HCV ECHO Didactic

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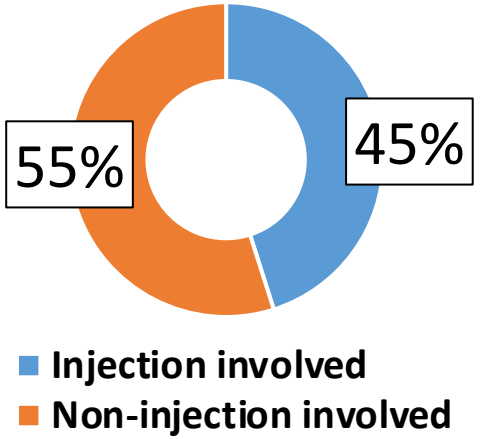
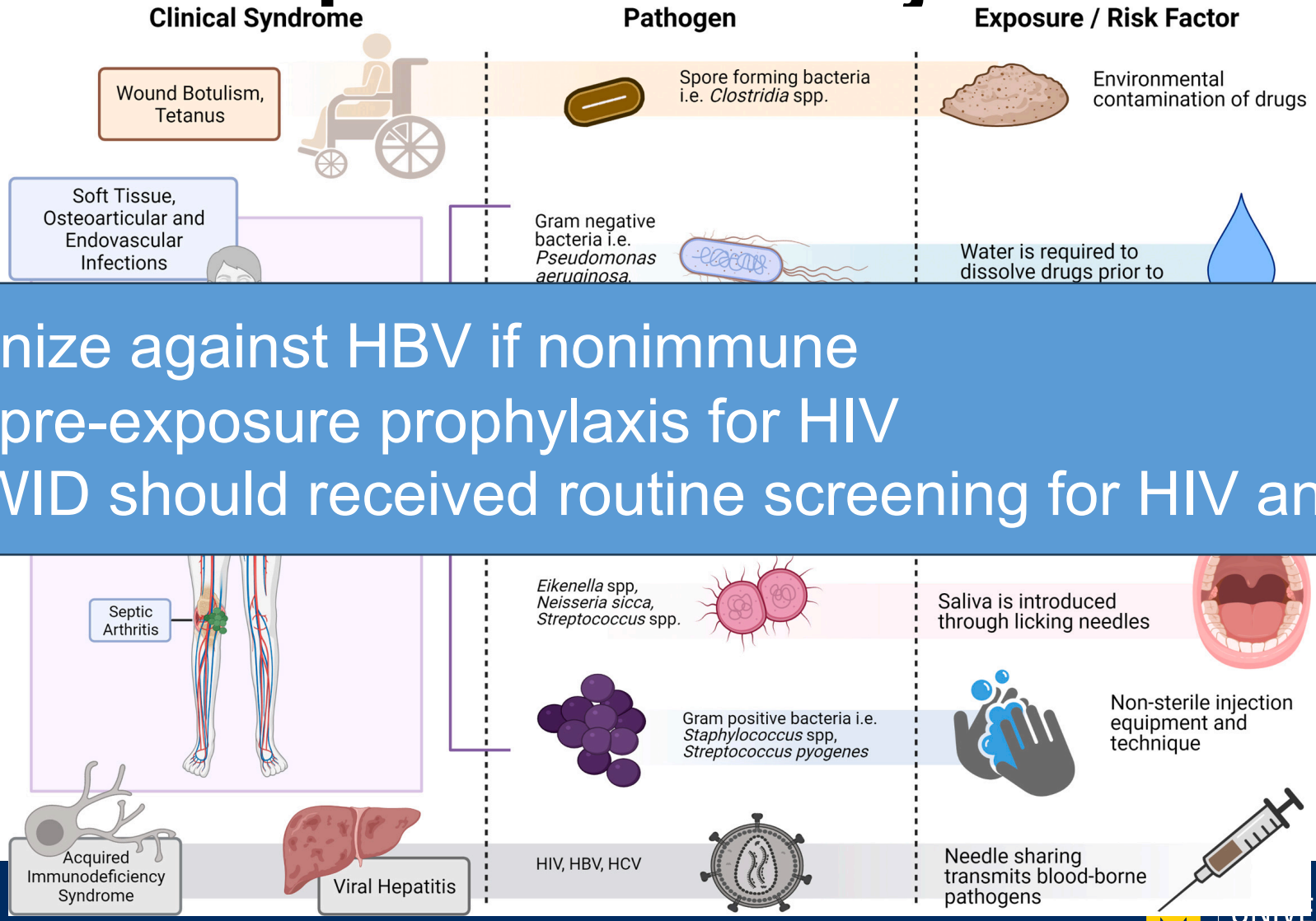
HCV Prevention

Epidemiology of Injection Drug Use in the US

- In the last 20 years, there has been an increase in injection drug use across the U.S.
- 2011: ~775, 000 PWID (0.3% of the US population ≥ 13 years of age
- 2018: ~3,700,000 (~1.5% of adult population)
- Shifting routes of administration – smoking emerging as a more common route
- In 2020, slightly less than half (45.1%) of overdose deaths were estimated to be injection-involved



Infectious Complications of Injection Drug Use

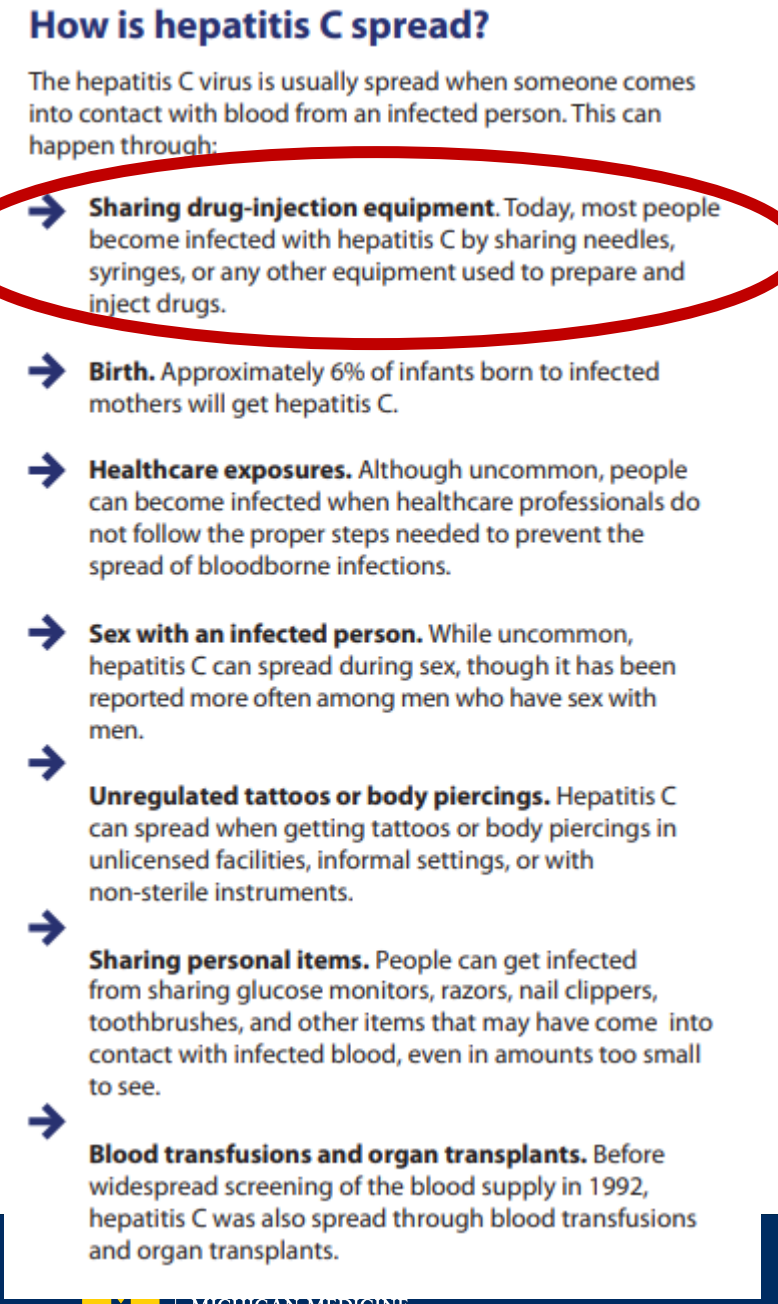


- Immunize against HBV if nonimmune
- Offer pre-exposure prophylaxis for HIV
- All PWID should received routine screening for HIV and HCV

Marks LR, et al. Med Clin North Am. Jan 2022

Hepatitis C Virus (HCV) and IDU

- HCV is preventable and curable
- HCV is usually spread when someone encounters blood from an infected person.
- IDU remains the most common risk factors for acquiring HCV in the US
- In 2020,among persons with acute HCV and available risk behavior information, 66% reported a history of IDU in the prior 6 months
- IDU is also a risk factor for reinfection with HCV, with infection rates estimated to be between 5 and 6 per 100 person years.

