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

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I have no conflicts of interest to disclose

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Objectives

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

Hepatitis C Epidemiology

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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.

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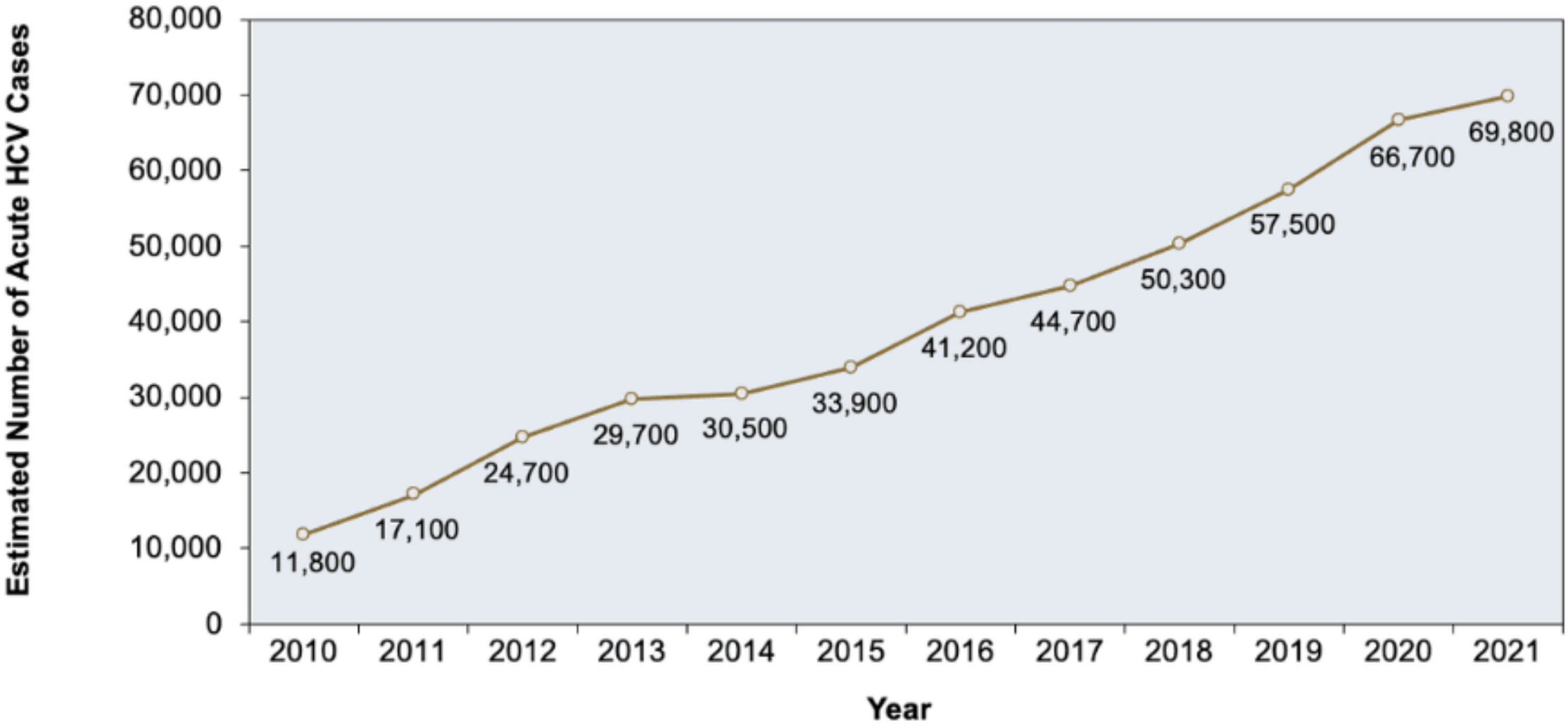

Alaska Proportion of Newly Reported Chronic Hepatitis C Cases Among Adults Age ≥ 18Y, By Age Group and Year

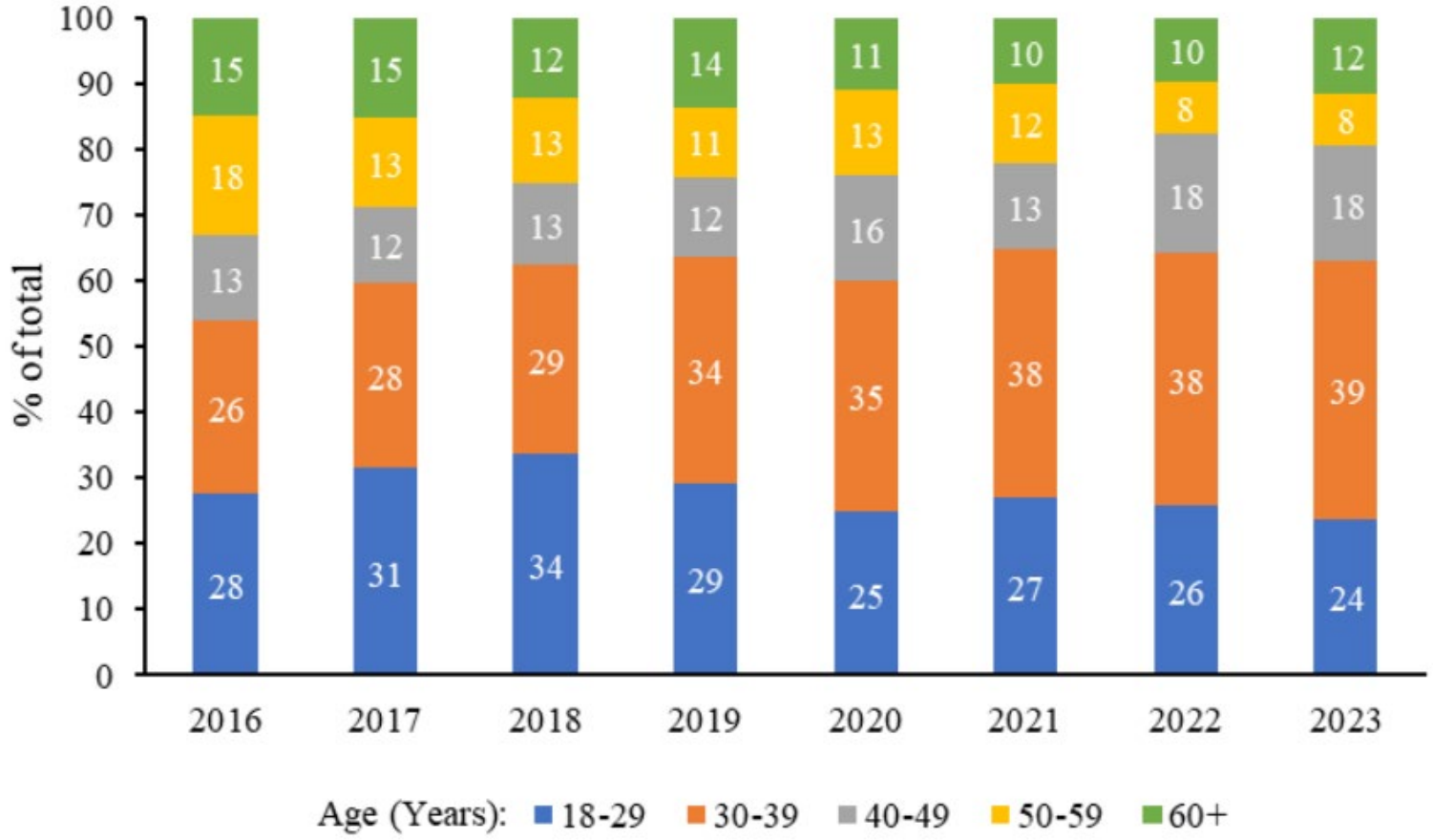

Figure 2. Proportion of Newly Reported Chronic Hepatitis C Cases Among Adults Aged ≥18 years, by Age group and Year — Alaska, 2016–2023

Chronic Hepatitis C Rate per 100,000 Adults

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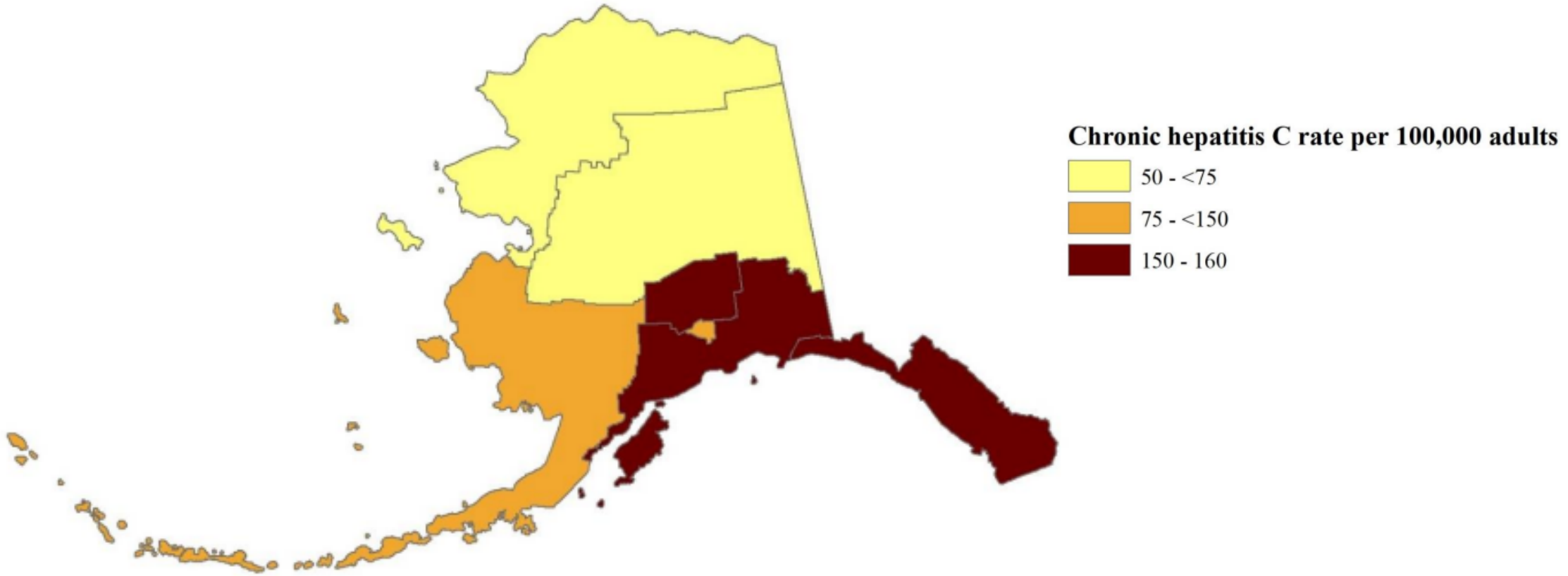
Figure 3. Average Age-Standardized Rate of Newly Reported Chronic Hepatitis C Cases per 100,000 Adults Aged ≥18 years, by Region — Alaska, 2016–2023



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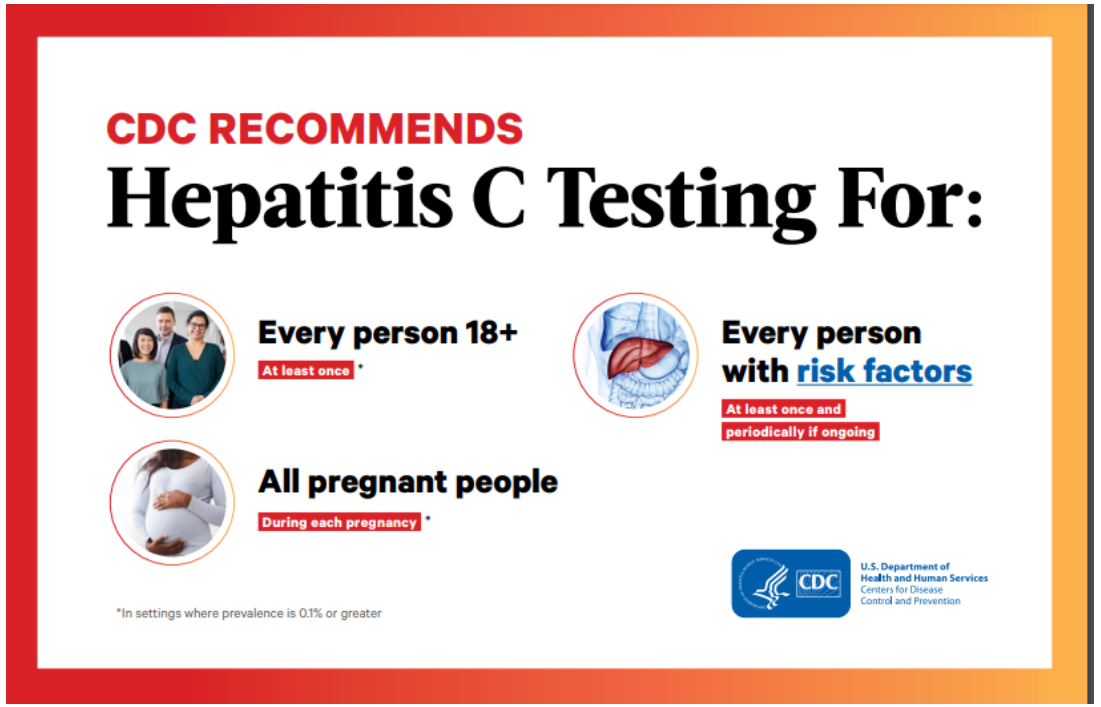
Adult Screening

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

  (RNA Qualitative or Quantitative Lab)



People AFAB are at Higher Risk for HCV Transmission

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- AFAB 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
  - Higher rates of equipment and syringe sharing in AFAB than AMAB
  - More AFAB using injection equipment after AMAB partners
  - More AFAB injected by others
- More likely than AMAB to have sex partners who inject drugs
  - Overlapping sexual and injection partnerships leads to increased injection risk
- PWID AFAB face increased stigma; less likely to participate in harm reduction services.

