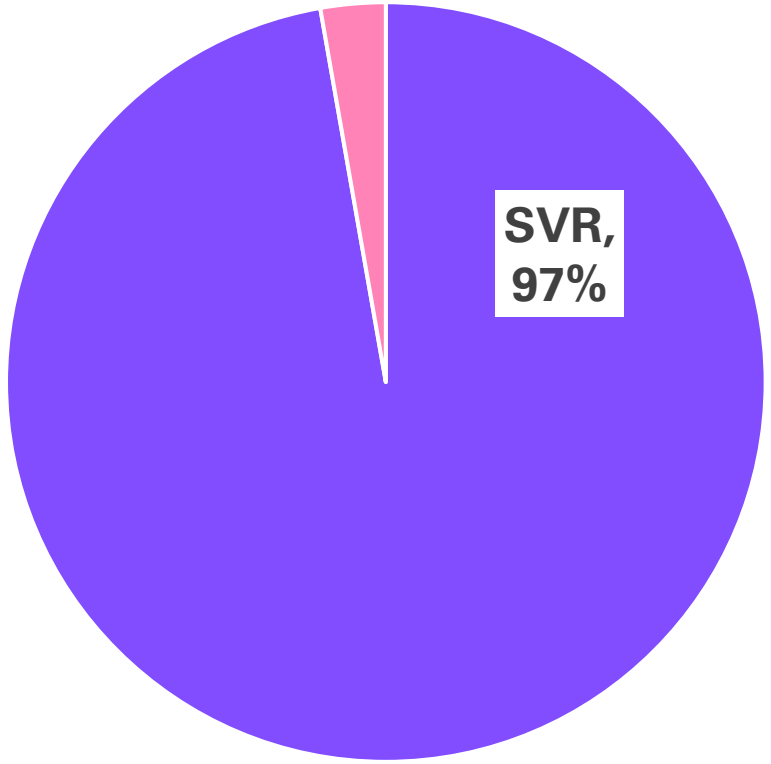
99% cure rate

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

1. Gilead Sciences Canada, Inc. EPCLUSA product monograph. Date of revision: Aug. 8, 2022; 2. Mangia A, et al . *Liver Int*. 2020;40:1841-52;
3. AbbVie Corporation. MAVIRET product monograph. Date of revision: Apr. 7, 2022; 4. Zuckerman E, et al. *Clin Gastroenterol Hepatol*. 2020;18:2544-53;
5. Curry MP, et al. *GastroHep*. 2020;2:64-71; 6. Flamm SL, et al. *Adv Ther*. 2020;37:2267-74.

