

**NATIONAL  
HEALTH CARE**  
*for the*  
**HOMELESS  
COUNCIL**



# **HEPATITIS C TREATMENT: HARM REDUCTION & MEETING COMPLEX NEEDS**

**VIRTUAL SYMPOSIUM | APRIL 5, 2023**

In Partnership with



# HRSA Disclaimer

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This symposium was developed with support from the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award to the National Health Care for the Homeless Council for \$1,967,147 with 0 percent financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more info visit [HRSA.gov](https://www.hrsa.gov)

# National Health Care for the Homeless Council

## Who We Are

- Since 1986, we have brought together thousands of [health care professionals](#), [medical respite care providers](#), [people with lived experience of homelessness](#), and advocates. Our 200+ Organizational Members include [Health Care for the Homeless](#) programs, respite programs, and housing and social service organizations across the country.

## What We Do

- We work to improve health care provision to people experiencing homelessness through [training and technical assistance](#), [researching](#) and sharing best practices, [advocating](#) for real solutions to end homelessness, and [uplifting voices](#) of people experiencing homelessness.

## What You Can Do

- [Learn more about how you can help support our mission. www.nhchc.org](http://www.nhchc.org)

# Agenda

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- 1 Welcome
- 2 Addressing Common Barriers to Treatment
- 3 Models of Care
- 4 Breakout Sessions –
  - Getting Started with Hep C Treatment
  - Supporting Treatment Completion
  - Addressing Advanced Liver Disease
  - Overcoming Insurance and Policy Barriers
- 5 Closing Plenary – Panel Discussion on Treatment Experiences

# Speakers

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- **Rachel Melson**, DNP, FNP-C, *Clinic Director, Swope Health*
- **Adrienne Simmons**, PharmD, MS, *Director of Programs, National Viral Hepatitis Roundtable*
- **Marguerite Beiser**, ANP-BC, AAHIVS, *Director of HCV Services, Boston Health Care for the Homeless Program*
- **Savanna Shores**, RN, Staff Nurse, *Jean Yawkey Place Clinic and Hepatitis C Program, Boston Health Care for the Homeless Program*
- **Keisa Rivera**, *Subject Matter Expert, Boston, MA*
- **Bryan Ghee**, *Subject Matter Expert, Philadelphia, PA*
- **Samantha Velez**, *Subject Matter Expert, Portland, ME*

# Learning Objectives

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## **Symposium participants will:**

1. Gain understanding of the clinical, diagnostic, and social assessments needed to determine the best treatment course and supports for each patient
2. Learn about how experiences of homelessness and substance use can impact treatment and support needs, and how best to support people through hepatitis C treatment completion
3. Learn about different primary care-based models of hepatitis C treatment, including how to decrease barriers to care, utilize outreach services, develop staffing models, and integrate hepatitis C treatment into other primary care services
4. Have the opportunity in breakout sessions to gain in-depth understanding of how to get started with hepatitis treatment in a primary care setting, strategies to support successful treatment completion for people experiencing homelessness, treating hepatitis C in people with advanced liver disease, and addressing common insurance and policy barriers

# Breakout Sessions

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1. Getting started with hepatitis treatment in a primary care setting

2. Treatment support strategies for people experiencing homelessness and/or using drugs

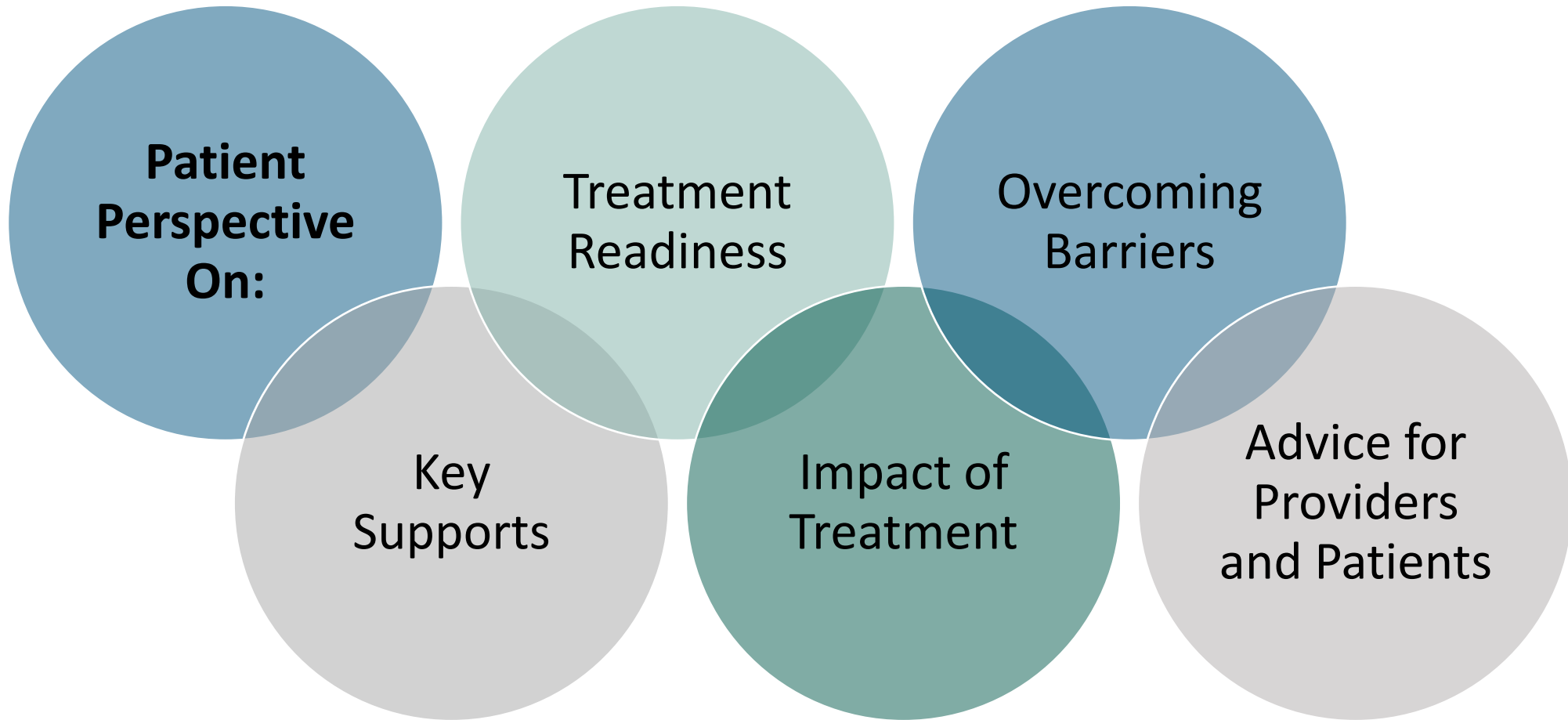
3. Treating hepatitis C in people with advanced liver disease

4. Addressing common insurance and policy barriers



# Expert Panel on Treatment Experiences

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# HEPATITIS C PROVIDER POCKET GUIDE

NATIONAL  
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COUNCIL

2023

## THIS GUIDE IS BROUGHT TO YOU BY:



Swope Health implemented a Hepatitis C treatment program in 2019 after witnessing a significant need in the community it serves. They continue to be dedicated to helping all persons have access to this life saving treatment.

**Developed by Dr. Rachel Melson, DNP, FNP-C**  
**Outreach Clinic Director, Swope Health**

## IN COLLABORATION WITH:



## Screening and Treatment Guideline References

CDC. Testing Recommendations for Hepatitis C Virus Infection. <http://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>

AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>.

# Continuing Education Credits

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- 3.0 hours offered
- Complete the evaluation following the symposium to access continuing education credits



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INTERPROFESSIONAL CONTINUING EDUCATION

**Joint Accreditation Statement:** In support of improving patient care, this activity has been planned and implemented by Amedco LLC and National Health Care for the Homeless Council. Amedco LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team. Amedco Joint Accreditation #4008163.

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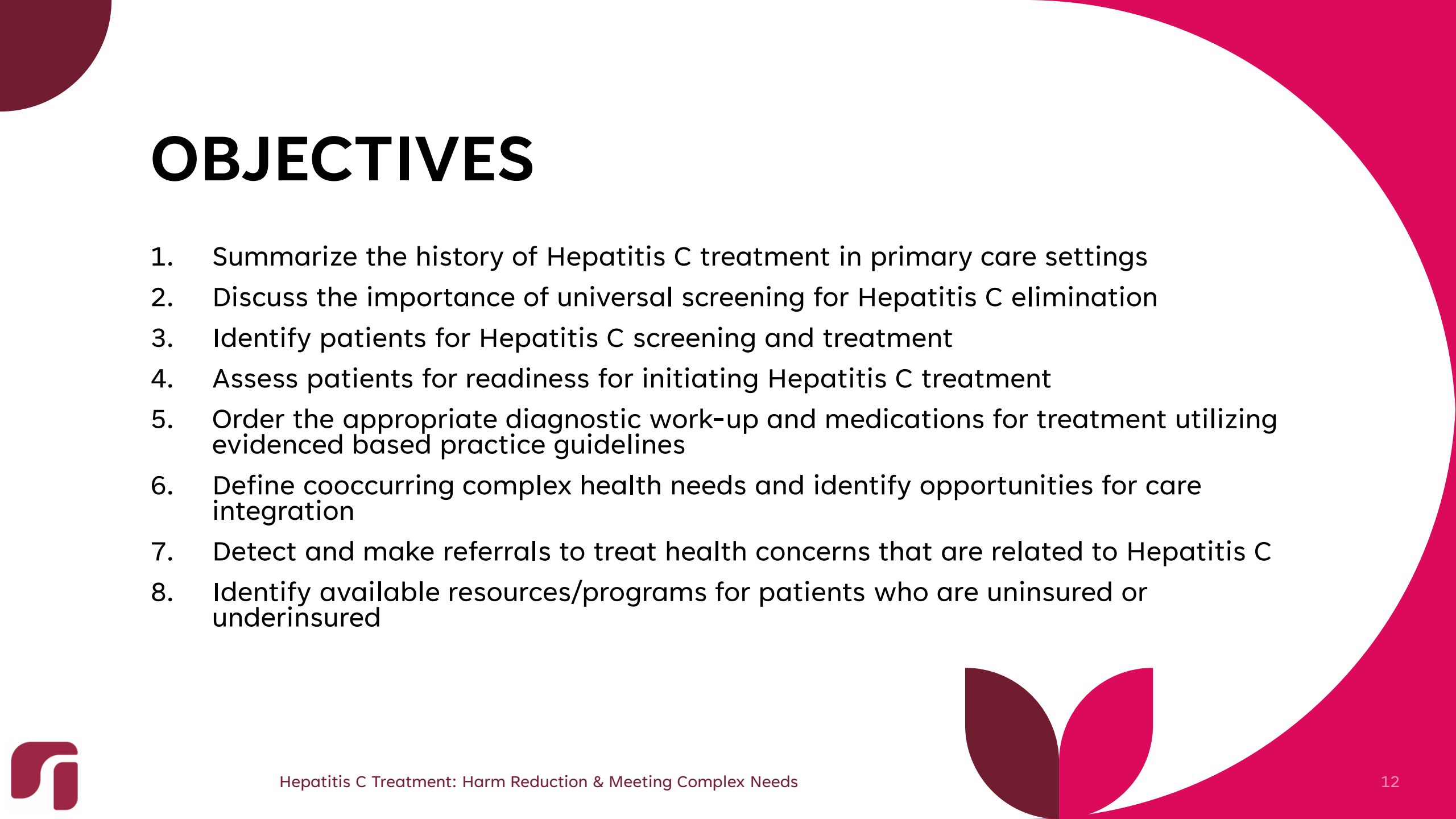
# Hepatitis C Treatment: Harm Reduction & Meeting Complex Needs

Rachel Melson, DNP, FNP-C



# OBJECTIVES

1. Summarize the history of Hepatitis C treatment in primary care settings
2. Discuss the importance of universal screening for Hepatitis C elimination
3. Identify patients for Hepatitis C screening and treatment
4. Assess patients for readiness for initiating Hepatitis C treatment
5. Order the appropriate diagnostic work-up and medications for treatment utilizing evidenced based practice guidelines
6. Define cooccurring complex health needs and identify opportunities for care integration
7. Detect and make referrals to treat health concerns that are related to Hepatitis C
8. Identify available resources/programs for patients who are uninsured or underinsured



# It is time to end the Hepatitis C epidemic.

There is a **CURE** for **Hepatitis C**.