New Pediatric Screening Recommendation

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Prevalence of HCV in Children and Adolescents in the United States

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

Maternal HCV

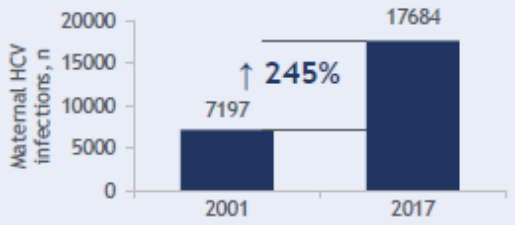
Total Cases

154,016

% of Total Live Births

0.24%

Number of Maternal HCV Infections Over Time



Pediatric HCV

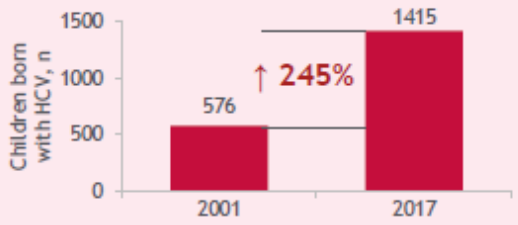
Total Born with HCV

8,649

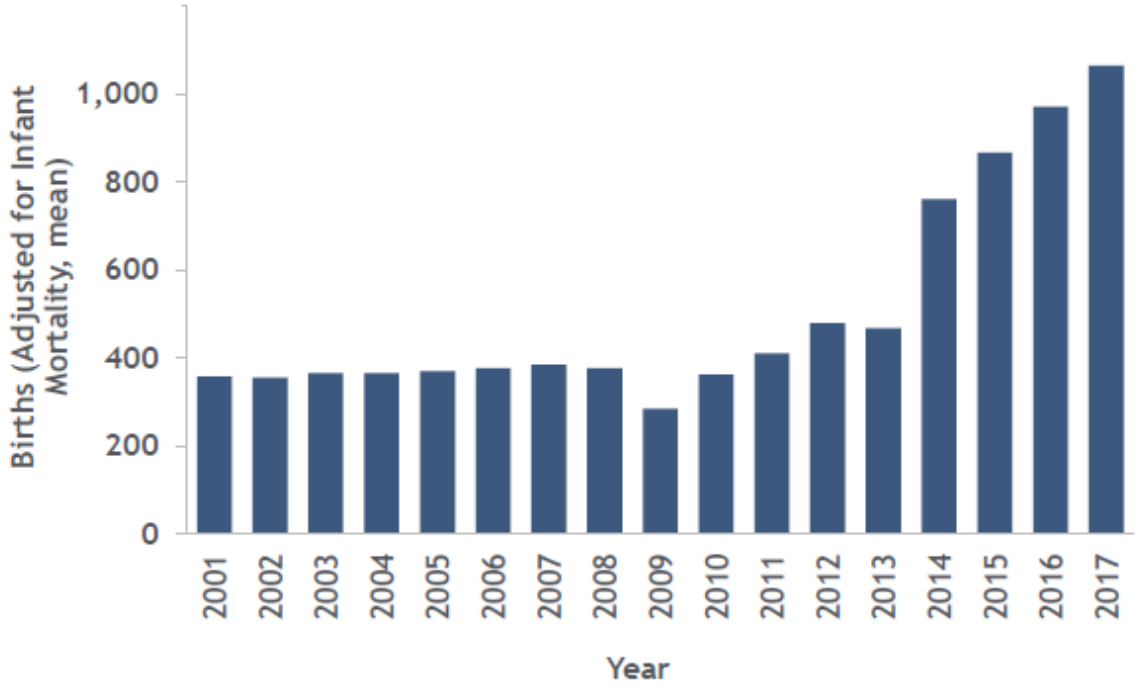
% of Total Live Births

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

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- **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

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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

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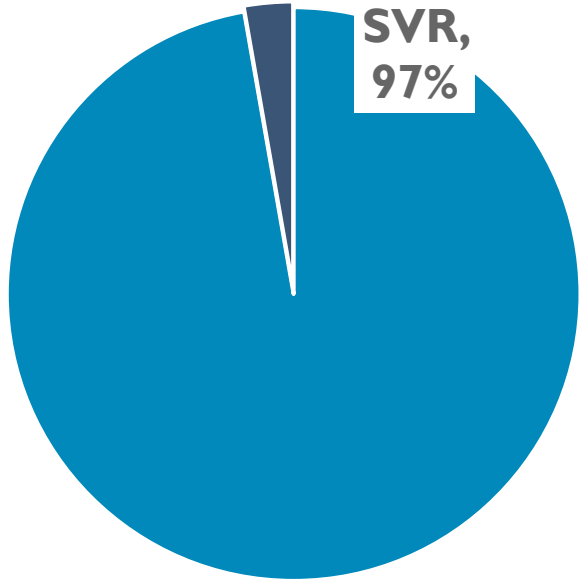
Global Data

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

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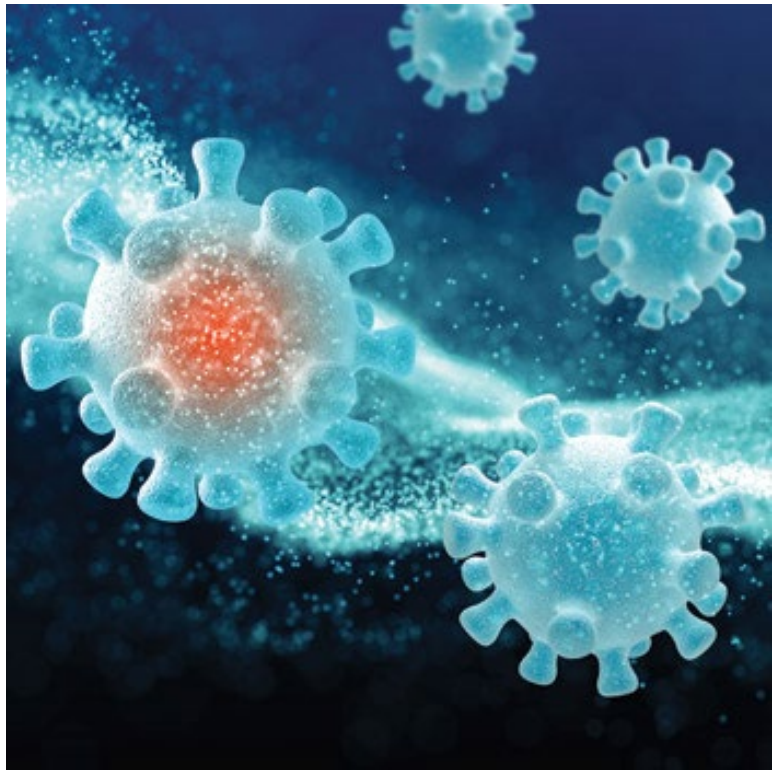
- Eligibility: Adults with HCV (any genotype) who do **not** have decompensated cirrhosis and have **not** previously been treated.
- Who is not eligible for simplified HCV therapy:
  - HBsAg positive, current pregnancy, known or suspected HCC, prior liver transplantation, end-stage renal disease (eGFR <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)



- www.hcvguidelines.org

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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

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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.

Be Aware of Potential Drug Interactions

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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)

HCV Simplified Treatment for Alaska Tribal Health System

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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

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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

Hepatitis C Online: www.hepatitis.uw.edu

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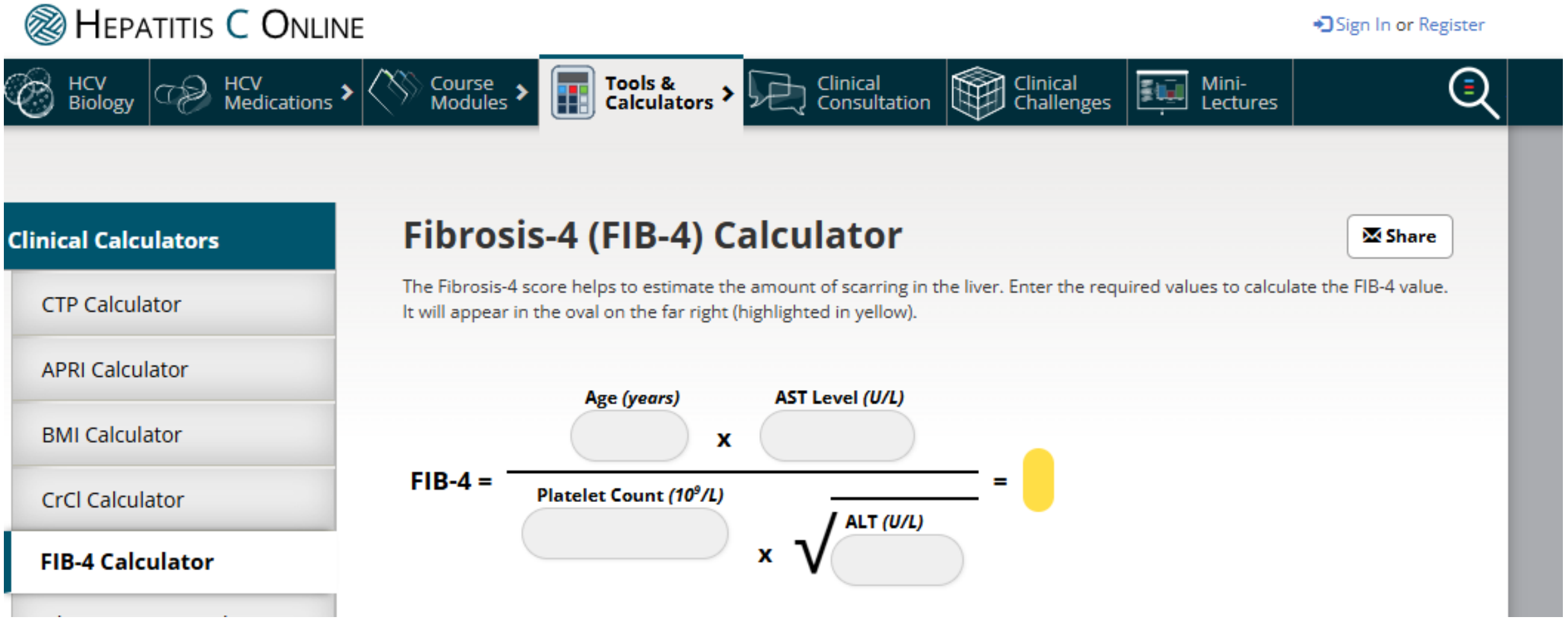

Step 3: Write Prescriptions / Start Treatment

- 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

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

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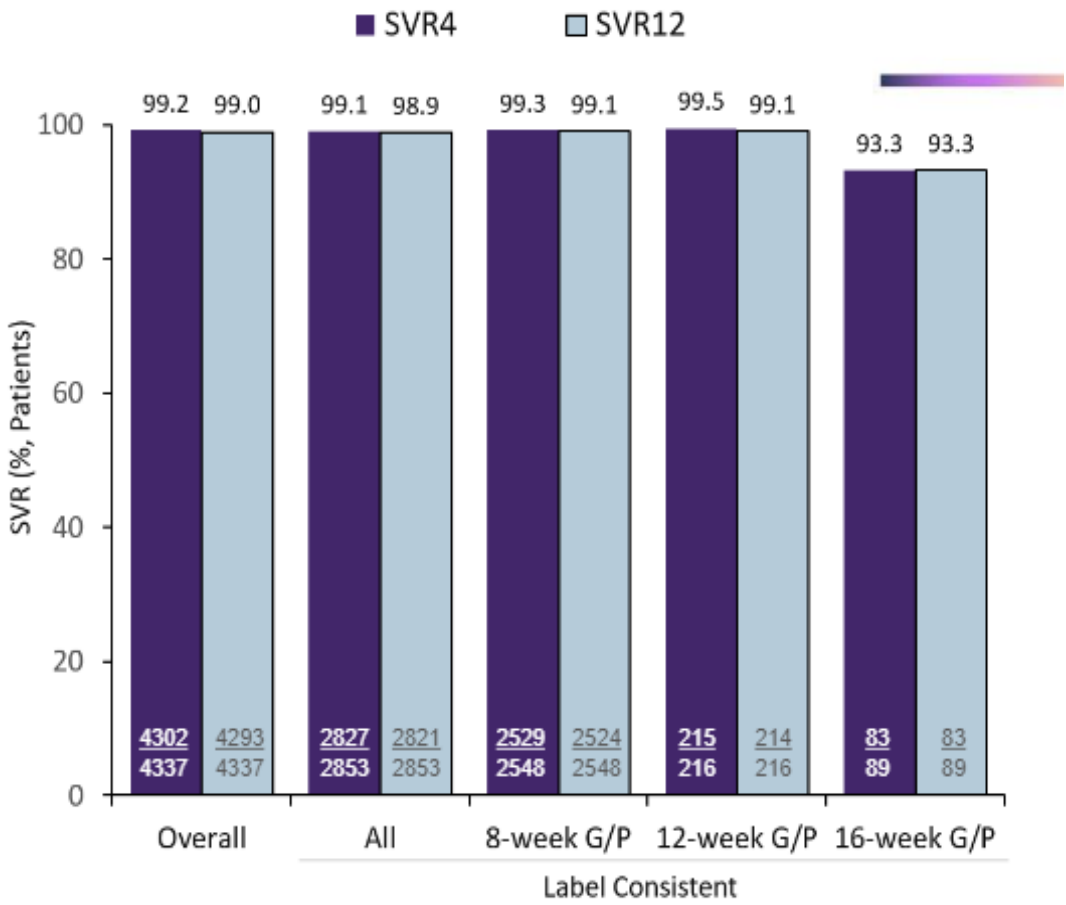
- Patients receiving G/P in clinical trials
- >99% of patients that achieved SVR4 achieved SVR12
- All patients that did not achieve SVR4 did not achieve SVR12 (NPV=100%; sensitivity=100%)
- Specificity was 79.5%, indicating the majority of patients relapsing do so by post-treatment week 4