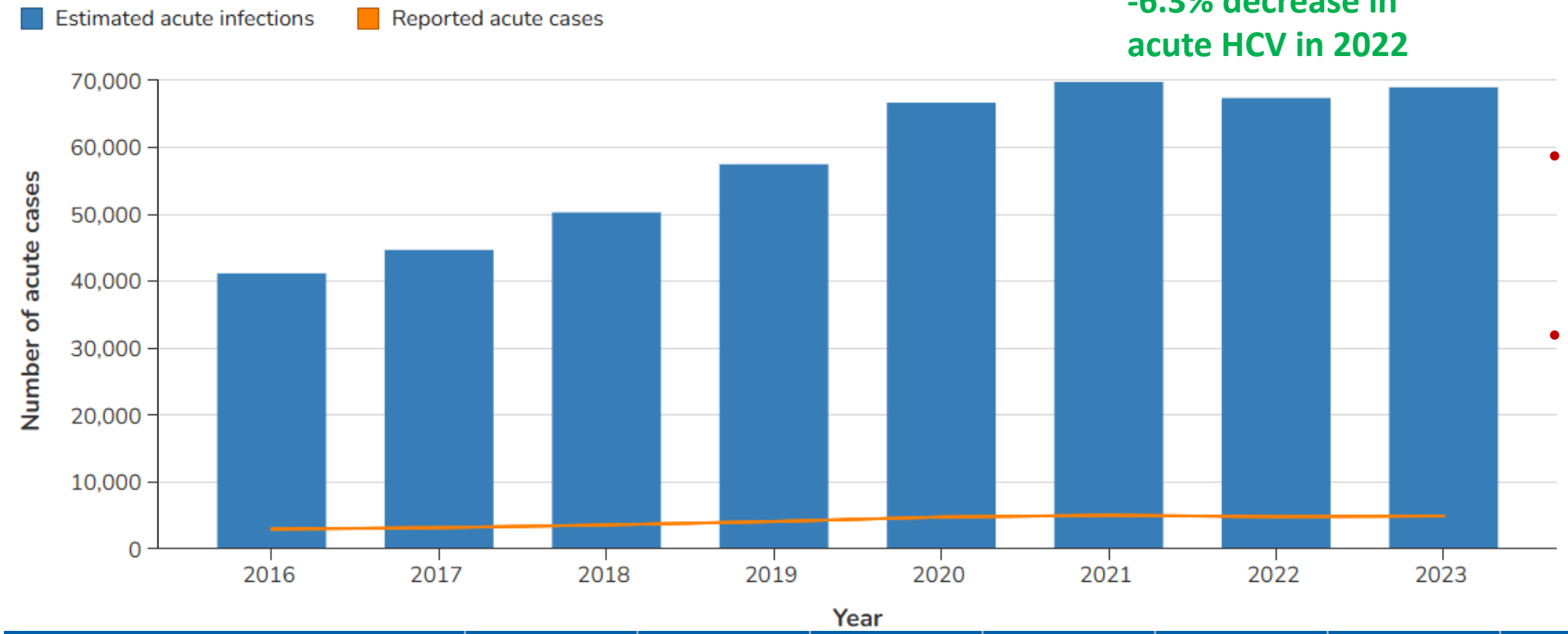


How is hepatitis C spread?

The hepatitis C virus is usually spread when someone comes into contact with blood from an infected person. This can happen through:

- **Sharing drug-injection equipment.** Today, most people become infected with hepatitis C by sharing needles, syringes, or any other equipment used to prepare and inject drugs.
- **Birth.** Approximately 6% of infants born to infected mothers will get hepatitis C.
- **Healthcare exposures.** Although uncommon, people can become infected when healthcare professionals do not follow the proper steps needed to prevent the spread of bloodborne infections.
- **Sex with an infected person.** While uncommon, hepatitis C can spread during sex, though it has been reported more often among men who have sex with men.
- **Unregulated tattoos or body piercings.** Hepatitis C can spread when getting tattoos or body piercings in unlicensed facilities, informal settings, or with non-sterile instruments.
- **Sharing personal items.** People can get infected from sharing glucose monitors, razors, nail clippers, toothbrushes, and other items that may have come into contact with infected blood, even in amounts too small to see.
- **Blood transfusions and organ transplants.** Before widespread screening of the blood supply in 1992, hepatitis C was also spread through blood transfusions and organ transplants.

Acute HCV Cases in the US, 2016-2023



-6.3% decrease in acute HCV in 2022

- **101,525 cases of newly reported chronic HCV during 2023.**
- **11,194 HCV-related deaths reported during 2023.**

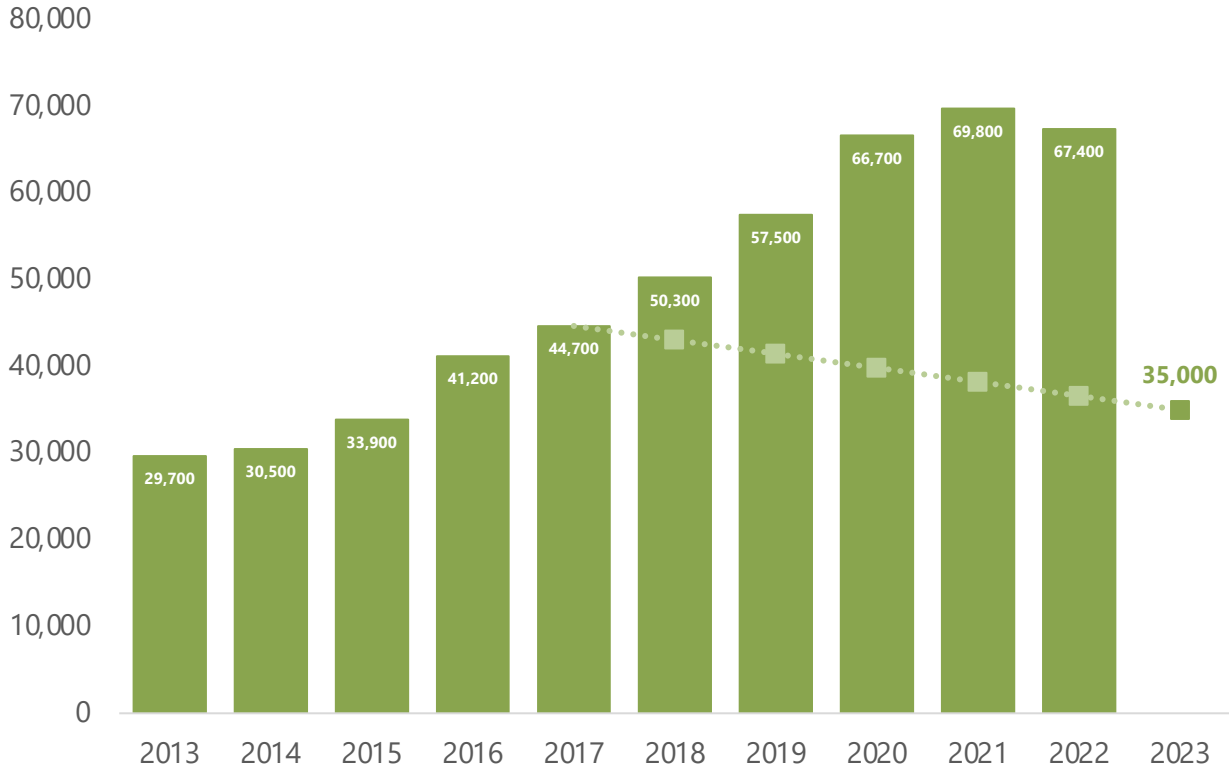
	2016	2017	2018	2019	2020	2021	2022	2023
Estimated acute infections	41,200	44,700	50,300	57,500	66,700	69,800	67,400	69,000
Reported acute cases	2,967	3,216	3,621	4,136	4,798	5,023	4,848	4,966

https://www.cdc.gov/hepatitis-surveillance-2023/hepatitis-c/index.html

National Progress Report 2025 Goals

Reduce estimated new hepatitis C virus infections by ≥20%

Estimated new hepatitis C virus infections and annual targets for the United States by year



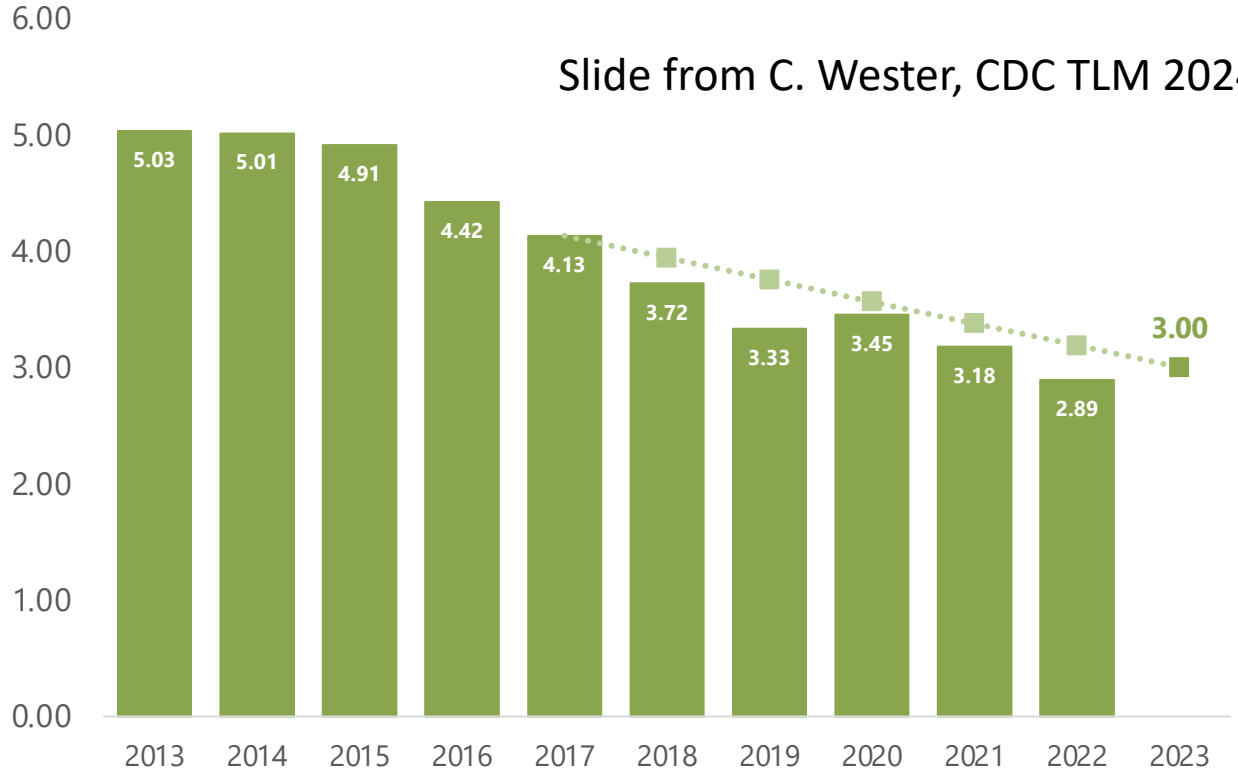
National Progress Report 2025 Goal

Status: Moving *toward* annual target, but annual target was not fully met

Reduce overall hepatitis C-related deaths by ≥20%

Age-adjusted rate of hepatitis C-related deaths and annual targets for the United States by year