AN/AI Treatment in Alaska



In 1266 ATHS patients who were tested for SVR

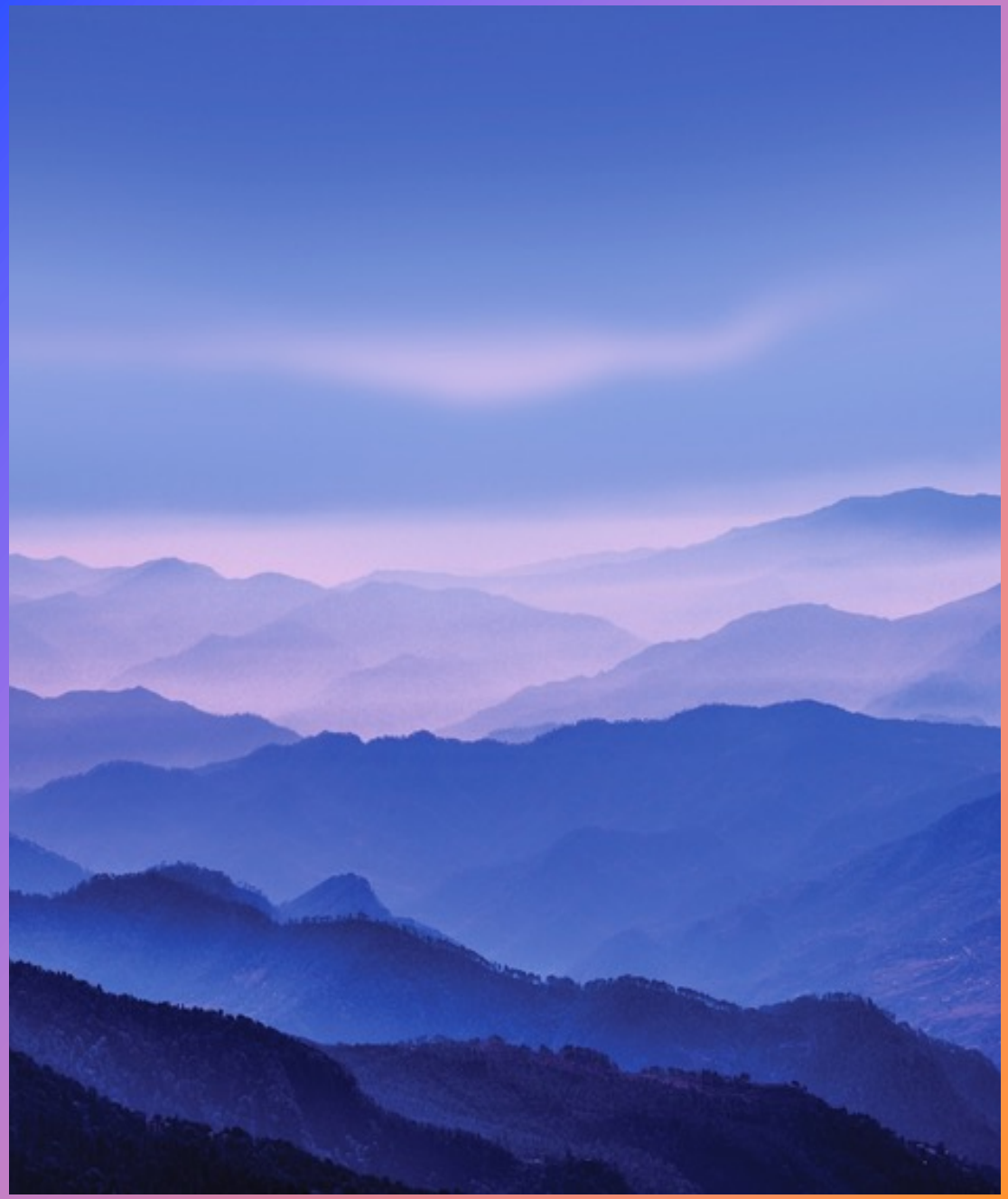
SIMPLER

HCV SIMPLIFIED TREATMENT

SIMPLIFIED TREATMENT – 3 EASY STEPS

1. Check FIB-4 and assess for cirrhosis
2. Pre-Treatment Labs/Assessment
3. Write Prescription/Start Treatment

