Cured! The Role of the Psychiatrist in the Treatment of Hepatitis C

Sherry Nykiel, MD, DFAPA

Vishesh Argarwal, MD

Presented at the ASAM 55th Annual Conference, Dallas TX

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Disclosure Information (Required)

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April 7, 2024 8:30AM

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- No Disclosures

Learning Objectives

- By the end of the workshop, participants will:
  - Know the current recommendations for when, in whom and how to initiate treatment for Hepatitis C
  - Compare and contrast the differences in treatment course, effectiveness & side effects between interferon-based & direct-acting antiviral therapies & how this affects treatment options for psychiatric patients
  - Recognize the barriers to achieving the World Health Organization's goal of eradicating Hepatitis C as a public health problem by 2030 and develop strategies to overcome these barriers
  - Gain the confidence to aggressively identify and treat Hepatitis C in their own practice and to advocate for robust HCV screening and treatment in their communities

HCV By the Numbers

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How many people are living with chronic Hepatitis C worldwide?

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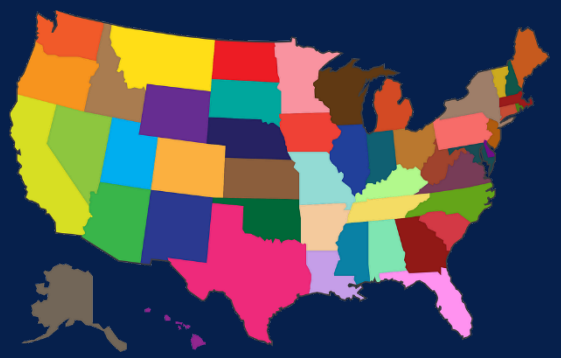
HCV By the Numbers

- Worldwide
  - An estimated 58 million people have chronic HCV
  - About 1.5 million new infections occur each year
  - 290,000 people died from HCV in 2019
    - Main causes: cirrhosis and hepatocellular carcinoma

https://www.who.int/news-room/fact-sheets/detail/hepatitis-c

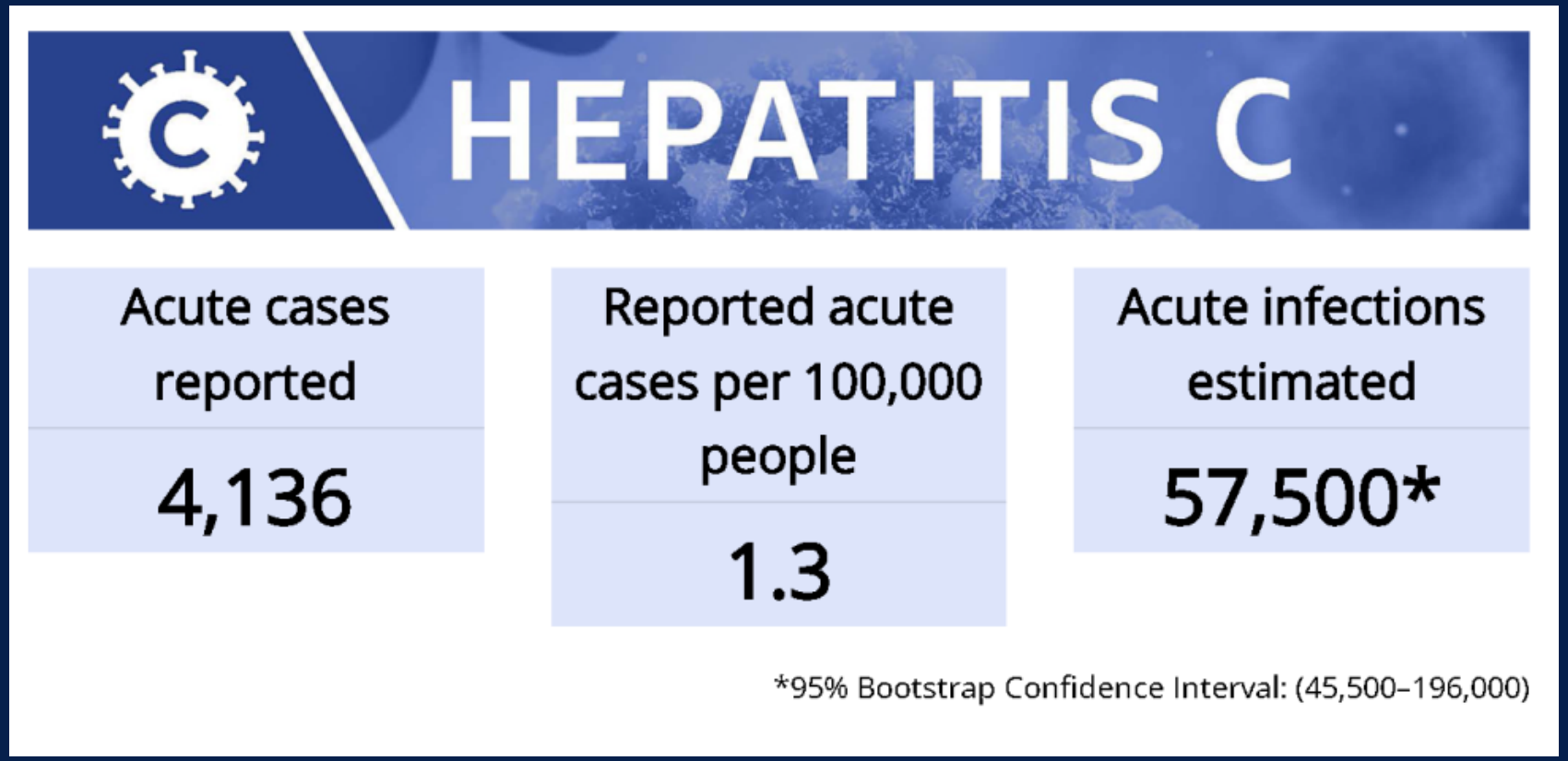
HCV By the Numbers

- United States
  - An estimated 3.5 million people have chronic HCV
  - About 17,000 people are newly infected yearly
  - Every year, approximately 15,000 Americans die from HCV-related liver disease



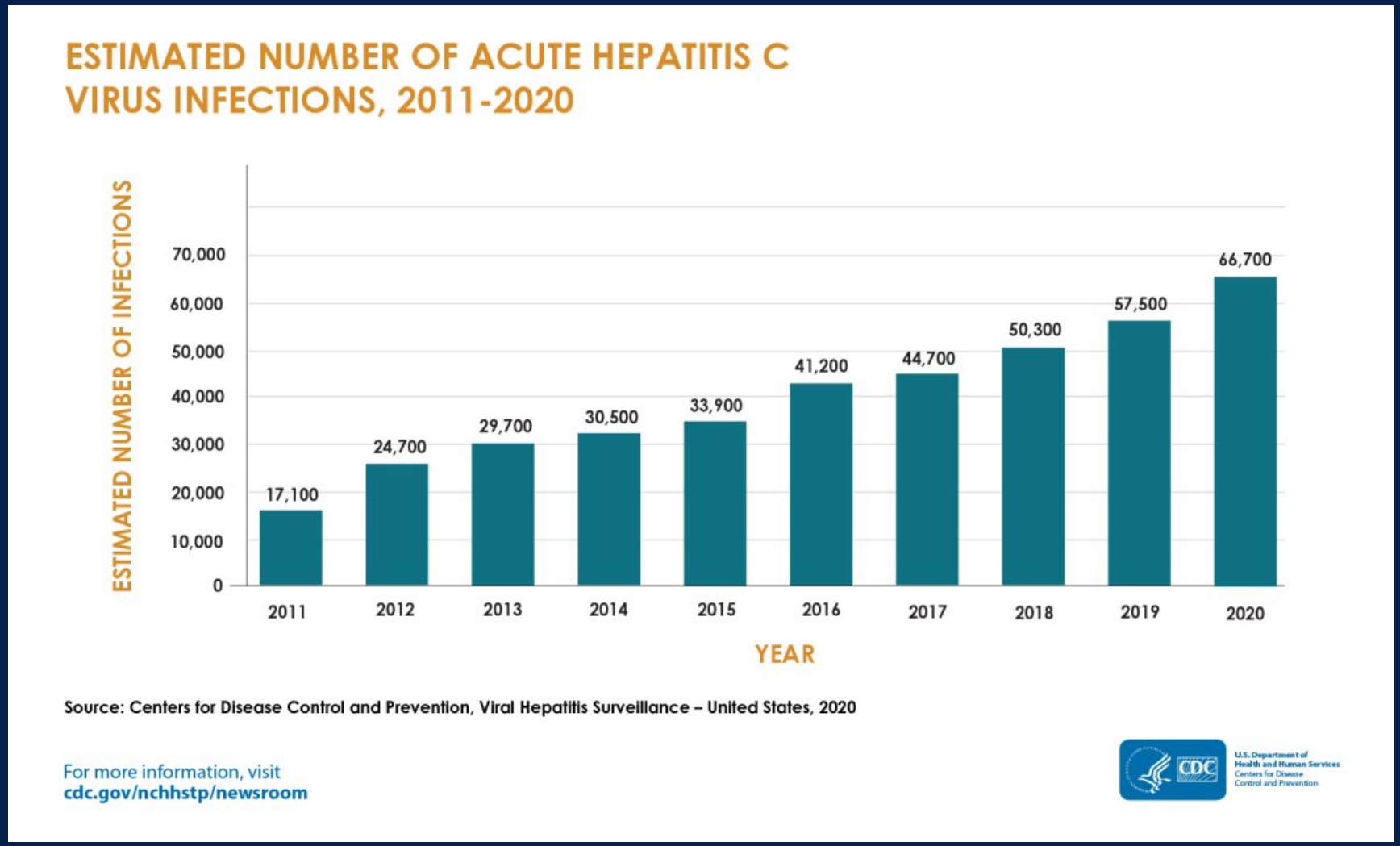
https://liverfoundation.org/liver-diseases/viral-hepatitis/hepatitis-c

CDC 2019 Viral Hepatitis C Report



https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#a2

HCV By the Numbers



https://www.cdc.gov/nchhstp/newsroom/multimedia-resources/vh-multimedia-resources.html

HCV By the Numbers

- Approximately 30% of those infected with HCV will spontaneous clear the virus within 6 months without any treatment
- The remaining 70% will develop chronic HCV
  - Up to 75% of those with chronic HCV are unaware they are infected.
- 15-30% of those with chronic HCV will develop cirrhosis within 20 years.

https://www.who.int/news-room/fact-sheets/detail/hepatitis-c

HCV By the Numbers

- 15-30% of those with chronic HCV will develop cirrhosis within 20 years.
- Those who develop cirrhosis have a:
  - 1%-4% annual risk of developing hepatocellular carcinoma
  - 3%-6% annual risk of hepatic decompensation
    - These patients have a 15%-20% chance of death in the following year

https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#a2

Who is at risk for HCV?