Unfortunately, many persons do not know their Hepatitis C status or have access to treatment. This has led to more than 15,000 people dying from Hepatitis C and related illnesses every year.

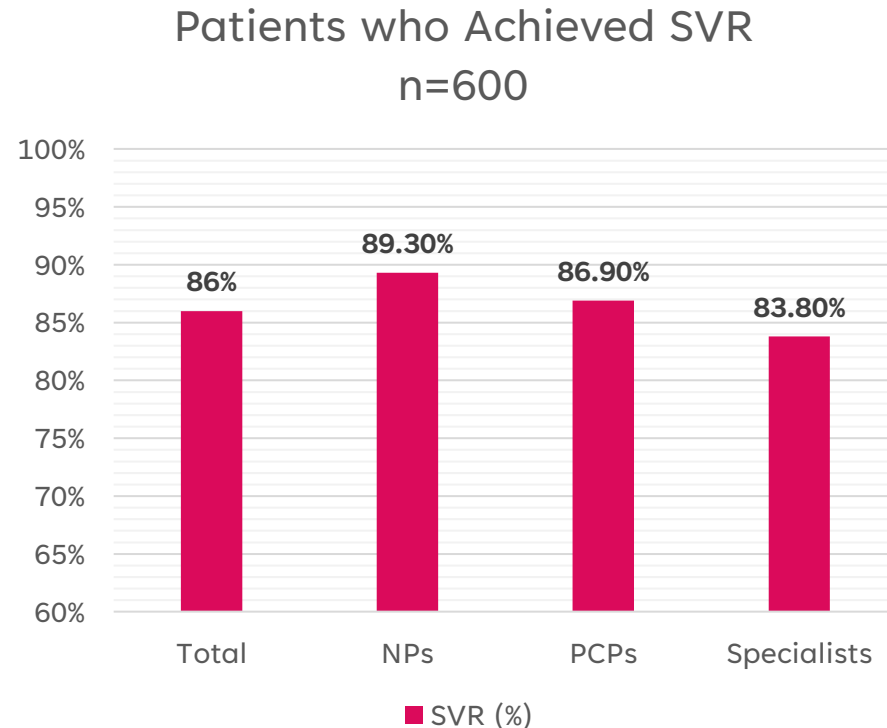
**Hepatitis C disproportionately affects our unhoused population.**



# Hepatitis C Screening and Treatment



# Hepatitis C Treatment in Primary Care Settings



- High Efficacy of HCV Treatment by Community Based Primary Care Providers:  
**The ASCEND Study** (Kattakuzhy et al.)
- Supported by the NIH, CDC, Institute of Human Virology, and Gilead Sciences
- Multi-center, open label, non-randomized, phase IV clinical trial of 600 patients at 13 community health centers in Washington DC; initiated in 2015
- Patients were distributed to receive treatment from either a nurse practitioner (NP), primary care physician (PCP), or a specialist
- **Demonstrated that HCV treatment administered independently by PCPs and NPs is safe and equally effective as care observed with experienced specialists**





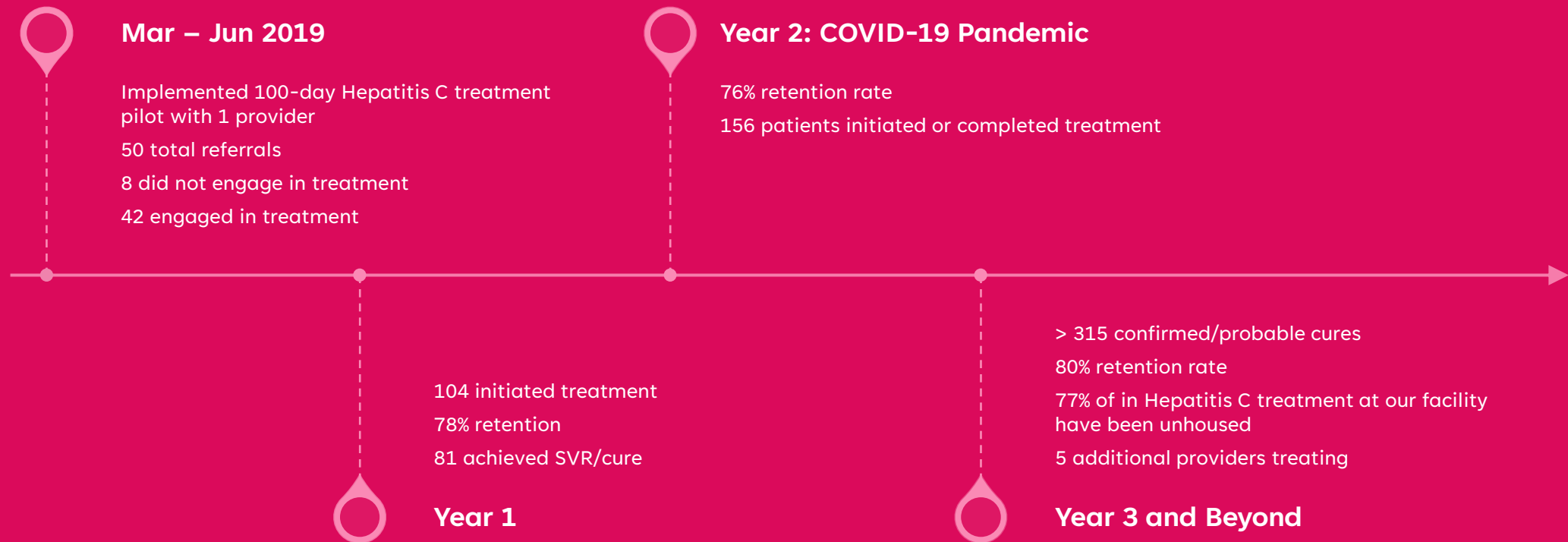
# Hepatitis C Treatment in Primary Care Settings



- Swope Health is a FQHC that has provided healthcare to the underserved in Kansas City for over 50 years
- Implemented a Hepatitis C treatment program in 2019 through our Outreach Clinic
- The Outreach Clinic provides holistic medical care for our unhoused population in a variety of settings (rough sleeping, shelters, transitional living, half-way houses, DV shelters, doubling up, etc.) at our Central clinic and on or Mobile Medical unit
- We provide the opportunity for rapid HIV and HCV testing for all patients



# Swope Health



# Screening guidelines: CDC 2020

## Universal Screening

At least once in a lifetime for all adults aged 18 years and older

All pregnant women during each pregnancy

One-time screening regardless of age among people with recognized conditions or exposures:

- HIV positive
- History of injection drug use and shared needles, syringes, or other drug preparation equipment
- People who ever received maintenance hemodialysis
- People with persistently abnormal ALT levels
- Prior recipients of transfusions or organ transplants before 1992
- Healthcare, emergency, and public safety personnel after exposures to HCV-positive blood
- Children born to mothers with HCV infection

## Routine Periodic Screening

For people with ongoing risk factors, while risk factors persist:

- People who currently inject drugs and share needles, syringes, or other drug preparation equipment
- People who ever received maintenance hemodialysis

**Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many they may be reluctant to disclose stigmatizing risks.**



# HEPATITIS C PROVIDER POCKET GUIDE

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2023

**Swope Health** in collaboration with the **National Health Care for the Homeless Council** and the **National Viral Hepatitis Round Table** have created a Hepatitis C Provider Pocket Guide to help providers caring for the unhoused population prevent, screen, and treat Hepatitis C in their clinics.

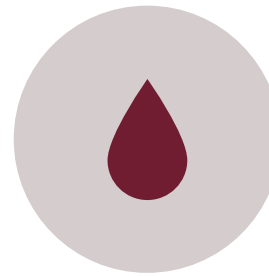
Much of the information shared today can be found in the guide.



# Screening Lab Tests



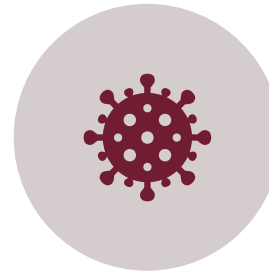
**HCV antibody with reflex  
to RNA**



**Rapid/point of care  
antibody test**



**HCV antibody testing  
should not be tested  
without reflexive RNA  
unless it is for rapid testing**



**If the rapid test is positive,  
order a confirmatory HCV  
RNA**

# Direct-Acting Antivirals

Direct-acting antivirals are a combination of antiviral drugs that target stages of the hepatitis C virus reproductive cycle.

DAA's are inhibitors of the NS3/4A protease, the NS5A protein, and the NS5B polymerase. NS3/4A protease inhibitors are inhibitors of the NS3/4A serine protease, an enzyme involved in post-translational processing and replication of HCV.

They are more effective than older treatments such as ribavirin and interferon.

MEDICATION	DOSING
<b>Mavyret</b> Glecaprevir (300 mg) - Pibrentasvir ( 120 mg)	100mg / 40mg tablets 3 tablets once daily
<b>Epclusa</b> Sofosbuvir (400 mg) - Velpatasvir (100 mg)	400 mg / 100 mg tablets 1 tablet once daily
<b>Harvoni</b> Ledipasvir (90mg) - Sofosbuvir (400 mg)	90 mg / 400 mg tablets 1 tablet once daily
<b>Zepatier</b> Elbasvir (50 mg) - Grazoprevir ( 100 mg)	50 mg / 100mg tablet 1 tablet once daily
<b>Vosevi</b> Sofosbuvir (400 mg) - Velpatasvir (100 mg) - Voxilaprevir (100 mg)	400 mg /100mg /100 mg 1 tablet once daily



# Treatment Selection

## Simplified Treatment for Treatment-Naïve Adults Without Cirrhosis

### Mavyret

Glecaprevir (300 mg) -  
Pibrentasvir ( 120 mg)  
for 8 weeks

OR

### Epclusa:

Sofosbuvir (400 mg) -  
Velpatasvir (100 mg)  
for 12 weeks

## Treatment-Naïve Adults With Compensated Cirrhosis

### Mavyret

Glecaprevir (300 mg) - Pibrentasvir ( 120 mg) for 8 weeks

*Epclusa is an option, however resistance testing may be necessary for genotype 3.*

## Patient Monitoring

After 4 weeks and at end of treatment: PLT, AST/ALT, HCV RNA

Assess for worsening of liver function and decrease in HCV RNA

**CURE = Sustained Virologic Response (SVR)**

Sustained Virologic Response is an undetectable HCV RNA 12 weeks or later after the completion of DAA HCV treatment





The new CDC guidelines specifically recommend universal hepatitis B screening of adults aged 18 years and older with a triple panel, which includes:

1. HBsAg
2. Antibody to HBsAg
3. Total antibody to hepatitis B core antigen

# Test Interpretation

## Antibody Negative + RNA Negative

- No exposure or active Hepatitis C
- No treatment indicated, continue routine periodic screening if indicated

## Antibody Positive + RNA Negative

- Exposure to Hepatitis C, no current active virus
- No treatment indicated at this time
- If there is a concern for recent exposure → recheck RNA

## Antibody Positive + RNA Positive

- **Treatment indicated**
- Order diagnostic evaluation

“

Prescribing direct acting antivirals for Hepatitis C should be as routine for healthcare providers as prescribing medications for diabetes.