Slide from C. Wester, CDC TLM 2024



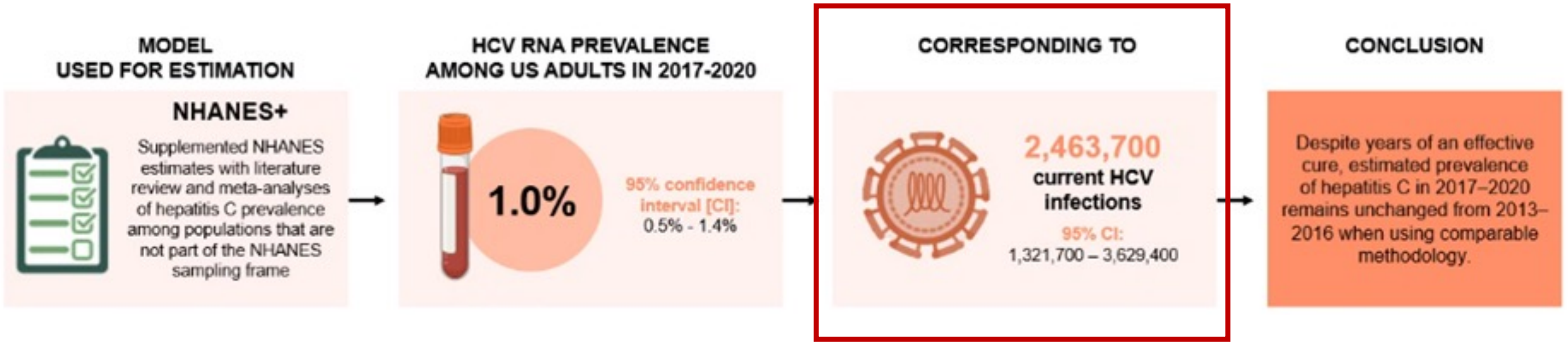
National Progress Report 2025 Goal

Status: Met or exceeded current annual target

Estimating the Prevalence of HCV in the US, 2017-2020

The National Health and Nutrition Examination Survey (NHANES) underestimates the true prevalence of hepatitis C virus (HCV) infection.

By accounting for populations inadequately represented in NHANES, we **created two models to estimate the national hepatitis C prevalence** among US adults during 2017–2020.



- In 2007-2019: 1,357,000 cured and 916,000 new infections
- In 2022: prevalence unchanged as new infections are outpacing cures

Slide adapted from N. Terrault DDW 2025

Hall E, Hepatology 2025; Blach S, J infect Public Health 2023; 2021 Viral Hepatitis Surveillance Report CDC

SSPs and HCV Prevention

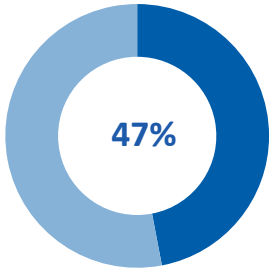
- The best way to prevent the spread of HCV infections is for PWID to stop injecting them. If that is not possible, use sterile injection equipment for each injection to reduce the risk of infection and prevent outbreaks.
- SSPs are associated with an estimated 50% reduction in HIV and HCV infections.
- Transmission is reduced by over two-thirds when combined with medications that treat opioid dependence (also known as medication-assisted treatment).
- SSPs act as a bridge to other health services, including HCV testing and treatment and medication-assisted treatment.

1. CDC. Surveillance for Viral Hepatitis — United States, 2016. 2. CDC Estimated HIV incidence and prevalence in the United States, 2010–2015. HIV Surveillance Supplemental Report. 2018; 3. Platt L, et al. Needle syringe programmes and opioid substitution therapy for preventing hepatitis C transmission in people who inject drugs. Cochrane Database Syst Rev. 2017;9:CD012021. 4. Fernandes RM, et al. BMC Public Health. 5. HIV and Injection Drug Use – Vital Signs – CDC. December 2016.

SSPs provide essential harm reduction services to people who inject drugs (PWID).

There are an estimated 3.7 million PWID nationally.

Half of urban PWID report receiving services from an SSP in the past year.



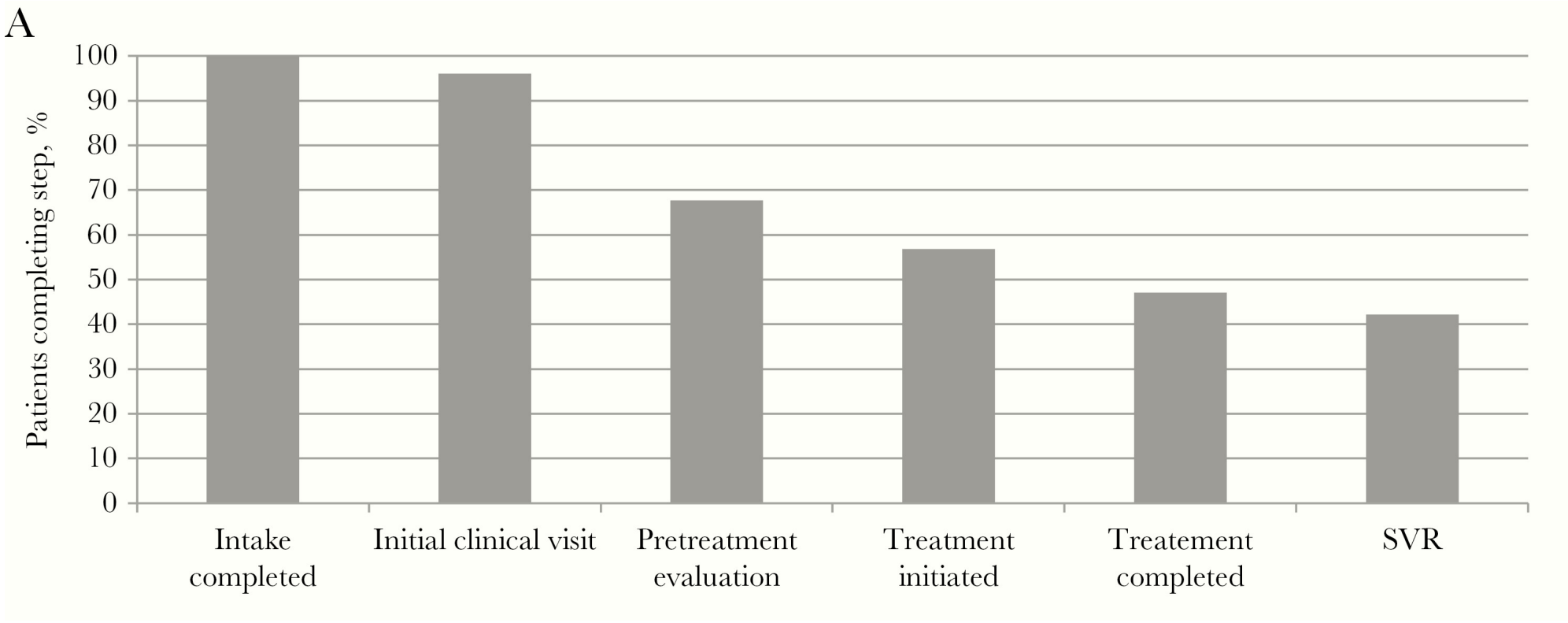
Almost half of SSPs report offering some form of HCV testing.

The prevalence of hepatitis C among PWID is high (range 23–44%).

Bradley H et al. Estimated Number of People Who Inject Drugs in the United States. Clin Infect Dis. 2023 Jan 6;76(1):96-102.
HIV Infection Risk, Prevention, and Testing Behaviors Among Persons Who Inject Drugs — National HIV Behavioral Surveillance Injection Drug Use. 2018.
Program and Operational Characteristics of Syringe Services Programs — United States 2020–2021. 2023.
Injection Drug Use Surveillance Project — United States, 2021–2023. 2023.
Chapin-Bardales J et al. Hepatitis C virus infection and co-infection with HIV among persons who inject drugs in 10 U.S. cities-National HIV Behavioral Surveillance, 2018. Int J Drug Policy. 2024.

SSPs that co-locate hepatitis C care can achieve results comparable to other clinical settings.

Care cascade for co-located hepatitis C care at an SSP — New York City, 2015–2018 (N= 102)



Winetsky D et al. Psychosocial Factors and the Care Cascade for Hepatitis C Treatment Colocated at a Syringe Service Program. J Infect Dis. 2020 Sep 2;222(Suppl 5):S392-S400.

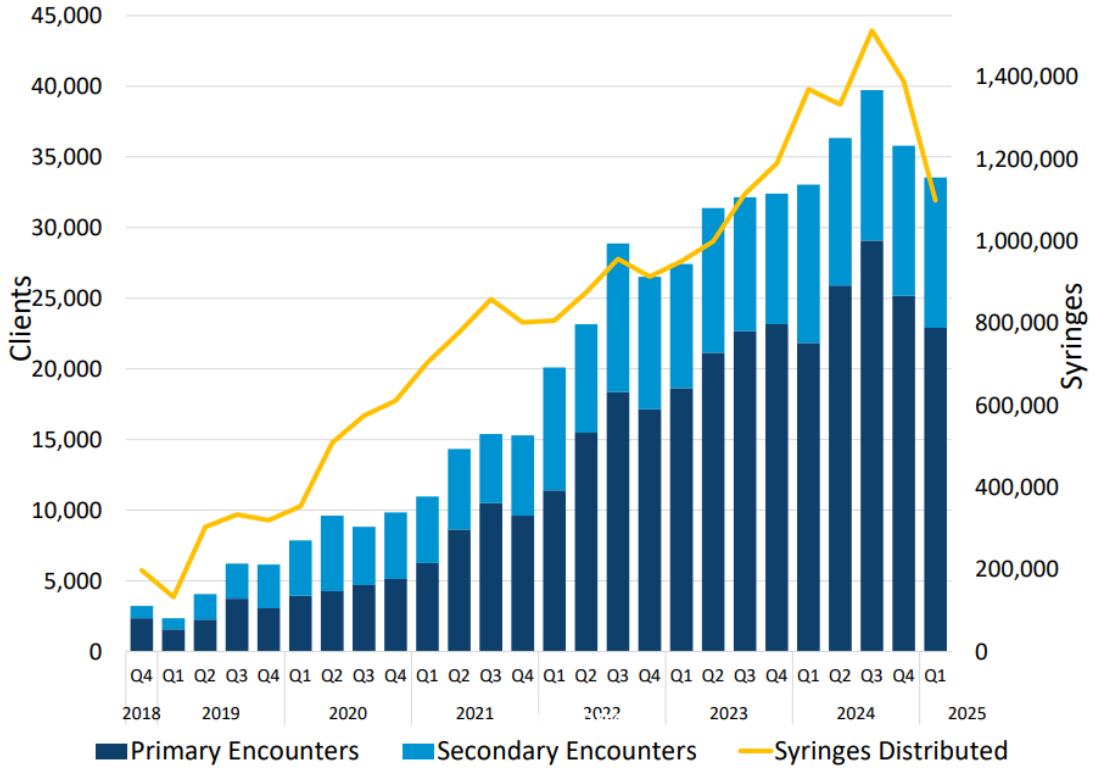
SSPs in Michigan

October 1, 2018 – March 31, 2025:

Total Participants	Total Indirect Contacts
338,958	175,609

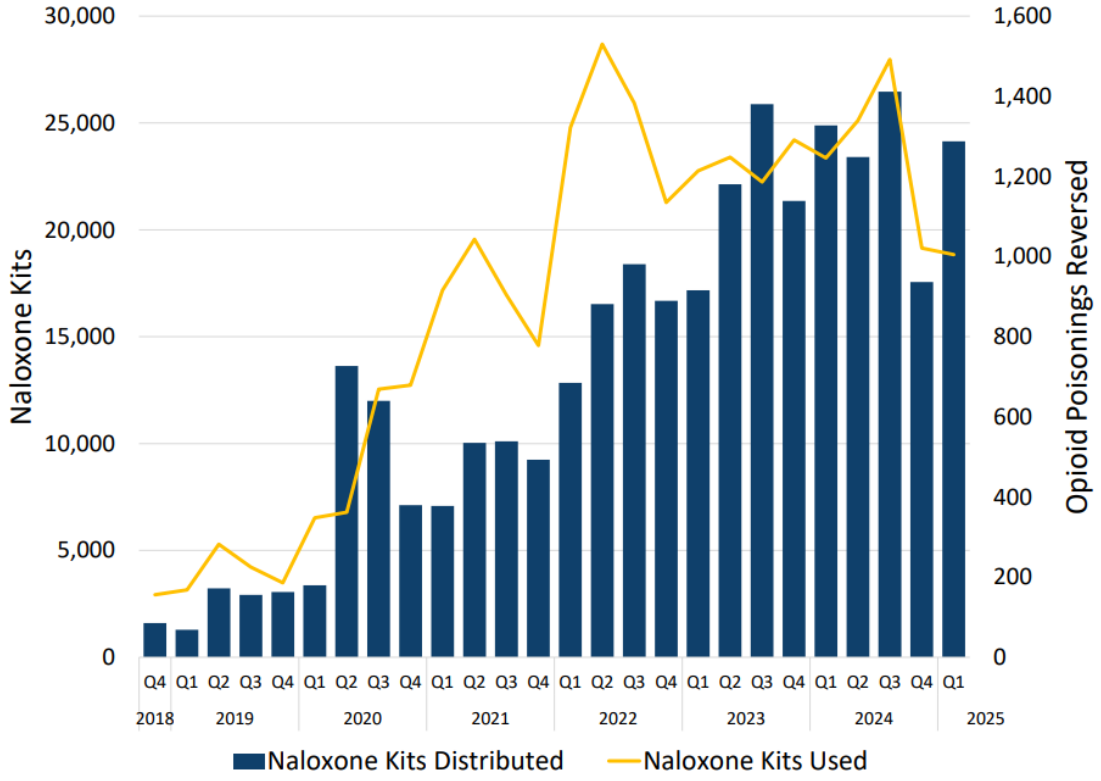
Total Syringes Distributed: 21.0 Million

Clients Served + Syringes Distributed



**Indirect contacts are individuals who receive supplies through a person who directly accesses an SSP.*

Naloxone Kits Dispensed + Lives Saved

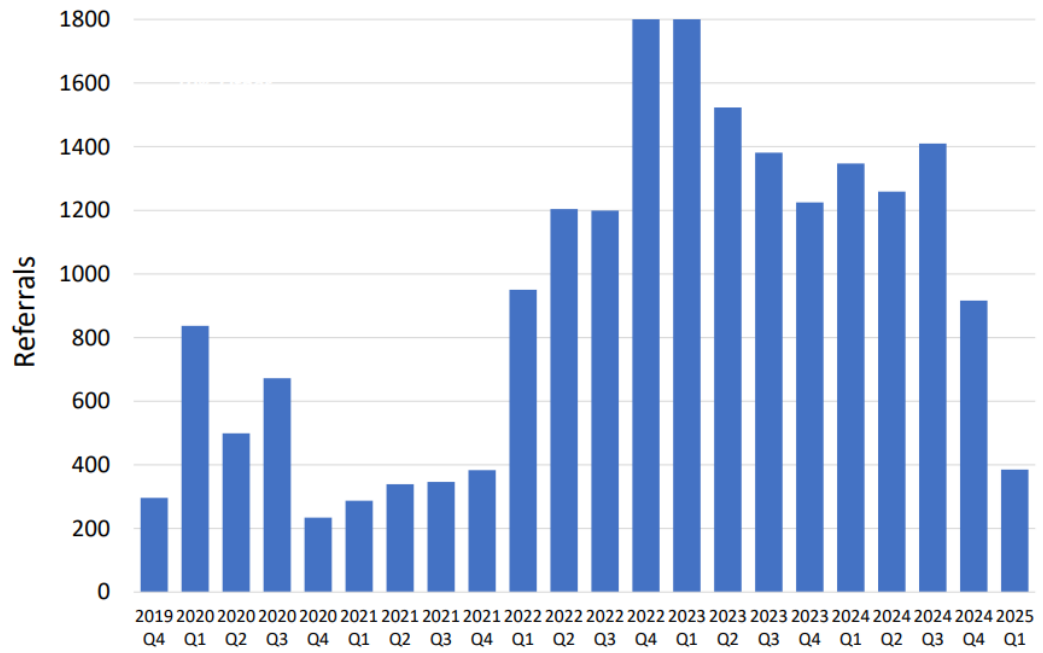


** Naloxone use represents the successful reversal of a potentially fatal opioid poisoning. Uses are self-reported by individuals directly accessing the SSP.*

MDHHS SSP data accessed July 17, 2025

SSPs in Michigan

SUD Treatment Referrals



** The graph shows the raw counts of the number of SSPs referrals to substance use disorder treatment by quarter.*

Testing & Linkage to Care

Total number: October 1, 2018 –March 31, 2025

	Tests Conducted	*Tested Positive*	*Linked to Care*
HIV	4,612	43	86
Hepatitis C	5,060	611	345

Barriers to hepatitis C linkage to care:

- Cost of treatment
- Previous Medicaid restrictions requiring documentation of six months of abstinence from illicit drugs & alcohol
- Access to HCV treatment providers / insufficient provider capacity to treat hepatitis C
- Treatment misconceptions
- Stigma

MOUD programs serve clients with opioid use disorder in a variety of modalities.

≥1 million people are on MOUD in the United States

Methadone can only be provided by opioid treatment programs (OTPs).

Buprenorphine can be provided in a variety of settings and the 2023 X-Waiver elimination increased its use.

https://aspe.hhs.gov/reports/early-changes-after-2021-hhs-buprenorphine-practice-guidelines

Medications for Opioid Use Disorder

- Buprenorphine-naloxone and methadone reduce risk of:
- Acquiring HCV and/or HIV in PWID
- Illicit opioid use, injection drug use, and sharing of injection equipment
- Overdose death among persons on treatment

Options for MOUD

Methadone

- Full opioid agonist prescribed and dosed through a methadone maintenance program
- Patients visit the methadone program up to daily for dosing
- Many formulations are available, but the oral liquid form is used in most clinics

Buprenorphine

- Partial opioid agonist that can be prescribed like other prescription medications in an office setting
- Often co-formulated with naloxone (suboxone)
- Typically administered transmucosally 1-3 times a day; however a monthly extended releases injection is also available

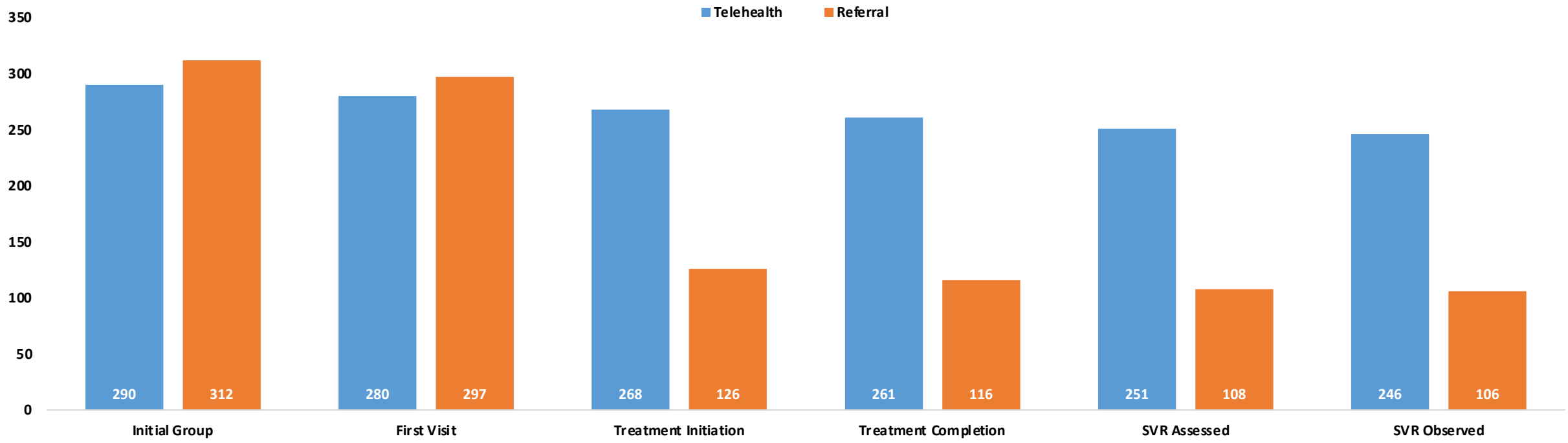
Individualize treatment choices to patient preference

Providers with DEA registration (with scheduled 3 authority) may prescribe according to state law

Treatment at MOUD Programs with telehealth can be highly effective.

- A randomized controlled trial of hepatitis C treatment at OTPs demonstrated significant benefit of telehealth compared with referral for treatment.
- In the telemedicine group, 92.4% (268/290) initiated treatment compared with 40.4% (123/312) of those referred for treatment.

Hepatitis C care cascade among people randomized to telehealth treatment or referral — New York State, 2017–2020.