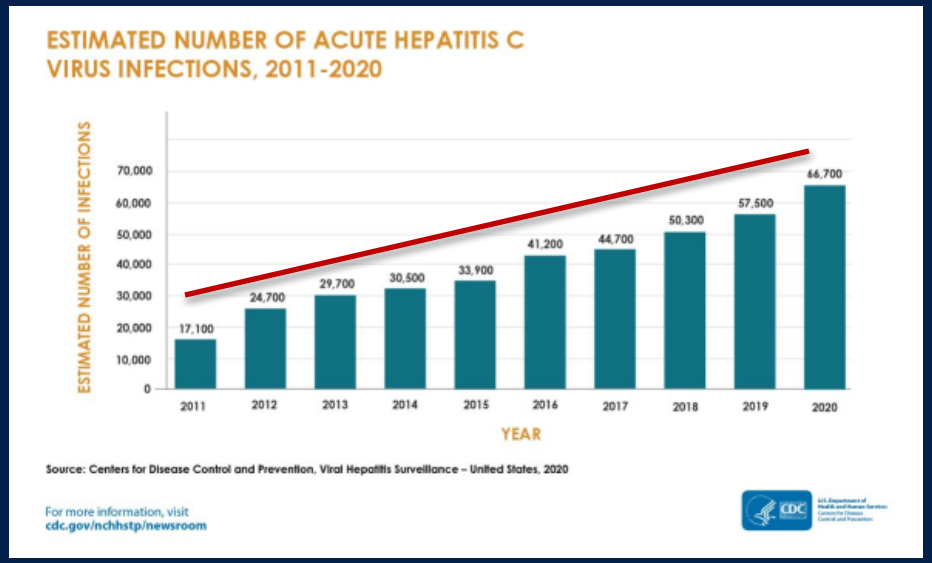
Reported risk behaviors or exposures*† among reported cases of acute HCV infection

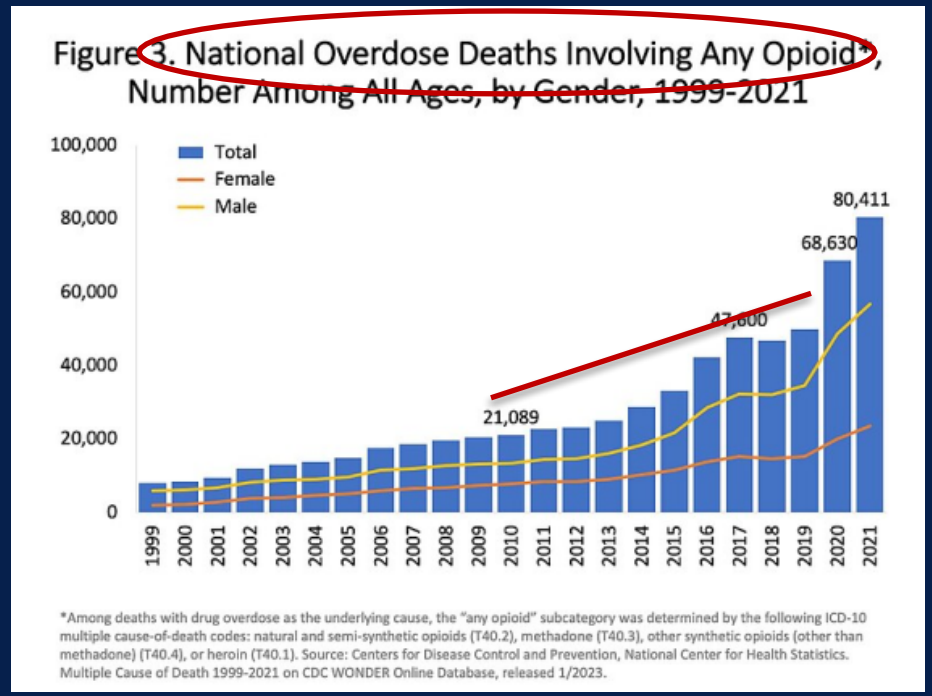
Risk behaviors/exposures	Risk identified*	No risk identified	Risk data missing
Injection drug use	1,302	650	2,184
Multiple sexual partners	223	594	3,319
Surgery	179	888	3,069
Sexual contact §	142	334	3,660
Needlestick	91	886	3,159
Men who have sex with men ¶	42	315	2,114
Household contact (non-sexual) §	36	440	3,660
Dialysis patient	61	1,249	2,826
Occupational	7	1,278	2,851
Transfusion	3	1,105	3,028

https://www.cdc.gov/hepatitis/statistics/2019surveillance

Who is at risk for HCV?

- HCV is most common among people who inject drugs (PWID)
- Dramatic increases in new infections tied to the opioid epidemic





https://www.cdc.gov/nchhstp/newsroom/multimedia-resources/vh-multimedia-resources.html

CDC National Center for Health Statistics Multiple Cause of Death 1999-2021 on CDC WONDER online database released 1/2023

Who is at risk for HCV?

By Age†

20–29 years: 2.9 cases per 100,000 people
30–39 years: 3.2 cases per 100,000 people
40–49 years: 1.7 cases per 100,000 people

By Risk

Injection Drug Use (IDU): Among the 1,952 reported cases with IDU information available, 1,302 (67%) report IDU

By Race/Ethnicity†

American Indian/Alaska Native:
3.6 cases per 100,000 people

- Disproportionally affects:
  - Those without insurance
  - American Indian and Alaska Native persons
  - Non-Hispanic Black persons
  - Justice involved populations
    - inmates in correctional facilities account for up to ⅓ of US HCV cases
    - Most of these are accounted for by inmates sharing needles while injecting drugs
  - Severely and persistently mentally ill populations

CDC: Hepatitis C FAQs for Health Professionals. Available from: http://www.cdc.gov/hepatitis/hcv/hcvfaq
Rosenberg SD, Goodman LA, Osher FC, et al: Prevalence of HIV, hepatitis B, and hepatitis C in people with severe mental illness. Am J Public Health 2001; 91(1):31

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Treatment is recommended for all patients with acute or chronic HCV infection except those (choose all that apply)

ⓘ Start presenting to display the poll results on this slide.

Who should be treated for HCV?

- Treatment is recommended for all patients with acute or chronic HCV infection **except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation or another directed therapy**.
  - Actively using substances? Treat
  - Unstable housing? Treat
  - Already had treatment and now reinfected? Treat
  - Genotype not documented? Treat
  - Fibrosis stage not documented? Treat

https://www.hcvguidelines.org/evaluate/when-whom

HCV Treatment: Then and Now

Then

- Interferon injections and ribavirin pills
  - Sustained virologic response of less than 45%
  - Moderate to severe side effects in many patients
  - Regimen requires injections and pills, lasting 24-48 weeks
  - Drug interactions: minimal

Now

- Direct Acting Antivirals (DAAs)
  - Sustained virologic response of nearly 95%
  - Minimal side effects which are mild when they occur
  - Regimen requires one pill a day for 8-12 weeks
  - Drug interactions: minimal
    - CYP4503A – Daclatasvir, Simeprevir
    - p-glycoprotein substrate - Ledipasvir, Sofosbuvir

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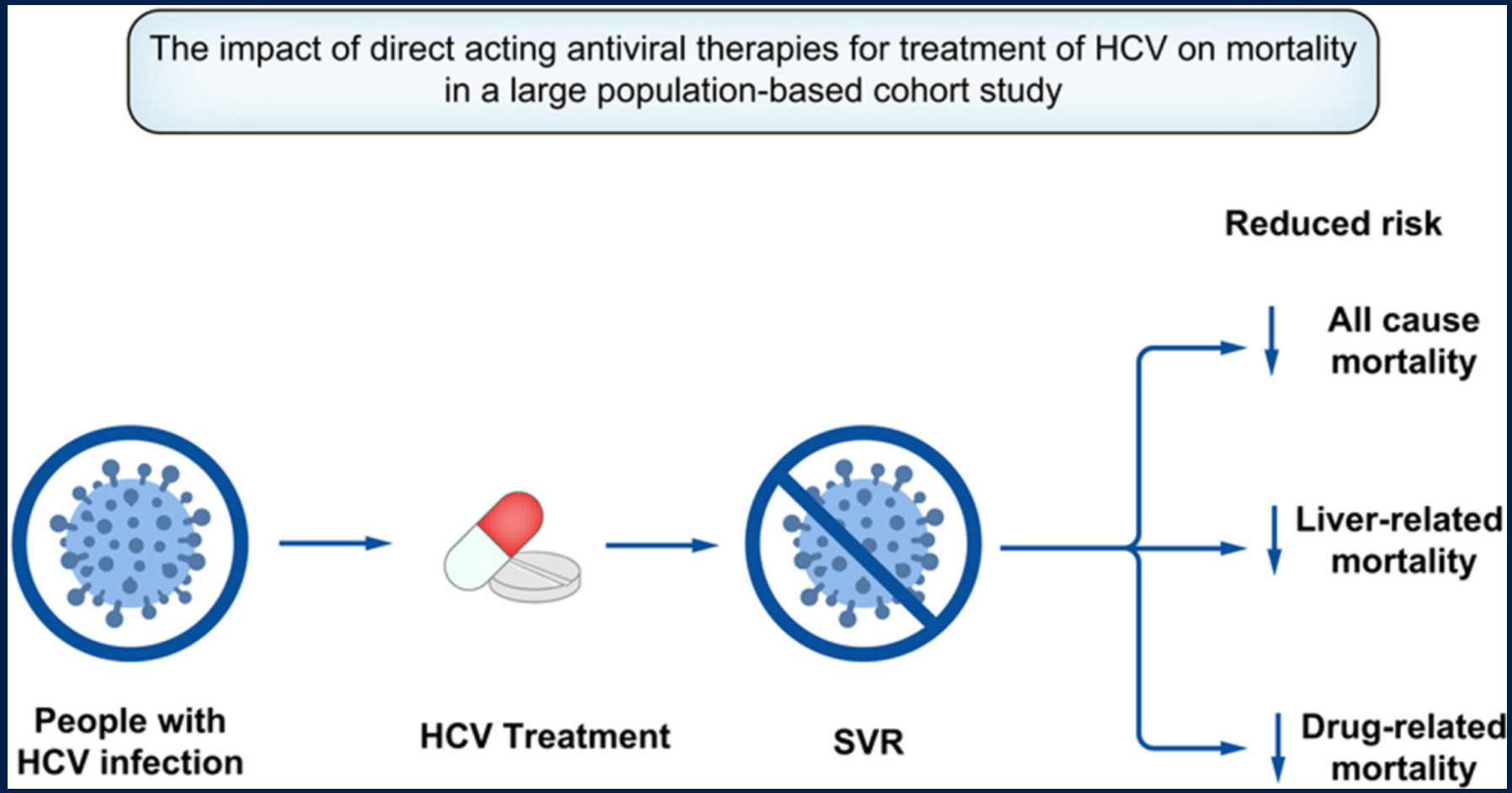
Direct Acting Antivirals: Efficacy



Janjua, Naveed Z, et al. "Impact of Direct-Acting Antivirals for HCV on Mortality in a Large Population-Based Cohort Study." *Journal of Hepatology*, vol. 75, no. 5, 1 Nov. 2021, pp. 1049–1057, https://doi.org/10.1016/j.jhep.2021.05.028. Accessed 29 Sept. 2023.