Our unhoused population need all of us.  
The biggest hurdle is getting started.

”



# Hepatitis C Treatment: The Basics

## Clinical Guidelines

- <https://www.hcvguidelines.org/>
- To provide healthcare professionals with timely guidance, the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America have developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for HCV management.
- New sections will be added, and the recommendations will be updated on a regular basis as new information becomes available.



# Treatment Decision Making

Is the patient ready for treatment?

Does the patient have a co-infection?

Does the patient have advanced liver disease? Are there signs of decompensation?

Is the patient insured?

What barriers might they face in completing treatment?



# Barrier Assessment

- Coverage of medication
  - Mode of transportation
  - Physical disabilities or chronic health conditions
  - Behavioral health concerns
  - Substance use
- **Is the patient ready for treatment?**
    - If yes, TREAT
    - If no, assess concern, provide education about transmission and disease progression, and keep opportunity open



# Pretreatment Assessment



FIBROSIS EVALUATION TOOL	SUSPECTED CIRRHOSIS FINDING
Noninvasive serologic tests	FibroSure, FibroTest, etc.: F4
Transient elastography	FibroScan stiffness >12.5 kPa
Fib-4 Calculation	>3.25
Clinical Evidence	Liver nodularity, PLT <150,000





# Fibrosis Evaluation

## Hepatic Fibrosis

Dynamic scarring process in which chronic inflammation stimulates production and accumulation of collagen and extracellular matrix proteins (EMP)

Untreated Hepatitis C will lead to increased total EMP content and fibrosis development

**Fibrosis is a precursor to cirrhosis and establishing the level fibrosis helps predict liver-related morbidity and mortality**

## Evaluation Options

FibroSURE (LabCorp) or FibroTEST (Quest)

FibroScan (transient elastography)

FIB-4 & APRI Calculations

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

$$\frac{\text{AGE} \times \text{AST}}{\text{PLT} \times \sqrt{\text{ALT}}} = \text{FIB-4}$$

> 3.25 is predictive of advanced cirrhosis

$$\frac{\frac{\text{AST}}{40}}{\text{PLT}} \times 100 = \text{APRI}$$

> 1.0 is predictive of cirrhosis

### CTP Scoring

Points	1	2	3
Encephalopathy	NONE	Grade 1-2	Grade 3-4
Ascites	NONE	Mild-Mod	Severe
Bilirubin	<2	2-3	>3
Albumin	>3.5	2.8-3.5	<2.8
PT or	<4	4-6	>6
INR	<1.7	1.7-2.3	>2.3

### CTP Class

**A** = 5-6 points

Least Severe

**B** = 7-9 points

Moderately Severe

**C** = 10-15 points

Most Severe

**Cirrhosis Severity**

# Fibrosis Evaluation

Indications for Ultrasound				
Concern for Hepatocellular Carcinoma or Cirrhosis				
Low PLT ( $< 150$ )	Elevated AFP	Elevated Fibrosis: F3 or F4	FIB-4 $> 3.25$ or APRI $> 1.0$	Discordant results



Ultrasounds should be checked every 6 months to screen for Hepatocellular Carcinoma and advanced liver disease



# Medication Considerations

- **Statins or other cholesterol lowering agents:** Can lead to an increased risk of rhabdomyolysis
- **Certain vitamins:** Excess iron intake without deficiency can promote hepatic injury; avoid St. John's Wort
- **Certain seizure medications:** Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- **GERD/Acid suppressing medications:** Suppressing GI acidity can lead to DAAs being less effective
- **Warfarin:** Monitor INR for subtherapeutic anticoagulation
- **Diabetic Medications:** Monitor for hypoglycemia
- **Ethinyl Estradiol:** May lead to hepatotoxicity
- **Antiarrhythmics:** Avoid amiodarone, can lead to toxicity and bradycardia

These are not all the potential interactions.

You can check your patient's medication list using:

[www.hep-druginteractions.org](http://www.hep-druginteractions.org)



# Treatment Considerations

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Short life expectancy that cannot be improved by HCV treatment, liver transplant, etc.

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Women who are pregnant or breast feeding

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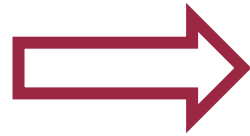
Children under 3

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# Referral Considerations

**Consider referring to higher level of care or accessing specialist consultation:**



Project ECHO  
Clinician Consultation Center

- Co-Infection is present (Hepatitis B and/or HIV)
- History of organ transplant
- Cirrhosis is highly suspected
  - Fibrosis stage 4
  - Low PLT and two noninvasive tests are discordant
  - Signs of decompensation (CTP Score)



# Complex Health Needs



# Advanced Liver Disease: Compensated vs. Decompensated

- The CTP scoring system incorporates five parameters: serum bilirubin, serum albumin, prothrombin time, severity of ascites, and grade of encephalopathy
- Compensated Cirrhosis: < 9
- Decompensated Cirrhosis: > 10

CTP Scoring				CTP Class	
Points	1	2	3		
Encephalopathy	NONE	Grade 1-2	Grade 3-4	A = 5-6 points Least Severe	
Ascites	NONE	Mild-Mod	Severe	B = 7-9 points Moderately Severe	
Bilirubin	<2	2-3	>3	C = 10-15 points Most Severe	
Albumin	>3.5	2.8-3.5	<2.8		
PT or	<4	4-6	>6		
INR	<1.7	1.7-2.3	>2.3		
				Cirrhosis Severity	

**The transition from compensated to decompensated cirrhosis occurs at a rate of approximately 5 to 7% per year**



# Compensated Cirrhosis

Cirrhosis is compensated in the asymptomatic patient with or without gastroesophageal varices.

Persons with compensated cirrhosis are not jaundiced and have not yet developed ascites, variceal bleeding, or hepatic encephalopathy.

## Important Screenings

- **Hepatocellular Carcinoma (HCC)**
  - All persons with cirrhosis should undergo surveillance for HCC with hepatic ultrasound every 6 months
  - For patients with chronic HCV infection and cirrhosis, surveillance for HCC should continue after treatment for HCV, even if the individual obtained a sustained virologic response.
- **Gastroesophageal Varices**
  - Varices develop at a rate of approximately 8% per year in patients with cirrhosis.
  - All patients with cirrhosis should undergo screening with an upper endoscopy to identify those individuals who may benefit from taking a nonselective beta-blocker for prophylaxis.

# Decompensated Cirrhosis

Decompensated cirrhosis is defined by the development of jaundice, ascites, variceal hemorrhage, hepatic encephalopathy, or a calculated CTP score of 10 to 15

Survival is poor in persons with decompensated cirrhosis, and they should be considered for liver transplantation.

A MELD score should be calculated for all persons with decompensated cirrhosis to better estimate the survival probability and to determine eligibility for transplantation.

Individuals with a MELD score greater than or equal to 15, or decompensated cirrhosis, should be considered for a liver transplantation evaluation.



# MELD Scoring

## Model for End-Stage Liver Disease (MELD) Score

$$\text{MELD} = 3.78 \times \log_e \text{ serum bilirubin (mg/dL)} + \\ 11.20 \times \log_e \text{ INR} + \\ 9.57 \times \log_e \text{ serum creatinine (mg/dL)} + \\ 6.43 \text{ (constant for liver disease etiology)}$$

### NOTES:

- If the patient has been dialyzed twice within the last 7 days, then the value for serum creatinine used should be 4.0
- Any value less than one is given a value of 1 (i.e. if bilirubin is 0.8, a value of 1.0 is used) to prevent the occurrence of scores below 0 (the natural logarithm of 1 is 0, and any value below 1 would yield a negative result)

<https://www.hepatitisc.uw.edu/page/clinical-calculators/meld>



**Patients with HCV-related cirrhosis who undergo treatment and achieve a cure have a dramatically decreased 10-year risk of all-cause mortality (hazard ratio [HR] = 0.26), liver-related mortality or transplantation (HR = 0.06), hepatocellular carcinoma (HR = 0.19), and hepatic decompensation (HR = 0.07).**



# Key Populations

- Certain key populations have a higher burden and risk of transmission and acquisition of the Hepatitis C virus than the general population.
- Persons experiencing various levels of homelessness, persons who inject drugs (PWID), men who have sex with men (MSM), and persons with a history of incarceration experience unique barriers when accessing healthcare, including Hepatitis C testing and treatment.



# Recommendations For Persons Experiencing Homelessness

- Every patient encounter should include a risk factor assessment and testing for HCV and HIV as indicated.
- Primary care providers should treat Hepatitis C for all patients experiencing homelessness unless referral is indicated given the severity of the disease.
- Hepatitis C treatment should be individualized and include a model of shared decision-making.
- HCV care should be integrated to include harm reduction services, substance use treatment, behavioral health, and treatment of comorbidities or other co-occurring conditions.



# Recommendations For Persons Experiencing Homelessness

- Community partners (shelters, transitional living facilities, etc.) should be engaged in care coordination to assist patients in treatment completion.
- Utilize peer education and peer advocates to reduce self-stigma and encourage engagement with treatment.
- Address stigma and misinformation of HCV and treatment costs and perceived barriers to care with patients and community partners.



# Recommendations for All At-Risk Key Populations

## Testing

- At least annual HCV testing is recommended
- At least annual HCV-RNA testing is recommended for persons with continued risk factors, e.g. drug use after previous RNA testing
- Test at initiation of HIV PrEP and at least annually

## Risk Factors

- Counseling about measures to reduce the risk of HCV transmission to others, risk of reinfection, and measures to prevent HCV infection and transmission
- PWID should be offered linkage to harm reduction services

## Treatment

- Active or recent drug use or a concern for reinfection is NOT a contraindication to HCV treatment
- All persons regardless of current or on-going risk factors should be offered HCV treatment and linked to care





# Harm Reduction

**Harm reduction** is an evidenced-based approach that aims to:

- Reduce the negative health, social, and economic consequences related to drug use and other health behaviors
- Promote public health, human rights, and social justice

Examples: medication assisted treatment (MAT), syringe exchange programs & sharps disposal, drug checking programs (fentanyl test strips), safer sex & drug use supplies, overdose prevention & naloxone distribution



# Naloxone/Narcan Candidate Screening Questions

## Patient Screening\*

Have you ever experienced an overdose?

In the last year, have you used an illegal drug or a prescription medication for non-medical reasons or that was not prescribed to you?

Are you taking a prescribed opioid or benzodiazepine?

Have you recently left prison/correctional facility or a detox/rehab facility?

Have you ever witnessed an overdose?

Does someone in your home or care use illegal drugs or have a substance use disorder?

## Provider Considerations

If the patient has not used in the last year, when was the last time? Is there a concern for relapse?