	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



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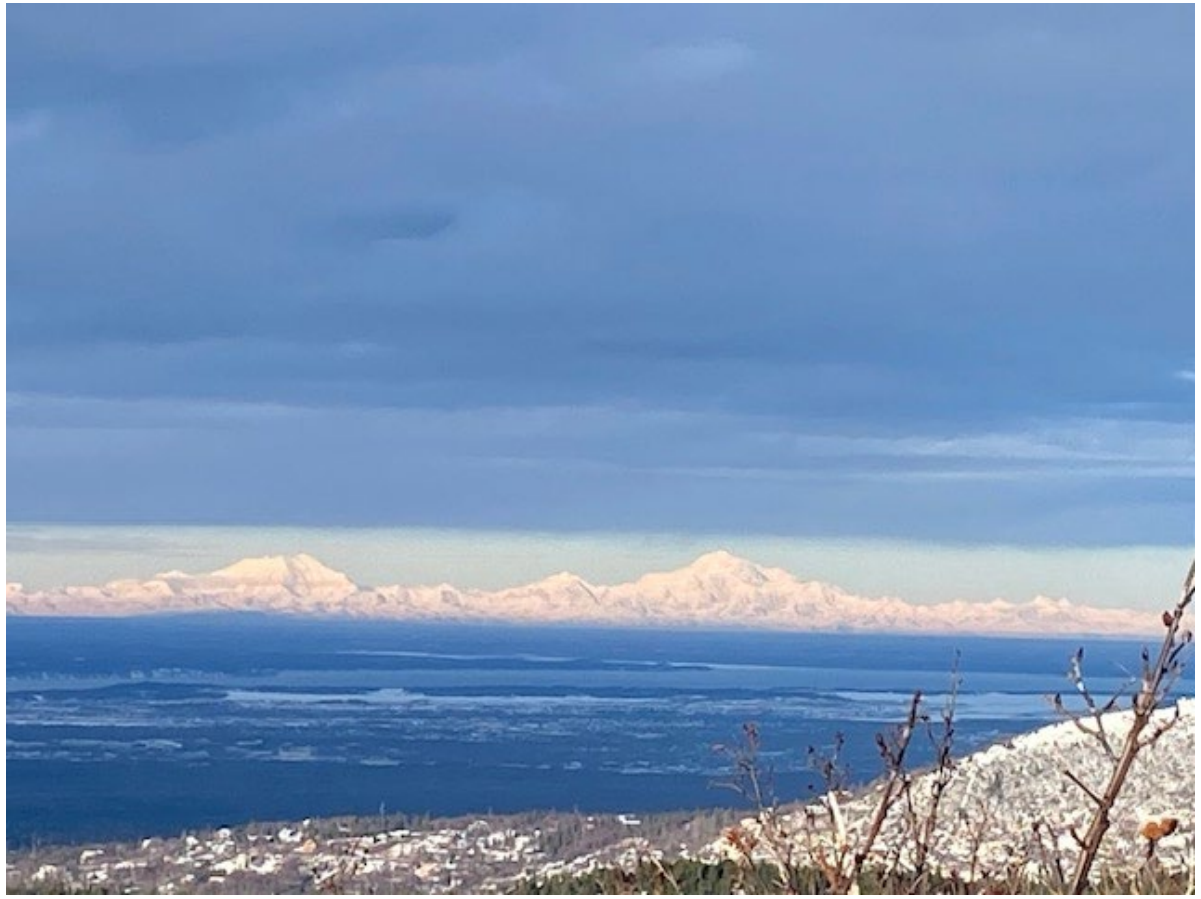
Lesser Discussed HCV Treatment Scenarios

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



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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

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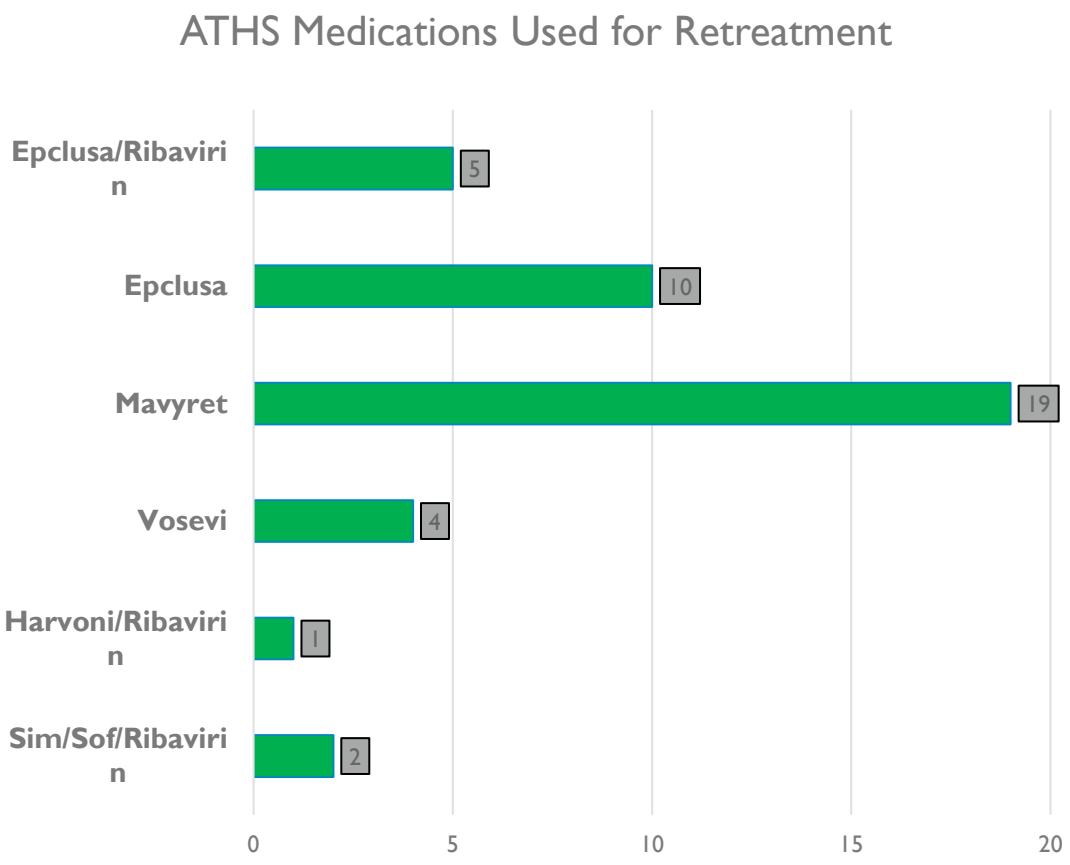
- Thirty-six studies were included (6,311 person-years of follow-up)
- **Overall rate of HCV reinfection was 5.9/100 person-years (95% CI 4.1 – 8.5) among people with recent drug use (injecting or non-injecting)**
- 6.2/100 person-years (95% CI 4.3 – 9.0) among people recently injecting drugs
- 3.8/100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

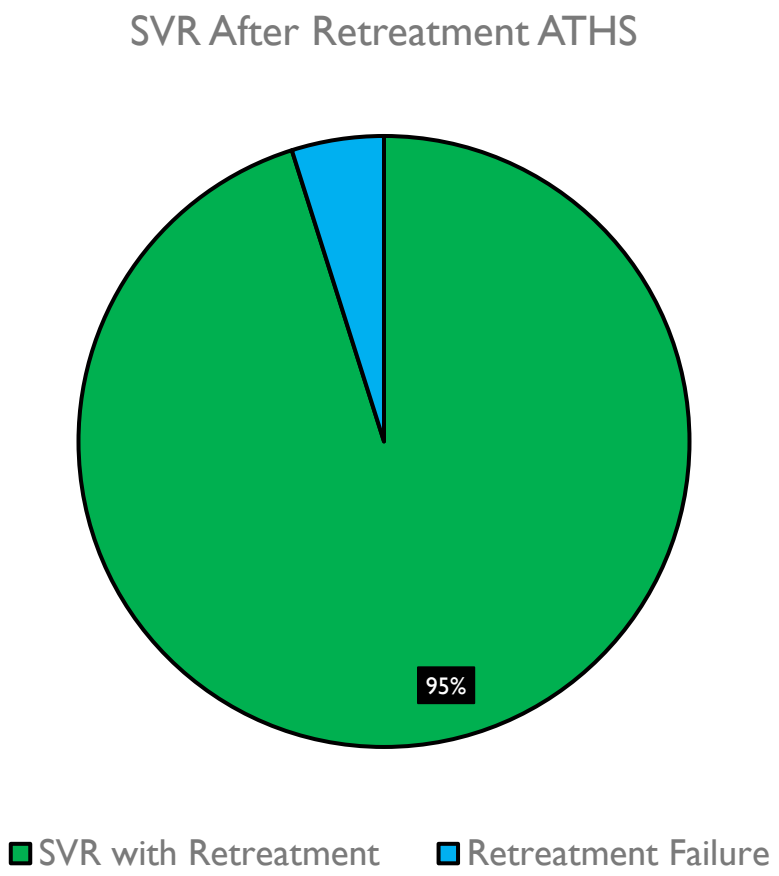
Stratified analysis

- 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

Retreatment After Treatment Failure or Reinfection





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

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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

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- 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.

Current guidelines

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

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

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

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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

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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

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Hepatitis C and Breast/Chest Feeding

Recommendations Regarding Breastfeeding and Postpartum Care for HCV-Infected Women	
RECOMMENDED	RATING ⓘ
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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

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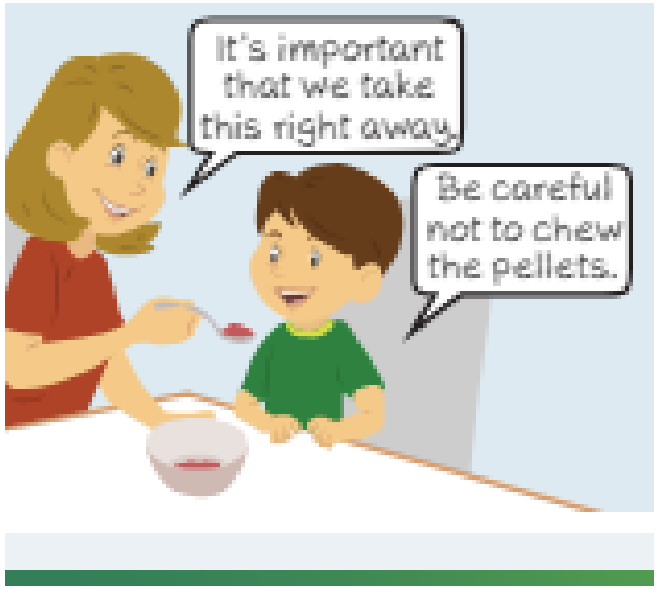
Pediatric HCV Therapy

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

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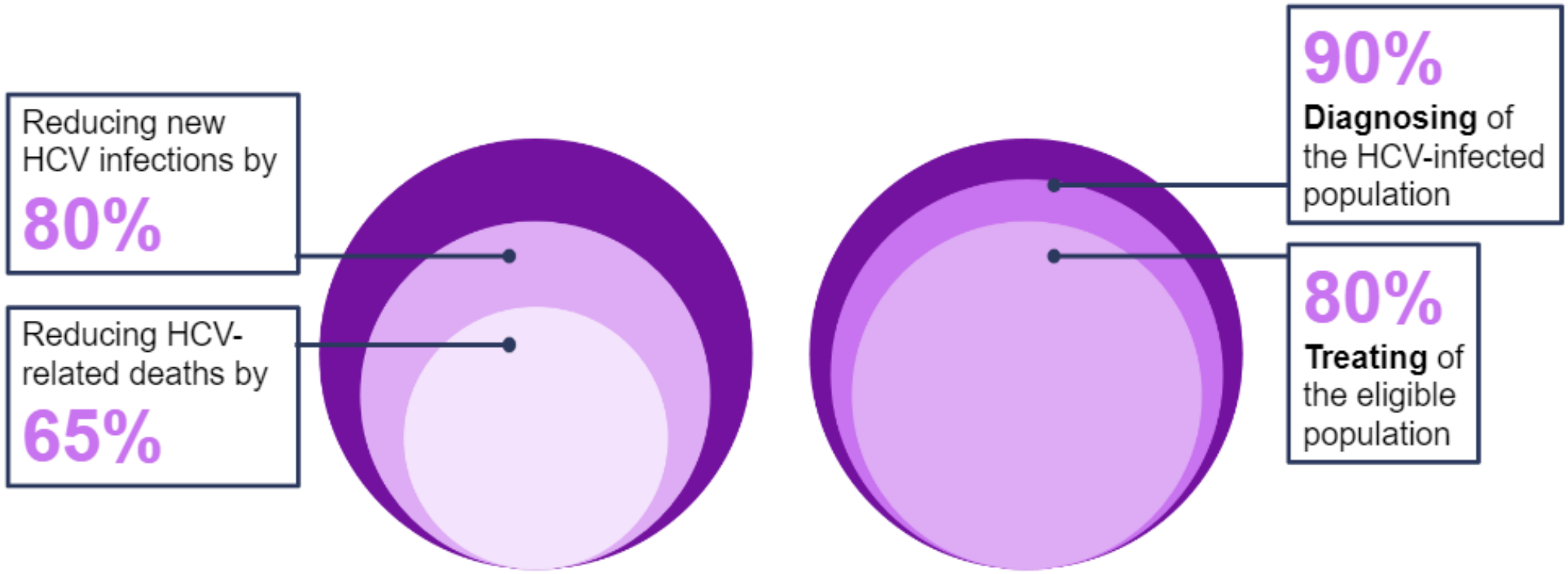
WHO Elimination Target