Treat early and often

- Initiating treatment with DAAs in earlier stages of acute or chronic infections leads to:
  - Reduced extrahepatic manifestations
  - Improved quality of life
  - Reduced risk of fibrosis and hepatocellular carcinoma
  - Cost effectiveness
  - Improved population health through reduced risk of transmission

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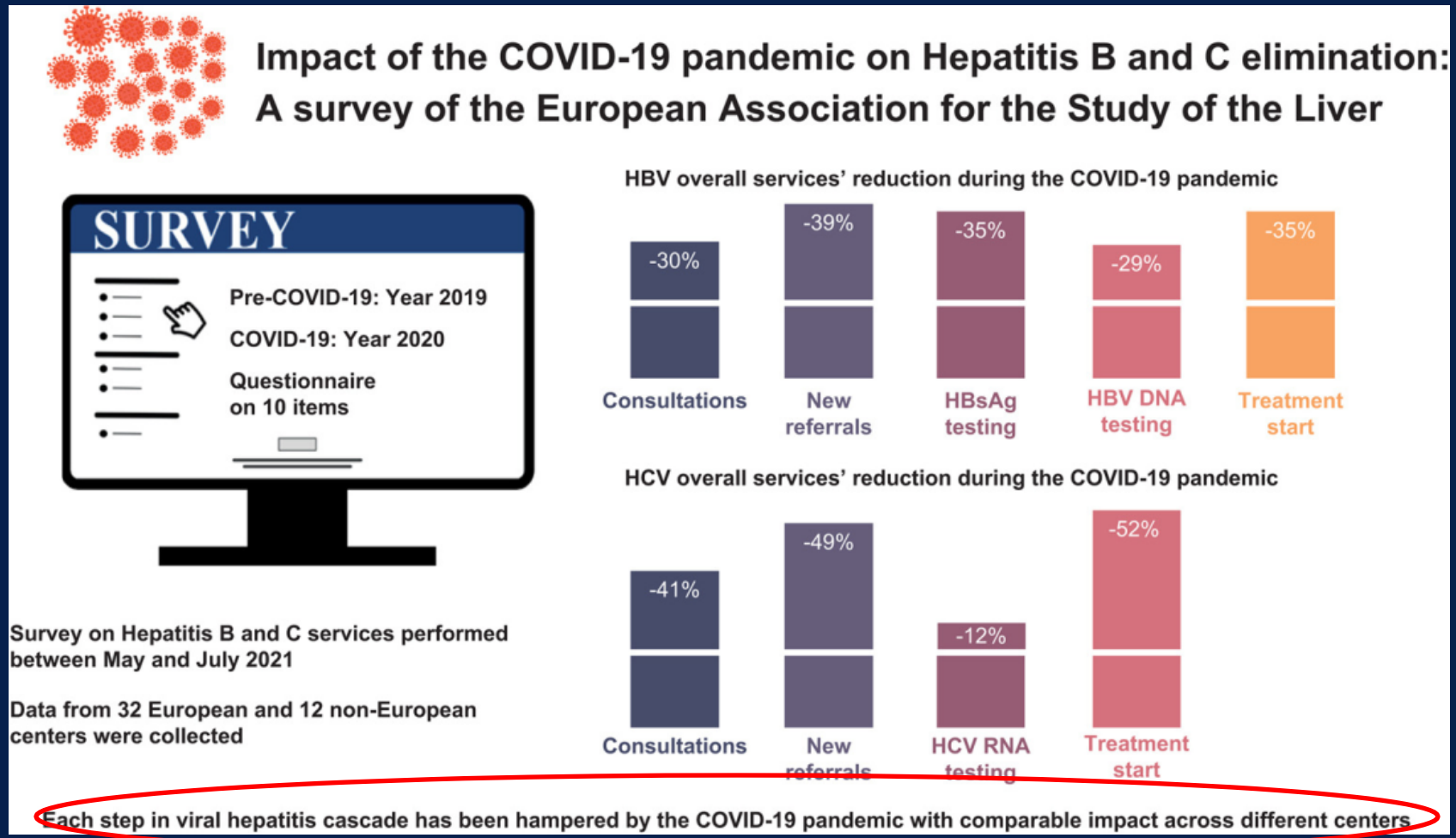
  - Reduced risk of fibrosis and hepatocellular carcinoma
  - Cost effectiveness
  - Improved population health through reduced risk of transmission
  - A cure for HCV

Eradication of HCV by 2030

- "WHO's global hepatitis strategy, endorsed by all WHO Member States, aims to reduce new hepatitis infections by 90% and deaths by 65% between 2016 and 2030."

www.who.int/health-topics/hepatitis/elimination-of-hepatitis-by-2030

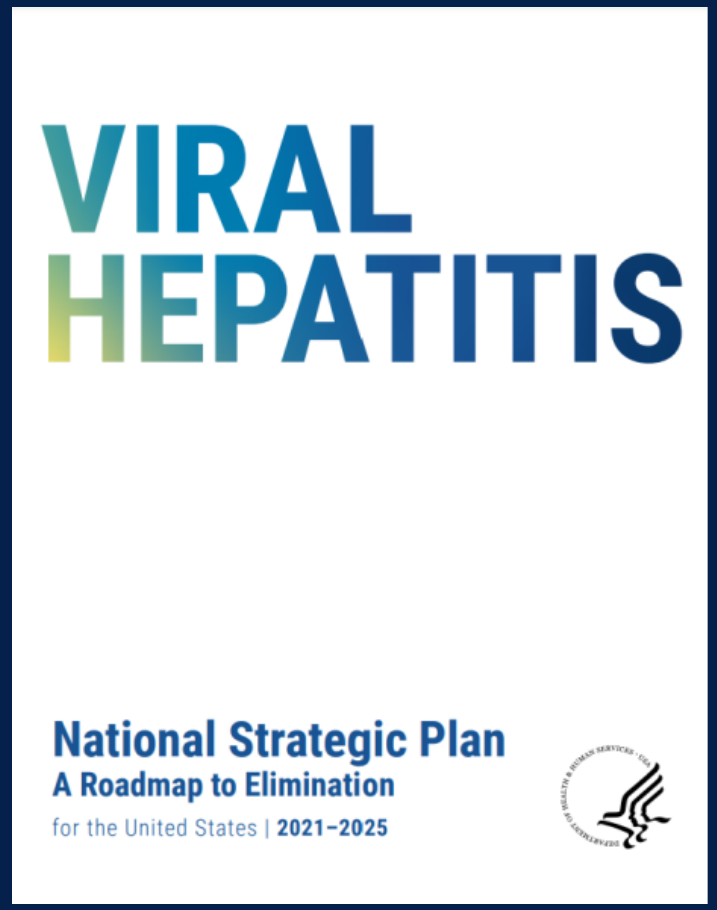
Eradication of HCV by 2030?



"Each step in the viral hepatitis cascade has been hampered by the COVID-19 pandemic "

Kondili, Loreta A., et al. "Impact of the COVID-19 Pandemic on Hepatitis B and c Elimination: An EASL Survey." *JHEP Reports*, vol. 4, no. 9, 1 Sept. 2022, p. 100531, www.sciencedirect.com/science/article/pii/S2589555922001033, https://doi.org/10.1016/j.jhepr.2022.100531. Accessed 10 Apr. 2023.

Roadmap to Elimination



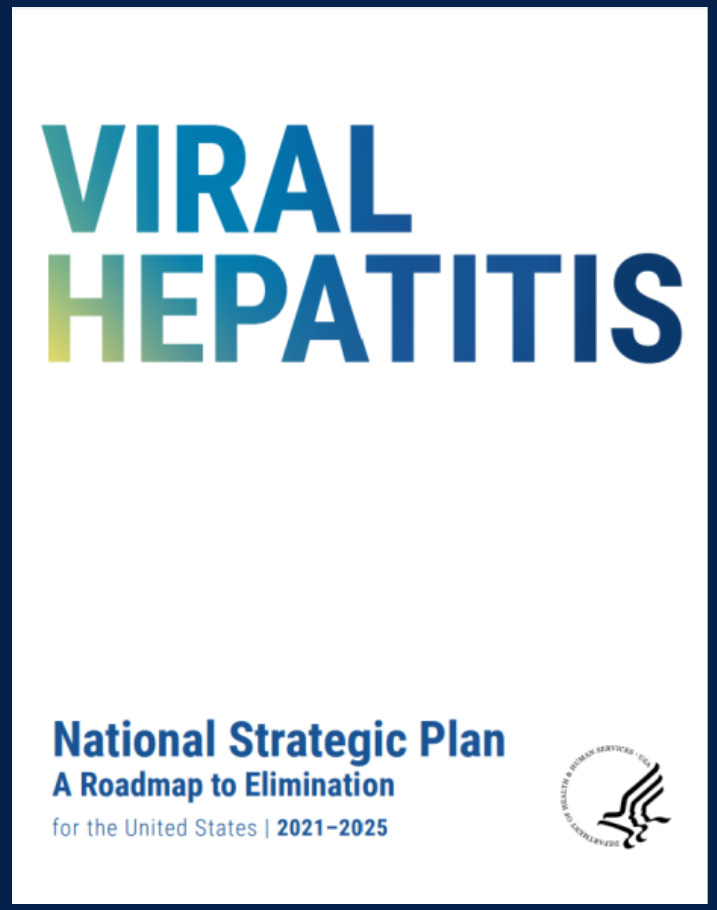
VISION

The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf

Roadmap to Elimination



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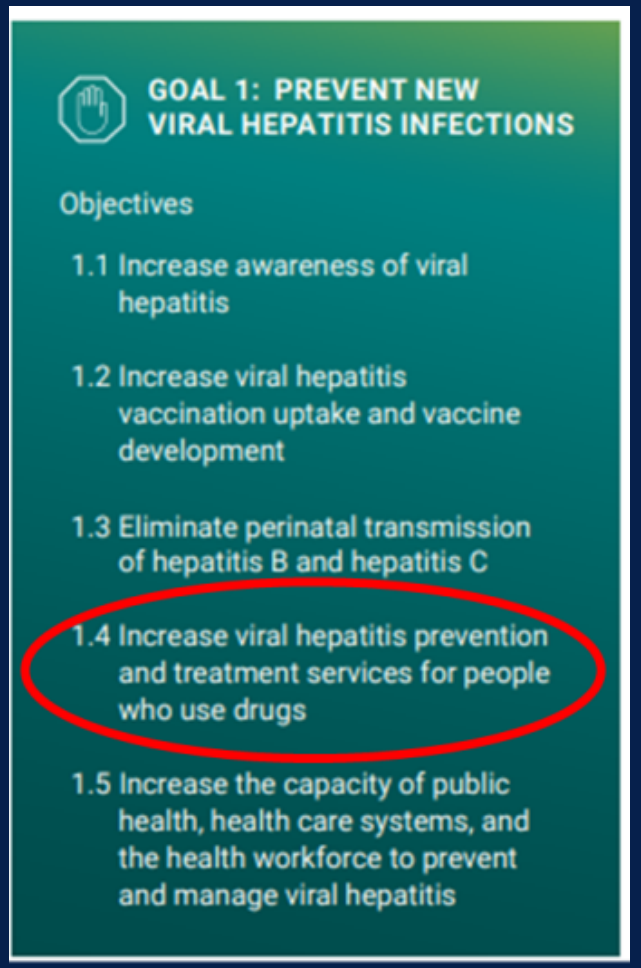
- HCV infections are prevented
- Every person knows their status
- Every person with HCV has high quality healthcare and treatment
- Every person with HCV lives free from stigma and discrimination

https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf

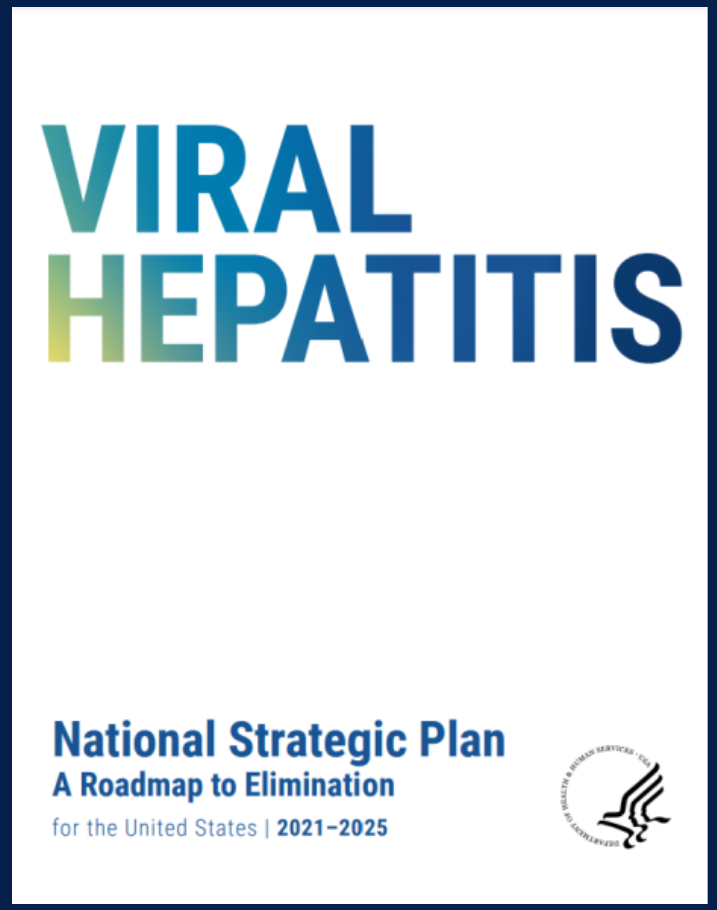
Prevention



- "Comprehensive, community-based prevention services such as syringe services programs (SSPs) and opioid use disorder (OUD) treatment, together can prevent approximately 75% of hepatitis C infections."

https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf

Roadmap to Elimination



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- HCV infections are prevented
- Every person knows their status
- Every person with HCV has high quality healthcare and treatment
- Every person with HCV lives free from stigma and discrimination

https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf

Who should be screened?