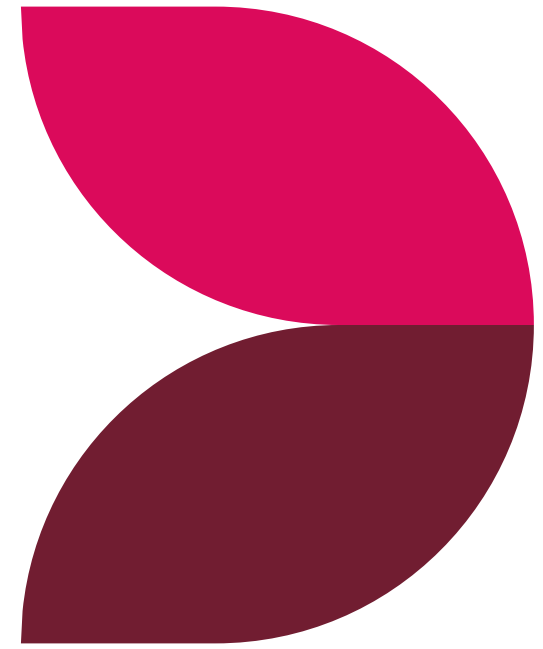
Is the opioid high dose (> 50 MME/day)?

Is the patient at risk for returning to using a high dose of a substance they are no longer tolerant to?



**\*A yes to any of these questions warrants a naloxone prescription**

# Patient and Provider Resources



**HEPATITIS C  
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**2023**

You can access this guide here:

[www.nhchc.org](http://www.nhchc.org)

# Clinical Resources

## Hepatitis C Online

- [www.hepatitisc.uw.edu](http://www.hepatitisc.uw.edu)
- Education on the diagnosis, monitoring, and management of HCV
- Free CME and CNE/CE including pharmacology CE for APRNs
- Clinical Calculators/Tools: CTP, FIB-4, APRI; CAGE, AUDIT-C

## Clinical Consultation Center

- [www.nccc.ucsf.edu/clinician-consultation/hepatitis-c-management](http://www.nccc.ucsf.edu/clinician-consultation/hepatitis-c-management)
- Consultation for treatment decision-making and management of co-morbidities, complications, and special populations with experts
- Warm-line: (844) 437-4636; Monday – Friday, 9 a.m. – 8 p.m. ET

## ECHO

- [www.showmeecho.org/clinics/hepatitis-c](http://www.showmeecho.org/clinics/hepatitis-c)
- Provides collaboration, support and ongoing learning with HCV experts
- Sessions include didactic information and participant case studies
- No cost to attendees with CME available for session participation



# Patient resources:

## Prescription assistance

### Gilead: Support Path

- Medications: Epclusa, Vosevi, Harvoni, Solvadi
- [www.mysupportpath.com](http://www.mysupportpath.com)

### AbbVie: myAbbVie Assist

- Medication: Mavyret
- [www.abbvie.com/patients/patient-assistance/program-qualification/mavyret-program-selection.html#myabbvie](http://www.abbvie.com/patients/patient-assistance/program-qualification/mavyret-program-selection.html#myabbvie)



# Patient resources: Co-Pay Assistance

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<b>My Good Days</b>	Insurance Type: Medicare or Military
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[www.mygooddays.org](http://www.mygooddays.org)

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<b>HealthWell Foundation</b>	Insurance Type: Any
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[www.healthwellfoundation.org](http://www.healthwellfoundation.org)

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<b>Patient Access Network</b>	Insurance Type: Any
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[www.panfoundation.org](http://www.panfoundation.org)

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<b>Patient Advocate Fund</b>	Insurance Type: Any
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[www.patientadvocate.org](http://www.patientadvocate.org)

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# Patient resources: Co-Pay Coupons

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## Epclusa

Coverage: \$5 per monthly prescription

[www.epclusa.com/sign-up-eligibility](http://www.epclusa.com/sign-up-eligibility)

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## Mavyret

Coverage: \$5 per monthly prescription

[www.mavyret.com/savings-card](http://www.mavyret.com/savings-card)

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## Vosevi

Coverage: \$5 per monthly prescription

[www.vosevi.com/co-pay-coupon-registration](http://www.vosevi.com/co-pay-coupon-registration)

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## Harvoni

Coverage: \$5 per monthly prescription

[www.harvoni.com/support-and-savings/co-pay-coupon-registration](http://www.harvoni.com/support-and-savings/co-pay-coupon-registration)

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“

It is rare to have the opportunity,  
using a simple and safe oral  
medication, to eliminate a lethal  
disease. But that is the situation  
facing the United States with  
Hepatitis C.

”

**Rachael Fleurence, MSc, PhD**

**Senior Advisor to Francis Collins, MD, PhD  
Science Advisor to the President**



# References

## Support for Treatment in Primary Care

Kattakuzhy, S., Gross, C., Emmanuel, B., Teferi, G., Jenkins, V., Silk, R., ... & Kottlil, S. (2017). Expansion of treatment for hepatitis C virus infection by task shifting to community-based nonspecialist providers: a nonrandomized clinical trial. *Annals of internal medicine*, 167(5), 311-318.

## Guidelines for testing and treatment:

AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C.

<http://www.hcvguidelines.org>

CDC. Testing Recommendations for Hepatitis C Virus Infection.

<http://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>



# Thank you

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# Break

---

- Stretch, rest, hydrate!
- We will begin again in 10 minutes
- Next Up: Models of Care



# Evolving Models of Hepatitis C Care

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## About NVHR

# Meet NVHR

- We're a coalition of patients, health care providers, community-based organizations, and public health partners fighting for an equitable world free of viral hepatitis.
- We're also a program of the Hepatitis Education Project, a community-based organization in Seattle, WA



Adrienne Simmons  
(she/her)

Director of Programs

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Daniel Raymond  
(he/him)

Director of Policy

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Lauren Canary  
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Public Health Advisor

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# Our Work

## Programs

- Hepatitis C: State of Medicaid Access
- Hep Elimination
- HepNET: Hepatitis Network for Education and Testing
- Voices4Hep

## Policy

- Elimination
- Funding
- Harm Reduction
- Health Equity
- Immunizations
- Testing

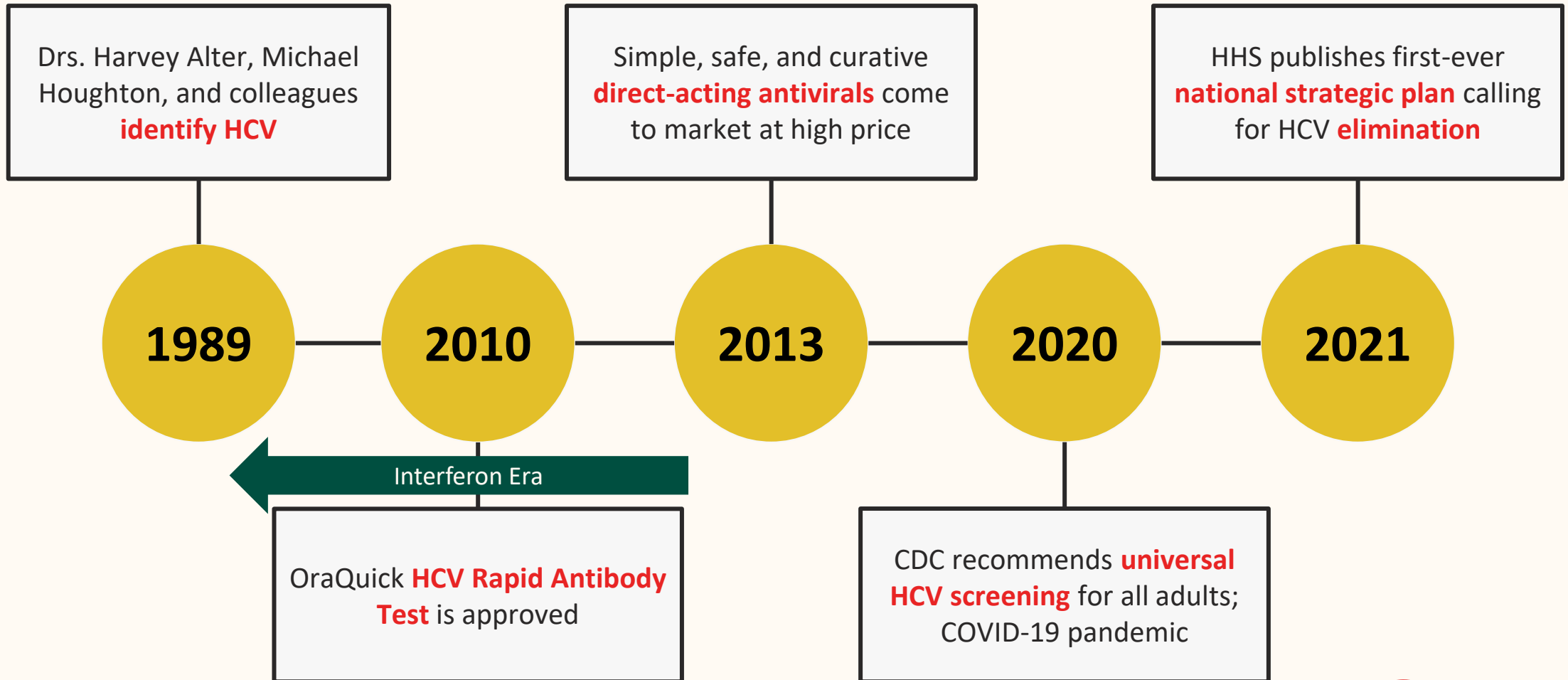
Resource development, including webinars, fact sheets, and toolkits  
To learn more about our work, visit [www.nvhr.org](http://www.nvhr.org)