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

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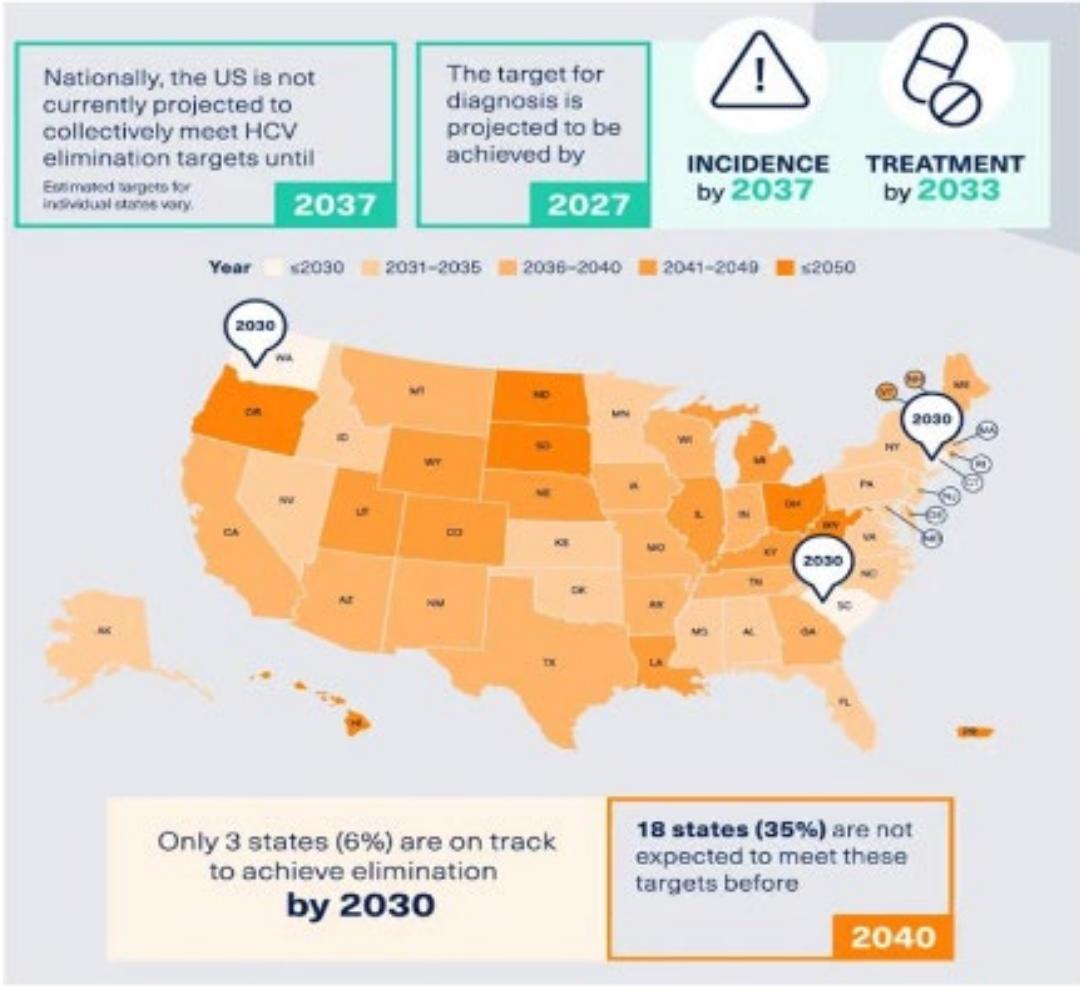
Progress Toward HCV Elimination in the United States

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 Ahcieve the World Health Organization's Eliminatiorn Targets for Hepatitis C.

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

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- Source: CDC

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

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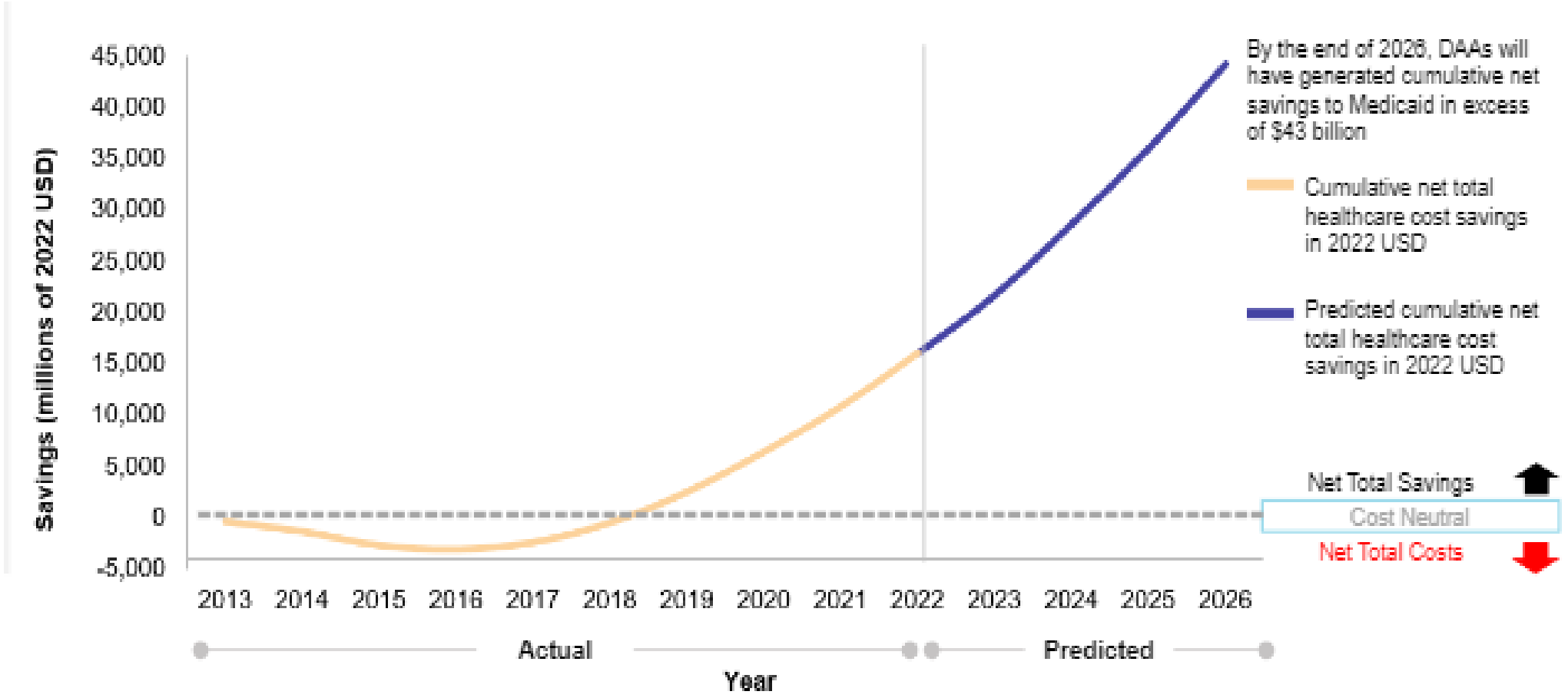

Within a decade of introduction, DAAs provided Medicaid with a cumulative net total healthcare savings* of more than $15 billion and projected to increase up to $43 billion by 2026.

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

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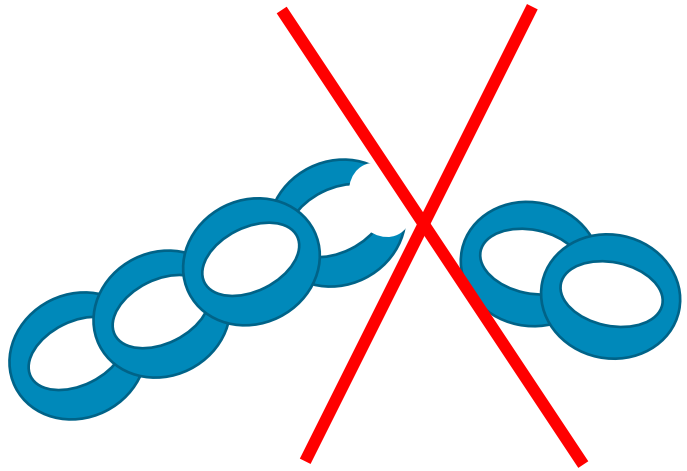
Current Missed Opportunities

- 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

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

Alcohol-associated Liver Diseases: Awareness is the Cure

Kena K. Desai MD

Tim Collins MPH, MS, MA

Hillary Booth

Learning Objectives:

- Recognize that Alaskans suffer from alcohol-associated liver disease mortality at high rates.
- Recognize that AN/AI women of child-bearing age are more affected by alcohol-associated liver disease mortality then AN/AI men.
- Understand that treatment of alcohol use disorder works to prevent development and progression of alcohol-associated liver disease.
- Advise that pharmacotherapy for alcohol use disorder in liver disease, including liver cirrhosis, is safe.

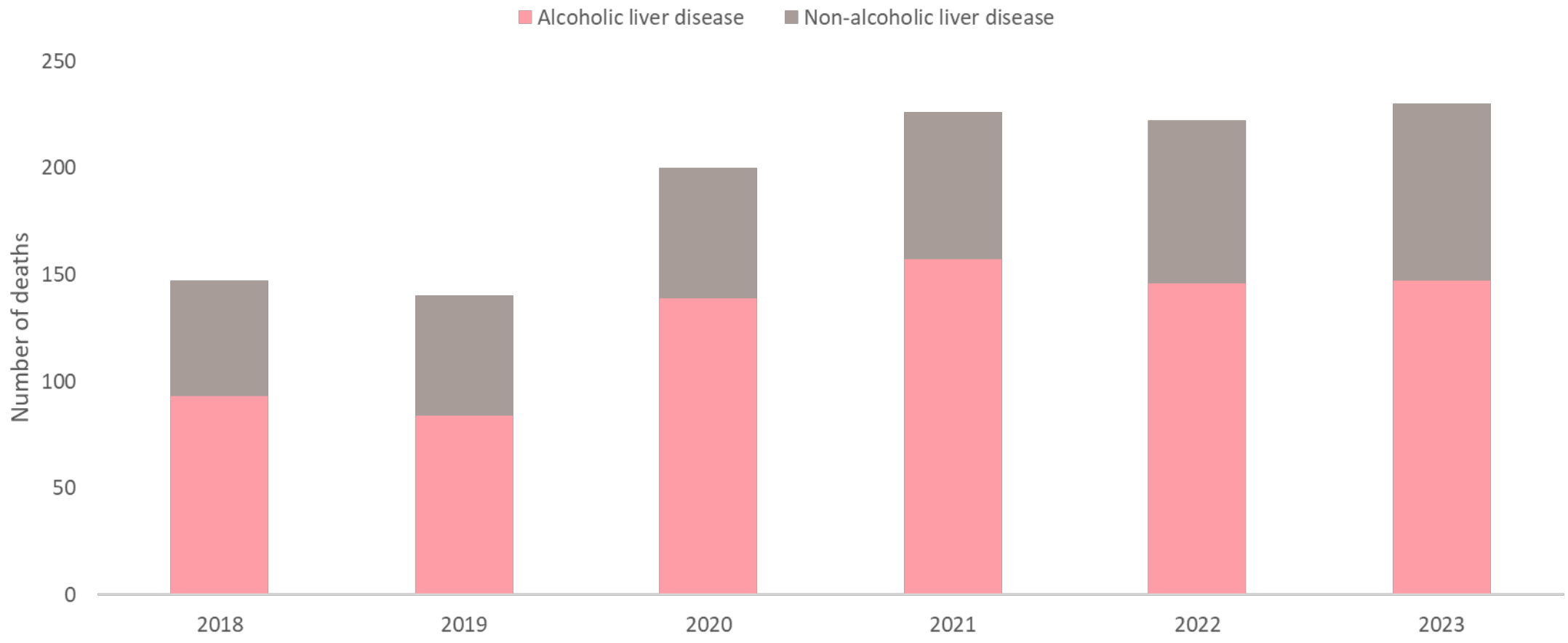
Case 1: Martha is a 30 year old female, with a history of depression, insomnia and alcohol use disorder, that presents for post-hospitalization follow-up for alcohol hepatitis.

- Server in a restaurant, is single and has no children
- She would drink alcohol with co-workers after her restaurant shift ended
- Had been drinking vodka or whiskey, 4 to 6 glasses nightly, for 5 years
- During the Covid-19 pandemic, she lost her job and alcohol use increased to ½ a bottle of "Fifth (750 ml)"
- She had presented to the emergency room 2x for alcohol withdrawal symptoms
- In January 2023, she developed symptoms of abdominal pain/bloating, loss of appetite and fatigue
- In the weeks that followed, she developed yellowing of the eye and skin, as well as swelling of the legs
- She presents to the emergency room in 03/2023 with worsening jaundice, abdominal distention and lower extremity edema

- Vital signs: 98.4 F / HR – 142 / BP – 107/66 / RR-24 / 95% on RA / 60.4 kg / BMI - 24
- Serum Labs: WBC – 24 / platelets – 105 / INR – 2.8 / Total Bilirubin – 18 / AST – 230 / ALT – 190 / alkaline phosphatase - 250
- Ascites Fluid: no indication of spontaneous bacterial peritonitis
- MELD 3.0 score (additional variables to enhance accuracy and address disparity btw. men and women): 34 – > 52% 90 days survival .