Clinician Summary of USPSTF Recommendation

Screening for Hepatitis C Virus Infection in Adolescents and Adults

March 2020

What does the USPSTF recommend?

B **For adults aged 18 to 79 years:**

Screen adults for hepatitis C virus (HCV) infection.

To whom does this recommendation apply?

Asymptomatic adults aged 18 to 79 years (including pregnant persons) without known liver disease.

What's new?

This recommendation expands the population that should be screened. The USPSTF now recommends that all adults aged 18 to 79 years be screened. Previously, it recommended screening adults born between 1945 and 1965 and others at high risk.

How to implement this recommendation?

Screen. Screen adults aged 18 to 79 years with anti–HCV antibody testing followed by confirmatory polymerase chain reaction testing.

a. The USPSTF also suggests that clinicians consider screening persons younger than 18 years and older than 79 years who are at high risk for infection (eg, those with past or current injection drug use).

Adults with a positive screening test result are usually followed up with a diagnostic evaluation using 1 of various noninvasive tests. Treatment typically consists of oral direct-acting antiviral regimens for 8 to 12 weeks.

Important considerations include:

- Communicating that screening is voluntary and undertaken only with the patient's knowledge
- Informing patients about HCV infection, how it can (and cannot) be acquired, the meaning of positive and negative test results, and the benefits and harms of treatment
- Providing patients the opportunity to ask questions and to decline screening

How often?

One-time screening for most adults.

Periodically screen persons with continued risk for HCV infection (eg, persons with past or current injection drug use). There is limited evidence to determine how often to screen persons at increased risk.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation.

U.S. Preventive Services TASK FORCE

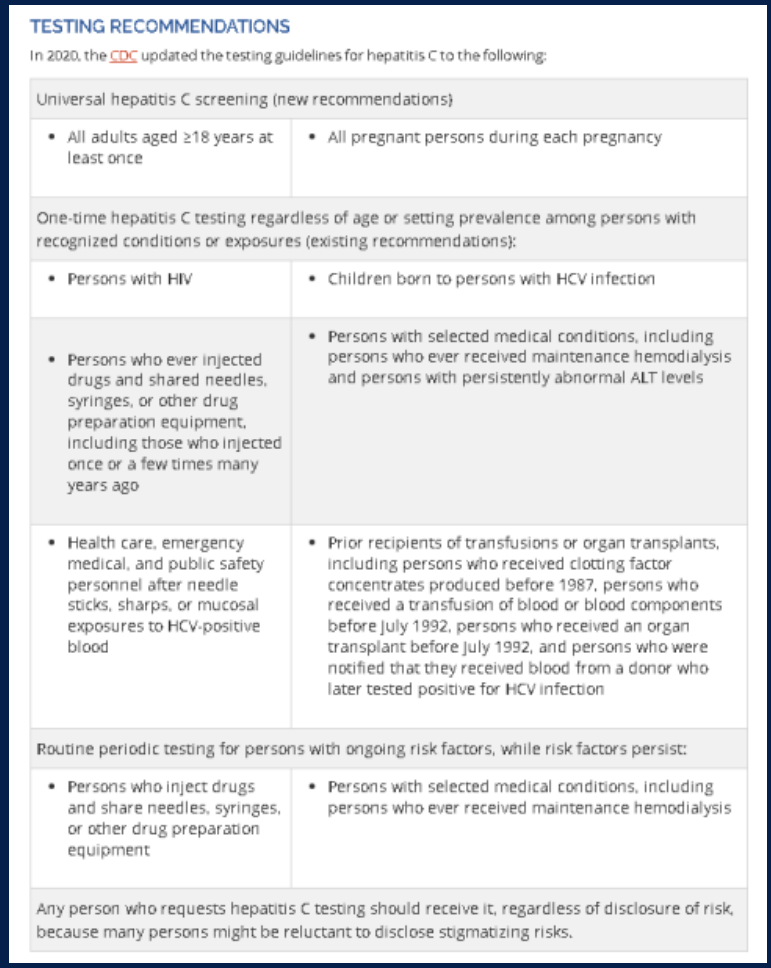
www.uspreventiveservicestaskforce.org

- All asymptomatic adults aged 18-79 years (including pregnant persons at every pregnancy) without known liver disease
- Consider screening persons younger than 18 and older than 79 who are at high risk for infection

www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening

Who should be screened?

- "Any person who requests HCV testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks."



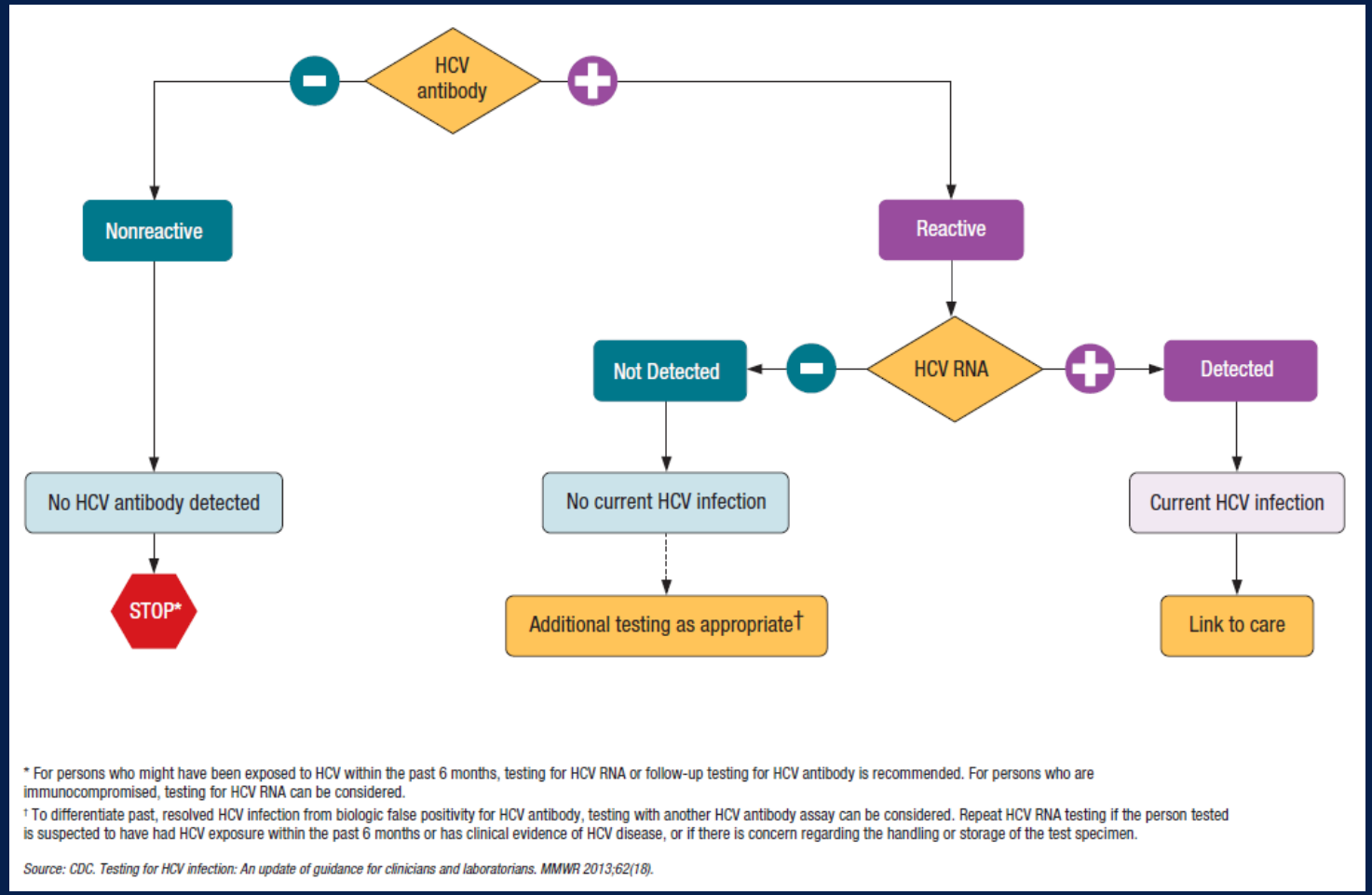
TESTING RECOMMENDATIONS

In 2020, the CDC updated the testing guidelines for hepatitis C to the following:

Universal hepatitis C screening (new recommendations)	
• All adults aged ≥18 years at least once	• All pregnant persons during each pregnancy
One-time hepatitis C testing regardless of age or setting prevalence among persons with recognized conditions or exposures (existing recommendations):	
• Persons with HIV	• Children born to persons with HCV infection
• Persons who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago	• Persons with selected medical conditions, including persons who ever received maintenance hemodialysis and persons with persistently abnormal ALT levels
• Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood	• Prior recipients of transfusions or organ transplants, including persons who received clotting factor concentrates produced before 1987, persons who received a transfusion of blood or blood components before July 1992, persons who received an organ transplant before July 1992, and persons who were notified that they received blood from a donor who later tested positive for HCV infection
Routine periodic testing for persons with ongoing risk factors, while risk factors persist:	
• Persons who inject drugs and share needles, syringes, or other drug preparation equipment	• Persons with selected medical conditions, including persons who ever received maintenance hemodialysis
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.	

/www.longbeach.gov/health/diseases-and-condition/information-on/hepatitis-c/hepatitis-c---providers/
https://www.cdc.gov/mmwr/volumes/69/rr/rr6902a1.htm

Barriers to Treatment: Screening



CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18)

Barriers to Treatment: Screening

- Step One: Initial HCV antibody screening
  - Use CLIA-waived rapid test, or lab-based assay
    - Non-reactive indicates no presence of HCV antibodies
    - Reactive indicates:
      - Current HCV infection, or
      - Past HCV infection that has resolved, or
      - False positivity

CDC. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm

Barriers to Diagnosis: Screening

- Step 2: If antibody screening test is reactive, conduct or refer for an RNA test to detect active infection
- RNA testing can be conducted using blood from:
  - A venipuncture sample subsequent to antibody screening, or
  - A single initial venipuncture in which two specimens are collected in separate tubes, or
  - A single initial venipuncture sample automatically directed to RNA testing after a reactive antibody screening (reflex-to-RNA), or
  - A separate venipuncture sample collected after reactive rapid test using a fingerstick sample

CDC. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm

Barriers to Diagnosis: Screening

- This process can take up to two weeks and patients need to return a third time, often to a different treatment setting to initiate treatment.
- Many patients are lost to follow-up (LTFU)
- "Test and treat"
  - Point of care testing and treatment has been shown to decrease the number of LTFU patients, increase SVR and decrease reinfection rates
  - Point of care testing is not currently available in the United States

Aleman, Soo, et al. "Frequent Loss to Follow-up after Diagnosis of Hepatitis c Virus Infection: A Barrier toward the Elimination of Hepatitis c Virus." *Liver International*, 15 Apr. 2020, https://doi.org/10.1111/liv.14469. Accessed 28 Apr. 2020 .