www.hcvguidelines.org



SIMPLIFIED TREATMENT – 3 EASY STEPS

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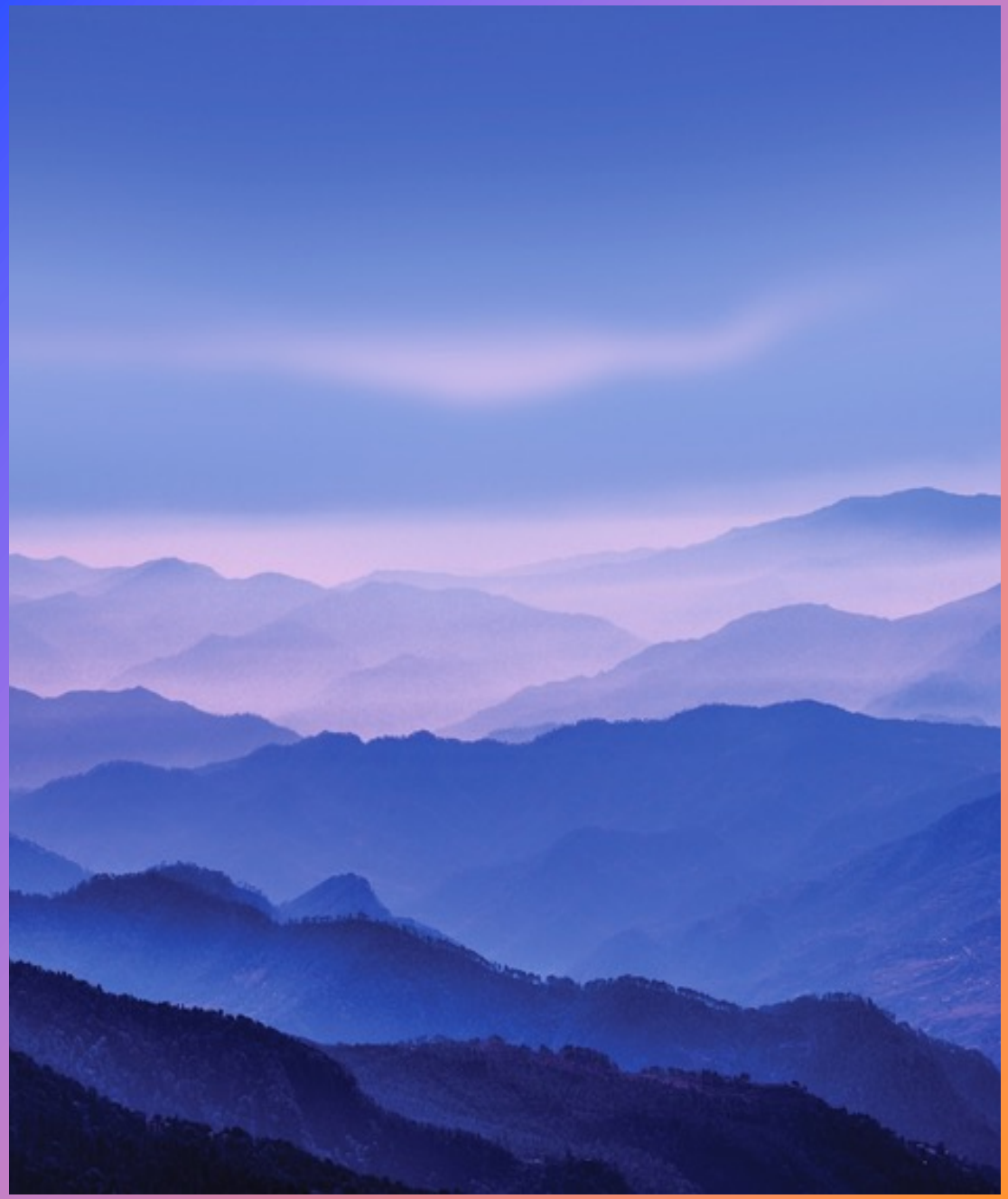
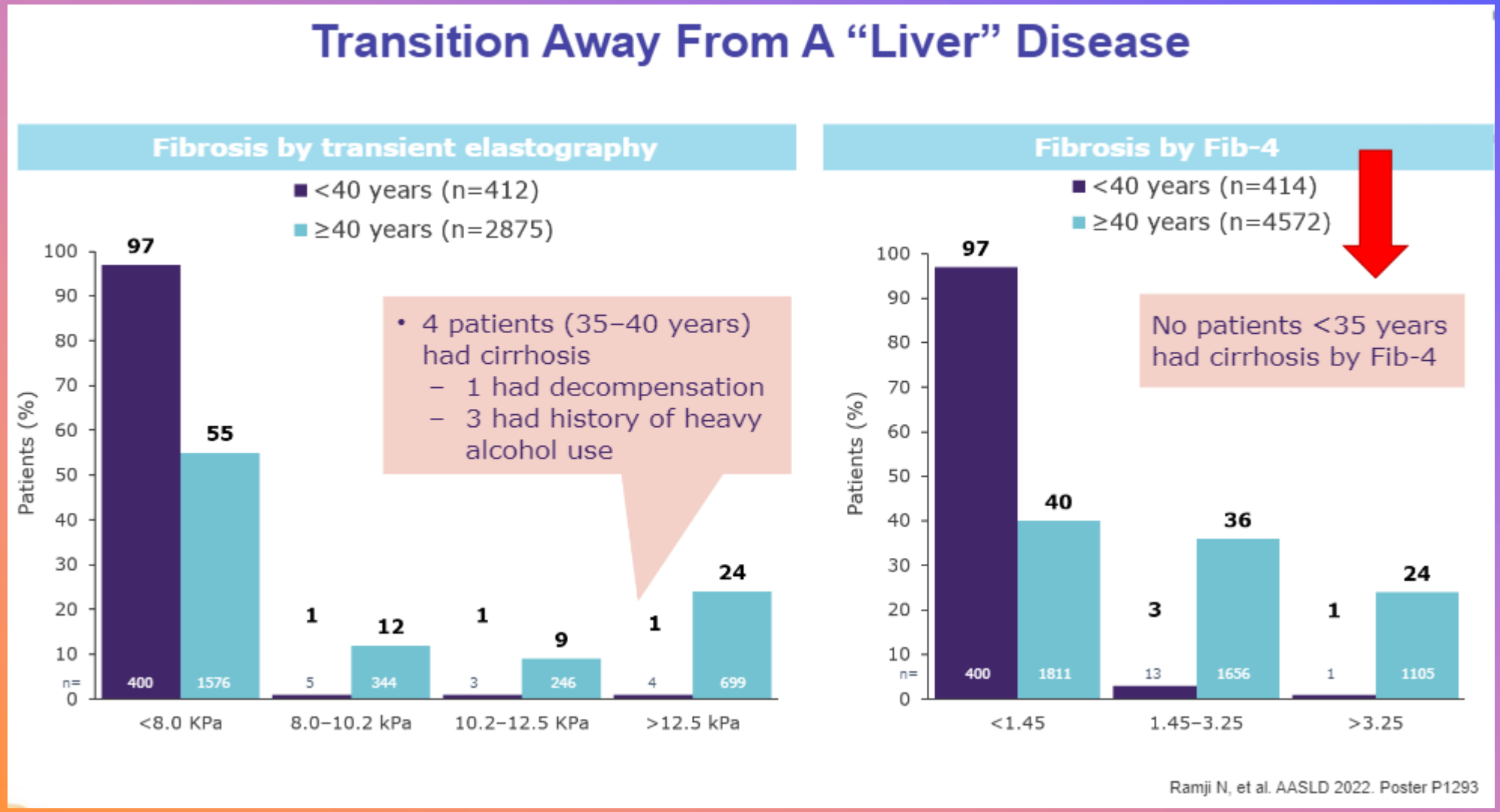
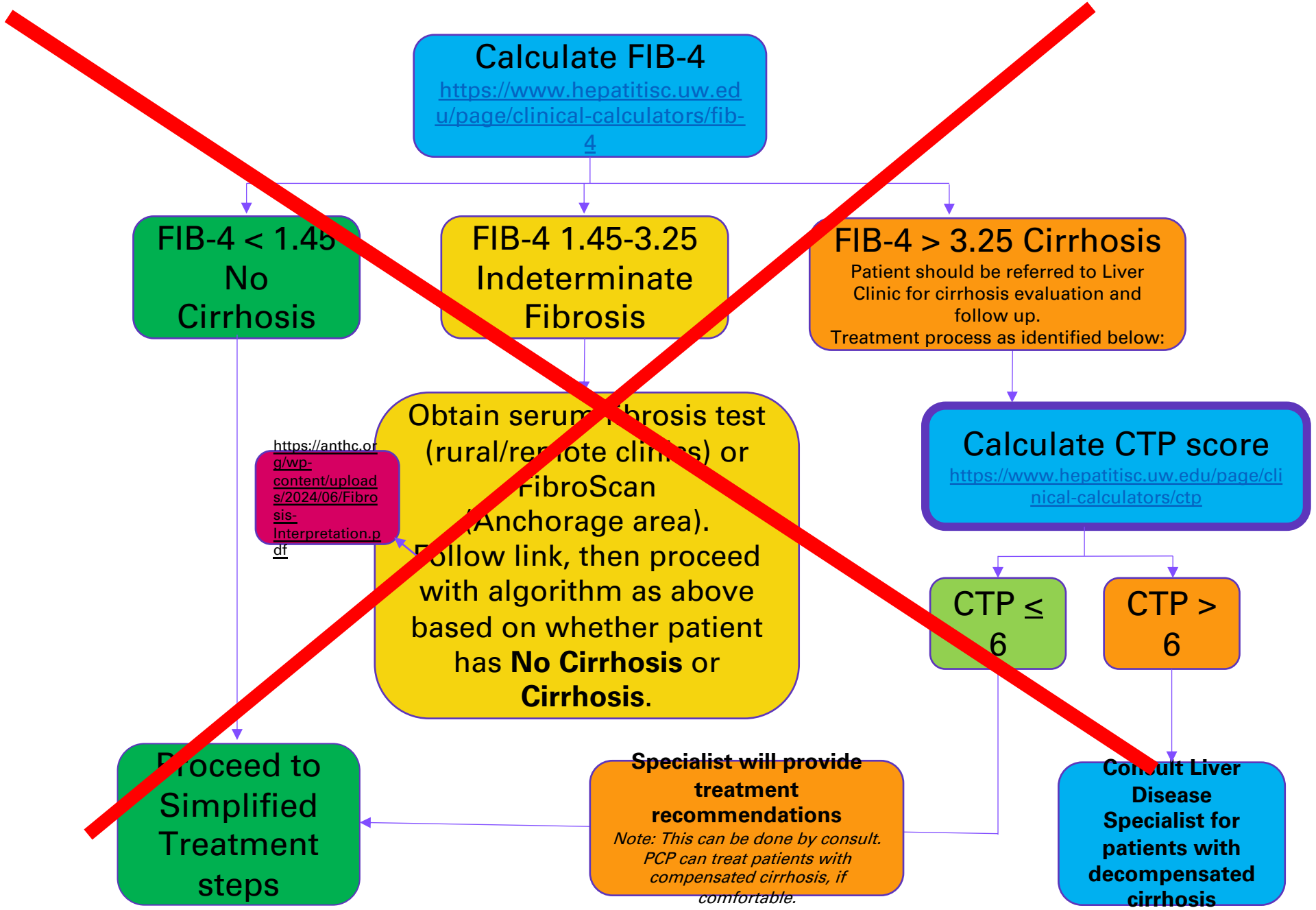
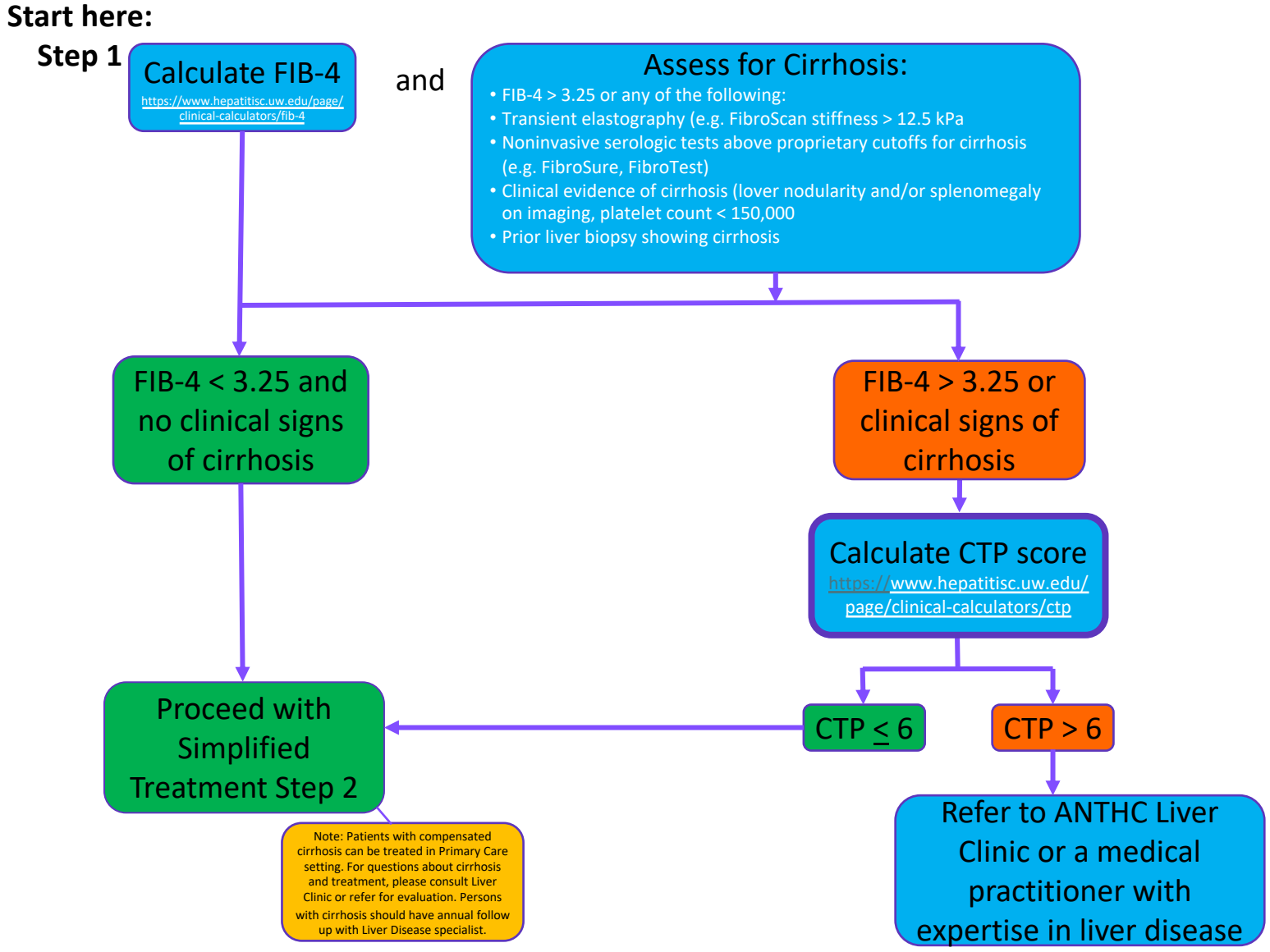