- **She is hospitalized for alcohol hepatitis.**

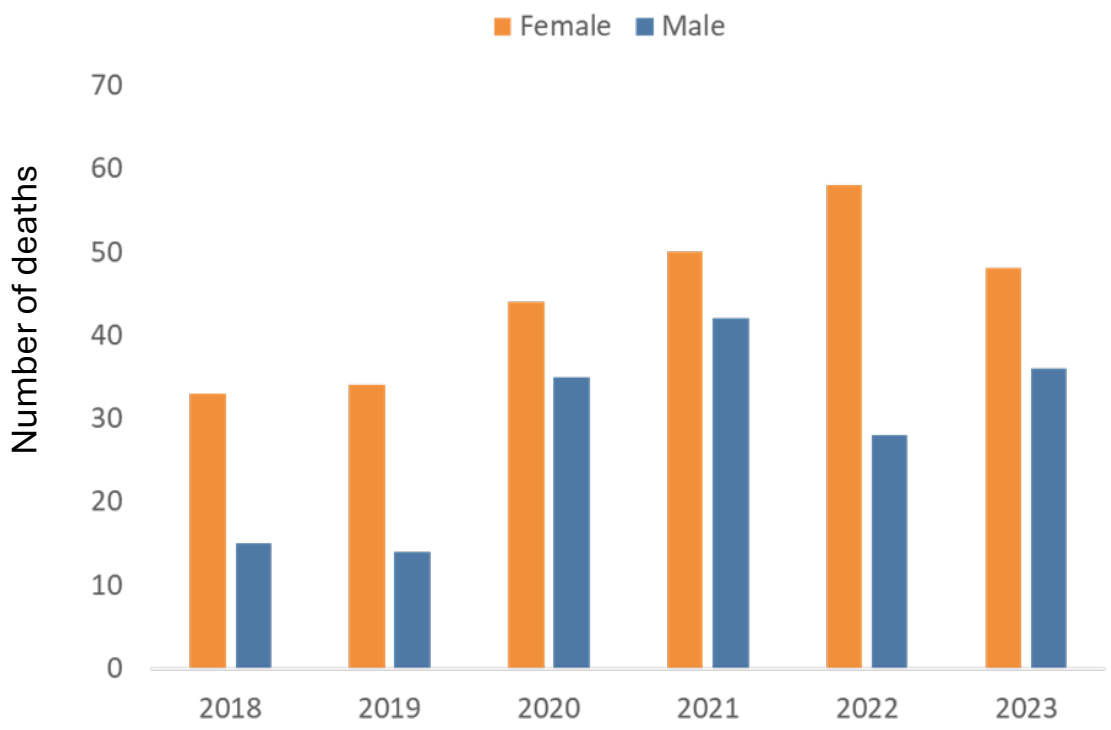
Number of liver disease deaths, alcohol-associated and non-alcohol associated, Alaska residents, 2018 through 2023



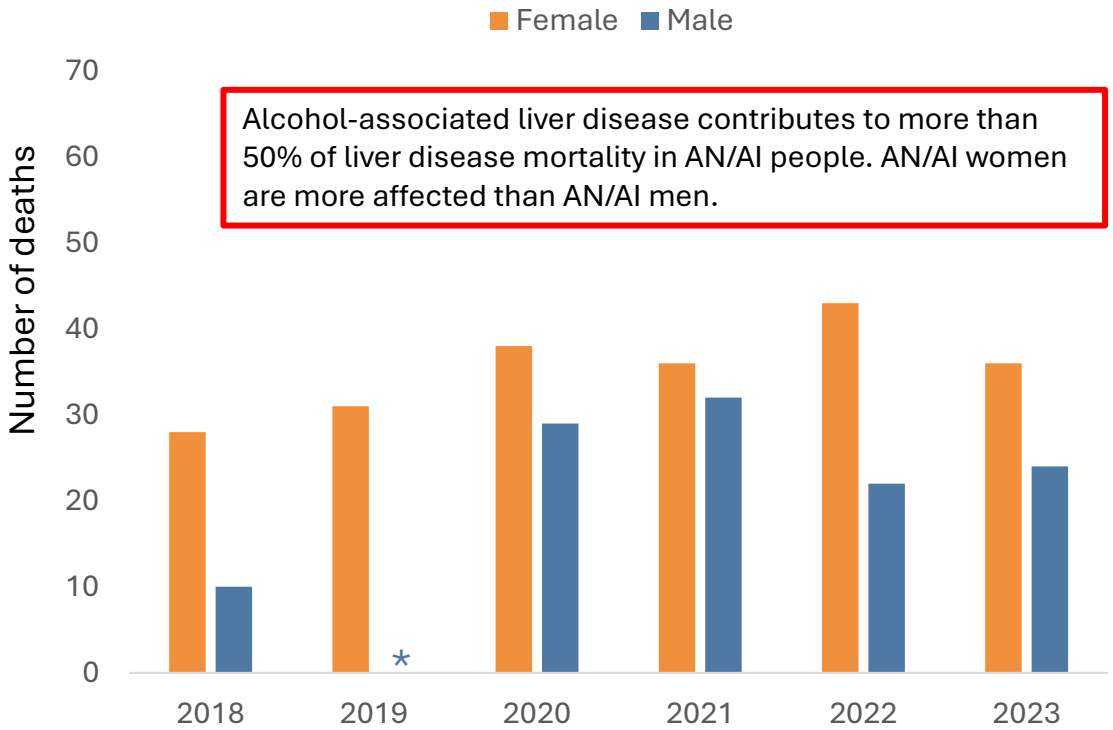
Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Final Multiple Cause of Death Files, 2018-2021, and from provisional data for years 2022-2024, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

Number of all cause liver disease and alcohol-associated liver disease deaths, Alaska residents, AN/AI, by sex, 2018-2023.

All cause liver disease mortality

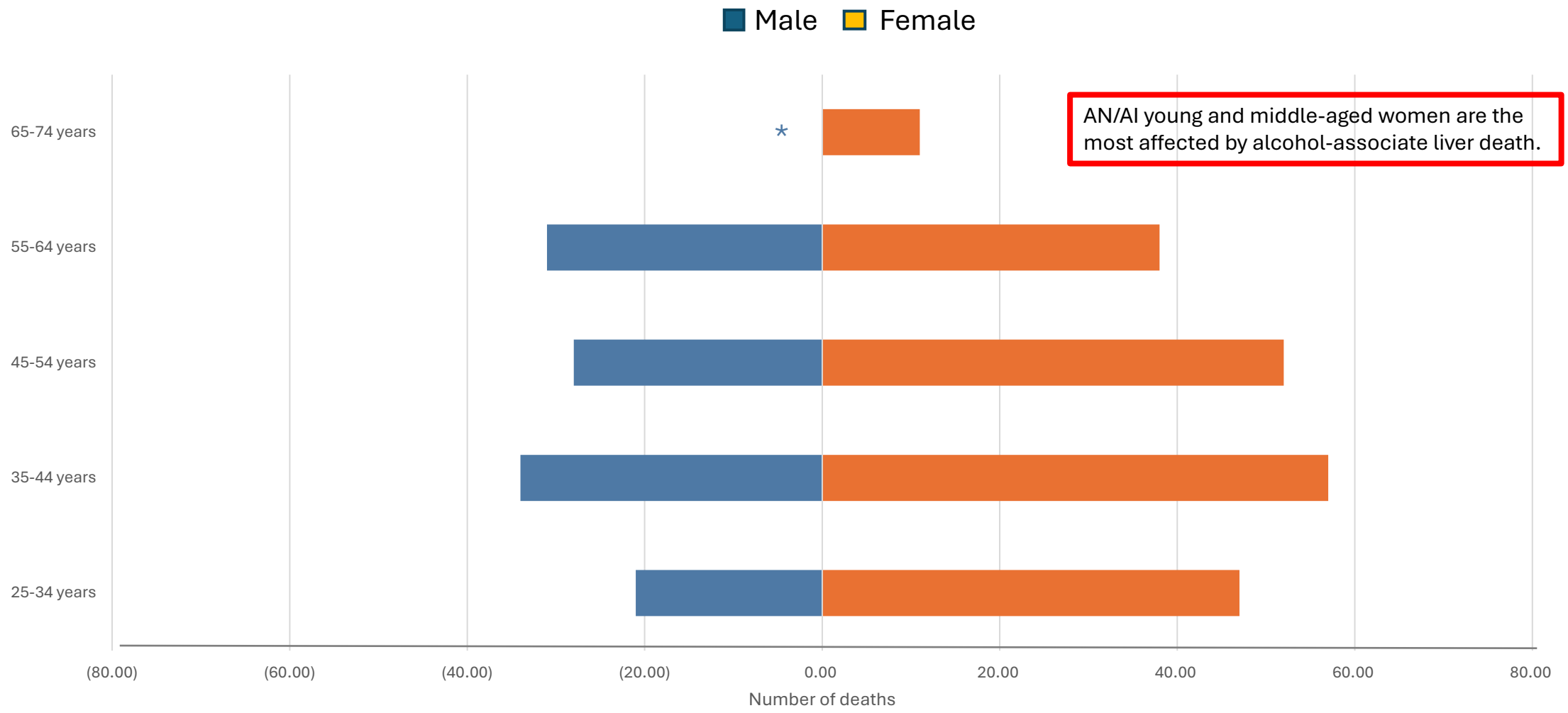


Alcohol-associated liver disease mortality



* Suppressed due to low counts. CDC, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Final Multiple Cause of Death Files, 2018-2021, and from provisional data for years 2022-2024, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

Number of alcohol-associated liver disease deaths, Alaska residents, AN/AI only, by sex and ten-year age group, 2018-2023



* Suppressed due to low counts. CDC, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Final Multiple Cause of Death Files, 2018-2021, and from provisional data for years 2022-2024, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

- Martha reports that since her hospitalization she has not drunk alcohol, but is having alcohol cravings, insomnia and severe pain and tingling in her hands and feet.

- She is interested in medications for alcohol cravings, but not in alcohol rehab because she wants to return to work.

- Vital signs: 97.8 F / HR – 110 / BP – 98/66 / RR – 14 / 95% on RA / 54 kg / BMI - 22
- mild icterus, jaundice, + spider angiomata on chest and arms
- abdomen is distended, but soft and no tender, + caput medusa
- Trace lower extremity edema

- Labs: WBC – 12 / platelets – 80 / INR – 2.1 / T.Bil – 11 / AST – 86 / ALT – 60 / Alk Phos - 178
- MELD 3.0 = 28 -> 80%, 90 days survival

- **She asks what will happen if I drink alcohol?**

Awareness is the Cure

Clear message:

- **The only cure for alcohol-associated liver disease is stopping alcohol use.**
- **If you want to live, you can never drink alcohol again.**

Awareness is the Cure

Recognition of Sentinel Events: Emergency room and hospitalizations

1. Alcohol intoxication, withdrawals and alcohol-associated accidents
2. Alcohol hepatitis
3. Alcohol-associated decompensated liver failure

Good evidence that treatment the of the etiological cause of liver disease, alcohol use disorder, improves clinical outcomes.

Etiological cure prevents further decompensation and mortality in patients with cirrhosis with ascites as the single first decompensation event. Tonon et al. Hepatology 2023; 78:1149-1158.

Retrospective design - chart review from 01/2003 to 03/2023.

Study population: (n = 622)
Patients with liver cirrhosis and ascites as the 1st decompensation event.

Primary end point:
- Next decompensation event
- Death
- Liver transplant
- End of study 09/2023

TABLE 1 - Characteristics of patients at inclusion

	Patients (n = 622)
Age (y) – mean ± SD	56.5 ± 11.2
Sex (M vs. F), n (%)	423 (68)
Etiology, n (%)[a]	
HCV	142 (22.8)
HBV	58 (9.3)
Alcohol	366 (58.8)
NASH	75 (12.1)
Autoimmune/cholestatic	30 (4.8)
Other	36 (5.8)

Addiction Specialist

TABLE 2 - Characteristics of patients according to the response to an etiological treatment

	Cured (n = 146)	Controlled (n = 170)	Not controlled (n = 306)	*p*
Age (y), mean ± SD	56.0 ± 10.6	54.7 ± 11.2	57.7 ± 11.4	0.014[a]
Sex (M vs. F), n (%)	103 (70.5)	108 (63.5)	212 (69.3)	0.328
Etiology, n (%)[b]				
HCV	65 (44.5)	6 (3.5)	71 (23.2)	<0.001
HBV	10 (6.8)	25 (14.7)	23 (7.5)	0.024
Alcohol	83 (56.8)	120 (70.6)	163 (53.3)	0.001

Alcohol-Associated liver cirrhosis with ascites:
- 6 months of sobriety = Cured.
- Sobriety maintain through the study period with a median follow=-up of 4 years.