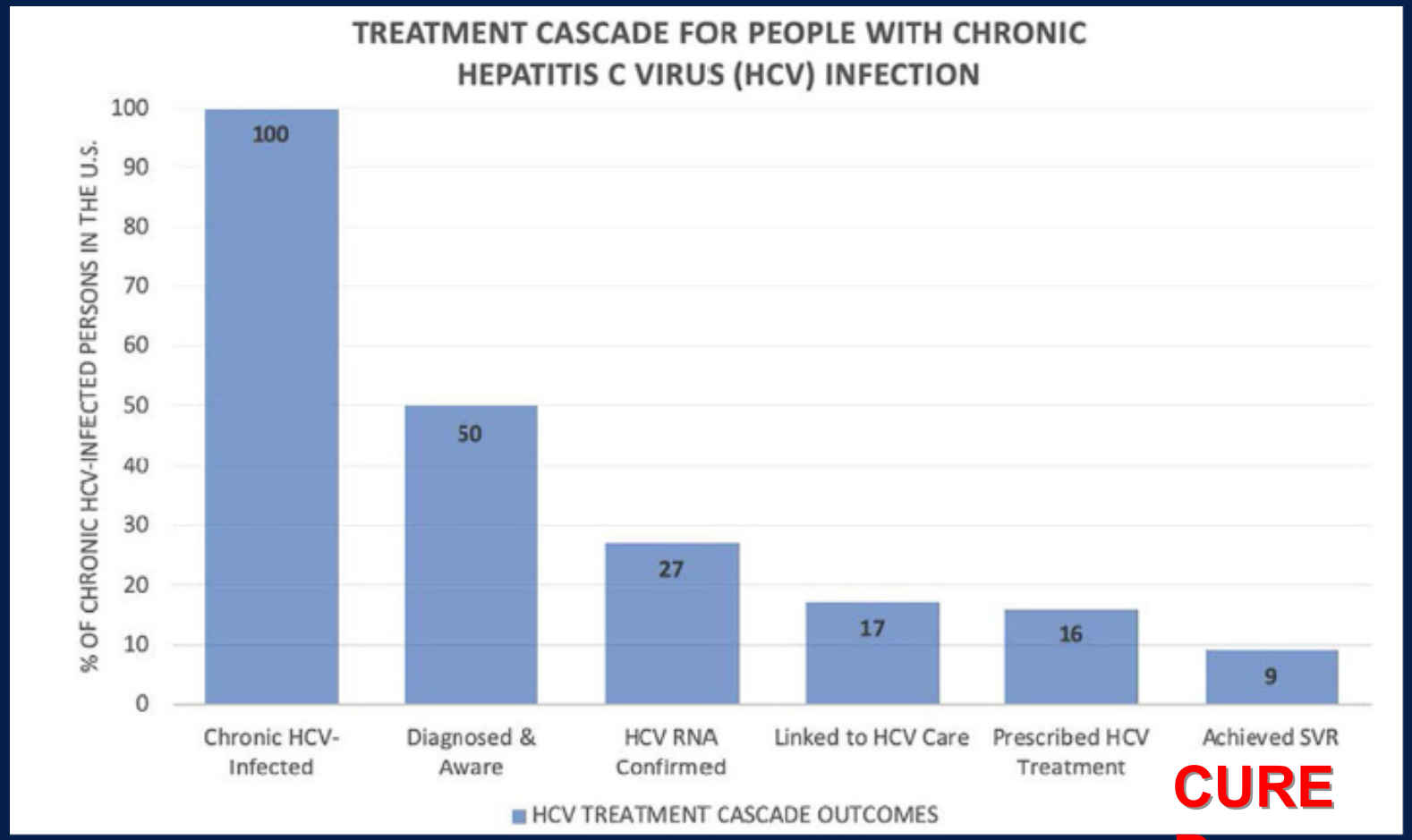
Forns, Xavier, et al. "Point-of-Care Hepatitis c Testing and Treatment Strategy for People Attending Harm Reduction and Addiction Centres for Hepatitis c Elimination." *Journal of Viral Hepatitis*, vol. 29, no. 3, 1 Mar. 2022, pp. 227–230, pubmed.ncbi.nlm.nih.gov/34806812/, https://doi.org/10.1111/jvh.13634. Accessed 13 Nov. 2023.

Barriers to Diagnosis: Screening

- A Swedish study showed that 2/3 of patients who were screened and diagnosed with chronic HCV were LTFU without access to DAA treatment/cure
  - Predictors included young age, male, less education, presence of psychiatric conditions, unmarried
  - May also be due to lack of symptoms, lack of understanding of the long-term consequences of the infection, and unmet SDOH needs

Aleman, Soo, et al. “Frequent Loss to Follow-up after Diagnosis of Hepatitis c Virus Infection: A Barrier toward the Elimination of Hepatitis c Virus.” *Liver International*, 15 Apr. 2020, https://doi.org/10.1111/liv.14469. Accessed 28 Apr. 2020.

HCV Treatment Cascade



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Yehia, Baligh R., et al. "The Treatment Cascade for Chronic Hepatitis c Virus Infection in the United States: A Systematic Review and Meta-Analysis." *PLoS ONE*, vol. 9, no. 7, 2 July 2014, p. e101554, https://doi.org/10.1371/journal.pone.0101554. Accessed 17 Sept. 2021.

Barriers to Treatment

- According to a 2023 Canadian study, prior to the introduction of DAAs <20% of clinicians were likely to provide HCV treatment to current PWID and 90% were likely to treat former PWID.
- Since the introduction of DDAs, 64% of surveyed clinicians indicated willingness to treat PWID currently and 97% would treat former PWID
- Adherence concerns were among the most reported

Park, Haesuk, et al. “Clinician Barriers, Perceptions, and Practices in Treating Patients with Hepatitis c Virus and Substance Use Disorder in the United States.” *Preventive Medicine Reports*, vol. 32, 1 Apr. 2023, pp. 102138–102138, https://doi.org/10.1016/j.pmedr.2023.102138. Accessed 26 Feb. 2024.

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Which of the following populations have been proven to have low adherence rates to the DAA treatment regimen?

ⓘ Start presenting to display the poll results on this slide.

Barriers to Treatment

- ADHERENCE
  - Both clinicians and patients cling to a false belief that certain high-risk populations will not adhere to the treatment regimen
  - Multiple studies have shown high adherence rates similar in populations traditionally considered at risk for non-adherence including patients with psychiatric conditions, people who inject drugs (actively or in the past) and those stable in MOUD treatment

Back, David, et al. “Efficacy and Safety of Glecaprevir/Pibrentasvir in Patients with Chronic HCV Infection and Psychiatric Disorders: An Integrated Analysis.” *Journal of Viral Hepatitis*, vol. 26, no. 8, 20 May 2019, pp. 951–960, https://doi.org/10.1111/jvh.13110. Accessed 1 Sept. 2023.

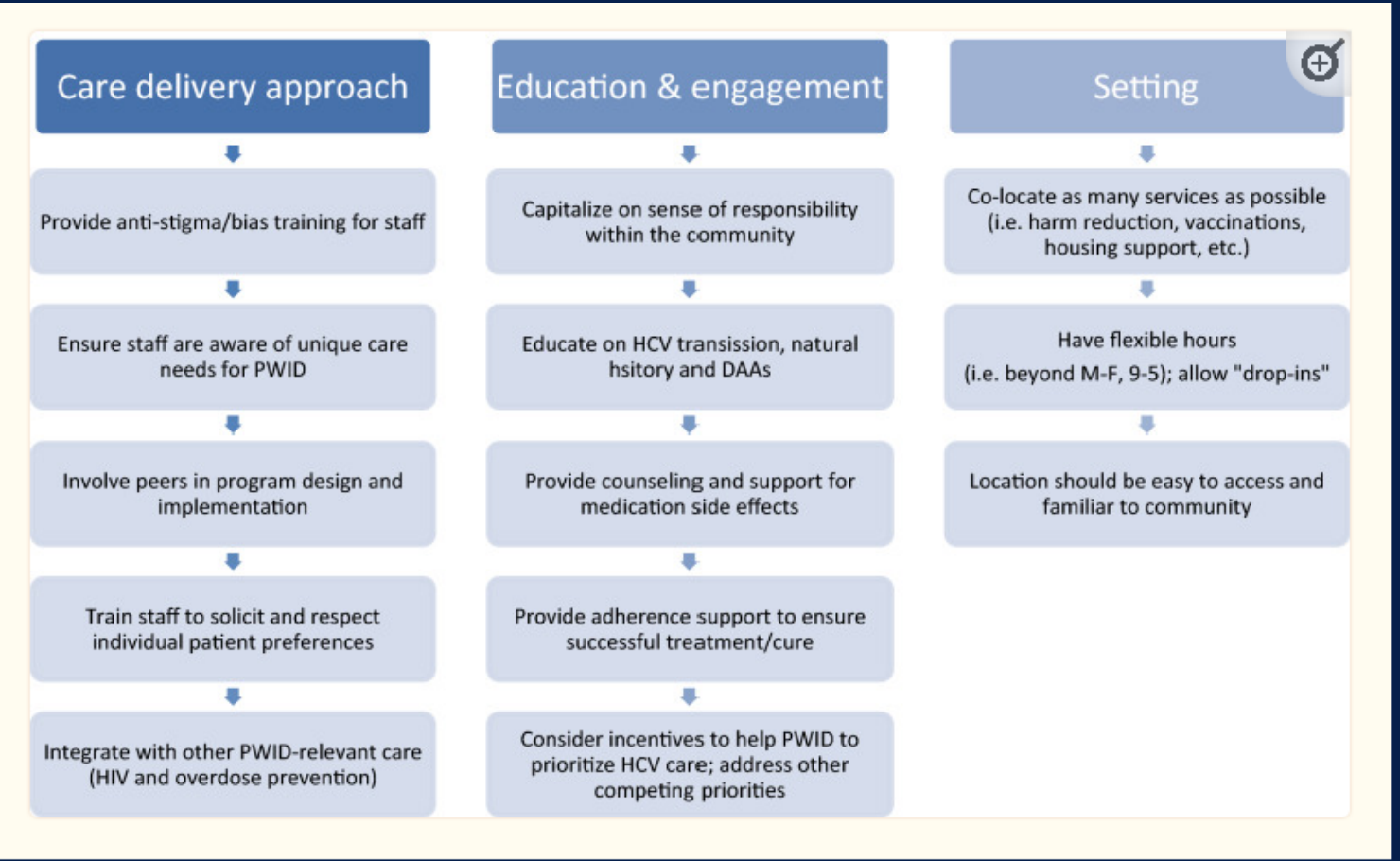
Barriers to Treatment

- ADHERENCE
  - Active drug use has been shown to have no substantial effects on virologic outcomes
  - Lower adherence may be tolerated without affecting SVR
    - One study showed that with a daily adherence rate of 78%, SVR was 94%

Akiyama, Matthew J., et al. “Intensive Models of Hepatitis c Care for People Who Inject Drugs Receiving Opioid Agonist Therapy.” *Annals of Internal Medicine*, vol. 170, no. 9, 9 Apr. 2019, p. 594, https://doi.org/10.7326/m18-1715.

Care Delivery Model Recommendations

- PWID require care delivery models specific to their needs and must address stigma, unmet SDOH needs and have flexibility built in to help maximize adherence.



Tsui, Judith I, et al. ""Treat My Whole Person, Not Just My Condition": Qualitative Explorations of Hepatitis c Care Delivery Preferences among People Who Inject Drugs." *DOAJ (DOAJ: Directory of Open Access Journals)*, vol. 16, no. 1, 12 Aug. 2021, https://doi.org/10.1186/s13722-021-00260-8. Accessed 9 Aug. 2023.

Barriers to Treatment

- HCV disproportionally affects those living with serious mental illness
- Global HCV prevalence for those living with severe mental illness is 4.6-17.4% compared to ~0.5-2.3% for the general population

Girardin, François, et al. “Hepatitis c Prevalences in the Psychiatric Setting: Cost-Effectiveness of Scaling-up Screening and Direct-Acting Antiviral Therapy.” *JHEP Reports*, vol. 3, no. 3, June 2021, p. 100279, https://doi.org/10.1016/j.jhepr.2021.100279. Accessed 3 May 2023.

Barriers to Treatment

- Psychiatric hospitals are an overlooked setting for *diagnosing and treating* these high-risk individuals
- Lack of side effects such as depression, anxiety, insomnia and other psychiatric symptoms make DAAs a safe option for those with mental illness

Girardin, François, et al. “Hepatitis c Prevalences in the Psychiatric Setting: Cost-Effectiveness of Scaling-up Screening and Direct-Acting Antiviral Therapy.” *JHEP Reports*, vol. 3, no. 3, June 2021, p. 100279, https://doi.org/10.1016/j.jhepr.2021.100279. Accessed 3 May 2023.