Talal AH, Markatou M, Liu A, Perumalswami PV, Dinani AM, Tobin JN, Brown LS. Integrated Hepatitis C-Opioid Use Disorder Care Through Facilitated Telemedicine: A Randomized Trial. JAMA. 2024

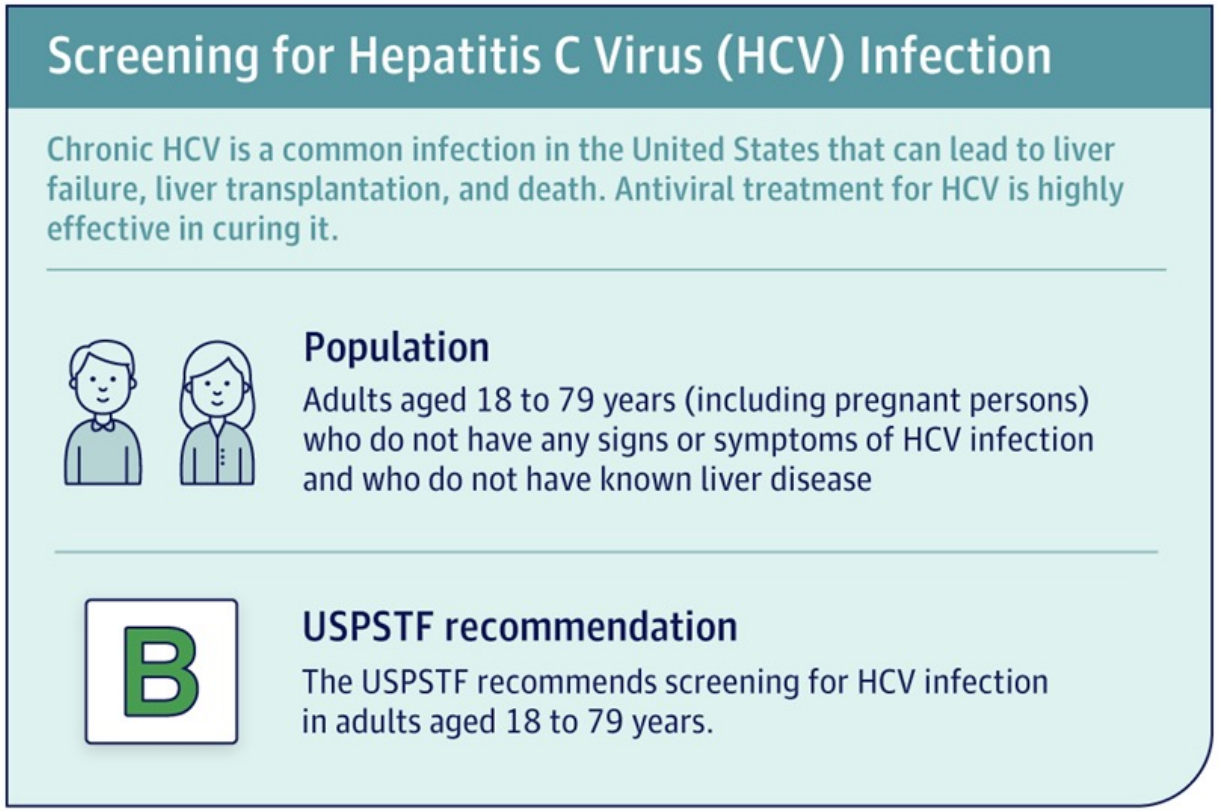
HCV Treatment

- Thanks to robust harm reduction services and advances in treatment, HCV is both preventable and curable.
- Direct-acting antiviral (DAA) treatment is recommended for nearly all people diagnosed with HCV.
- An 8–12-week course of oral DAA therapy cures more than 95% of people infected with HCV
- Treatment saves lives, prevents transmission, and is cost saving.
- There is no vaccine for HCV
- If untreated, long-term HCV infection can eventually cause chronic liver disease, which can range from mild to severe, including cirrhosis and liver cancer.

HCV Testing

Universal Adult HCV Testing Recommendations

- HCV screening at least once in a lifetime for all adults aged ≥18 years*
- HCV screening for all pregnant women during each pregnancy*
- All persons with risk factors including IDU should be tested for HCV, with periodic testing while risk factors persist.
- Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks.



*except in settings where the prevalence of HCV infection is <0.1%

1. CDC HCV https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm
2. Jin J. JAMA March 2020

The Xpert® HCV runs on the CLIA-waived GeneXpert® Xpress platform, bringing HCV NAT testing to the point of care

FDA NEWS RELEASE

FDA Permits Marketing of First Point-of-Care Hepatitis C RNA Test

Test Enables Single-Visit Testing and Treatment for Hepatitis C

Share | Post | Linkedin | Email | Print

For Immediate Release: June 27, 2024

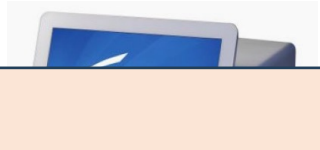
Step 1: Fingerstick

- for BD microtainer
- Use deep lancet to ensure adequate volume
- Valid for clinical use only up to 4 hours

Step 2: Sample Loading

- 100 µL needed for HCV NAT
- Load into cartridge with specialized pipette with overflow valve

Step 3: Run Test



- Load into Xpress system
- 60-minute runtime
- Positive tests may result as soon as 41 minutes
- Qualitative result

The newly authorized POC HCV RNA test can improve diagnoses and treatment

Slide adapted from C. Wester, CDC TLM 2024

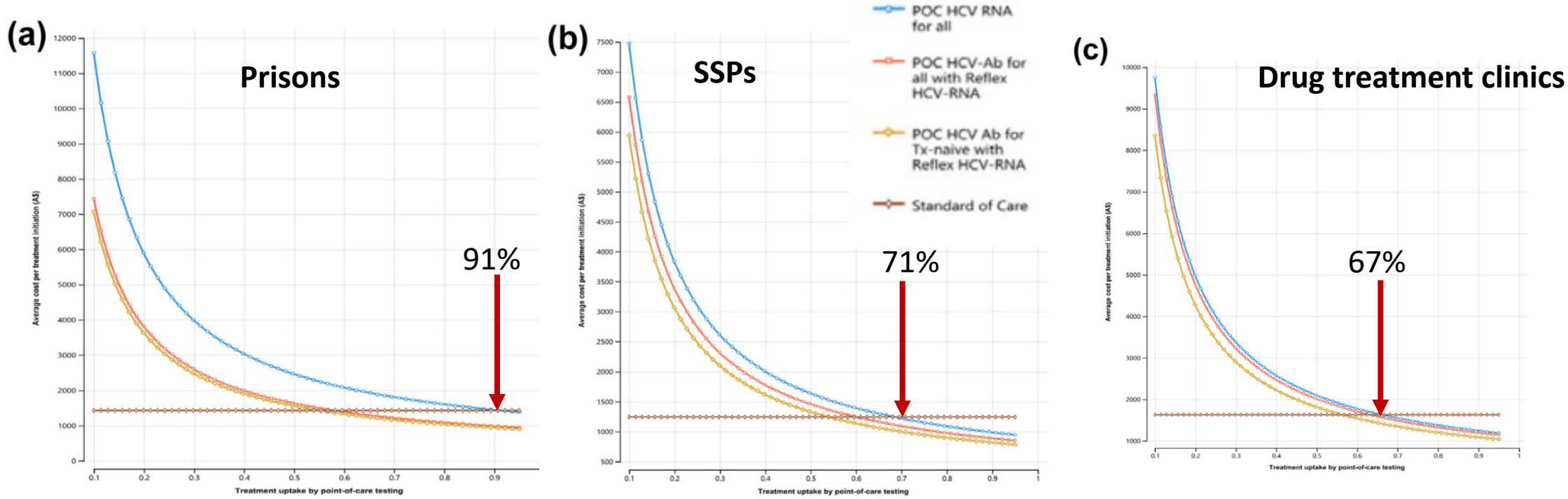
https://www.cepheid.com/en-US/tests/blood-virology-womens-health-sexual-health/xpert-hcv-info.html

Which Settings Optimal for POC HCV RNA Testing

- High prevalence
- Lack phlebotomy and other laboratory testing
- Brief or episodic encounters with immediate treatment

POCT Cost-Effective only if Linked with High Treatment Initiation

Threshold analysis of equivalent cost per treatment initiation for POCT treatment uptake



- Increasing treatment initiation rates to 67-91% with immediate point-of-care HCV RNA testing needed for the higher cost point of care HCV RNA testing to be preferred strategy

Shiy S, et al. Lancet 2023

Focus on Test and Treat Opportunities

AASLD-IDSA HCV Guidelines

HCV Treatment is indicated for:

ALL patients with HCV infection, except those with short life expectancies that cannot be remediated. (I, A)

Simple point of care diagnostics → Lab or elastography based fibrosis staging → Prescribe DAA

HCV RNA POCT (HBsAg*, HIV)
*not yet available

FIB-4 or VCTE

Prescription or DAA in hand

Ideal = Single Visit

GeneXpert® HCV RNA

Slide adapted from N. Terrault DDW 2025

Need for Test and Treat in Settings with High Infection Burden and/or low Access

- Recognition of undiagnosed and untreated in particular settings– need to be targeted for diagnosis and treatment (microelimination)