Etiological cure prevents further decompensation and mortality in patients with cirrhosis with ascites as the single first decompensation event. Tonon et al. Hepatology 2023; 78:1149-1158

TABLE 3 - Predictors of further decompensation in multivariable analysis

	Model 1 (including CTP)	
	HR (95% CI)	p
Age (y)	1.02 (1.01–1.03)	0.001
Female (vs. Male)	0.57 (0.41–0.78)	<0.001
Creatinine (mg/dL)	1.04 (0.90–1.21)	0.560
Sodium (mmol/L)	0.95 (0.93–0.96)	<0.001
Alcohol etiology	1.01 (0.78–1.28)	0.956
Varices at inclusion (vs. no varices)	1.45 (1.12–1.87)	0.005
CTP class		
B (vs. A)	1.64 (1.19–2.26)	0.002
C (vs. A)	2.03 (1.37–3.01)	<0.001
Etiologic treatment		
Cured etiology (vs. not controlled)	0.46 (0.29–0.73)	0.001
Controlled etiology (vs. not controlled)	0.87 (0.26–1.21)	0.423
Era (before 2014 vs. 2014–2021)	1.00 (0.79–1.27)	0.996

Abbreviation: CTP, Child-Turcotte-Pugh score.

Etiological cure was independently associated with fewer decompensation events (p =0.001).

TABLE 4 - Risk of each further decompensation according to etiological cure and controlled etiology (adjusted for age, sex, CTP class, creatinine, varices, sodium, etiology, era)

	HR (95% CI)	p
Refractory ascites		
Cured etiology (vs. not controlled)	0.331 (0.151–0.624)	0.001
Controlled etiology (vs. not controlled)	0.933 (0.599–1.451)	0.757
Variceal bleeding		
Cured etiology (vs. not controlled)	0.430 (0.159–1.146)	0.091
Controlled etiology (vs. not controlled)	1.169 (0.600–2.287)	0.641
HE		
Cured etiology (vs. not controlled)	0.502 (0.301–0.837)	0.008
Controlled etiology (vs. not controlled)	0.798 (0.522–1.22)	0.300
HRS-AKI		
Cured etiology (vs. not controlled)	0.328 (0.124–0.865)	0.024
Controlled etiology (vs. not controlled)	0.649 (0.334–1.262)	0.203
SBP		
Cured etiology (vs. not controlled)	0.411 (0.212–0.793)	0.008
Controlled etiology (vs. not controlled)	0.734 (0.447–1.204)	0.221
ACLF		
Cured etiology (vs. not controlled)	0.357 (0.189–0.673)	0.001
Controlled etiology (vs. not controlled)	0.768 (0.475–01.241)	0.280
HCC		
Cured etiology (vs. not controlled)	0.943 (0.522–1.701)	0.847
Controlled etiology (vs. not controlled)	0.711 (0.366–1.379)	0.313

Abbreviations: ACLF, acute-on-chronic liver failure; HRS-AKI, hepatorenal syndrome acute kidney injury; SBP, spontaneous bacterial peritonitis.

Etiological cure prevents further decompensation and mortality in patients with cirrhosis with ascites as the single first decompensation event. Tonon et al. Hepatology 2023; 78:1149-1158

TABLE 5 - Predictors of mortality in multivariable analysis

	Model 1 (including CTP)	
	HR (95% CI)	***p***
Age (y)	1.04 (1.02-1.05)	< 0.001
Female (vs. male)	0.57 (0.41–0.78)	<0.001
Creatinine (mg/dL)	1.09 (0.93–1.27)	0.270
Sodium (mmol/L)	0.97 (0.94–1.01)	0.142
Alcohol etiology	0.99 (0.74–1.32)	0.962
Varices at inclusion (vs. no varices)	1.21 (0.89–1.62)	0.219
CTP class		
B (vs. A)	1.89 (1.30–2.74)	<0.001
C (vs. A)	1.95 (1.21–3.15)	0.005
Etiologic treatment		
Cured etiology (vs. not controlled)	0.35 (0.23–0.56)	<0.001
Controlled etiology (vs. not controlled)	0.72 (0.51–1.02)	0.064
Era (before 2014 vs. 2014–2021)	0.82 (0.61–1.11)	0.211

Abbreviation: CTP, Child-Turcotte-Pugh score.

During the follow-up period (4 years):

- 250 people died = 40% (199 were due to liver disease)
- 140 people underwent liver transplantation = 17%

Etiological cure was associated with lower risk of liver related mortality ($p < 0.001$).

Control of the etiology did not reach statistical significance for decompensation events (p -0.423) or mortality (p – 0.064).

"…the aim of etiological treatment in alcohol-associated liver cirrhosis should be complete abstinence."

Awareness is the Cure

Ask: Why do you drink alcohol?

Grief
Fear of withdrawal
Uncontrolled Pain / neuropathic pain
Insomnia
Anxiety/ Depression
Boredom

Address: the reason why they are drinking excessively.

I asked Martha why she drinks alcohol?

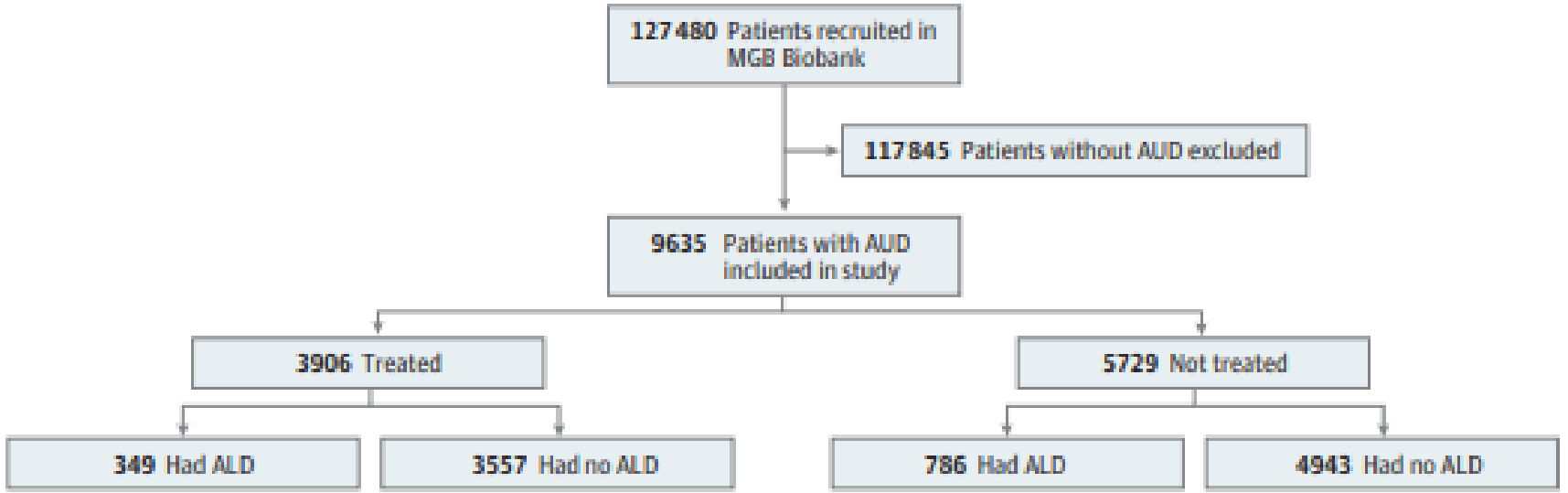
- Initially it was for fun and enjoyment with friends.
- Then her cousin passed away and she drank alcohol heavily for several weeks.
- After that, she was able to decrease the alcohol use but was not able stop daily alcohol drinking.
- She needed the alcohol to help her fall asleep.
- Covid-19 pandemic happened; she lost her job. She started drinking alcohol out of boredom.
- Would need to drink alcohol in the morning to prevent anxiety and palpitations.
- After a few months, she developed severe pins and needle sensation in her hands and feet. She would drink alcohol to decrease those symptoms and so that she could fall asleep.

She asks is it safe for her to take medications for alcohol cravings like naltrexone?

Incidence and Progression of Alcohol-Associated Liver Disease After Medical Therapy for Alcohol Use Disorder. AGL Vannier et al. JAMA Network Open. 2022 5(5)

- Retrospective Design
- Mass General Brigham Biobank
- Period of study 2010 – 2021 – mean follow-up period was 10 years
- Patient with alcohol use disorder (AUD), with and without cirrhosis -> treatment with medical addiction therapy (MAT) was compared to no treatment.

Figure 1. Flowchart of Patient Selection



Patients with alcohol use disorder (AUD) were considered to be treated if they received 3 prescriptions for at least 1 of the following: disulfiram, acamprosate, naltrexone, gabapentin, topiramate, or baclofen. ALD indicates alcohol-associated liver disease; MGB, Mass General Brigham.

Incidence and Progression of Alcohol-Associated Liver Disease After Medical Therapy for Alcohol Use Disorder. AGL Vannier et al. JAMA Network Open. 2022 5(5)

1. Does medical addiction therapy in patients with AUD reduce the risk of developing alcohol-associated liver disease?

Table 2. Odds Ratios for the Development of Alcohol-Associated Liver Disease After Medical Addiction Therapy

Medical addiction therapy	Adjusted odds ratio (95% CI)	*P* value
Any pharmacotherapy	0.37 (0.31-0.43)	<.001
Gabapentin	0.36 (0.30-0.43)	<.001
Topiramate	0.47 (0.32-0.66)	<.001
Baclofen	0.57 (0.36-0.88)	.01
Naltrexone	0.67 (0.46-0.95)	.03
Disulfiram	0.86 (0.43-1.61)	.66
Acamprosate	2.59 (1.84-3.61)	<.001

In patients that were treated with MAT: start time for therapy was 6.4 years after the index diagnosis of AUD!

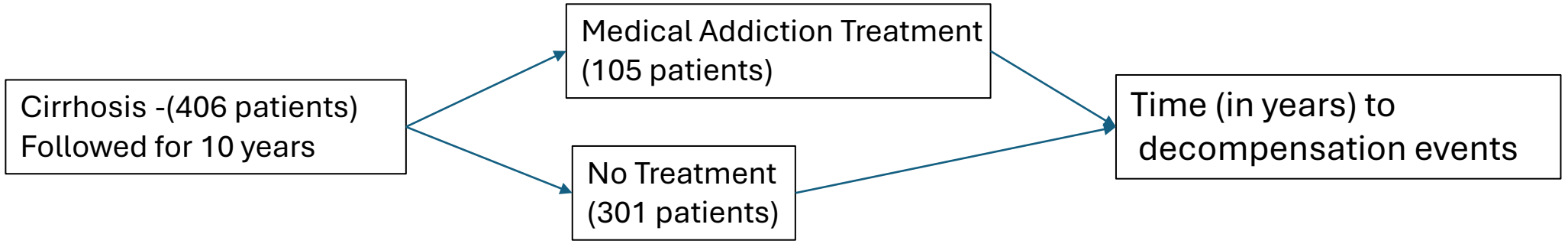
Incidence and Progression of Alcohol-Associated Liver Disease After Medical Therapy for Alcohol Use Disorder. AGL Vannier et al. JAMA Network Open. 2022 5(5)

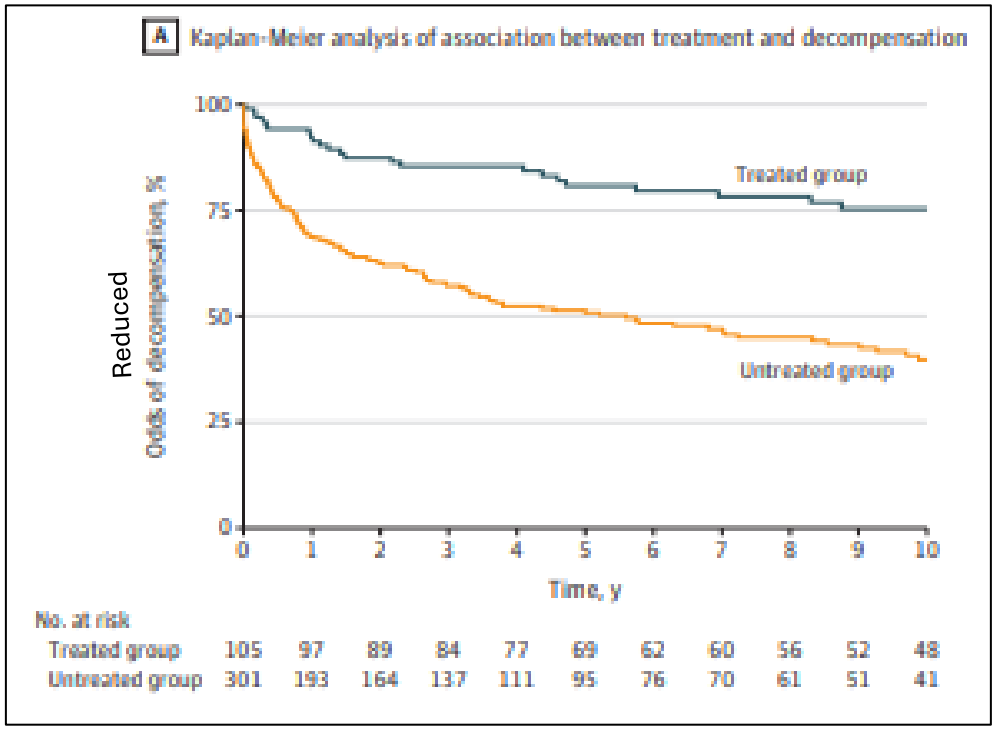
2. Does medical addiction therapy prevent the progress of alcohol-associated liver disease to the first incidence of hepatic decompensation?
   - ascites
   - spontaneous bacterial peritonitis
   - esophageal varices bleed
   - hepatic encephalopathy