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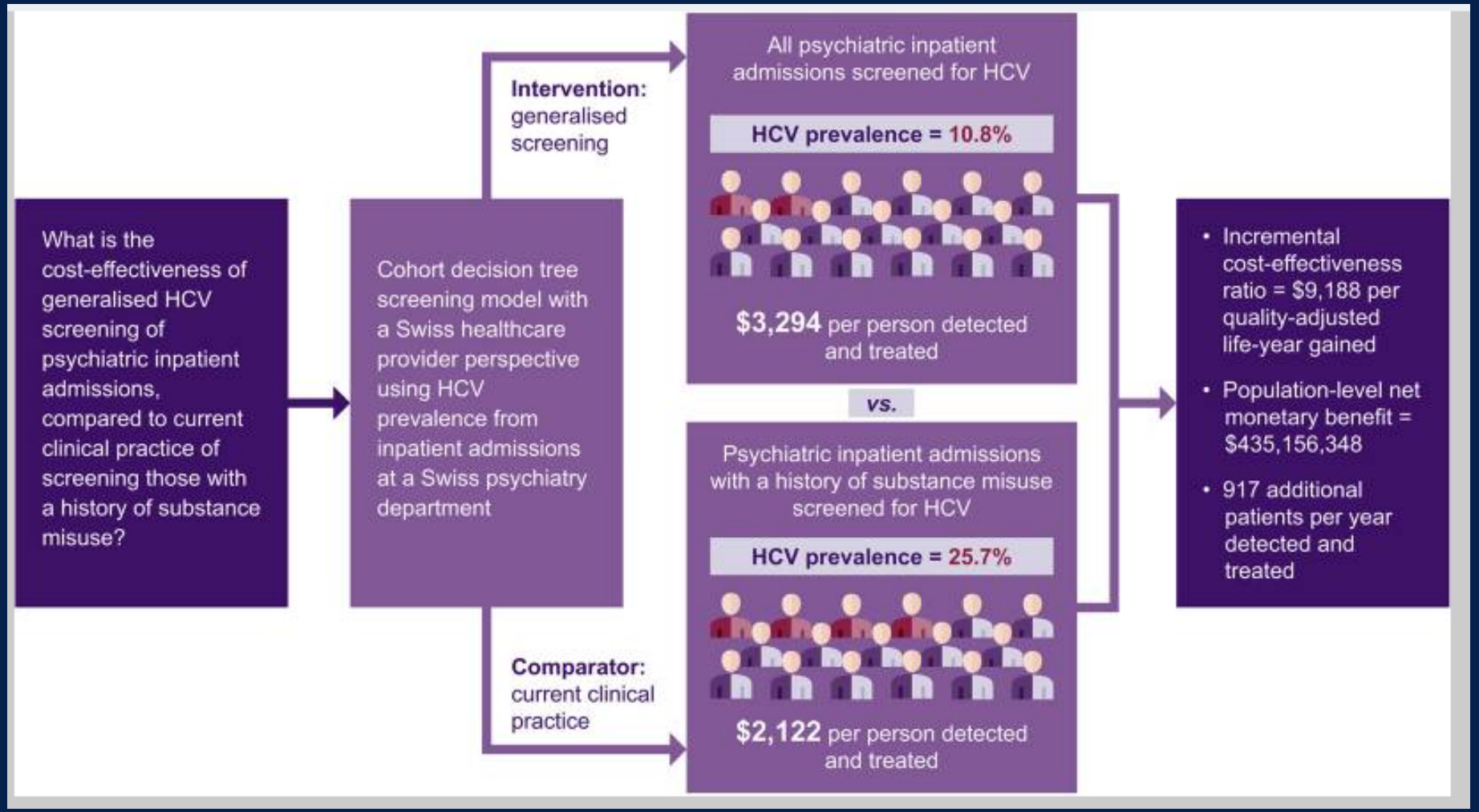

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Barriers to Treatment

THE PROJECT

Hepatitis C: State of Medicaid Access is the culmination of work by the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) to definitively assess the state of access to DAAs for Medicaid enrollees across America. Through a national report and state-by-state report cards, the project provides an in-depth evaluation of DAA access in each state's Medicaid program, while highlighting successes in access expansion as well as ongoing challenges.

- Most significant restrictions to treatment:
  - Prior Authorization
  - Fibrosis Restrictions
  - Substance Use Restrictions
  - Prescriber Restrictions
  - Retreatment Restrictions
  - Access in Managed Care

https://stateofhepc.org/about/

Barriers to Treatment

- Prior Authorization
  - Physicians spend an average of 45-120 min/week and an average of 14.9 hours/week to complete the PA process
  - Many require submission of clinical information not supported by scientific evidence

Park, Haesuk, et al. “Clinician Barriers, Perceptions, and Practices in Treating Patients with Hepatitis c Virus and Substance Use Disorder in the United States.” *Preventive Medicine Reports*, vol. 32, 1 Apr. 2023, pp. 102138–102138, https://doi.org/10.1016/j.pmedr.2023.102138. Accessed 26 Feb. 2024.

Barriers to Treatment

- 2022

Delaware Medicaid and Medical Assistance
Request for Prior Authorization
Hepatitis C Agents
Submit request via: Fax – 1-302-454-0224 or Website – https://medicaid.dhss.delaware.gov

Prior Authorization Conditions

General Requirements

- Medications may only be approved as part of a regimen that is FDA approved for the client's genotype. This includes indication, dosing regimen, and duration.
- Duration of approved therapy shall not exceed 12 weeks, and should be peg-interferon free when possible.
- If the client is actively abusing alcohol or IV drugs, or has a history of abuse, there must be documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse and an offer of a referral for substance use disorder treatment.
- The clients must sign the informed consent form.
- Clients with co-morbid HIV must have undetectable HIV viral load or a CD4 count of at least 350 cells/µL.

Direct Acting Antivirals

- Effective January 1, 2017, documentation of fibrosis stage 2, 3 or 4 preferably by noninvasive technology (Fibroscan) or serum tests (Fibrosure, Fibrotest).
- Effective January 1, 2018, clients with a *current* diagnosis of Hepatitis C *of any fibrosis stage* can be approved with appropriate documentation including a genotype from a recent laboratory result
- Notwithstanding fibrosis score and effective immediately, treatment shall be covered upon a showing of medical necessity, which may include documentation of:

  - extrahepatic symptoms that affect ADLs, including but not limited to: fatigue, nausea, mental changes, joint pain, depression, sore muscles, arthritis, nerve damage and jaundice;

  or

  - diagnosis of at least one (1) of the following co-morbidities:
    - HIV+;
    - Hepatitis B infection;
    - Lymphoma
    - Awaiting or post solid organ transplant (e.g. heart, kidney, liver).
    - Documentation of labs or biopsy showing fast progressing fibrosis that would require treatment earlier than the approved fibrosis stage;

  or

  - other showing of medical necessity, as defined in Appendix H of the DMMA Provider Policy Manual and supported with appropriate documentation.

Hepatitis C: State of Medicaid Access Report Card

Delaware

Grade	Recommendations to Improve Patient Access
D	• Remove prior authorization for HCV treatment. • Remove substance use restrictions. • Remove retreatment restrictions. • Ensure transparency and parity across FFS and MCOs regarding HCV coverage criteria. • Remove additional restrictions as described below.

State Overview

As of February 2022, 282,299 individuals were enrolled in Medicaid and CHIP.[1] It is estimated that as of 2016, 6,300 people were living with HCV in Delaware.[2] Delaware Medicaid contracts with two managed care organizations (MCOs): AmeriHealth Caritas Delaware and Highmark Health Options (Blue Cross and Blue Shield of Delaware).[3]

The Connecticut Medicaid Preferred Drug List includes sofosbuvir/velpatasvir, Mavyret, and Epclusa.[4]

Deductions		Policy
Prior Authorization	-8	Prior authorization is required for all HCV treatment regimens.[5]
Fibrosis Restrictions		Delaware Medicaid does not impose fibrosis restrictions.[6]
Substance Use Restrictions	-12	Delaware Medicaid imposes substance use restrictions. "If the client is actively abusing alcohol or IV drugs, or has a history of abuse, there must be documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse and an offer of a referral for substance use disorder treatment."[7] Additionally, the patient is required to sign a consent form that reads: "Alcohol must be avoided to prevent further harm to the liver. The use of alcohol during treatment may lead to coverage of medications being cancelled. Illegal substance must be avoided. Exposure to another form of Hepatitis C would make it more challenging to treat the viral infection. . . . By signing this document, I acknowledge that I have read the above information, that I will abide by all parts of it, and that failure may result in termination of my medication for hepatitis C."[8]
Prescriber Restrictions		Delaware Medicaid does not impose prescriber restrictions.[9]
Retreatment Restrictions	-8	Delaware Medicaid imposes retreatment restrictions. "If the client has failed prior therapy, then documentation of the reason for failure is required. Simple noncompliance with previous therapy may be considered a contraindication to retreatment."[10]
Access in Managed Care	-8	Highmark Health Options impose more stringent requirements than FFS. Highmark requires time-based HCV RNA testing, whereas FFS does not.[11] AmeriHealth Caritas impose the same requirements as FFS.[12]
Additional Restrictions	-4	Delaware Medicaid imposes additional restrictions as follows: • Documentation of genotype.[13] • Documentation of adherence agreement. If a patient fails to adhere to their medication, their treatment may be discontinued.[14]
Total Deductions -40		Total Score [100-Deductions]	Grade D