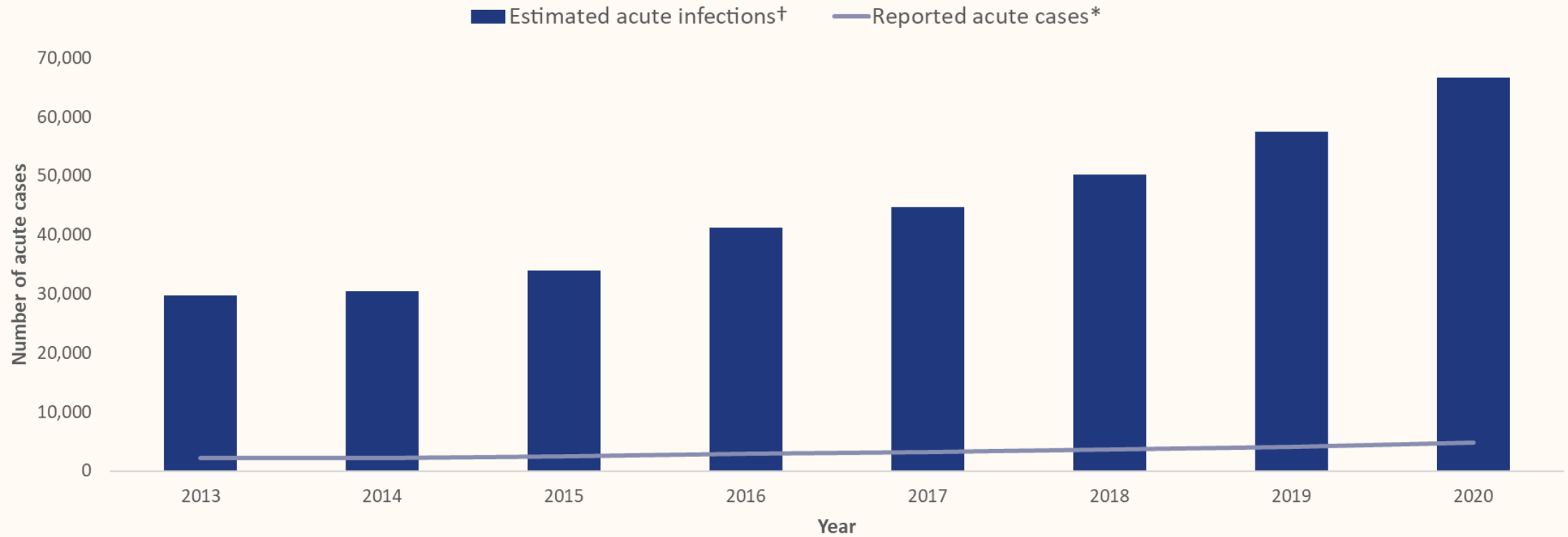


# Evolving Models of Hepatitis C Care

# Collectively, these hepatitis C milestones have transformed models of hepatitis C care



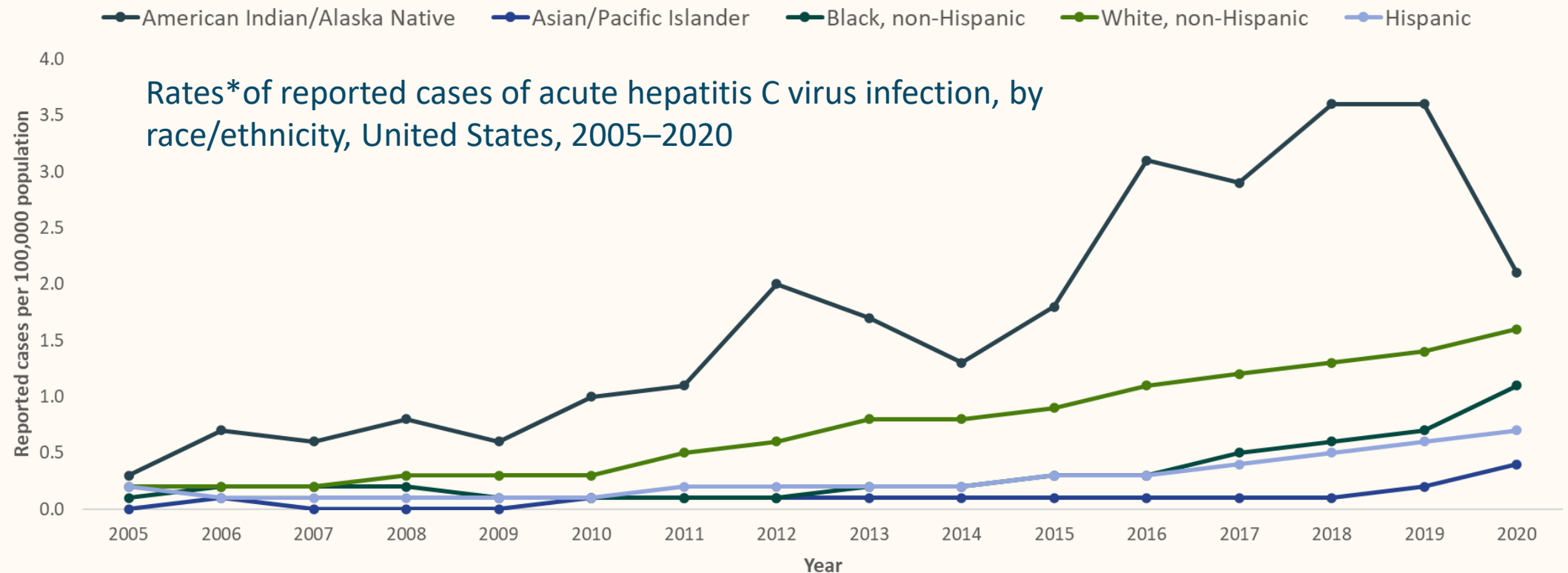
# HCV infections are rising



- The incidence rate of acute hepatitis C has more than doubled since 2013, and increased 15% from 2019.
- Persons aged 20-39 years had the highest incidence of acute hepatitis C.
- 66% of cases with risk information reported injection drug use.

# People of color have worse HCV outcomes

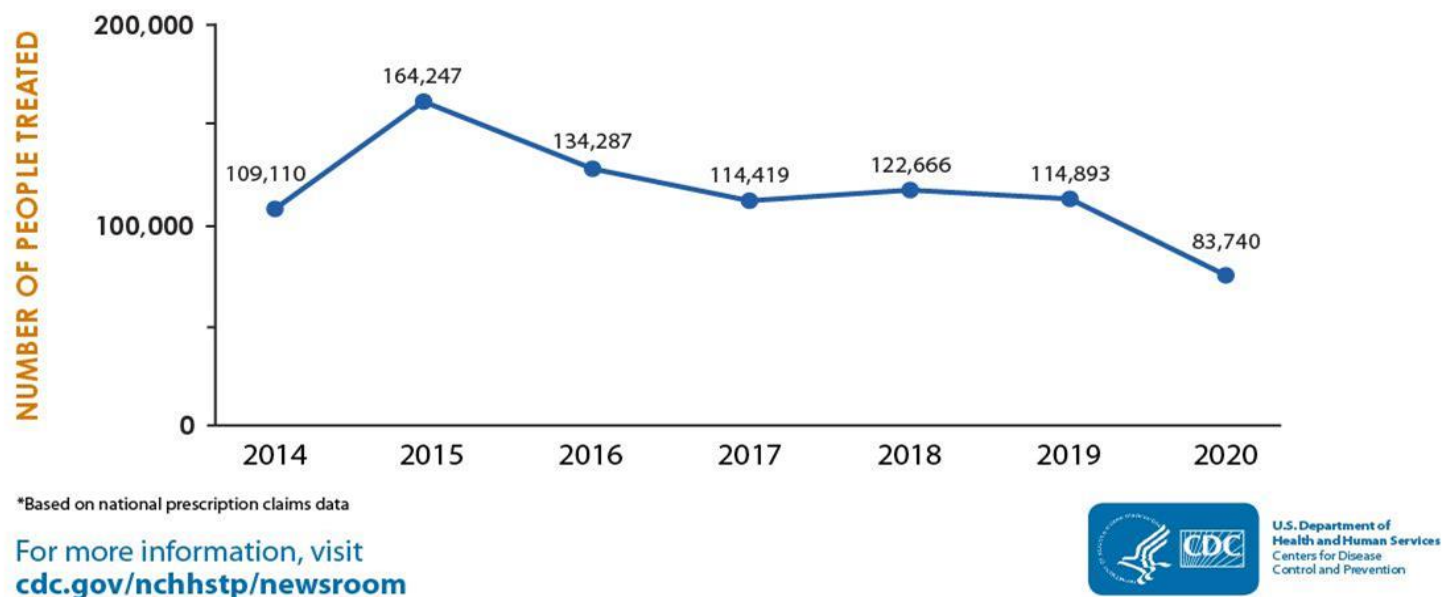
- Native Americans experience higher rates of acute HCV, and higher rates of HCV-related mortality, than any other racial/ethnic group
- Mortality rates are highest among Native American and Black people (3.2 times and 1.8 times, respectively) compared to white people



# As HCV cases rise, treatment rates are falling

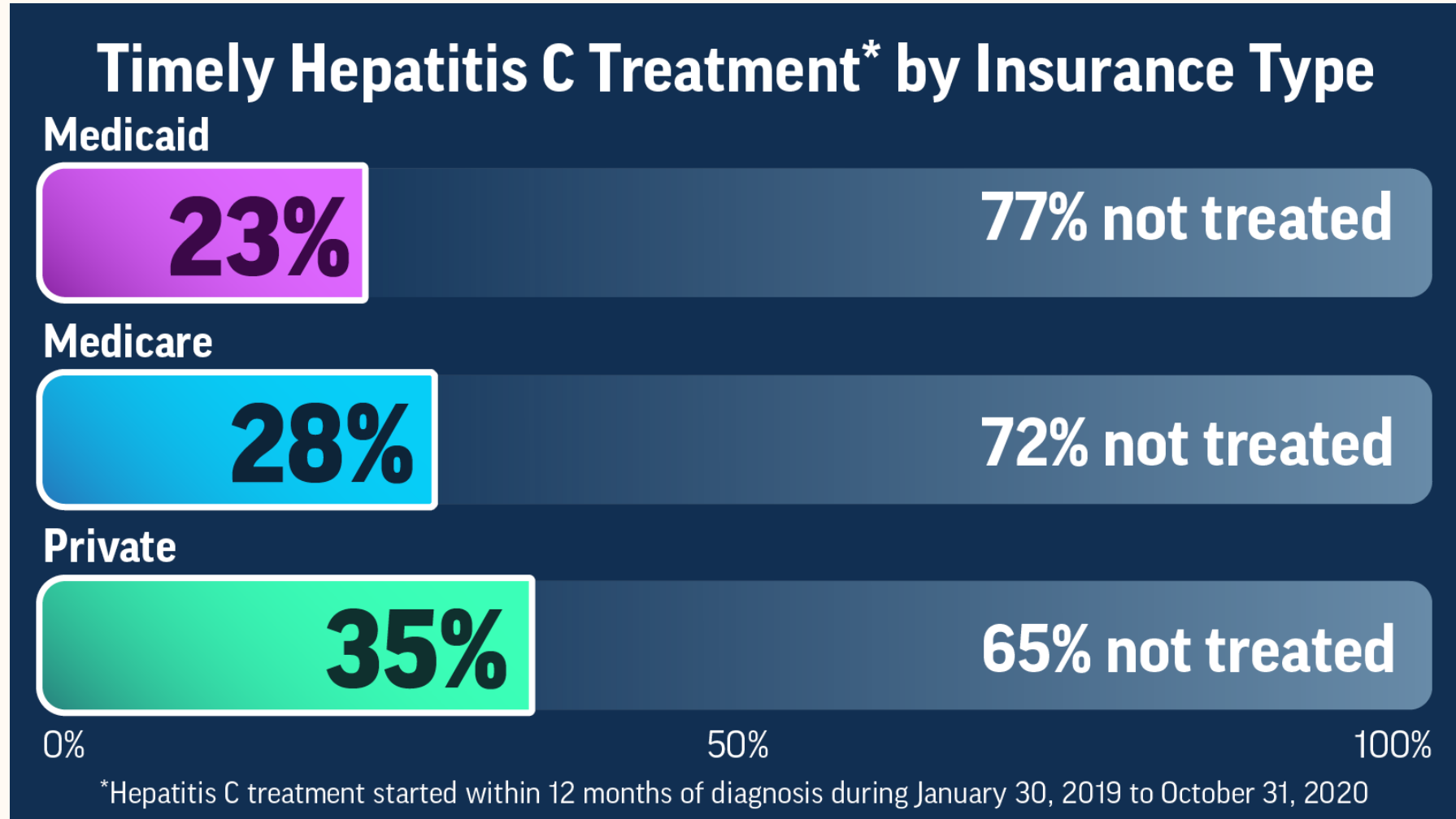
## THE NUMBER OF PEOPLE WHO INITIATED\* HEPATITIS C TREATMENT IN THE U.S. DECLINED FROM 2015 TO 2020

COVID-19-related disruptions to hepatitis C testing and treatment likely contributed to the decline in 2020



From 2014-2020, an average of **approximately 120,000 people** were treated each year, falling short of the *National Academies of Sciences, Engineering, and Medicine* estimate that **at least 260,000 people must be treated annually to eliminate hepatitis C by 2030**

# Only 1 in 3 of insured receive timely HCV treatment



# Sites of care have expanded beyond traditional settings to meet patients where they are.

Historically hepatitis C care was provided by specialists in large academic medical centers.