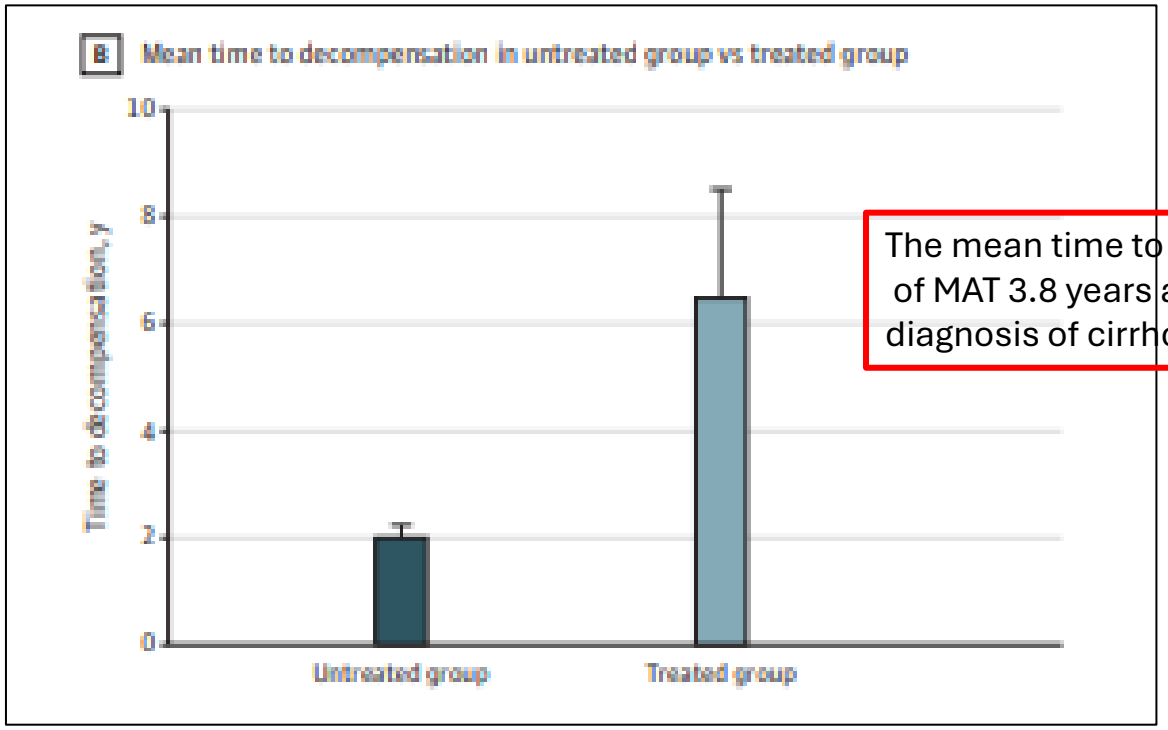
Table 3. Odds Ratios for Developing Hepatic Decompensation After Medical Addiction Therapy

Medical addiction therapy	Adjusted odds ratio (95% CI)	*P* value
Any pharmacotherapy	0.35 (0.23-0.53)	<.001
Naltrexone	0.27 (0.10-0.64)	.005
Gabapentin	0.36 (0.23-0.56)	<.001
Topiramate	0.43 (0.17-0.99)	.05
Baclofen	1.06 (0.39-2.69)	.91
Acamprosate	1.99 (0.99-4.059)	.06
Disulfiram	2.59 (0.54-13.26)	.24

Incidence and Progression of Alcohol-Associated Liver Disease After Medical Therapy for Alcohol Use Disorder. AGL Vannier et al. JAMA Network Open. 2022 5(5)







The mean time to initiation of MAT 3.8 years after the diagnosis of cirrhosis!

Awareness is the Cure

Martha had already completed medical detox while hospitalized (CIWA protocol). She was clinically improving and she thought that she may return to alcohol use due to severe cravings. After discussing and weighing the risks and benefits of Naltrexone:

- She started Naltrexone 50 mg PO daily and Gabapentin 300 mg PO BID, prn for alcohol cravings, anxiety and peripheral neuropathy.

- I also prescribed her gabapentin 600 mg PO QHS, prn for insomnia.

Patient accountability:

- "Although Naltrexone will not make you sick if you drink alcohol; starting Naltrexone means that you are making the commitment to stop alcohol use. You should not drink alcohol."

- Recommended outpatient or inpatient alcohol treatment. If liver transplant is needed in the future some form of structure alcohol treatment is going to be required.

Awareness is the Cure

- Over the next 12 months, I saw Martha in clinic 14 times -> 7 visits for paracentesis.
- She presented to the ED with liver related complications 31 times.
- She was hospitalized 15 times and received numerous paracentesis during the hospitalizations.

  - her longest hospitalization was 27 days

  - total days of hospitalization in the last 12 months was 118 days
- She went to University of Washington for evaluation of liver transplant. She has not been placed on the transplant list because;

  1. lack of consistent support system
  2. inconsistent participation a certified alcohol cessation program

- Current MELD 3.0 = 17

- **She asks what are the chances that she will get a liver transplant.**

ANMC Liver Transplant Data 2013-2023

Alcohol-associated liver cirrhosis is the #1 reason for liver transplant referrals at ANMC.

Listed for liver transplant = 53

Waiting list for transplant = 37

Alcohol-associated liver cirrhosis = 26
Female – 19
Male - 7

Alcohol-Associated liver disease**: 8 died on the transplant list.**
Female - 6
Male - 2

Transplanted = 16

Alcohol-associated liver cirrhosis = 6
Female – 2
Male - 4

Alcohol-associated liver disease: **1 died after transplant**
Female – zero
Male - 1

Liver transplant is still a treatment option, but it is a long road to transplant.
We need to get you set-up with an alcohol treatment program and help you identify good support people.

Case 2: Liz is a 40 year old female, with a history of anxiety and agoraphobia, that presents for evaluation of persistent transaminitis.

- She reports that she has been extremely anxious since her divorce 1 year ago. The main cause of her anxiety is living alone.

- She has gotten in the habit of having 3-4 vodka drinks after work to calm her nerves and help her fall asleep. Before her divorce she would only use alcohol on the weekends.

- A few months ago, she returned to her dry village to visit her father. After 2 days of abstinence, she started experiencing shakes, nausea, insomnia and overwhelming anxiety.

- Her friend gave her "Gab's," which made her symptoms bearable for the rest of her stay in the village.

- When she return to Anchorage she resumed alcohol use.

Vital signs and physical exam are normal.
Labs: AST – 120 / ALT – 40. Total bilirubin and platelets are normal. Viral hepatitis serology was normal.
FibroScan – Steatosis – 310 dB/m, Fibrosis – 7.2 KPa.

AUDIT-C Questionnaire

Patient Name _____ Date of Visit _____

1. How often do you have a drink containing alcohol?

- [ ] a. Never
- [ ] b. Monthly or less
- [ ] c. 2-4 times a month
- [ ] d. 2-3 times a week
- [x] e. 4 or more times a week

2. How many standard drinks containing alcohol do you have on a typical day?

- [ ] a. 1 or 2
- [x] b. 3 or 4
- [ ] c. 5 or 6
- [ ] d. 7 to 9
- [ ] e. 10 or more

3. How often do you have six or more drinks on one occasion?

- [x] a. Never
- [ ] b. Less than monthly
- [ ] c. Monthly
- [ ] d. Weekly
- [ ] e. Daily or almost daily

Audit C = 6

12 ounce beer (5% alcohol)

4-5 ounce glass of wine (12% alcohol)

1-1.5 ounce shot of hard alcohol (40% alcohol)

One unit of an alcoholic beverage contains approximately 12 grams of alcohol. A unit is roughly equivalent to one 12-ounce bottle of beer (5% alcohol); one 4-5-ounce glass of wine (12% alcohol); or one 1-ounce shot of hard liquor (40% alcohol). Note: there are many different kinds of beer and wine available that can contain more alcohol per unit than described above. Always check the label for alcohol content.

Audit C = 9

TABLE

Summary of *DSM-5* diagnostic features for alcohol use disorder[8,a]

Two of the following symptoms/behaviors must be present for at least 1 year, and be co-occurring with significant distress or impairment:

- More alcohol is consumed than intended or is consumed over a longer period of time than intended.
- Efforts to cut back or control drinking have not succeeded.
- Excessive time is spent obtaining, using, or recovering from alcohol.
- Alcohol cravings and urges persist.
- Use of alcohol has impaired follow-through on education, employment, or home obligations.
- Interpersonal problems have been caused or intensified by use of alcohol.
- Alcohol use has led to a reduction in or cessation of recreational, social, and employment activities.
- Use of alcohol has occurred in situations where it is dangerous.
- Alcohol use has continued despite knowledge of the problems it is causing.
- Tolerance to alcohol is evident—ie, drinking the same amount has little effect, or heavier use occurs to maximize alcohol's effects.
- Withdrawal is evident—ie, physiologic signs (tremors, nausea) occur or closely related drugs (eg, benzodiazepines) are taken to avoid withdrawal.

DSM-5, Diagnostic and Statistical Manual of Mental Disorders-5.

[a] Adapted from the *DSM-5*; American Psychiatric Association (2013).

DSM 5 criteria for alcohol use disorder (11):

Mild – 2 to 3
Moderate – 4 to 5
Severe – 6 or more

Diagnosis:
Moderate alcohol use disorder

Treatment:
Behavior health referral

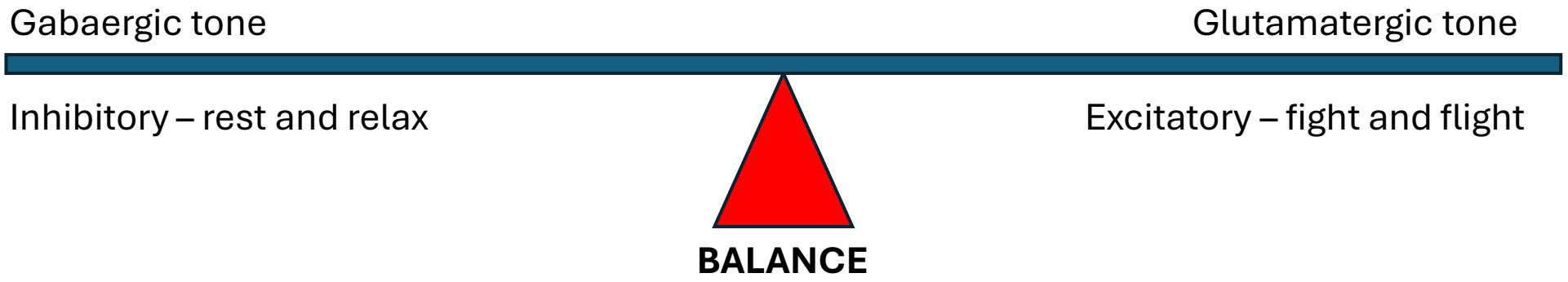
MAT:
Vivitrol 380 mg IM Q monthly
Gabapentin 300 mg PO BID and
600 mg PO QHS

Clearly review the symptoms of severe alcohol withdrawal and when she should go to the ER.

Follow-up with me in 1 month.

It is imperative that you decrease, or even better stop, alcohol use.

Nervous system affects of alcohol and Gabapentin:



Gabapentin safety profile:

1. Not a controlled or scheduled substance
2. Does not potentiate the affects of alcohol
3. Does not cause significant daytime sleepiness or decreased in performance
4. At normally prescribed doses, low risk for dependence and abuse

Abuse potential:

- Recreational opioid and prescription drug abusers – self-administer doses that far exceed therapeutic range
- Abrupt withdrawal of gabapentin in people that are using supratherapeutic doses can precipitate seizures

Medications for alcohol use disorder that I use in my Hepatology clinic.

	Naltrexone/Vivitrol	Gabapentin	Acamprosate (continued Rx from Detox).
Mechanism of action	Pure opioid receptor antagonist	Modulation of the excitatory and inhibitory neural pathways	Modulation of the excitatory and inhibitory neural pathways
Indication	Alcohol use disorder (does not require alcohol cessation to initiate) Opioid use disorder Chronic pain management Weight loss	Alcohol use disorder (off label) Partial epileptic seizures Postherpetic neuralgia Neuropathy (off label) Insomnia / Anxiety (off label)	Alcohol use disorder
Metabolism and clearance	Liver, renal and fecal excretion	None, renal excretion	None, renal excretion
Dosing	Naltrexone 50 mg PO daily Vivitrol 380 mg IM monthly (Vivitrol affect only last about 3 weeks, may need to supplement last week with oral Naltrexone)	Gabapentin 1800 mg PO daily divided BID-TID In renal disease: Decreased dosing is recommended	Acamprosate 666 mg (2 tabs of 333 mg) PO TID In renal disease: Acamprosate 333 mg PO TID CrCl < 30 contraindicated
Caution	Opioid use – can precipitate withdrawal Acute liver failure	Opioid and recreational drug use	TID dosing -> difficult compliance
Adverse Effects	Nausea Vivitrol - injection site reactions	Dizziness Withdrawal seizures when high doses are stopped abruptly	Diarrhea
Number need to treat	No heavy drinking days NNT = 8.6	Unknown and likely will not be studied since gabapentin is already generic	Abstinence NNT = 7.5
Cost	Naltrexone 50 mg (30 tabs) - $25 to$ 30 Vivitrol 380 mg IM Qmonth - $1450	300 to 600 mg (90 tabs) - $12 to $15	333 mg (2 tablets, 180 tabs) - $94.00

Key Points:

- **If your patient has advance liver fibrosis or cirrhosis, for any reason, the recommendation is they should never drink alcohol again.**

- **Etiological cure of alcohol-associated liver disease, ie. abstinence, decreases decompensation and mortality.**

- **Diagnose alcohol misuse and alcohol use disorder early and getting the person treatment will result in better outcomes.**

  (Audit C -> BHC, MAT and most importantly you).