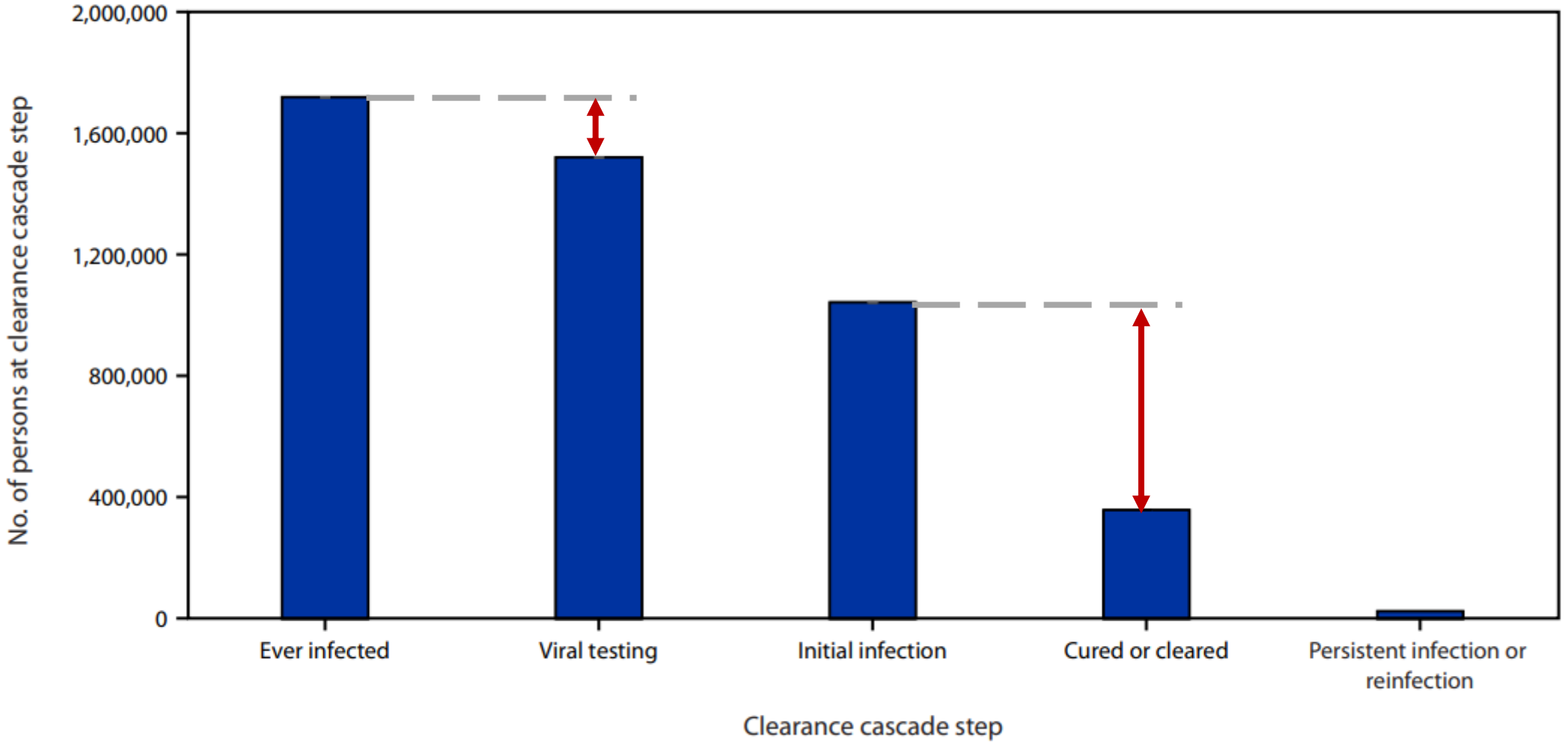
PWIDs
Justice Involved (Dept of corrections and large jails)
Unstably housed
Immigrants
Rural communities

Opioid Treatment Programs
Syring service programs
Opt-out approaches in prisons/jails
Mobile units
Clinics serving new arrivals
Telemedicine

Slide adapted from N. Terrault DDW 2025

HCV Testing and Treatment Gaps Remain

FIGURE 1. Hepatitis C virus clearance cascade using national commercial laboratory data — United States, 2013–2022

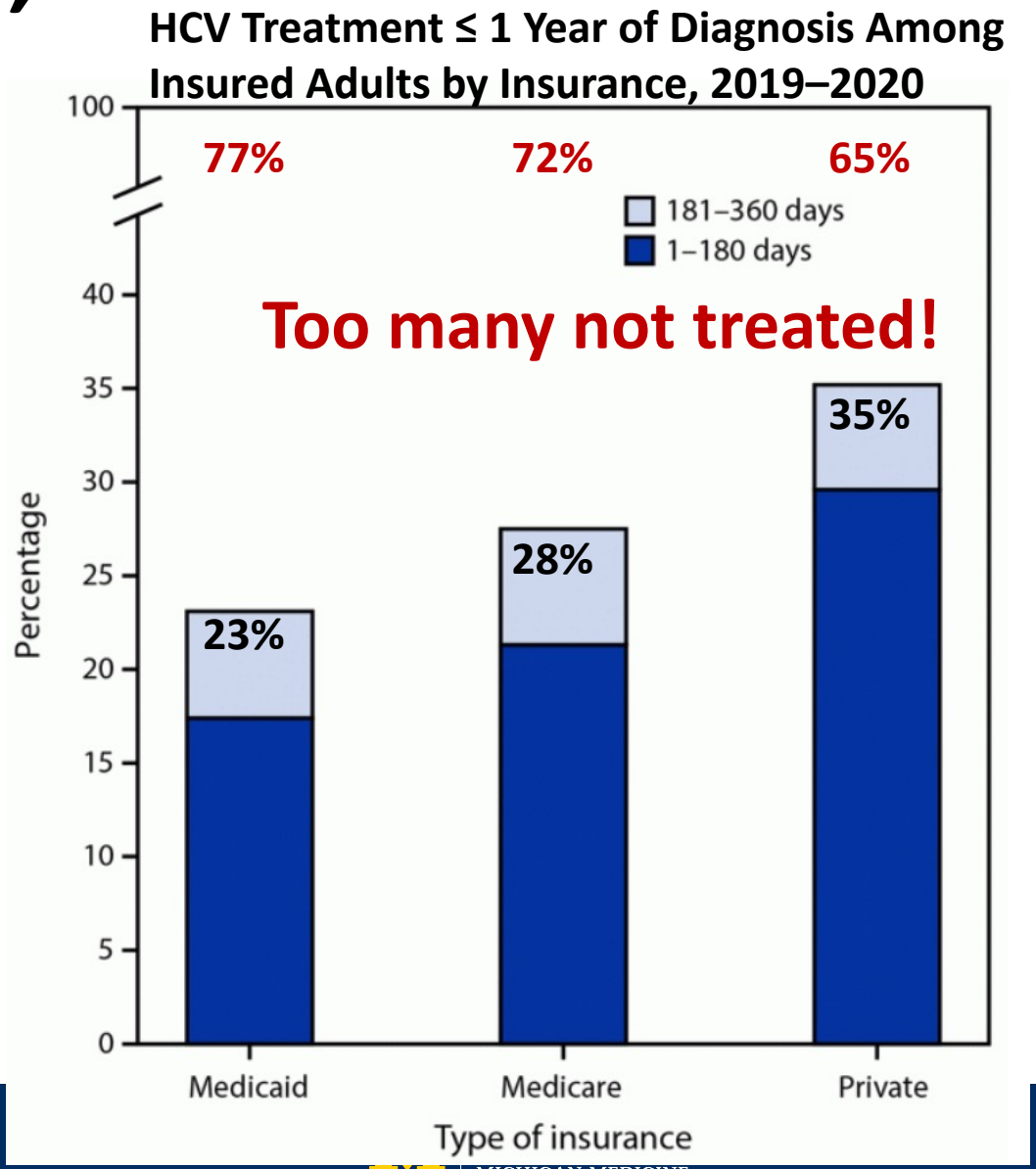


Source: Quest Diagnostics (January 1, 2013–December 31, 2022).

https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7226a3-H.pdf

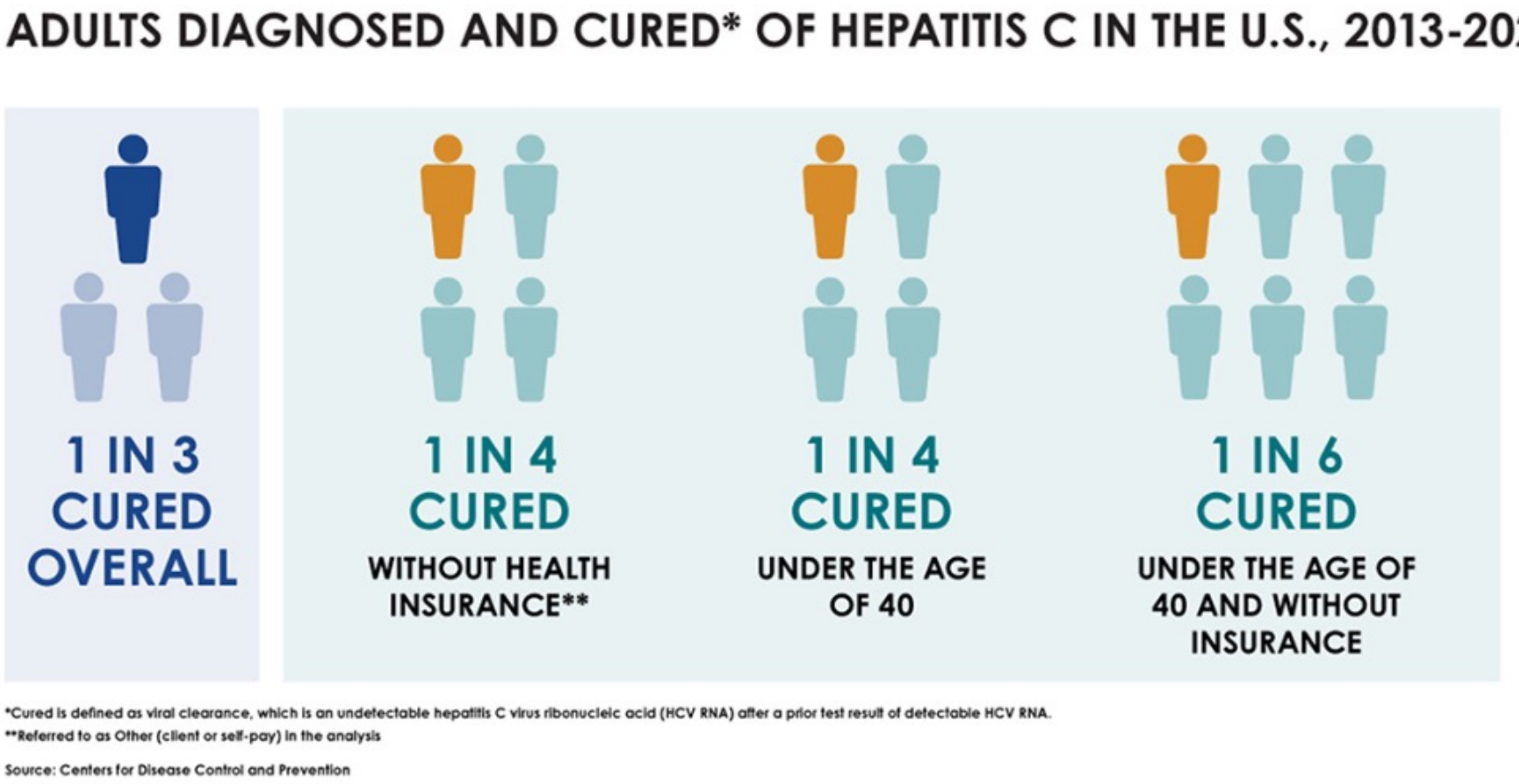
US HCV Treatment Trends, 2014-2023

- IQVIA database (National database of pharmacy claims) 2014-2023 utilizing first paid claims
- Results: 980,462 had evidence of DAA treatment in the US
- Many people who are diagnosed with HCV do not get timely treatment