Primary Care &  
Community  
Clinics

Telehealth

Community-  
Based  
Organizations

Mobile  
Clinics/Street  
Medicine

Correctional  
Facilities

# Screening is slowly improving, but linkage to care remains a challenge.

Universal HCV  
testing for all  
adults and  
pregnant people

FDA  
reclassification of  
HCV diagnostic  
tests

Increased use of  
reflex testing

Universal opt-out  
testing in jails and  
prisons



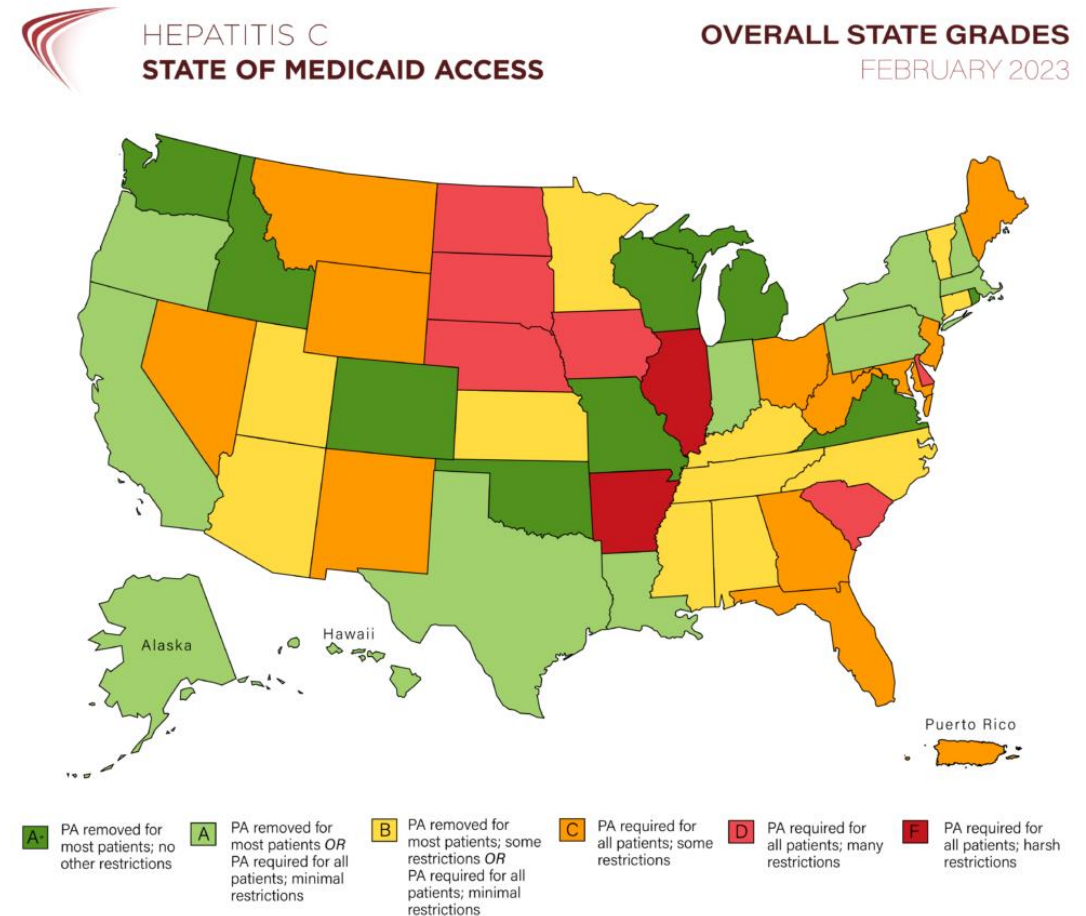
# While HCV treatment remains out of reach for many, there are notable improvements.

Advocacy and litigation have increased access to treatment for Medicaid beneficiaries and people who are incarcerated

21 states now allow access to DAAs in their Medicaid programs without requiring prior authorization (PA) for most patients

5 states (WA, LA, MI, MO, TX) have implemented innovative payment models to reduce the cost of treatment

Treatment is increasingly prescribed by non-physician prescribers (e.g., PA, NP, PharmD) using AASLD/IDSA Simplified Algorithm



To see how your state Medicaid program stacks up in HCV treatment access, visit [www.stateofhepc.org](http://www.stateofhepc.org)

# Potential National Hepatitis C Elimination Program presents a historic opportunity

- Dr. Francis Collins leading development of a proposal for a National HCV Elimination Program
- Early discussions include **financing strategies for direct-acting antivirals and novel HCV diagnostics**
- Funding not yet secured for program and program details not yet finalized

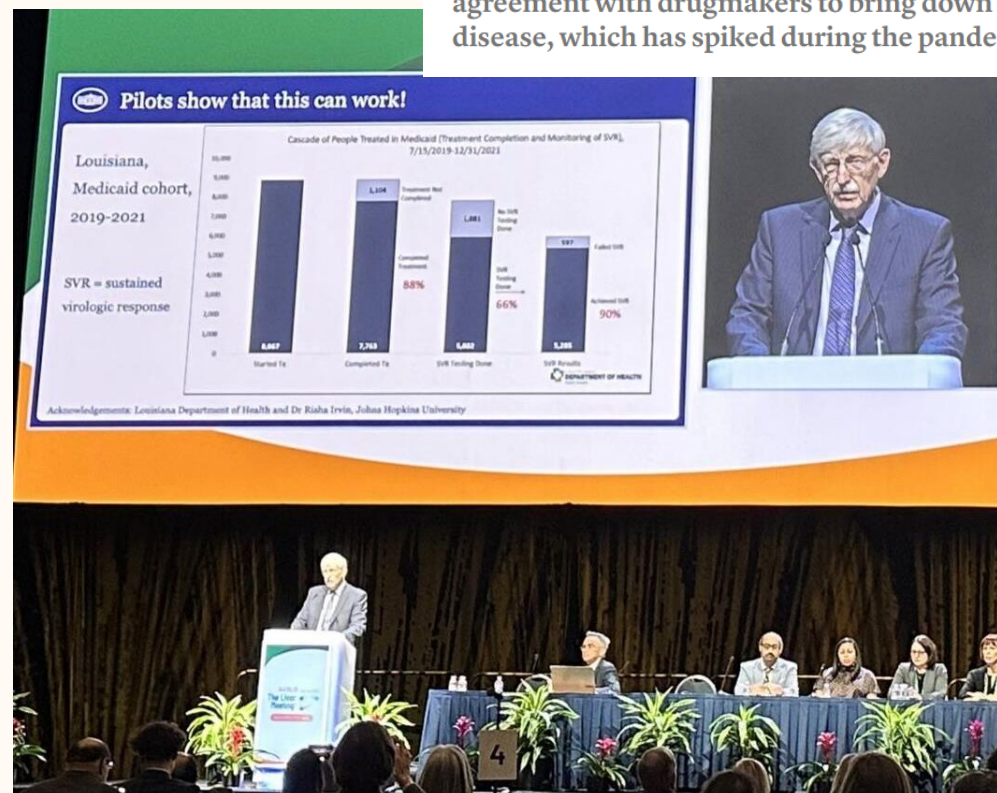
To learn more about the program, read the JAMA Viewpoint titled “A National Hepatitis C Elimination Program in the United States”

<https://jamanetwork.com/journals/jama/fullarticle/2802533>

## POLICY

### Administration eyes national hepatitis C treatment plan

The plan would streamline testing and treatment and secure an agreement with drugmakers to bring down the cost of treatment of the disease, which has spiked during the pandemic



**NVHR**  
National Viral Hepatitis Roundtable

# Key Considerations for HCV Models of Care

## Opportunities

- National Hepatitis C Elimination Program
- Commitments to elimination, health equity, syndemic approach
- COVID-19 pandemic (e.g., rapid diagnostics, telehealth)
- MINMON Study
  - Omits genotype
  - Dispenses full treatment course
  - Minimal on-treatment monitoring
- Expanding roles of pharmacists and other non-physician providers
- Integration and co-location of services in substance use treatment centers and low barrier settings

## Threats

- Uncertain prospects for sustained increases in federal funding
- Manufacturer restrictions on 340B Program
- Repoliticization of harm reduction



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## HCV treatment at Boston Health Care for the Homeless Program

# HCV epidemic in the US is disproportionately experienced by marginalized populations

HCV estimates in the United States	
Population studied	Prevalence
NHANES household survey <sup>12</sup>	1%
People who injected drugs (PWID) in the preceding year <sup>11</sup>	39.8%
7 homeless health care sites <sup>15</sup>	31%
Homeless PWIDs in LA <sup>10</sup>	77.6%
Incarcerated persons <sup>14</sup>	17%-64%

# How do you reconcile guidelines with your patient's real-life situation?

- HCVGUIDELINES.ORG: When and In Whom To Treat<sup>1</sup>

Goal of Treatment	
RECOMMENDED	RATING ⓘ
The goal of treatment of HCV-infected persons is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response.	I, A
Recommendation for When and in Whom to Initiate Treatment	
RECOMMENDED	RATING ⓘ
Treatment is recommended for all patients with chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert.	I, A

- Potential challenges to engagement
  - Competing priorities can impact adherence
    - Comorbidities
    - Work
    - Family obligations
    - Substance use
    - Unstable housing/homelessness
  - Logistics
    - Transportation
    - Medication storage
    - Phone
  - Threat of incarceration
  - Stigma

# Case #1

37 y/o male with past medical history of HCV and OUD, diagnosed with HCV 3 years ago. No prior work up.

- HCV risk factors
  - Hx of injection drug use
- Additional history:
  - Residing in the shelter or street or doubled up
  - Not currently on MOUD
  - Current injection use of opioids, utilizing SSP services
  - On TDF/FTC for HIV PrEP facilitated by outreach nursing staff
- HCV evaluation
  - HCV AB+, VL 1.2 million, G1a
  - ALT 175/AST 86
  - Plts 250k
  - All other chemistries normal
  - FIB-4 = 0.91, indicating high likelihood of minimal, F0-F1 fibrosis
  - HAV immune
  - HBV SAg -/anti-HBc+/anti-HBs <10
  - HIV negative



# Guiding principles for HCV care of people experiencing homelessness and/or using substances

- Everyone should be treated. **Reduce barriers, don't add them**
- Recognize that you have power to prioritize HCV care alongside other health issues
- There is no perfect situation
  - Kept appointments as proxy for stability
  - Capitalize on existing care relationships
- When is the wrong time for treatment?
  - Lack of contact info with no clear work-around
  - Lack of interest (referred by someone more invested than the pt)
  - Imminent transitions through SUDs tx continuum- follow up after transition is completed
- A value of treatment in the community is that readiness can be assessed over time. If there are concerns for nonadherence right now, keep the conversation going for future treatment