WHAT SIMPLIFIED TREATMENT DOES




Calculate 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 serum fibrosis test (rural/remote clinics) or FibroScan (Anchorage area). Follow link, then proceed with algorithm as above based on whether patient has **No Cirrhosis** or **Cirrhosis**.
https://anthc.org/wp-content/uploads/2024/06/Fibrosis-Interpretation.pdf
Calculate CTP score
https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp
CTP ≤ 6
CTP > 6
Proceed to Simplified Treatment steps
Specialist will provide treatment recommendations
Note: This can be done by consult. PCP can treat patients with compensated cirrhosis, if comfortable.
Consult Liver Disease Specialist for patients with decompensated cirrhosis

HCV Simplified Treatment
For Alaska Tribal Health System



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

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, asteryxis

ASSESS FOR CIRRHOSIS

HCV Simplified Treatment
For Alaska Tribal Health System

Start here:

Step 1

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

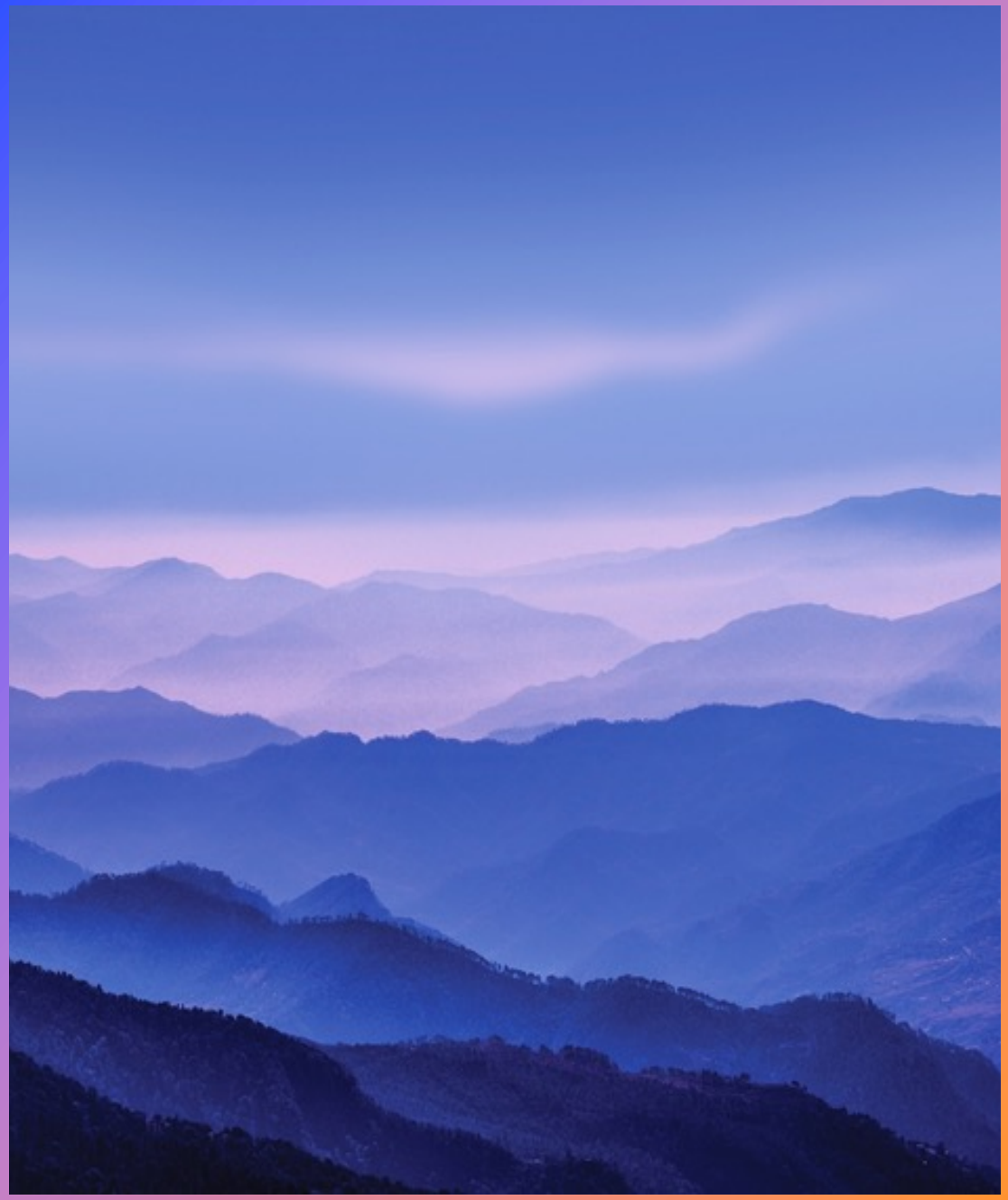
Step 2. Complete Pretreatment Labs & Assessment:	
Labs **Before beginning treatment:**	❑ Pregnancy Test and counseling about pregnancy risk of HCV medication should be offered to women of childbearing age.
Acceptable within 6 mos if no cirrhosis or 3 months if cirrhosis:	❑ CBC ❑ Hepatic function panel 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.

IS PATIENT READY FOR TREATMENT?

ARE YOU READY??



www.hep-druginteractions.org

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)

Simplified Treatment Medications

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

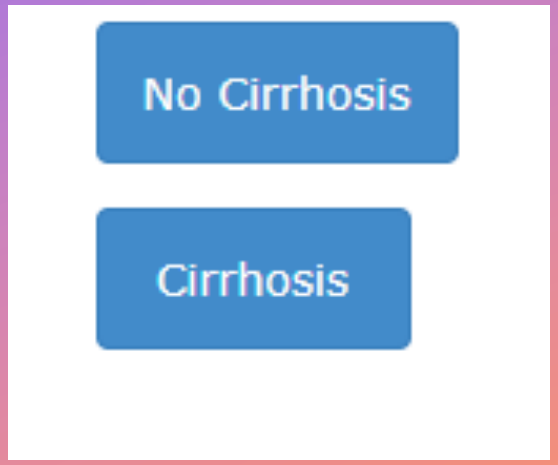
Safe in decompensated cirrhosis

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

STEP 3: Write prescription/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

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



On Treatment Monitoring and Follow Up after Treatment

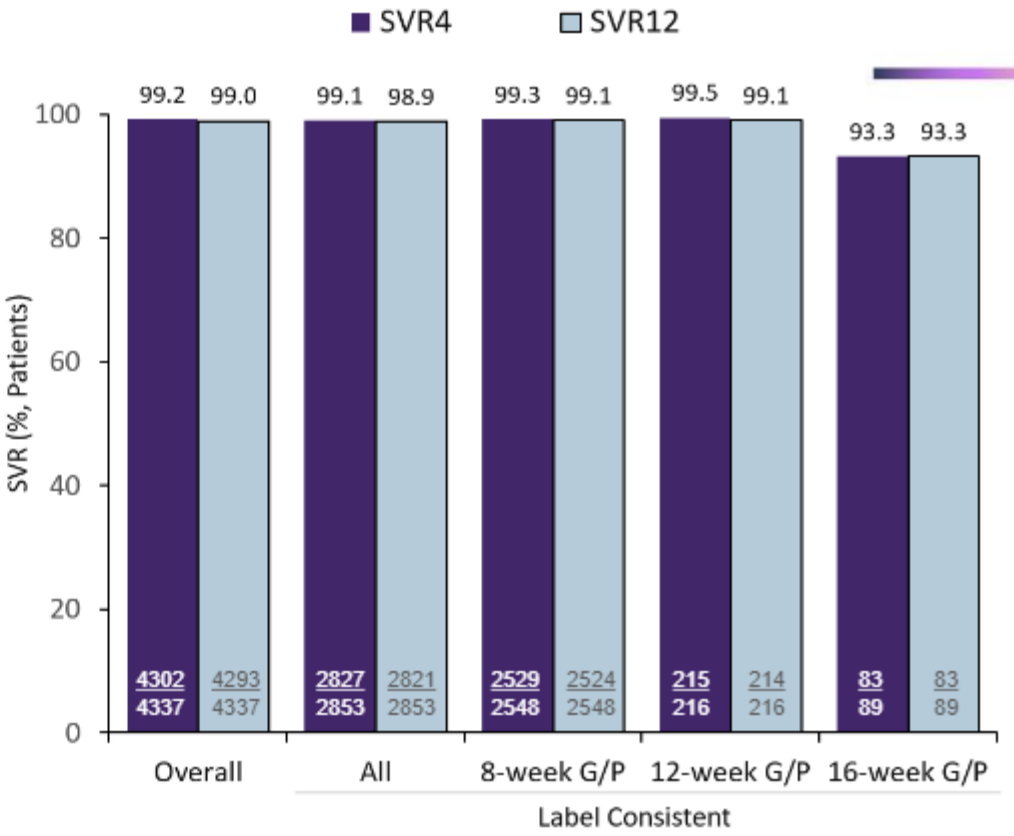
- **No on-treatment monitoring required**
- **Check for SVR after treatment**
- **Persons with cirrhosis need hepatocellular carcinoma screening q6months (RUQ US and AFP)**
- **Provide alcohol counseling; those with cirrhosis should abstain completely from alcohol**
- **Work up LFT elevations that continue**
- **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

- 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



SVR, sustained virologic response; SVR4, SVR at post-treatment Week 4; SVR12, SVR at post-treatment Week 12; PPV, positive predictive value; NPV, negative predictive value

- Achieving SVR4 was highly predictive of long-term SVR for patients treated with G/P, regardless of treatment duration
- All measures of concordance were similar between the overall group and the 8-week treatment duration group, demonstrating the high effectiveness of the shortest treatment regimen

Gane E, *et al*. *J Viral Hepat*. 2021;28(11):1635-1642.

24 y.o. female with ongoing IDU

Comes in for STI check

Labs 6/28/24:

HCV RNA 463,000 iu/mL

ALT 302

AST 280

Platelets 245,000

HIV negative

HBsAg negative

Current meds: None

Hepatitis B vaccine series completed 2002

Physical Exam: No cirrhosis findings

PATIENT CASE #1

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

62 y.o. male lives in Kodiak

h/o IDU 70s, no recent use

Drinks 6 pack beer about 4 times/week

Labs 9/4/24:
+HCV Ab, HCV RNA 590,000 iu/ml

ALT 59, AST 72

Platelets 140k/uL

Bili 1.2

Albumin 3.5

INR 1.3

HIV negative

HBcAb positive, HBsAg negative

Current meds: pravastatin 20mg, losartan 50mg daily

Physical exam: A&O x 3. No icterus or jaundice, has spider angiomas on chest, no ascites, no asterixis.

PATIENT CASE #2

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

HEPATITIS C TREATMENT LESSER DISCUSSED SCENARIOS

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.