Teshale E, et al. TLM 2024; Vital Signs CDC August 2022

HCV clearance rates are low overall and are lowest among younger adults without insurance



https://www.cdc.gov/media/releases/2023/p0629-hepatitis-c.html

Barriers to HCV Treatment

- Lack of awareness
- Stigma
- Two-step diagnostic testing
- High drug costs
- Insurance coverage gaps
- Insurance treatment restrictions
- Treatment not co-located
- Hardly reached populations

HCV Treatment is Simplified: Treatment naïve, no cirrhosis

Recommended Regimens*

- Glecaprevir (300 mg) / pibrentasvir (120 mg) to be taken with food for a duration of 8 weeks
- Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks

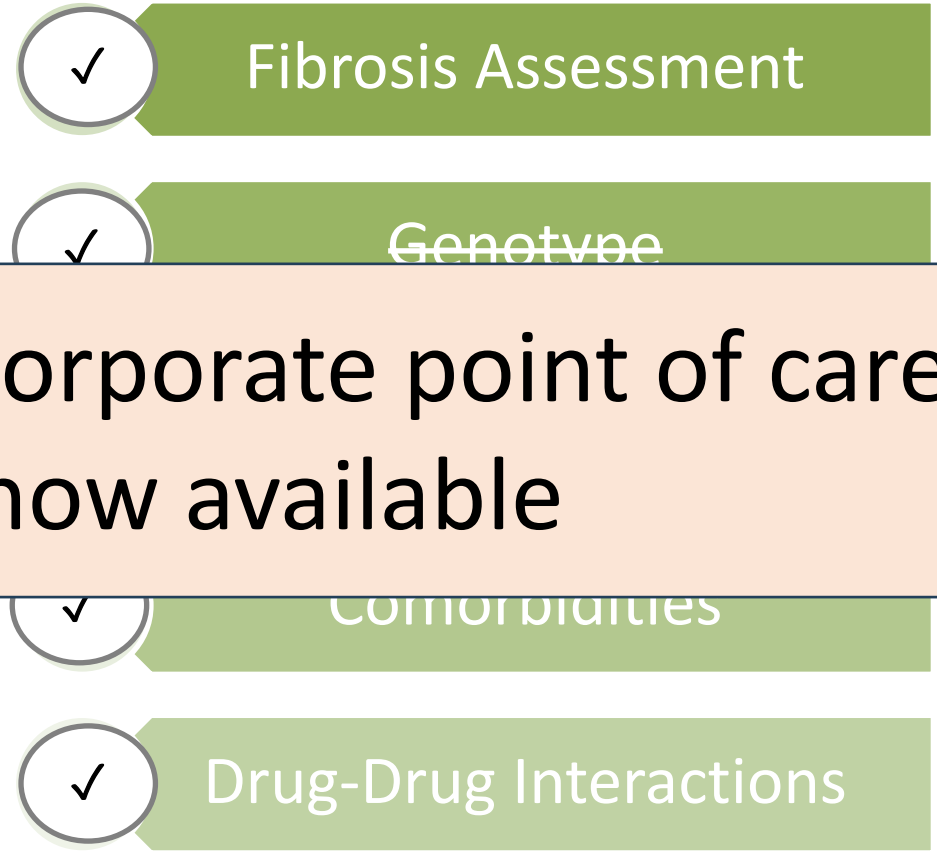
Limitation: Difficult to achieve in non- traditional settings

- Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis)
- HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

(see HCV guidance for treatment recommendations for these patients)

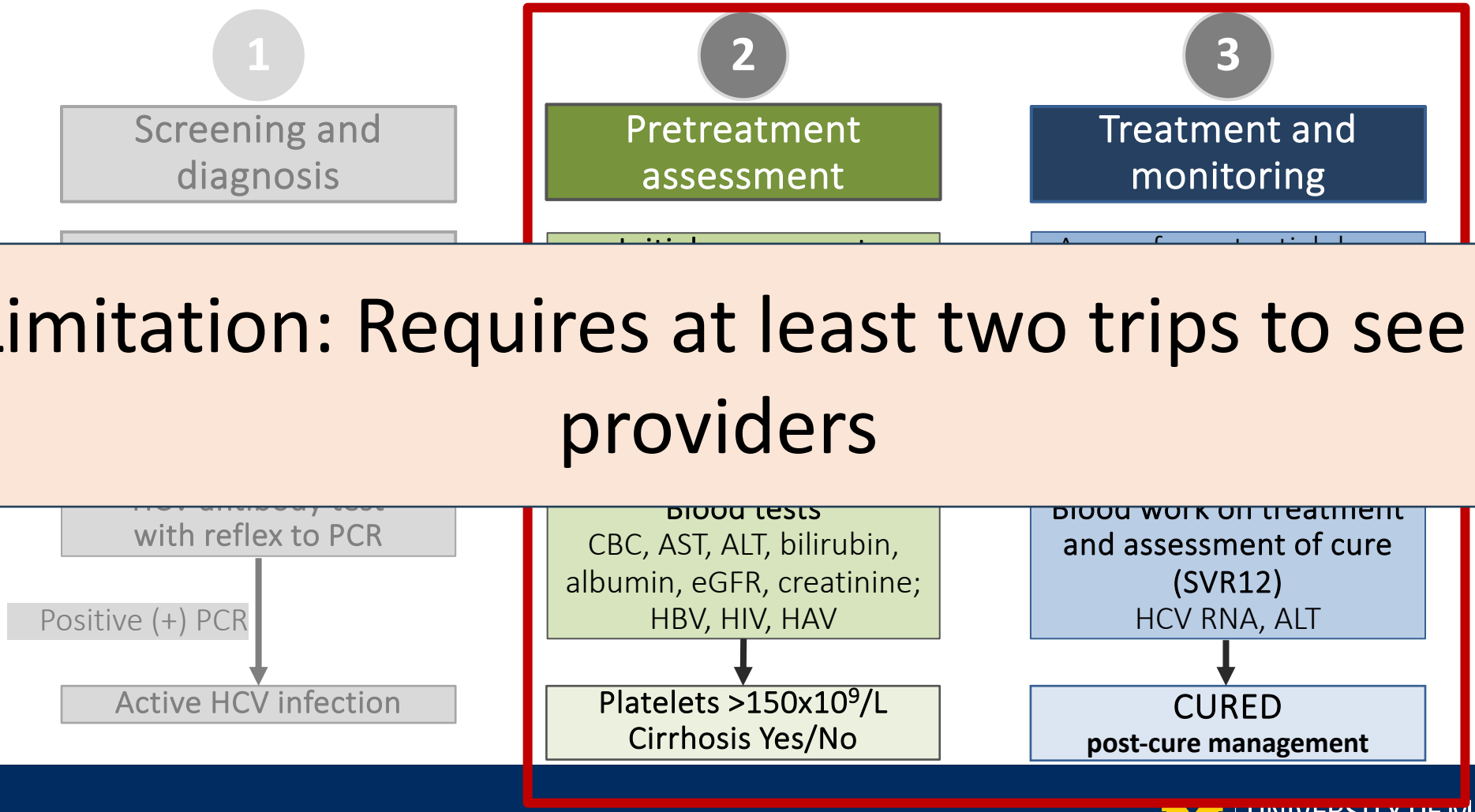
HCV Treatment is Simplified: Treatment naïve, no cirrhosis

- **Fibrosis assessment**
  - **ALL patients**
  - **DON'T MISS CIRRHOSIS**
- **Comorbidities**
  - CKD
  - HIV/HBV coinfection
- **Drug-drug interactions**



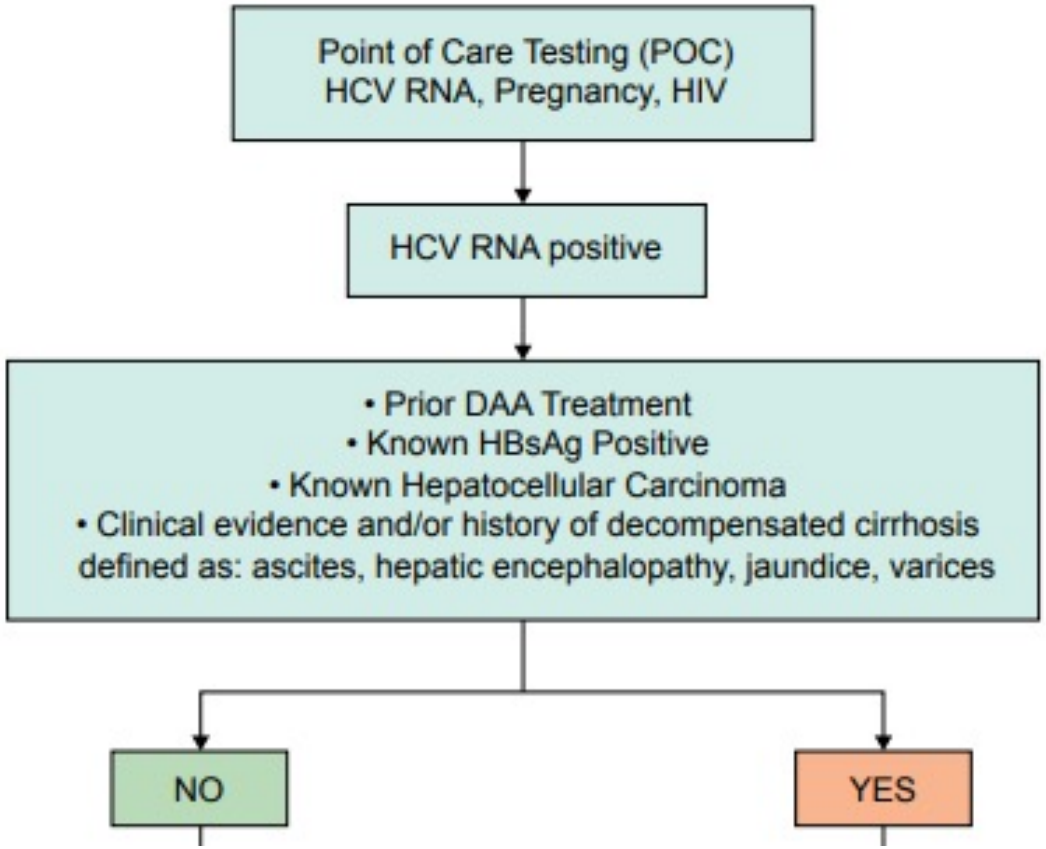
Limitation: Does not incorporate point of care testing that is now available