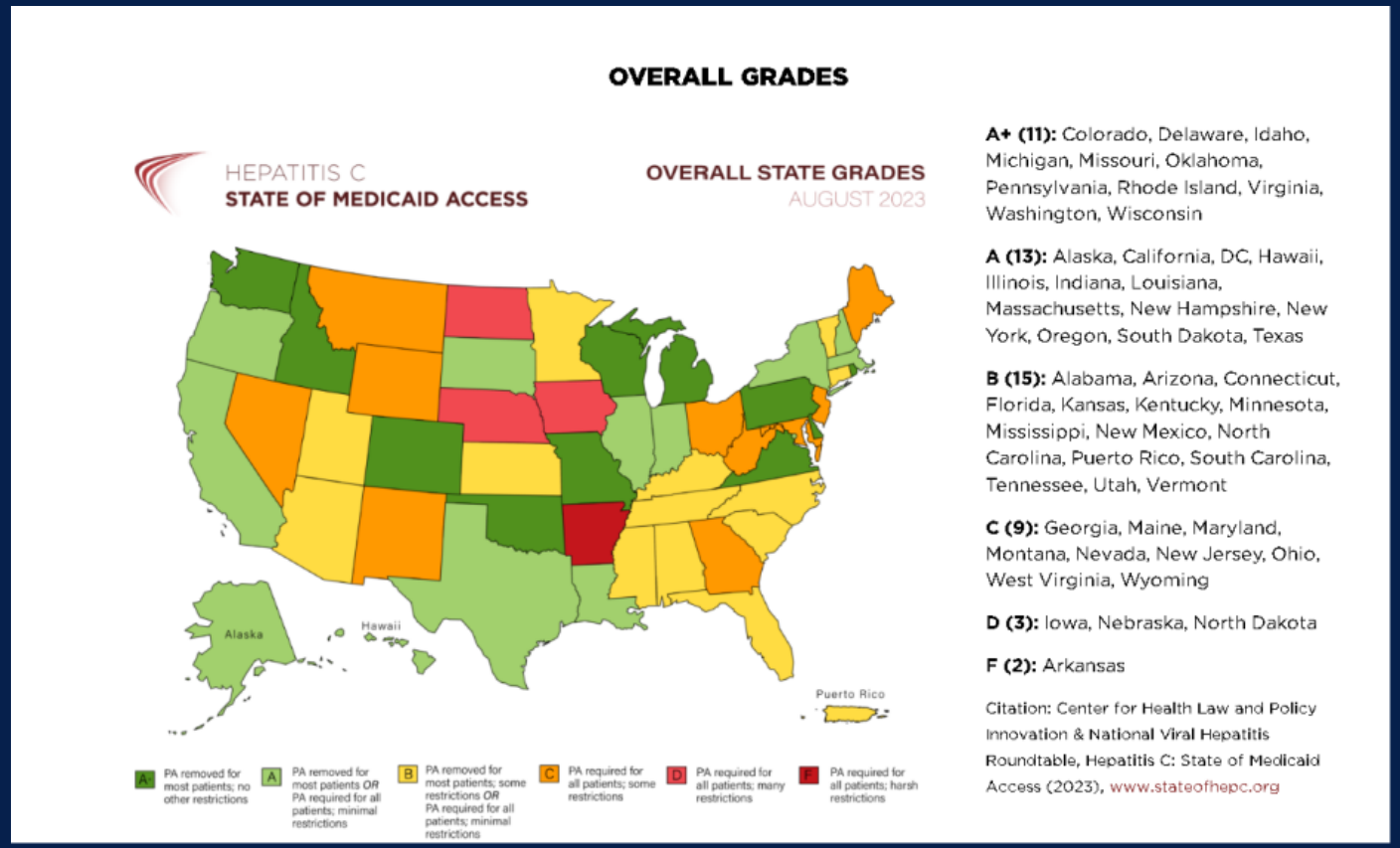
NVHR

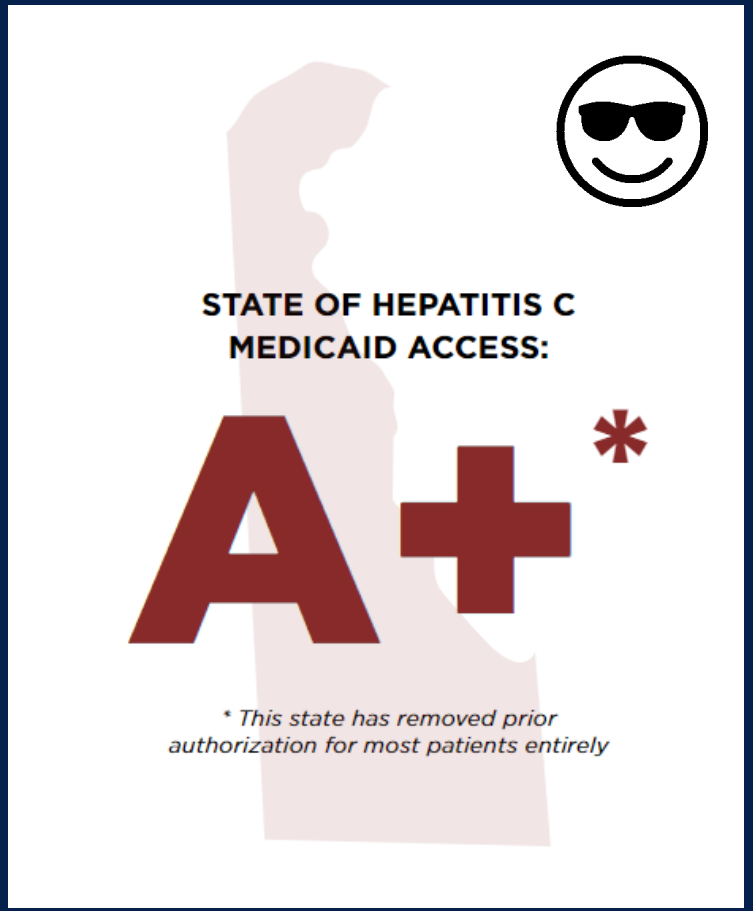
Hepatitis C: State of Medicaid Access | June 2022 | 1

https://stateofhepc.org/about/

Clinician Barriers to Treatment

2023





https://stateofhepc.org/2023-national-snapshot-report/

Barriers to Treatment

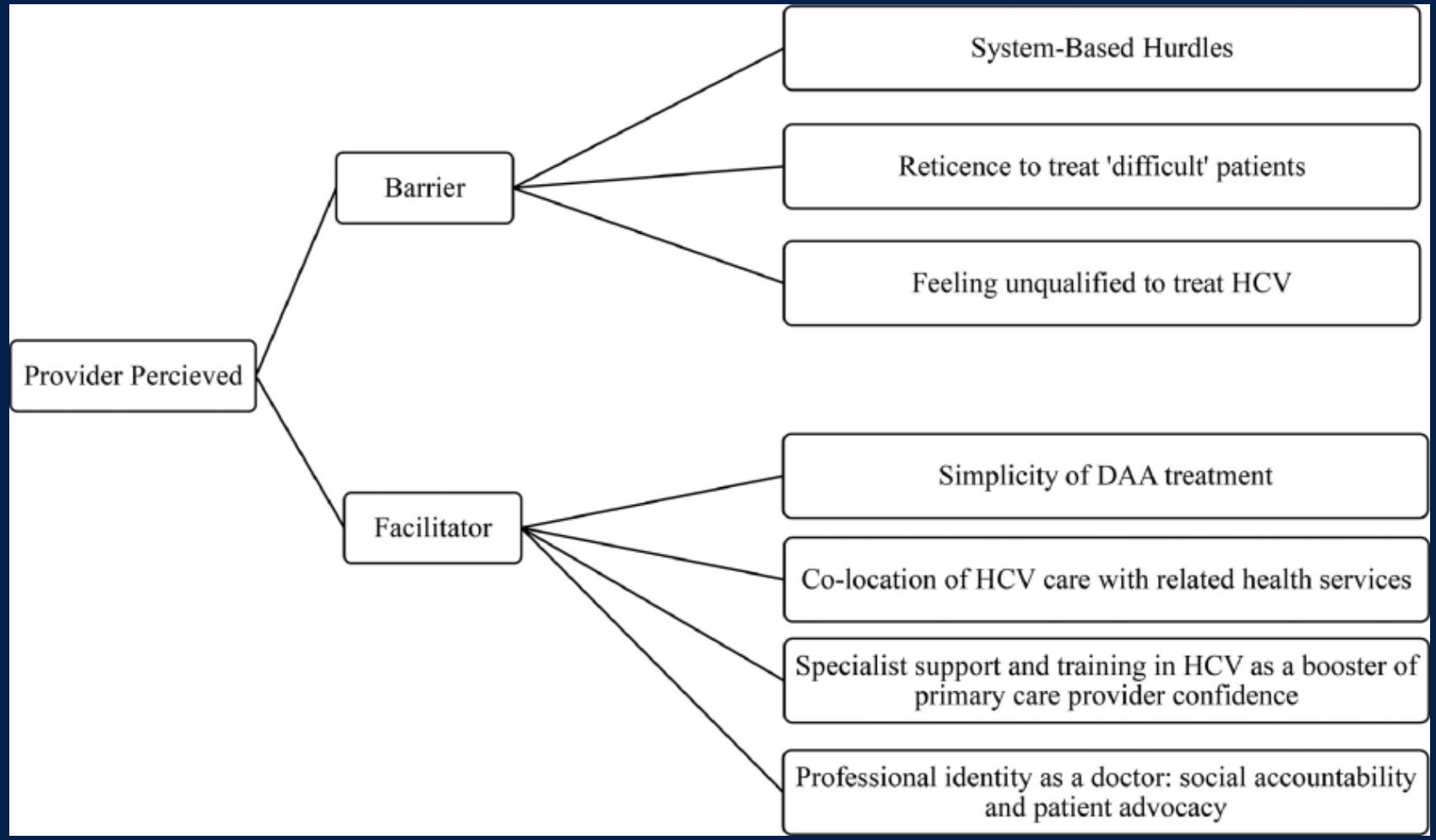
- Wholesale cost of DDAs is astronomical
- Production costs are between $10-$270 for the full 12-week regimen

TABLE 1. Approved Interferon-Free HCV Regimens

Regimen and manufacturer	Indication	Mechanism of action	Length of treatment	With ribavirin	Wholesale acquisition cost (12-w supply)*
Sofosbuvir and velpatasvir (Epclusa, Gilead Sciences, Foster City, CA)	All types (1–6)	Sofosbuvir: nucleotide analog NS5B polymerase Velpatasvir: HCV nonstructural protein 5A inhibitor	12 wk	Without	Data not yet available
Elbasvir and grazoprevir (Zepatier, Merck & Co., Kenilworth, NJ)	Types 1 and 4	Elbasvir: NS5A inhibitor Grazoprevir: NS3/4A protease inhibitor	12–16 wk (depending on previous treatment and subgenotype)	With or without	$54,600
Daclatasvir (Daklinza)	With sofosbuvir, types 1 and 3	Daclatasvir: NS5A inhibitor	12 wk	With or without	$63,000
Ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak, AbbVie Inc., Lake Bluff, IL)	Type 1, including compensated cirrhosis	Ombitasvir: NS5A inhibitor Paritaprevir: NS3/4A protease inhibitor Ritonavir: CYP3A inhibitor Dasabuvir: nonnucleoside NS5B palm polymerase inhibitor	12 wk, except for gentype 1a with cirrhosis	With (GT 1a) or without (GT 1b)	$83,300
Ombitasvir, paritaprevir, and ritonavir (Technivie, AbbVie Inc, Lake Bluff, IL)	Type 4	Ombitasvir: NS5A inhibitor Paritaprevir: NS3/4A protease inhibitor Ritonavir: CYP3A inhibitor	12 wk	With	$76,653
Ledipasvir, sofosbuvir (Harvoni, Gilead Sciences, Foster City, CA)	Type 1, including liver transplant recipients and patients with decompensated cirrhosis	Ledipasvir: NS5A inhibitor	12–24 wk	With or without	$94,500
	Type 4 including liver transplant recipients without cirrhosis, or with compensated cirrhosis and types 5 and 6 with or without compensated cirrhosis	Sofosbuvir: nucleotide analog NS5B polymerase			
Sofosbuvir (Sovaldi, Gilead Sciences, Foster City, CA)	Types 2 and 3	Nucleotide analog NS5B polymerase inhibitor	12–24 wk	With	$84,000
Simeprevir (Olysio, Janssen Pharmaceutical, Beerse, Belgium)	With sofosbuvir, type 1	NS3/4A protease inhibitor	12–24 wk	Without	$66,360