- **Naltrexone and gabapentin have good safely profiles in liver disease; be comfortable using them.**

References:

- **Etiological cure prevents further decompensation and mortality in patients with cirrhosis with ascites as the single first decompensation event. Tonon et al. Hepatology 2023; 78:1149-1158.**

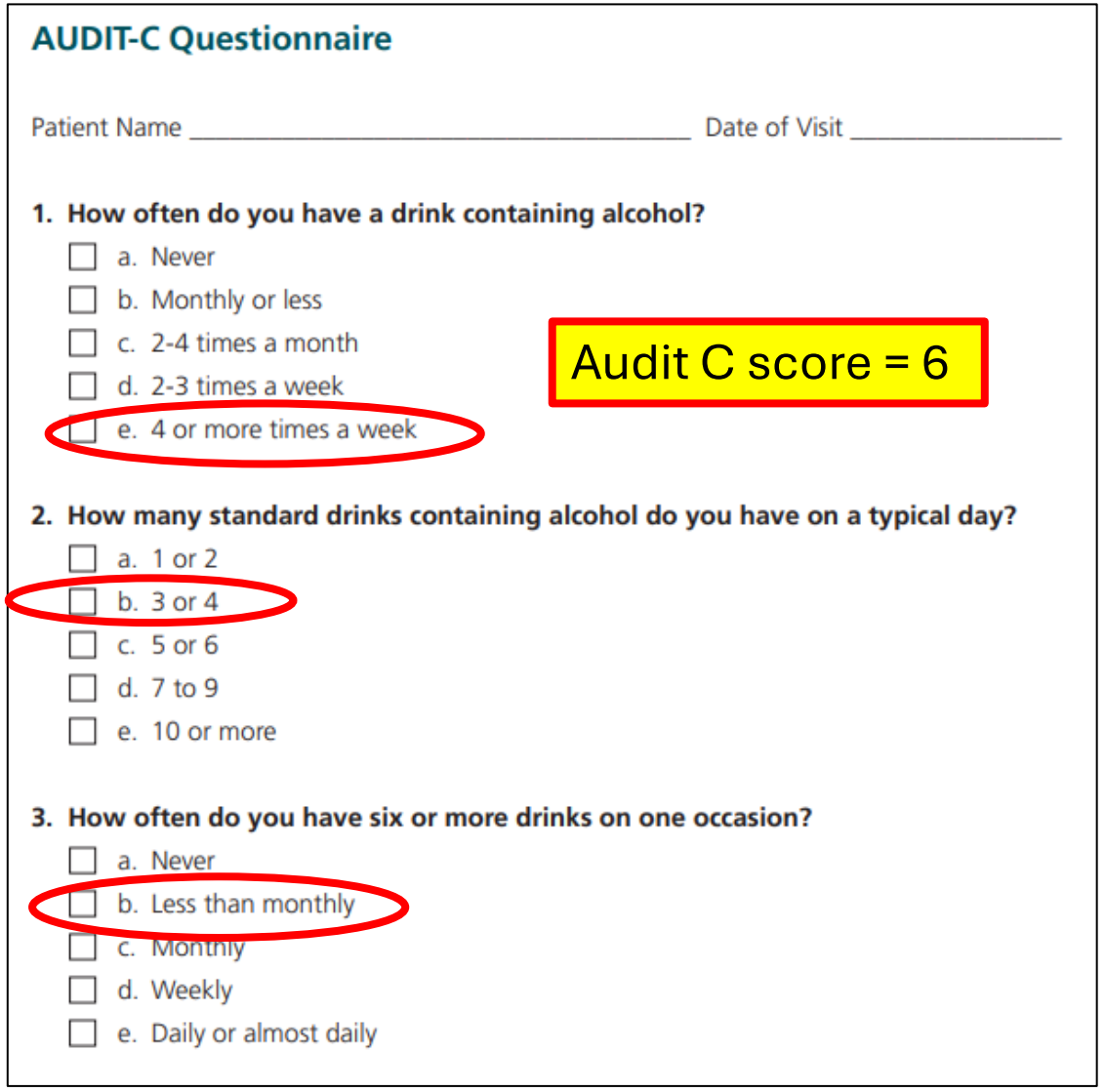
- **Incidence and Progression of Alcohol-Associated Liver Disease After Medical Therapy for Alcohol Use Disorder. AGL Vannier et al. JAMA Network Open. 2022 5(5).**

- **Ayyala et al. Naltrexone for alcohol use disorder: Hepatic saftety in patients with and without liver disease. Hepatology Communications. 2022 Oct 25. doi: 10.1002/hep4.2080.**

- **Mason et al. Gabapentin for the treatment of alcohol use disorder. Expert Opinion Investigating Drugs. 2018. January; 27(1): 113-124. dio: 10.1080.**

Case 3: Mr. Parker is a 48 year old male, with a MHx. of HTN, Hyperlipidemia, OSA, Morbid Obesity (BMI -46) and Type 2 Diabetes, that presents for evaluation of MASLD.

- He works in the IT.
- He is married with 4 children.
- He is on Ozempic 2 mg SubQ weekly for diabetes management. His HgBa1c – 7.2% (8.7% 1 yr ago) and his weight has decreased from 320 to 285 lbs.
- He drinks four 16 oz. of beer every night after work (4 nights/week) to relax and to help him sleep. He has been doing this for over 15 years.
- He states that he is a big guy and the nightly beers hardly affect him.
- FibroScan
  - steatosis score: 375 dB/m
  - fibrosis score: 10.4 KPa



AUDIT-C Questionnaire

Patient Name _____ Date of Visit _____

1. How often do you have a drink containing alcohol?

- ☐ a. Never
- ☐ b. Monthly or less
- ☐ c. 2-4 times a month
- ☐ d. 2-3 times a week
- ☐ e. 4 or more times a week

Audit C score = 6

2. How many standard drinks containing alcohol do you have on a typical day?

- ☐ a. 1 or 2
- ☐ b. 3 or 4
- ☐ c. 5 or 6
- ☐ d. 7 to 9
- ☐ e. 10 or more

3. How often do you have six or more drinks on one occasion?

- ☐ a. Never
- ☐ b. Less than monthly
- ☐ c. Monthly
- ☐ d. Weekly
- ☐ e. Daily or almost daily

TABLE

Summary of *DSM-5* diagnostic features for alcohol use disorder[8,a]

Two of the following symptoms/behaviors must be present for at least 1 year, and be co-occurring with significant distress or impairment:

- More alcohol is consumed than intended or is consumed over a longer period of time than intended.
- Efforts to cut back or control drinking have not succeeded.
- Excessive time is spent obtaining, using, or recovering from alcohol.
- Alcohol cravings and urges persist.
- Use of alcohol has impaired follow-through on education, employment, or home obligations.
- Interpersonal problems have been caused or intensified by use of alcohol.
- Alcohol use has led to a reduction in or cessation of recreational, social, and employment activities.
- Use of alcohol has occurred in situations where it is dangerous.
- Alcohol use has continued despite knowledge of the problems it is causing.
- Tolerance to alcohol is evident—ie, drinking the same amount has little effect, or heavier use occurs to maximize alcohol's effects.
- Withdrawal is evident—ie, physiologic signs (tremors, nausea) occur or closely related drugs (eg, benzodiazepines) are taken to avoid withdrawal.

DSM-5, Diagnostic and Statistical Manual of Mental Disorders-5.

[a] Adapted from the *DSM-5*; American Psychiatric Association (2013).

DSM-5 criteria for Alcohol Use Disorder
= Zero

Alcohol-Associated Liver Disease: A Guide for Patients.
U.S. Department of Veterans Affairs. www.Hepatits.VA. GOV

12 ounce beer (5% alcohol) = 4-5 ounce glass of wine (12% alcohol) = 1-1.5 ounce shot of hard alcohol (40% alcohol)

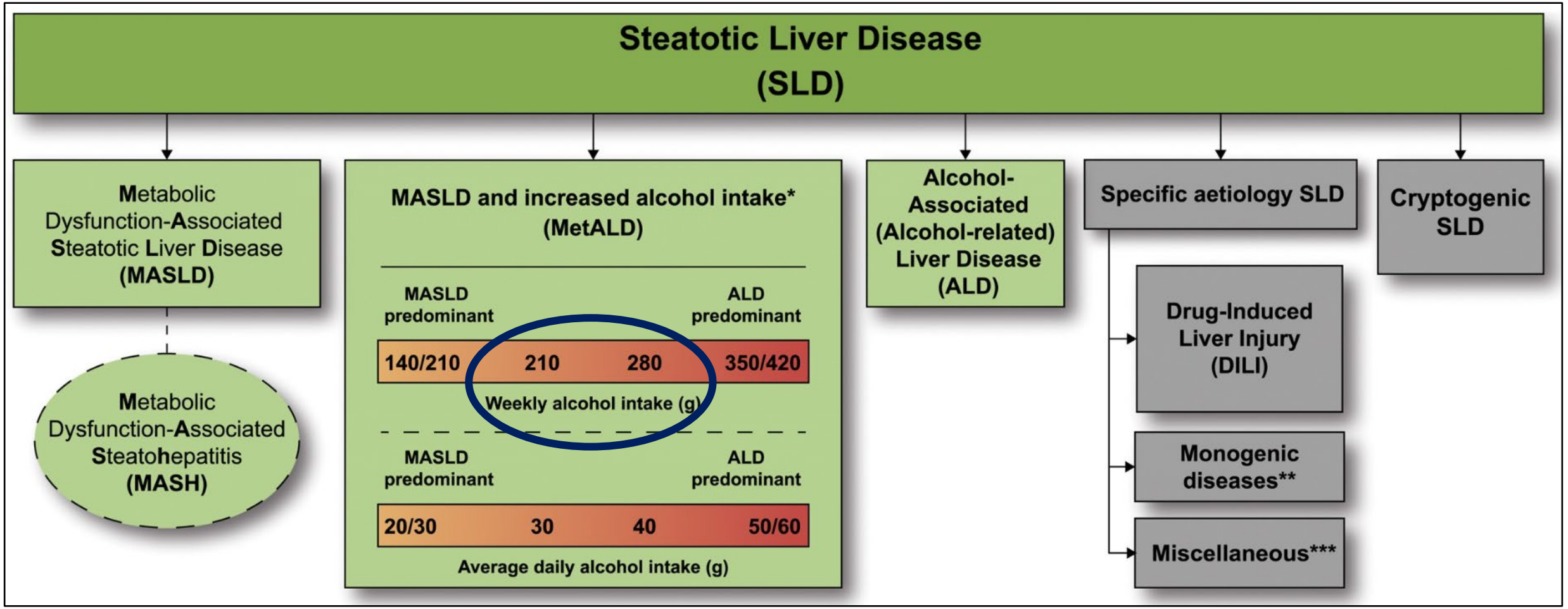
Four 16 oz. beers = 64 grams on nights that he uses alcohol.

64 grams x 4 nights/weekly = 256 grams/weekly

=> 12 grams of alcohol

One unit of an alcoholic beverage contains approximately 12 grams of alcohol. A unit is roughly equivalent to one 12-ounce bottle of beer (5% alcohol); one 4-5-ounce glass of wine (12% alcohol); or one 1-ounce shot of hard liquor (40% alcohol). Note: there are many different kinds of beer and wine available that can contain more alcohol per unit than described above. Always check the label for alcohol content.

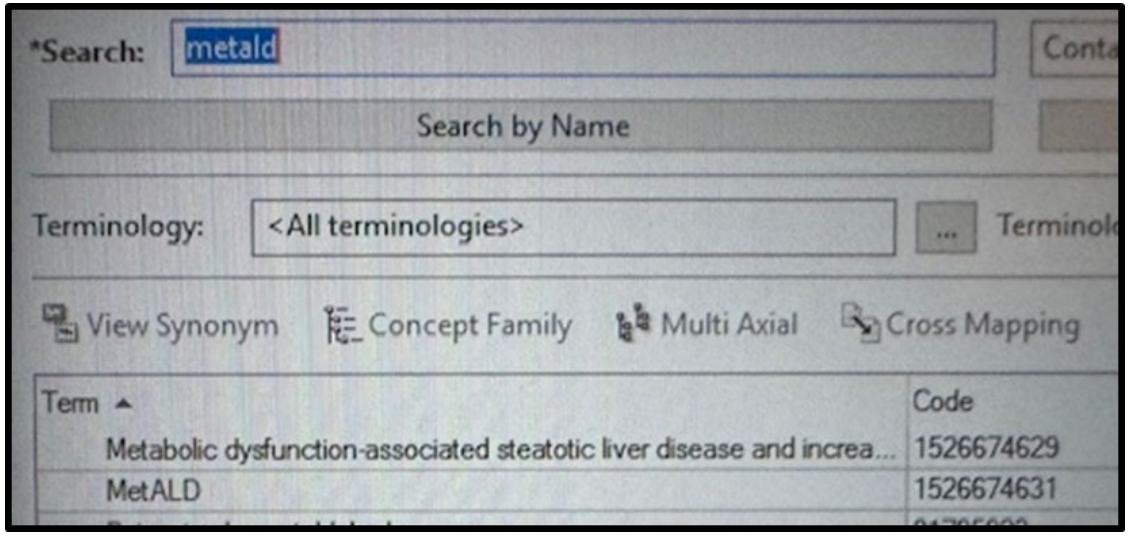
Met-ALD: Metabolic Dysfunction-Associated Steatotic Liver Disease and Increased Alcohol Intake



You have severe steatosis and F2 fibrosis, therefore you should stop all alcohol use.

Main Points for Met-ALD

Diagnostic Code is now available in CERNER.



Use the Audit C to help guide the diagnosis of Met-ALD.