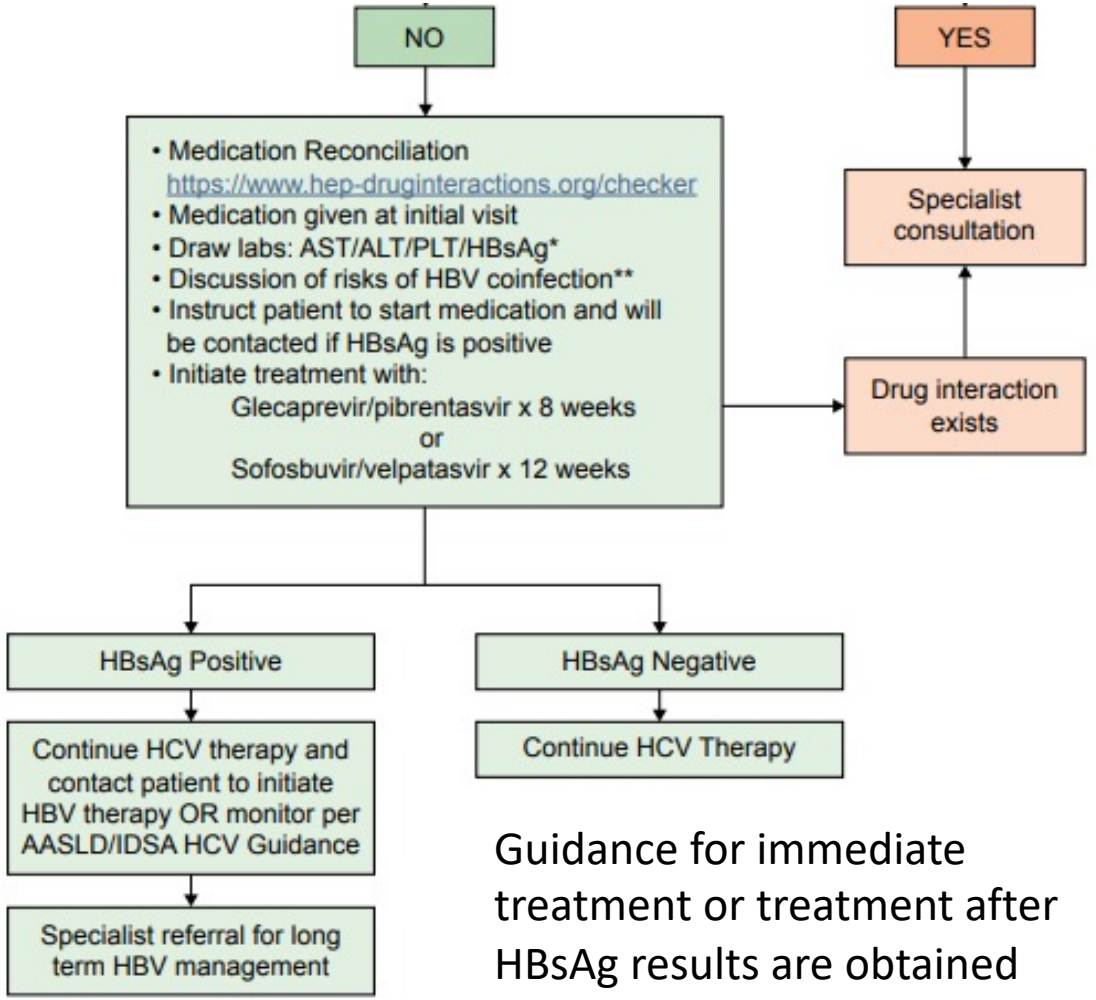
Approach for Management of HCV Infection



Limitation: Requires at least two trips to see providers

Hepatitis C Test and Treat Initial Visit

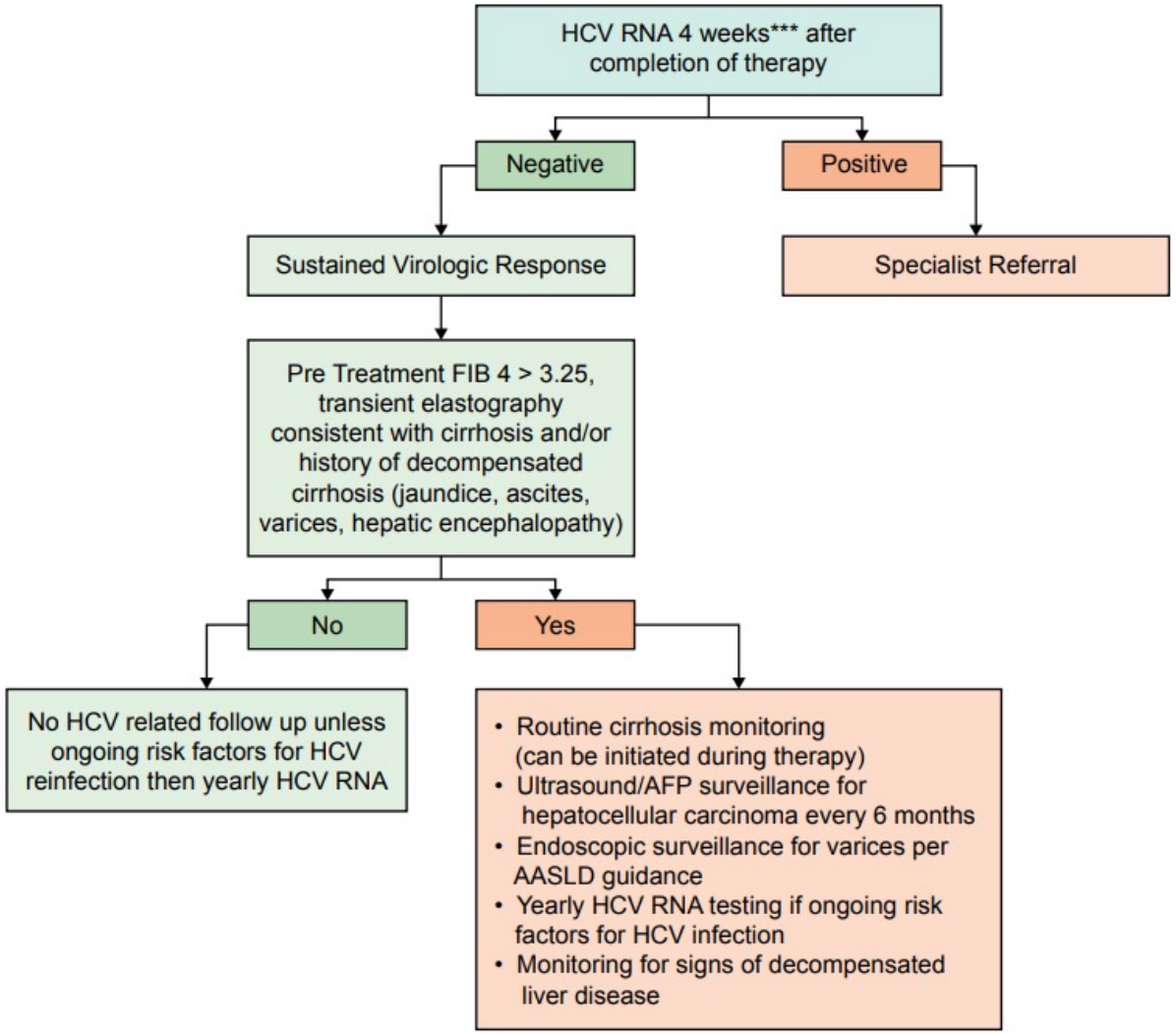




Guidance for immediate treatment or treatment after HBsAg results are obtained

https://www.hcvguidelines.org/

HCV Test and Treatment Algorithm: Follow Up



→ Earlier assessment of SVR
- High concordance between SVR 4 and SVR 12
- Risk of lack of follow-up and confirmation of cure/relapse

→ Need for post-SVR surveillance
- Based on pre-treatment FIB-4 or elastography
- Consider co-existing liver diseases (metabolic and alcohol)

Slide adapted from N. Terrault DDW 2025

Call for National Strategy to Achieve HCV Elimination in the US

National plan to insure access to diagnostics and DAAs

March 9, 2023

A National Hepatitis C Elimination Program in the United States

A Historic Opportunity

JAMA 2023

White House Budget Proposal $11.3 billion over five years

Over 10 years, compared to the status quo, the initiative will:

- Avert: 20,000 cases HCC; 49,100 cases diabetes; 25,000 cases CKD
- Avert: 24,000 deaths adding 220,000 life years
- Over 20 years, the health benefits would increase by more than 2-fold and cost savings by 3-fold

HCC= hepatocellular carcinoma, CKD= chronic kidney disease; DAA= direct acting antivirals

Chhatwal J, et al. NBER Working Paper Series 2023

Slide adapted from N. Terrault DDW 2025

Contact Information

Hi, Ponni P.

Northville, MI 48168-8560

This is not me

Review my information

SEND

PRINT AND MAIL

PREVIEW

Message

Sen. Gary Peters
(D-MI)

Sen. Elissa Slotkin
(D-MI)

Rep. Debbie Dingell
(D-MI-06)

Subject: Please Support the Cure Hepatitis C Act

Dear [[Recipient's Title and Name]]:

As a constituent and someone who wants to see viral hepatitis eliminated, I urge you to cosponsor the Cure Hepatitis C Act that authorizes an innovative purchasing model for hepatitis C direct acting antivirals (DAAs), which are 95% effective, and establishes the infrastructure necessary to support test-to-treat program for hepatitis C. Taken together, these components ensure people will get tested and have access to treatment immediately after diagnosis at no cost. Besides saving lives, the Congressional Budget Office found that the legislation will save over $6 billion in the 10-year budget window.

There are currently 2.2 million people living in the United States with hepatitis C, but many of them are unaware of their status and remain so until they develop complications. Chronically