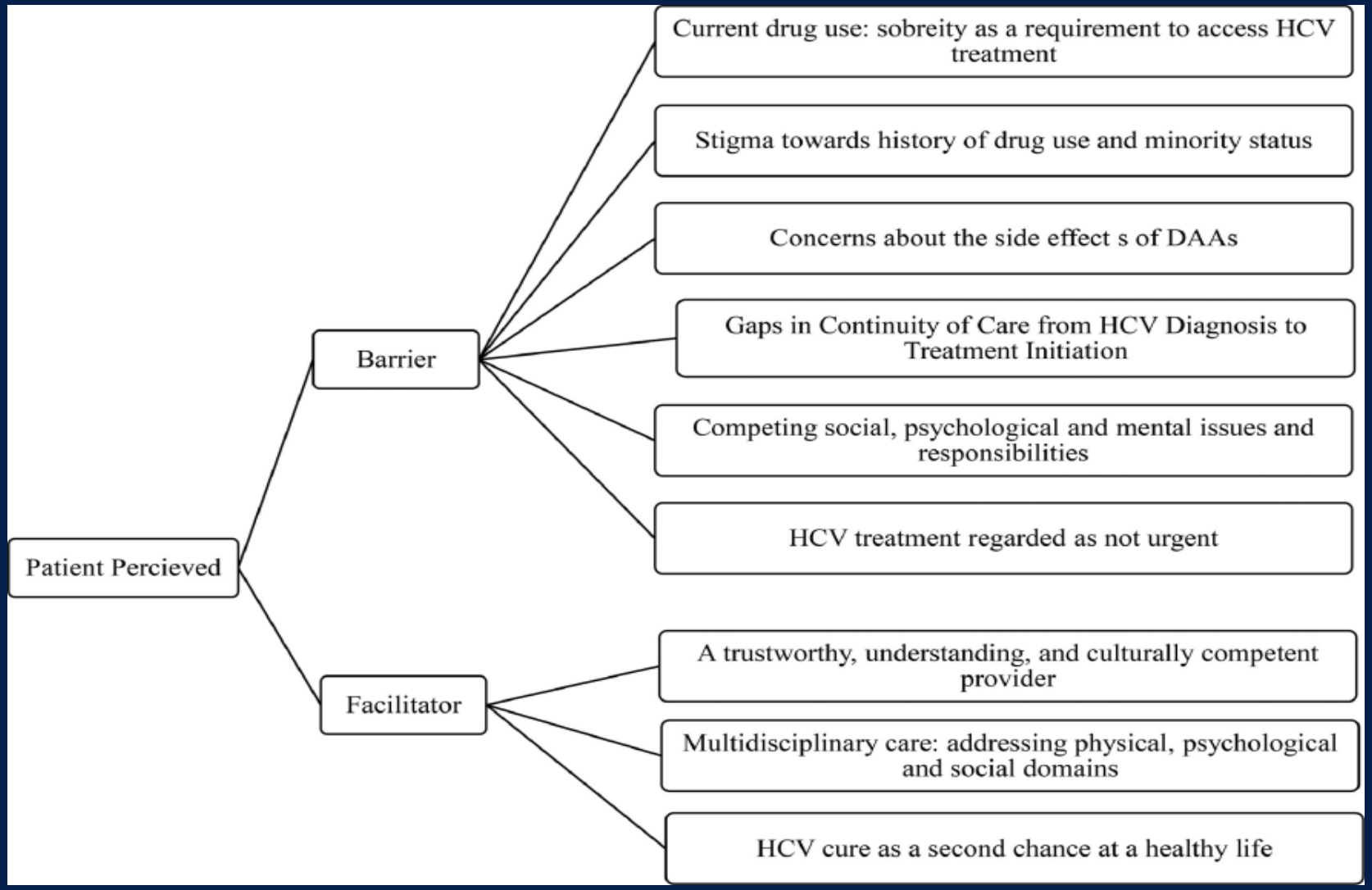
Chasser, Yvonne, et al. “Hepatitis c Treatment: Clinical Issues for Psychiatrists in the Post-Interferon Era.” *Psychosomatics*, vol. 58, no. 1, Jan. 2017, pp. 1–10, https://doi.org/10.1016/j.psym.2016.09.004. Accessed 19 May 2022.

Barriers and Facilitators to Treatment



Amoako, Afia, et al. "Patient and Provider Perceived Barriers and Facilitators to Direct Acting Antiviral Hepatitis c Treatment among Priority Populations in High Income Countries: A Knowledge Synthesis." *International Journal of Drug Policy*, Apr. 2021, p. 103247, https://doi.org/10.1016/j.drugpo.2021.103247.

Barriers and Facilitators to Treatment



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Psychiatrist's Role in HCV Treatment

WHAT IS A PSYCHIATRIST?

AMERICAN PSYCHIATRIC ASSOCIATION

For more information on psychiatry visit psychiatry.org

Psychiatry is the branch of medicine focused on the diagnosis, treatment and prevention of mental, emotional and behavioral disorders.

A psychiatrist is a medical doctor (an M.D. or D.O.) who specializes in mental health, including substance use disorders.

Psychiatrists are qualified to assess both the mental and physical aspects of psychological problems.

AMERICAN SOCIETY OF ADDICTION MEDICINE FOUNDED 1954 ASAM

Psychiatrist's Role in HCV Treatment

- Patients with severe mental illness (inclusive of SUD) are less likely to have access to education, screening, diagnostic confirmation and referral to treatment and face multiple obstacles to successful treatment adherence
- Psychiatrist must play a vital role in each part of the HCV treatment cascade

Psychiatrist's Role in HCV Treatment

- Prediagnosis
- Pretreatment
- During Treatment
- After treatment

TABLE 2. The Role of the Psychiatrist in the HCV Treatment Cascade

Stage in treatment cascade	Role of psychiatrist	Potential barriers	Proposed approach
Prediagnosis • Risk assessment • Screening • Education • Harm reduction	1. Inquire about risk factors at psychiatric clinic visits. 2. Screen high-risk patients. 3. Educate patients on HCV risk factors, consequences of infection, and importance of following up for test results. 4. Harm reduction via encouraging alcohol consumption reduction; provide information about clean needle programs and barrier protection for sexual activity.	1. Provider's lack of comfort ordering screening tests due to uncertainty in responding to positive screen results. 2. Patient is unwilling or uninterested in screening. 3. Provider's lack of comfort educating patients about HCV. 4. Provider's lack of awareness of resources, stigma, and patient's unwillingness to disclose risk factors.	1. Brief educational interventions to increase psychiatrists' knowledge of risk factors, prognosis, diagnostic testing, and updated treatments for HCV. 2. Develop rapport and trust over time. 3. Educational interventions for psychiatrists as previously mentioned, as well as readily available educational materials in offices for patients. 4. Information on community resources provided in offices, waiting rooms, and bathrooms; development of trust as mentioned earlier.
Pretreatment	1. Link patients to appropriate care. 2. Collaborate with specialist about treatment options. 3. Verify prescribed DAA does not interact with psychotropic medications.	1a. Patient with active mental illness/substance misuse. 1b. Logistical issues such as office location, copay, and stigma. 2. Provider's reluctance to take patients who may not adhere to costly treatment. 3. Provider's lack of awareness of drug-drug interactions.	1a. Reduction of burden of mental illness as much as possible; motivational interviewing and multifaceted treatment approach for patients with substance misuse (discussion in *Pretreatment* section). Screening with HAM-D and MOCA for depression and neuropsychiatric symptoms. 1b. HCV treatment incorporated into community mental health clinics, guided by specialists. Alternatively, traditional referral with increased attention to patient barriers by social worker or case manager. 2. Collaborative relationships over time between providers. 3. Increased provider education and awareness of clinical resources.
During treatment	1. Inquire about barriers to adherence; provide ongoing education and support. 2. Continued reduction of burden of active mental illness and substance misuse.	1. Patient's difficulty remembering to take a pill every day; taking medication for asymptomatic disease is a low priority. 2. Patient with active mental illness/substance misuse.	1. Graduated levels of support to increase adherence and ongoing education about HCV consequences and prognosis. 2. See proposed approach 1a in pretreatment section.

DAA = direct-acting antiviral; HAM = Hamilton Depression Rating Scale; HCV = hepatitis C virus; MOCA = Montreal Cognitive assessment.

Chasser, Yvonne, et al. "Hepatitis c Treatment: Clinical Issues for Psychiatrists in the Post-Interferon Era." *Psychosomatics*, vol. 58, no. 1, Jan. 2017, pp. 1–10, https://doi.org/10.1016/j.psym.2016.09.004. Accessed 19 May 2022.

Psychiatrist's Role in HCV Treatment

- Prediagnosis
  - Screen all patients – self or refer with strict follow-up
  - Provide education about risk factors, transmission, course of the infection and illness, consequences of non-treatment
  - Encourage harm reduction regarding alcohol use, clean needles and barrier protection for sexual activity
  - Work to address SDOH needs through treatment and/or referral

Psychiatrist's Role in HCV Treatment

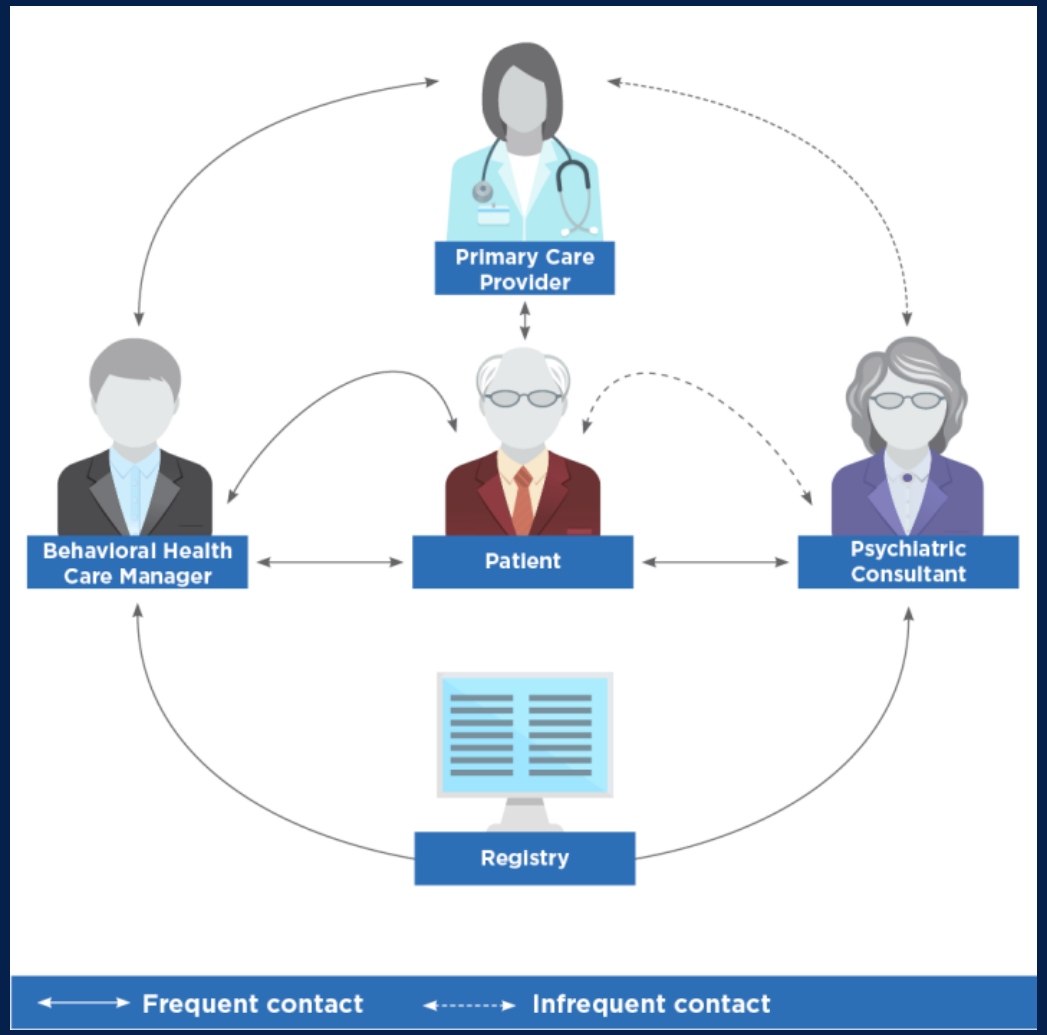
- Pretreatment
  - If not providing treatment, refer and assure establishment of appropriate care
  - Maintain regular contact with HCV treater and collaborate about treatment options and planning
  - Verify that DAA does not interact with psychotropics
  - Continue to assess and address SDOH

Psychiatrist's Role in HCV Treatment

- During treatment
  - Continue to maintain regular contact with HCV treater
  - Continue with harm reduction techniques
  - Continue to assess and address SDOH
- After treatment
  - Continue to assess and address risk factors and employ harm reduction techniques as necessary
  - Continue to assess and address SDOH
  - For those who do not achieve SVR, it will be important to address any emotional issues and disappointment the patient may experience as a result

Psychiatrist's Role in HCV Treatment

- The Collaborative Care Model
  - https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/get-trained



Final Takeaways/Summary

- Universal, one-time screening and appropriate, as needed screening of high-risk individuals is essential in identifying and curing people living with Hepatitis C
- Direct acting antivirals provide a cure for HCV
- Traditionally high-risk populations have been proven to have high adherence rates and are cured at the same rates at the general population
- PWID and seriously mentally ill people are disproportionally affecting which leaves psychiatry a vital role in the identification, treatment and eradication through cure of HCV.

Questions?

https://www.scienceofpeople.com/21-questions-game/

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