HCV REINFECTION

Hepatitis C reinfection after successful antiviral treatment among people who inject drugs: A meta-analysis

- 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

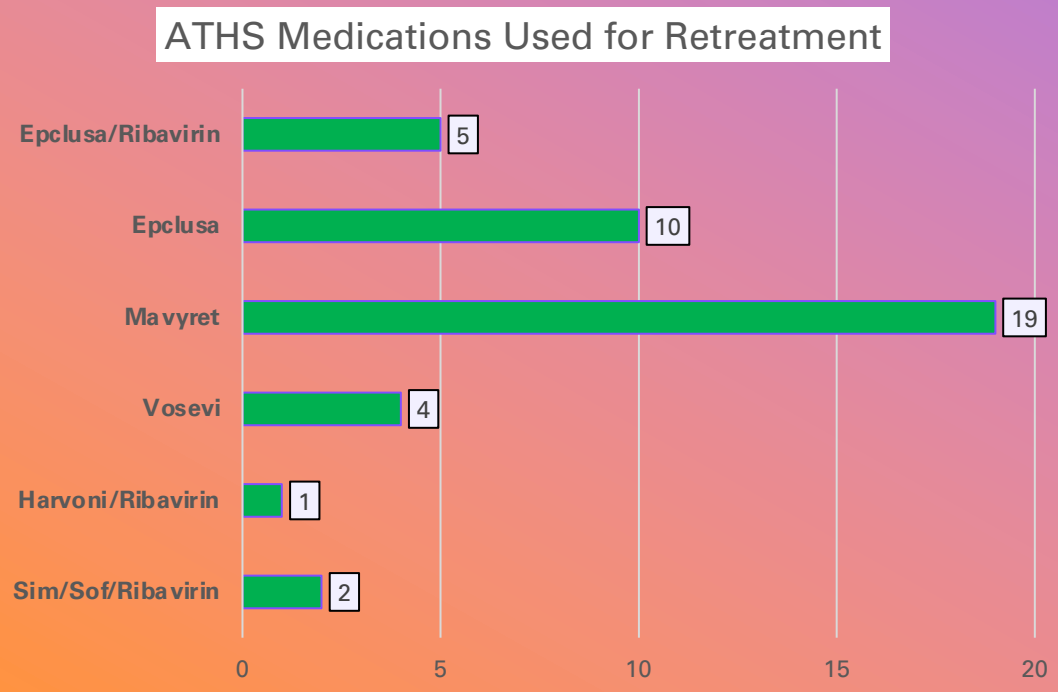
Stratified analysis

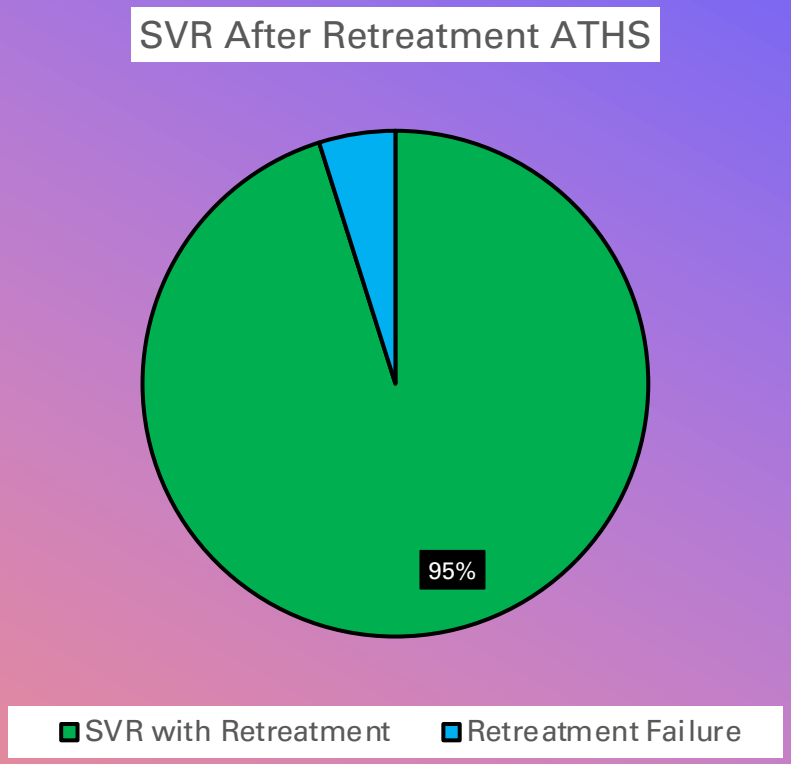
- **1.4/100 person-years (95% CI 0.8–2.6) among people receiving OAT with no recent drug use**
- 5.9/100 person-years (95% CI 4.0–8.6) among people receiving OAT with recent drug use
- 6.6/100 person-years (95% CI 3.4–12.7) among people with recent drug use not receiving OAT

Hajarizadeh B, et al. J Hepatol. 2020 Apr;72(4):643-657. doi: 10.1016/j.jhep.2019.11.012

RETREATMENT AFTER TREATMENT FAILURE OR REINFECTION

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





PREVENTING REINFECTION

Preventing reinfection starts with treatment

- *Persons who are actively injecting drugs should be high priority to treat*
- *Educate treatment patients about reinfection risk*
- *Provide harm reduction supplies*
- *Treat patients as well as partners, inner circle*

1 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

Recommendation for Universal Hepatitis C Screening in Pregnancy	
RECOMMENDED	RATING
As part of prenatal care, all pregnant women should be tested for HCV infection with each pregnancy, ideally at the initial visit.	I, B

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

There are no large-scale clinical trials evaluating the safety of direct-acting antivirals (DAAs) in pregnancy. A small study evaluating the pharmacokinetics of ledipasvir/sofosbuvir in pregnancy demonstrated 100% SVR12 and no safety concerns. Similarly, an international case series of 15 pregnant persons treated with ledipasvir/sofosbuvir reported 100% SVR12 and no early safety concerns in the women or their infants (Yattoo, 2018); (Chappell, 2020). Currently, there are no available data on the use of pangenotypic regimens during pregnancy.

Despite the lack of a recommendation, treatment can be considered during pregnancy on an individual basis after a patient-physician discussion about the potential risks and benefits.

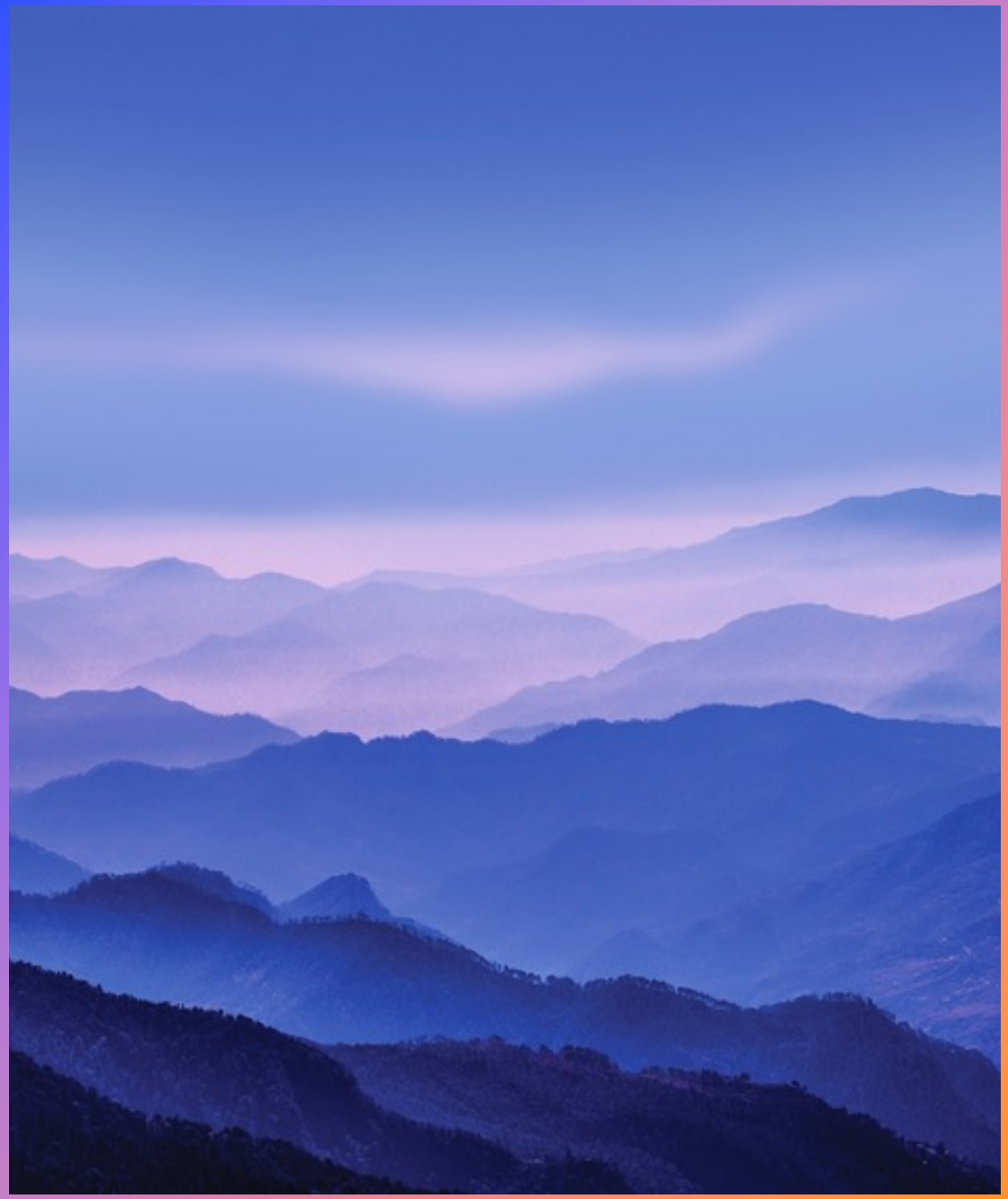
https://www.hcvguidelines.org/unique-populations/pregnancy