# Case #1, completed

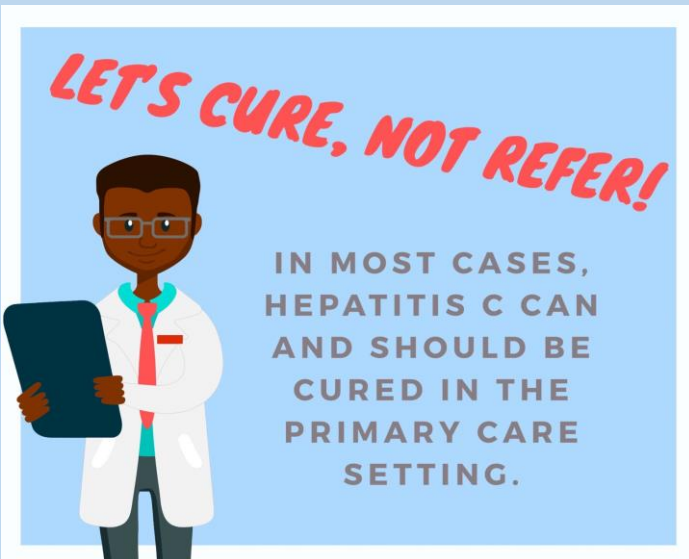
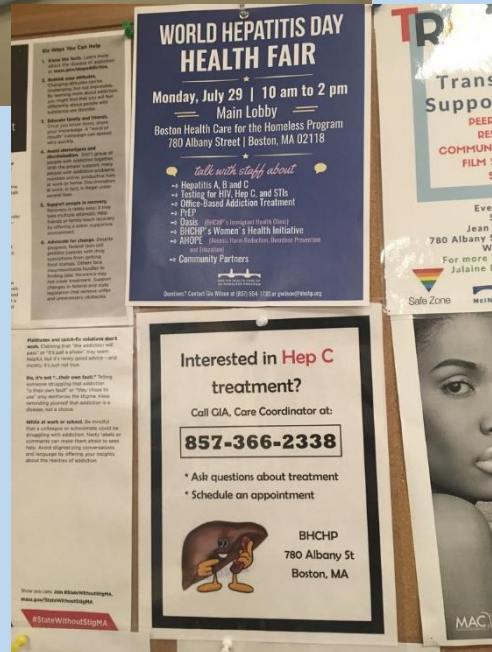
- Glecaprevir-Pibrentasvir x 8 weeks, chosen due to shortest duration
  - Counseled on rare but serious risk for HBV reactivation, instructed to contact team with any s/s of acute hepatitis
  - Weekly check-ins with patient via outreach nurse staff, adherence monitored by staff and med storage at outreach site
  - Week 4 VL = <15 not detected
  - End of treatment VL = <15 not detected
  - SVR 12 weeks post treatment completion = <15 not detected = cured!
  - Alongside HCV treatment, PrEP engagement continued and MOUD was initiated

**Throughout treatment, at SVR, and with ongoing care emphasize harm reduction counseling to prevent reinfection**

**Advise repeat screening if risk factors present q6-12 months**

# HCV Team

- Founded in 2014
  - Advent of DAA therapy
  - 23% prevalence at BHCHP identified with excess morbidity and cost<sup>4</sup>
  - 74% reported interest and confidence they could complete treatment, preference for BHCHP-based care<sup>3</sup>
- Structure
  - Core: care coordinators, nurse, data manager, and program director (NP)
  - Clinical evaluations: program director and non-specialist PCPs
- Funding
  - Majority of clinical care reimbursable to third-party payers
  - MA DPH and internal support for non-billable services



## INITIAL EVALUATION:

HCV genotype  
HCV VL  
Prior treatment history  
Fibrosis assessment (FIB-4, fibroscan, etc)  
HBV status  
Drug-drug interaction check  
If cirrhosis:  
    Child Pugh score (will need INR)  
    HCC screening (not required for tx, but for RHM)

Additional hx:  
    Duration of infection  
    Risk factors  
    Child-bearing status  
    Housing status  
    Current/hx of substance use  
    HIV coinfection/PrEP screening  
    Harm reduction practices/overdose prevention  
    Anabolic steroid use  
    Incarceration hx/possible risk for

## Formal treatment recommendation should include:

Medication, including duration  
Assessment of adherence potential  
Monitoring plan (confirm contact info)  
Review drug-drug interactions  
If relevant, risk for HBV reactivation  
Counsel on reinfection risk

## BHCHP HCV Treatment (Beiser, Jan 2022) Assessment and Monitoring Algorithm

HCV Care Coordinator  
Nurse  
Provider

### INITIAL HCV TREATMENT ASSESSMENT:

HCV genotype  
HCV VL  
Prior treatment history  
Fibrosis assessment (FIB-4, fibroscan, etc)  
HBV status  
Drug-drug interaction check  
If cirrhosis:  
    Child Pugh score (will need INR)  
    HCC screening (not required for tx, but for RHM)

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**Formal treatment recommendation should include:**  
Medication, including duration  
Assessment of adherence potential  
Monitoring plan (confirm contact info)  
If relevant, review risk for HBV reactivation  
Counsel on reinfection risk

### LINKAGE VIA CARE COORDINATOR:

Provider referral, external or patient-directed

HIVCT

Correctional linkage

### Preliminary RN visit

Baseline labs:  
HCV VL, HCV genotype  
CBC, CMP, +/- INR  
HIV Ag/Ab, PrEP screening  
HAV Ab, vax prn  
HBSAg, anti-HBc, anti-HBs, vax prn  
HCV education

### PRIOR AUTHORIZATION

Pharmacy navigation

### TREATMENT INITIATION (visit or drop-off)

WEEK 4 VISIT  
CBC, CMP, HCV VL

END OF TREATMENT VISIT  
CBC, CMP, HCV VL  
reinfection counseling

SVR 12 VISIT  
CBC, CMP, HCV VL, HIV Ag/Ab  
reinfection counseling

### WEEKLY ADHERENCE SUPPORT

Phone calls/texts

In-person pill-boxes or DOT

Outreach

Collaboration/coordination with other teams

Refill and appt scheduling coordination

Medication drop-offs

Trouble-shooting case management needs

Harm reduction, reinfection prevention counseling

# BHCHP HCV Treatment (Beiser, Jan 2022)

## Assessment and Monitoring Algorithm

HCV Care Coordinator  
Nurse  
Provider

### LINKAGE VIA CARE COORDINATOR:

Provider referral, external or patient-directed

Correctional linkage

HIVCT

### INITIAL HCV TREATMENT ASSESSMENT (RN/provider may collaborate, telehealth)

Quantitative or Qualitative HCV VL  
HBV status  
Prior treatment history  
Assessment to rule out decompensated cirrhosis (clinical or non-invasive marker)  
Drug interaction review

### TREATMENT INITIATION VISIT

(or med delivery)

### WEEKLY ADHERENCE SUPPORT

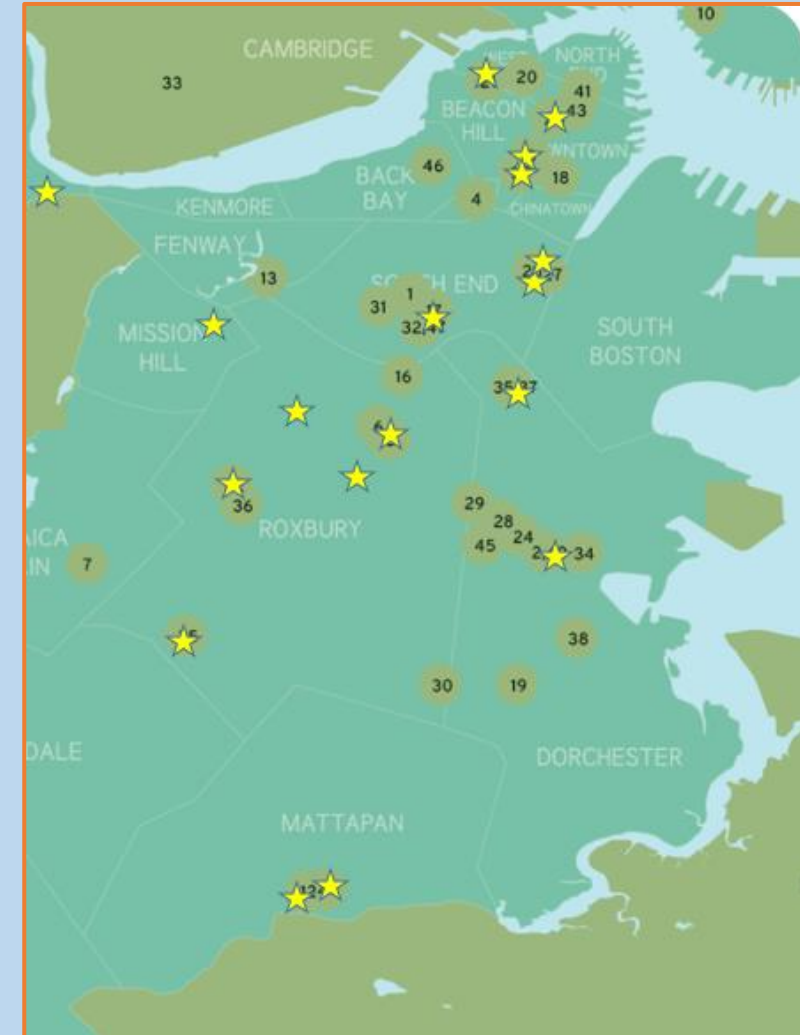
Phone calls/texts  
In-person pill-boxes or DOT  
Outreach  
Collaboration/coordination with other teams  
Refill and appt scheduling coordination  
Medication drop-offs  
Trouble-shooting case management needs  
Harm reduction, reinfection prevention counseling

Arrange for week 4 or EOT labs  
(in clinic or satellite lab)

SVR 12 labs

Reinfection/harm reduction counseling

Assess for durable cure or reinfection 1 year post-SVR or more often with RF with HCV VL



17 clinicians trained to integrate HCV treatment into their routine care at over 20 sites with centralized case management, nursing, and administrative support



# Core care provision by centralized team

- Care coordinators, nurse and data manager
  - Referral management
  - PA completion and navigation
  - Specialty pharmacy coordination
  - Frequent and flexible adherence support
  - Appointment (eg. Fibroscan) escorting
  - Cohort management/tracking
  - Outcomes assessments, research, etc



# Factors Associated with Sustained Virologic Response to Hepatitis C Treatment in a Homeless-Experienced Cohort in Boston, 2014–2020<sup>4</sup>

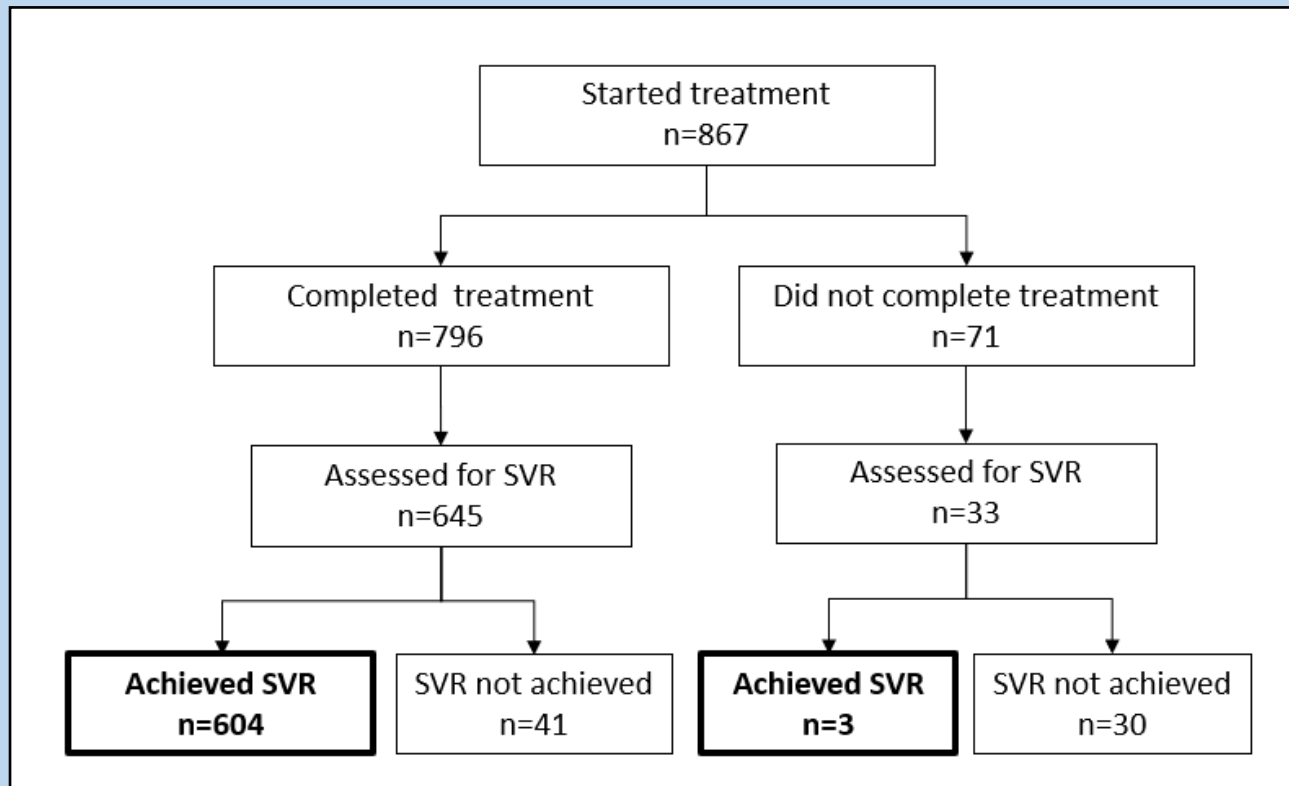


Marguerite E. Beiser, MS<sup>1</sup> , Leah C. Shaw, MPH<sup>1</sup>, Giavanna A. Wilson, BFA<sup>1</sup>, Khadija O. Muse, MPA<sup>1</sup>, Savanna K. Shores, BSN<sup>1</sup>, and Travis P. Baggett, MD, MPH<sup>1,2,3</sup>