ONGOING STUDIES OF HCV TREATMENT IN PREGNANCY

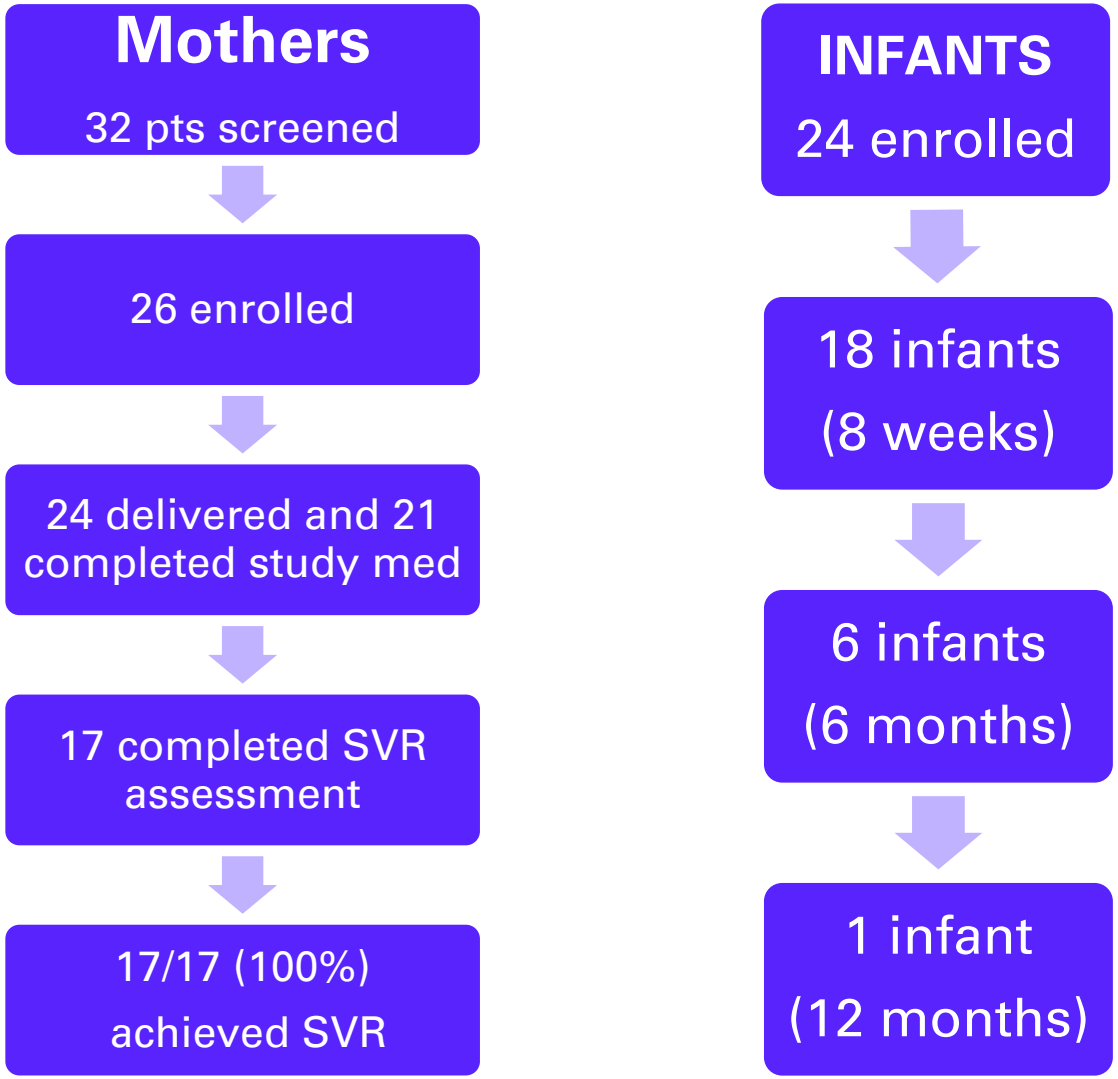
- Glecaprevir/pibrentasvir -Washington University School of Medicine, St. Louis, MO

- Sofosbuvir/velpatasvir - University of Pittsburgh/Multi-center – STORC Trial (has interim results)

https://clinicaltrials.gov/



STORC STUDY SOFOSBUVIR/VELPATASVIR INTERIM RESULTS



100% of infants tested are HCV RNA undetectable (n = 16)

Safety, Tolerability, and Outcomes of Sofosbuvir/Velpatasvir in Treatment of Chronic Hepatitis C Virus during Pregnancy: interim results from the STORC study (natap.org)

Weighing the Pros/Cons of Hepatitis C Treatment During Pregnancy

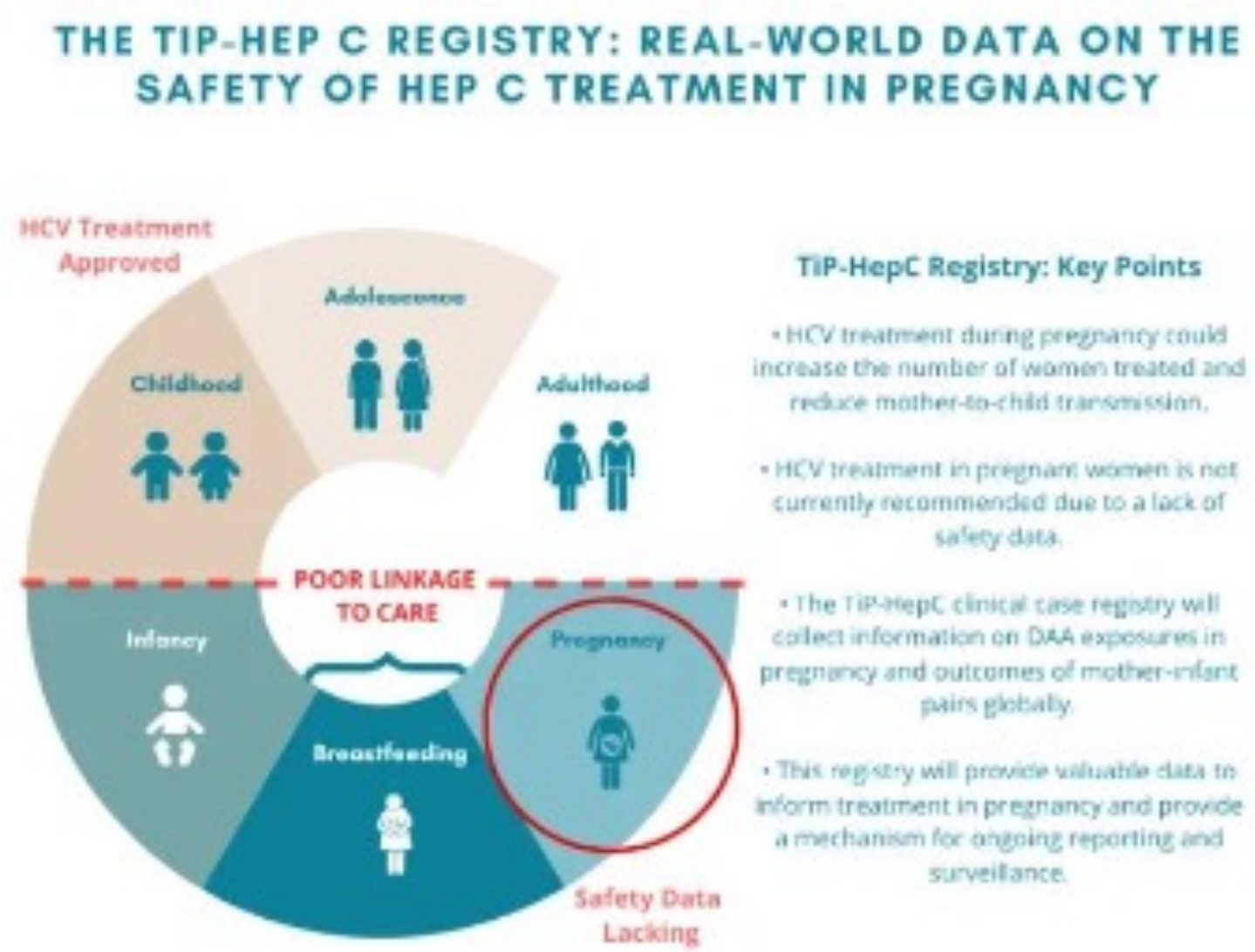
Pros

- Mother cured while engaged in pregnancy care
- Potential decrease in mother to child transmission of HCV
- Mother treated while covered by insurance
- Decrease in community transmission
- Potential decrease in HCV-associated adverse pregnancy outcomes

Cons

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

TIP-HEP C Registry



To submit a case: https://redcap.emory.edu/surveys/?s=C99K9EEYHRLNY8AR

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

SOFOSBUVIR/VELPATASVIR BREASTFEEDING STUDY

- Limited data available
- 1 pharmokinetic study on postpartum hepatitis C treatment
- Tested breastmilk of 4 women who did not intend to breastfeed
- Participants treated with sofosbuvir/velpatasvir for 12 weeks and were willing to provide pumped breast milk for study
- PK levels were done on the breastmilk and infant daily dose was calculated
- The estimated infant daily dose from breastmilk is less than 0.7% of daily dose in an adult and a child adjusted to weight
- Conclusion: Exposure to sofosbuvir and velpatasvir via breastmilk is minimal
- Additional data is needed to confirm safety and effect on milk production

https://www.natap.org/2024/CROI/croi_170.htm

Catherine Chappell, et al. University of Pittsburgh

PEDIATRIC HEPATITIS C TREATMENT

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

[1]Harvoni full prescribing information: https://www.gilead.com/~/media/files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf
[2]Epclusa full prescribing information: https://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf
[3]Mavyret full prescribing information: https://www.rxabbvie.com/pdf/mavyret_pi.pdf

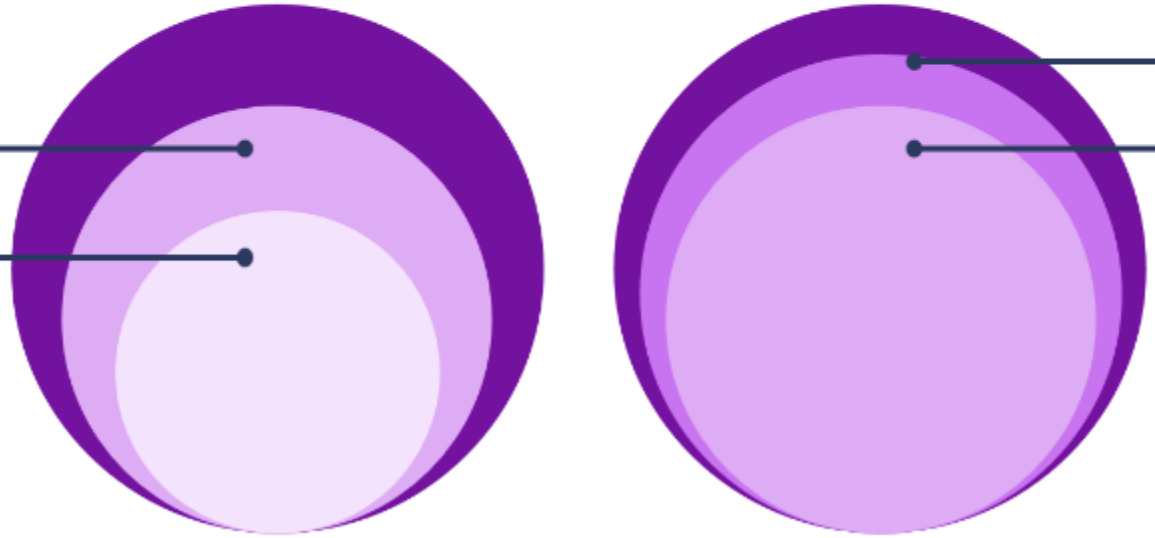
Achieving HCV Elimination

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:

Reducing new HCV infections by **80%**

Reducing HCV-related deaths by **65%**

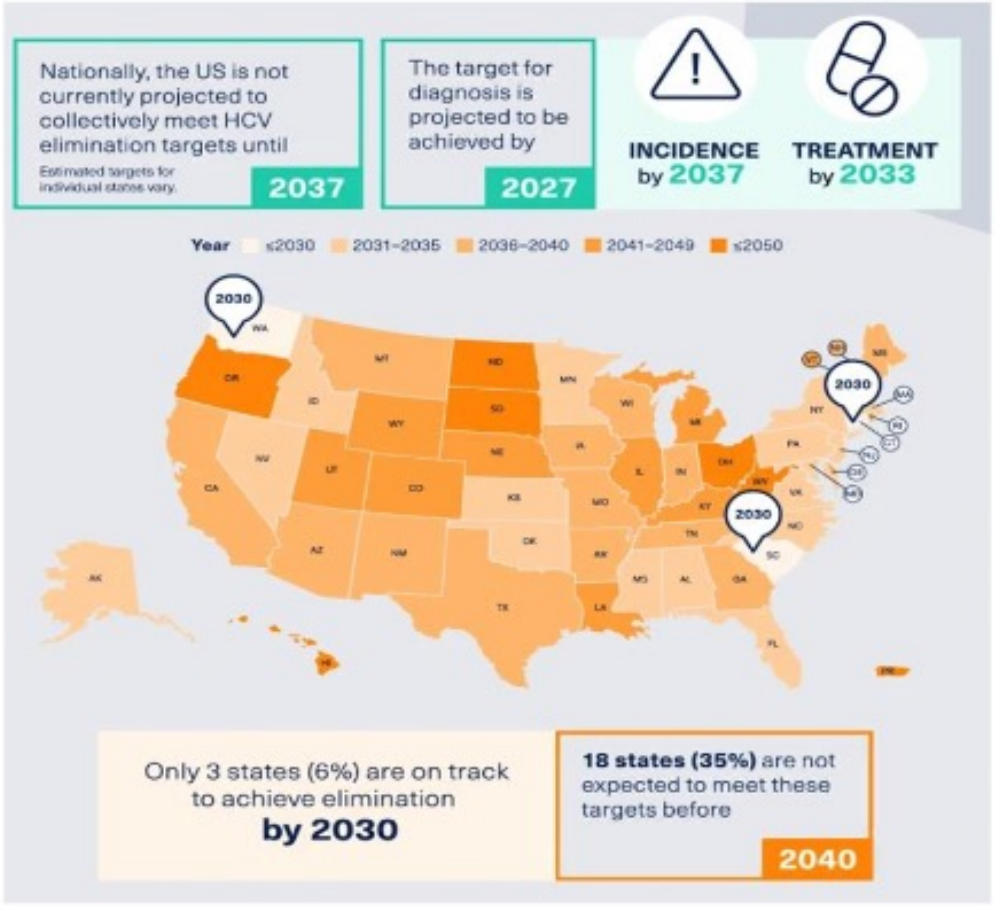


90% **Diagnosing** of the HCV-infected population

80% **Treating** of the eligible population

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

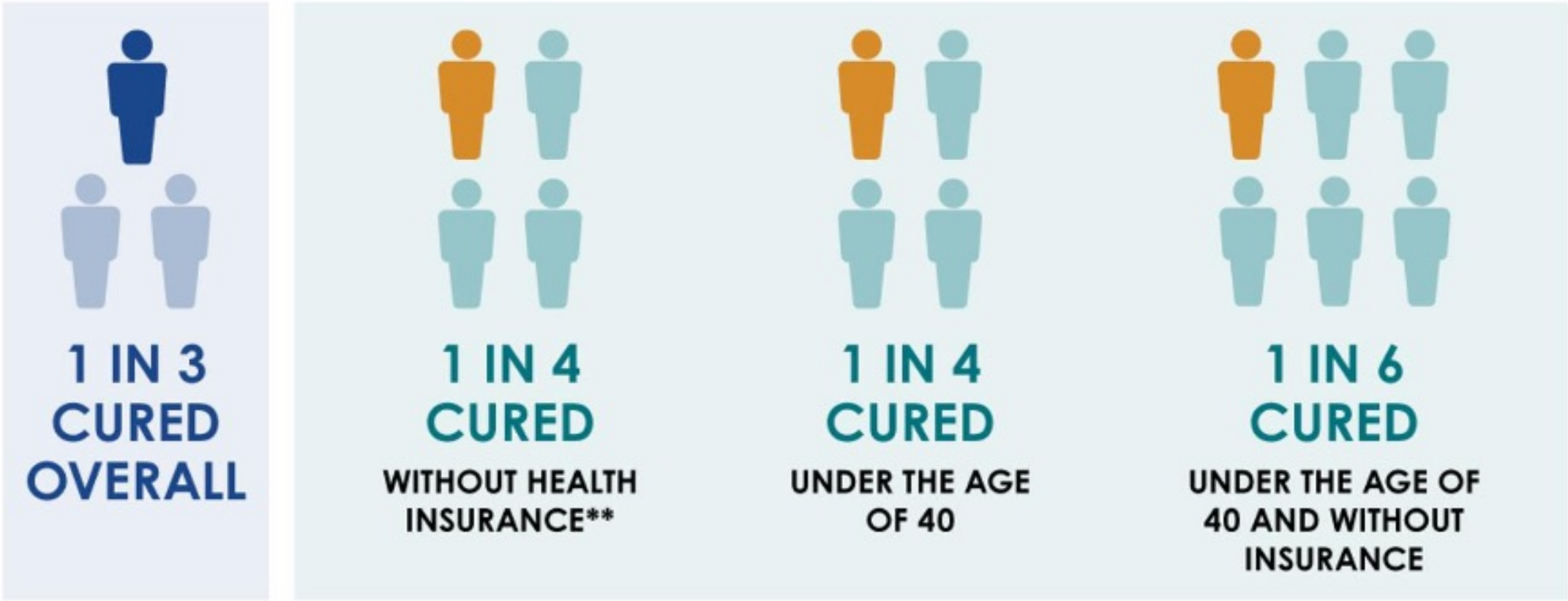
Progress Toward HCV Elimination in the United States



- 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. *Adv Ther* **38**, 423–440 (2021). https://doi.org/10.1007/s12325-020-01535-3

ADULTS DIAGNOSED AND CURED* OF HEPATITIS C IN THE U.S., 2013-2022



*Cured is defined as viral clearance, which is an undetectable hepatitis C virus ribonucleic acid (HCV RNA) after a prior test result of detectable HCV RNA.

**Referred to as Other (client or self-pay) in the analysis

Source: Centers for Disease Control and Prevention

US National HCV Elimination Plan

March 9, 2023

A National Hepatitis C Elimination Program in the United States

A Historic Opportunity

Rachael L. Fleurence, MSc, PhD[1]; Francis S. Collins, MD, PhD[1]

Author Affiliations | Article Information

JAMA. Published online March 9, 2023. doi:10.1001/jama.2023.3692

Highlights of the White House Plan

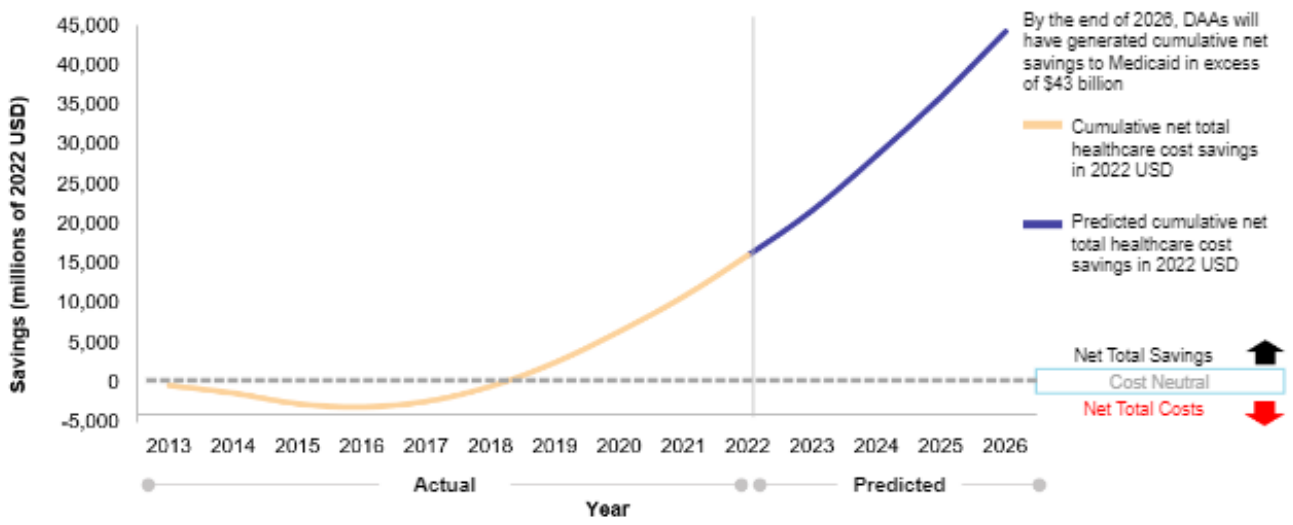
Proposed a plan to eliminate hepatitis C in five years in the United States through a mandatory authorization:

1. Supporting the development of point-of-care diagnostic tests to enable a test-to-treat model;
2. Broadening access to curative hepatitis C medications, primarily through a national subscription model; and
3. Expanding infrastructure needed to reach, test, and treat all affected individuals.

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

- 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.[1,2]

Medicaid cost savings with DAAs



¥Savings included hospitalizations, emergency department visits, physician office visits and prescription drug refills avoided as a result of DAA use

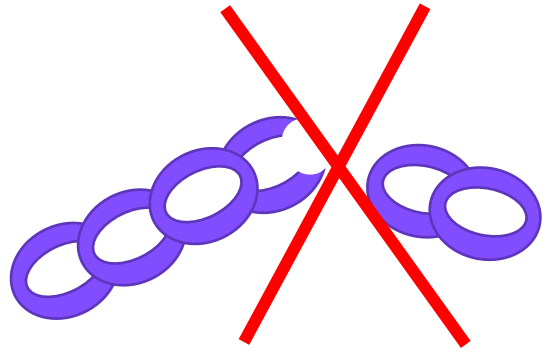
DAA: direct-acting antiviral; $M: dollars in millions; Act; PWID: People who inject drugs.

1. Roebuck MC. *Am J Manag Care*. 2022;28(12):630-631.
2. Roebuck MC, Liberman JN. *Am J Manag Care*. 2019;25(8):S131-S139.

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

20

Current Missed Opportunities



- Persons who test positive for hepatitis C aren't linked immediately to care/treatment
- Hepatitis C treatment rarely offered outside traditional healthcare settings

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

Conclusion

- 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 alcohol and opioid treatment but do not delay HCV treatment
- Be sure to link patients with ongoing SUD to harm reduction services

THANK YOU!

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www.anthc.org/hep