<sup>1</sup>Institute for Research, Quality, and Policy in Homeless Health Care, Boston Health Care for the Homeless Program, Boston, MA, USA; <sup>2</sup>Division of General Internal Medicine, Massachusetts General Hospital, Boston, MA, USA; <sup>3</sup>Department of Medicine, Harvard Medical School, Boston, MA, USA.

**RESULTS:** Of 867 individuals who started HCV treatment, 796 (91.8%) completed treatment, 678 (78.2%) were assessed for SVR, and 607 (70.0%) achieved SVR. In adjusted analysis, residing in stable housing (OR 3.83, 95% CI 1.85–7.90) and age > 45 years old (OR 1.53, 95% CI 1.04–2.26) were associated with a greater likelihood of achieving SVR. Recent drug use (OR 0.63, 95% CI 0.41–0.95) was associated with a lower likelihood of SVR. Age, housing status, and drug use status impacted retention at every step in the treatment cascade.

**CONCLUSION:** A large proportion of homeless-experienced individuals engaging in HCV treatment in a homeless health center achieved SVR, but enhanced approaches are needed to engage and retain younger individuals, those with recent or ongoing substance use, or those experiencing homelessness or unstable housing. Efforts to achieve HCV elimination in this population should consider the complex and overlapping challenges experienced by this population and aim to address the fundamental harm of homelessness itself.



**91.8% completed treatment**  
**70.0% ITT SVR**  
**89.5% mITT SVR**

# Nonadherence

- Don't let perfect be the enemy of the good
- Limited data on nonadherence
  - SIMPLIFY- no difference in SVR rate between adherence and nonadherent patients<sup>6</sup>
    - 9/11 pts who missed longer than 7 days achieved SVR
  - CANUHC- SVR rates dropped substantially with > 25% missed doses<sup>13</sup>
  - Hcvguidelines.org recently updated their guidance:  
<https://www.hcvguidelines.org/evaluate/monitoring#incomplete-adherence><sup>1</sup>



# Adherence support

- Determine your capacity for consistent support (staffing, storage, etc)
- Arrange your plan for adherence support early in the assessment process with the patient's input
- Within approved regimens, choose the one that will work best with your patient's schedule, competing priorities, locale, etc
- Join Savanna in the breakout for more in-depth discussion of adherence strategies!

# Reinfection

- 12.0/100 person-years at BHCHP → 25.0/100 py among people who were homeless at the time of HCV treatment and reported recent drug use<sup>2</sup>
- HCV tx is short, but spectrum of substance use and recovery is long
- Relapse is a part of life: we need to get comfortable with harm reduction, relapse prevention, and treatment provision across a range of needs
- Reinfection will happen for some, but opportunity for reexposure is decreased when more people are treated and cured
- Greatest reduction in HCV incidence effected by combination of HCV tx, scale up in tx for OUD, and needle syringe service provision<sup>7-9</sup>
- Primary care well suited for ongoing prevention of reinfection counseling and rescreening

# Case #2

53 yo male with past medical history of HCV and OUD, AUD, HTN, DM, COPD, depression, obesity, hyperlipidemia, and diagnosed with HCV approximately 30 years ago.

- HCV risk factors
  - Hx of injection drug use
- Additional history:
  - Residing in shelter
  - ETOH use is intermittently heavy, hx of section 35 for ETOH
  - On buprenorphine for OUD
  - Additional meds include: atorvastatin, omeprazole, metformin
- HCV evaluation
  - HCV Ab+, VL 6.9 million, G3
  - ALT64/AST81
  - Plts 38k
  - FIB-4 = 13.86- high likelihood of F3-F4 fibrosis
  - No prior diagnosis of cirrhosis
  - Sxs of profound fatigue, daytime sleepiness, forgetfulness

# HCV treatment for individuals with advanced liver disease

- In our HCH care we routinely see patients who have advanced illness and may have challenges and barriers to engaging in specialty care (eg. insurance, stigma, transportation, distrust or fear, competing priorities, etc)
- If these folks are working with us regularly, what can we do to bridge the gaps and ensure the highest quality of care and access?
- Please join my breakout session to discuss further!

# Pearls

- Your HCV treatment program should include these components, but can be organized and administered whichever way works for your program
  - Clinical assessment (prescriber)
  - Navigation through prior authorization and pharmacy system
  - Adherence support for patients on treatment
  - Tracking of patient outcomes

In our experience, these steps have helped us grow and expand:

- Standardize your assessment process and documentation
- Develop and centralize expertise and relationships with payers and pharmacies
- Start slow with a few individuals who are highly motivated and straightforward, clinically
- When in doubt, consult an experienced HCV treater!

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# Hepatitis C Treatment: Integration in Primary Care Settings

Rachel Melson, DNP, FNP-C



# OBJECTIVES

1. Discuss the relationship between HIV, HCV, and OUD and the importance of addressing the syndemic together
2. Discuss opportunities for care integration in primary care settings

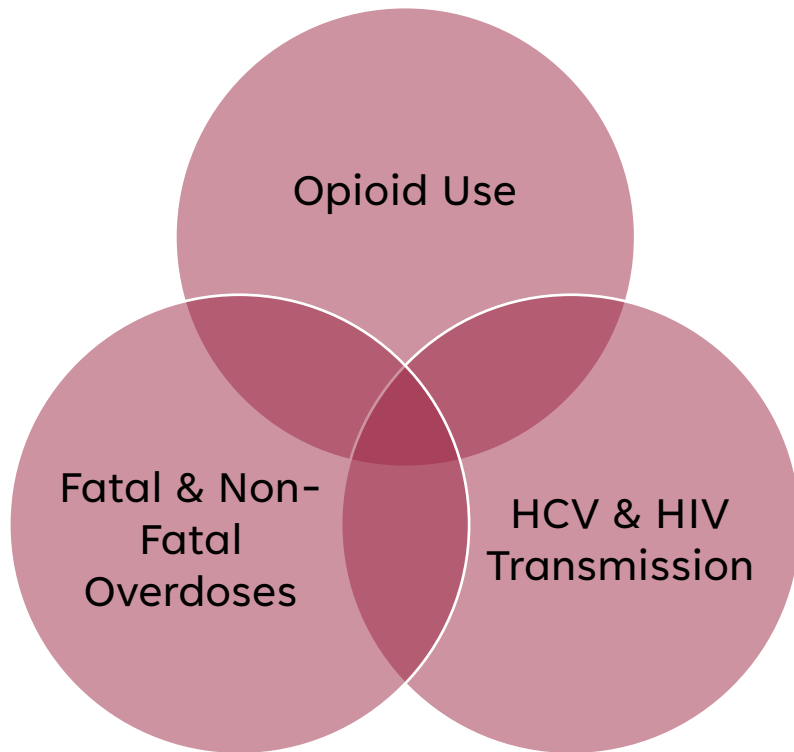




# The Syndemic



# “Synergistically interacting epidemics”



The opioid epidemic is probably best viewed as a set of **inter-related and overlapping epidemics** of the use of prescription and illicit opioids, fatal and non-fatal overdoses, and HIV and HCV transmission.



# HCV & OUD Treatment Opportunities

Should ideally be delivered in a multidisciplinary care setting with services to reduce reinfection risk and manage the common social and psychiatric comorbidities in this population

Regardless of the treatment setting, recent and active IDU are not absolute contraindications to HCV therapy

Persons cured of chronic HCV no longer transmit the virus to others

There is strong evidence from various settings in which PWID have demonstrated adherence to treatment and low rates of reinfection, countering arguments that have been commonly used to limit HCV therapy access in this patient population

Several health models have shown that even modest increases in successful HCV treatment among PWID can decrease prevalence and incidence



# HCV & OUD Treatment Opportunities

During your initial assessment and consultation with a patient who has Hepatitis C, ask about risk factors such as substance use

For patients presenting for treatment for OUD, ALWAYS screen for HIV and HCV (point of care if available)

If your patient is presenting for Hepatitis C treatment and is already on MAT, discuss opportunities to have the care consolidated to minimize appointments and risk of “no show”



# HCV Re-Infection in PWID

Although reinfection by hepatitis C virus occurs following successful treatment in people with recent drug use, the rate of hepatitis C reinfection is lower than the rates of primary infection.

The 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).

Data suggest that reinfection is rare in PWID who clear HCV with therapy even if they continue to inject drugs, provided steps are taken to minimize the risk.

Reinfection should not be used as a reason to withhold therapy from people with ongoing injection drug use.

PWID found to be HCV reinfected should be retreated.



# Harm Reduction Opportunities

Hepatitis C treatment with DAAs can safely be administered with other harm reduction practices including MAT and HIV PrEP medications.

## Overdose Prevention

- Naloxone distribution
- Fentanyl test strips

## MAT

- Suboxone, Subutex
- Vivitrol

## HIV PrEP

- Daily oral medications
- Long-acting injections

## Safer Use

- Syringe exchange
- Sharps disposal



# Care Integration

Collaboration > consolidation...don't take off more than you can chew, especially at first

Focus on what the patient is there requesting treatment for at that visit and engage when appropriate

Remember that HIV, HCV, and OUD are all risk factors for each other, and this is why care integration is so important



# Thank you

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# Breakout Sessions: Please select your breakout room

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1. Getting started with hepatitis treatment in a primary care setting

2. Treatment support strategies for people experiencing homelessness and/or using drugs

3. Treating hepatitis C in people with advanced liver disease

4. Addressing common insurance and policy barriers

# Break

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- Stretch, rest, hydrate!
- We will begin again in 10 minutes
- Next Up: Closing panel discussion about experiences with Hepatitis C treatment

# Panelists

- **KEISA RIVERA, Subject Matter Expert, Boston, MA**
- **BRYAN GHEE, Subject Matter Expert, Philadelphia, PA**
- **SAMANTHA VELEZ, Subject Matter Expert, Portland, ME**

## **Facilitators:**

**Courtney Pladsen**, DNP, RN: Clinical Director, National Health Care for the Homeless Council

**Kate Gleason-Bachman**, MPH, RN: Clinical and QI Nurse Manager, National Health Care for the Homeless Council

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