



Advances in Hep C Treatment: Integrated Care for Individuals with Substance Use Disorder

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Mountain Plains ATTC

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Faculty disclosure

- No financial disclosures



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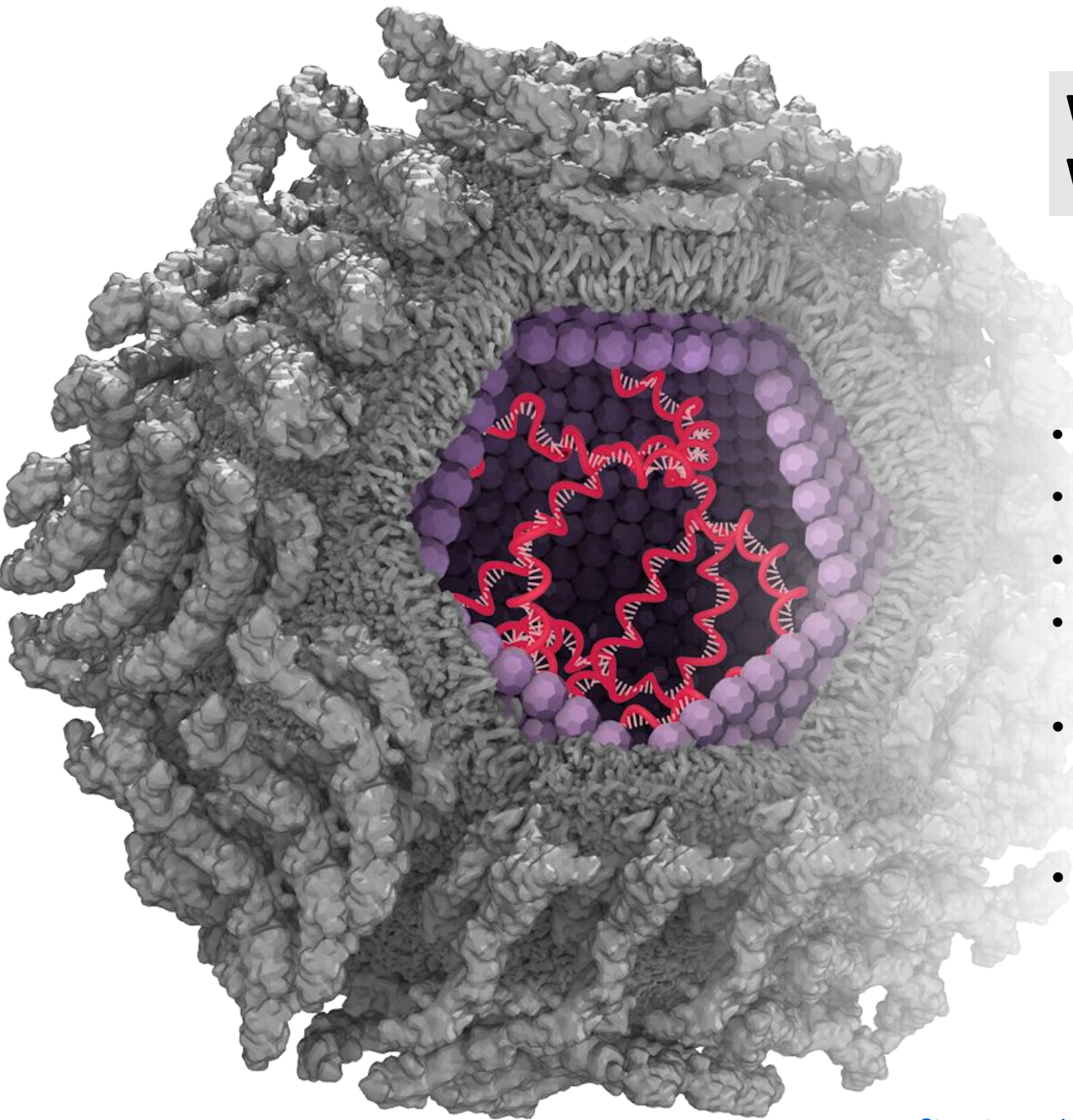
Learning Objectives

Learn about the epidemiology of hepatitis C and its overlap with substance use and other related disorders.

Review the clinical course of hepatitis C infection, options for treatment, and treatment outcomes.

Identify hepatitis C screening best practices and ways to incorporate hepatitis C screening, referrals, and treatment into substance use disorder treatment programs.

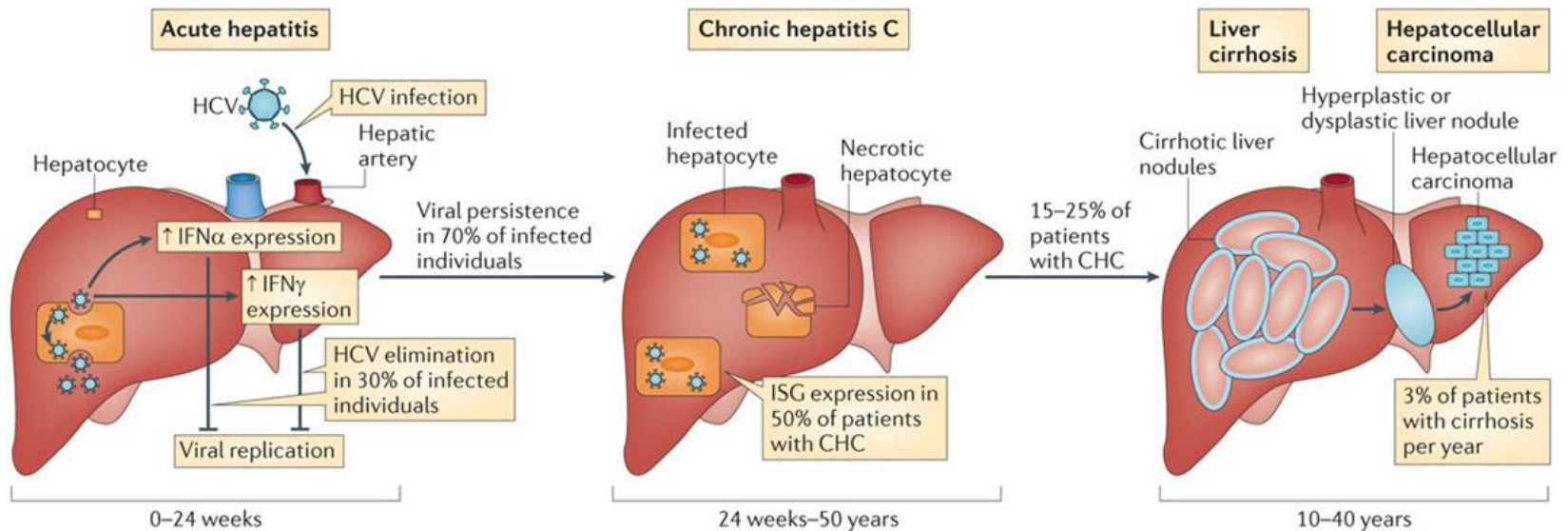
What is Hep C and Why Do We Care?



- RNA virus
- Blood borne pathogen
- Replicates in liver and blood
- Always replicating (never dormant/latent)
- First identified in 1989; blood supply testing began in 1992
- May survive outside human host for several days/weeks

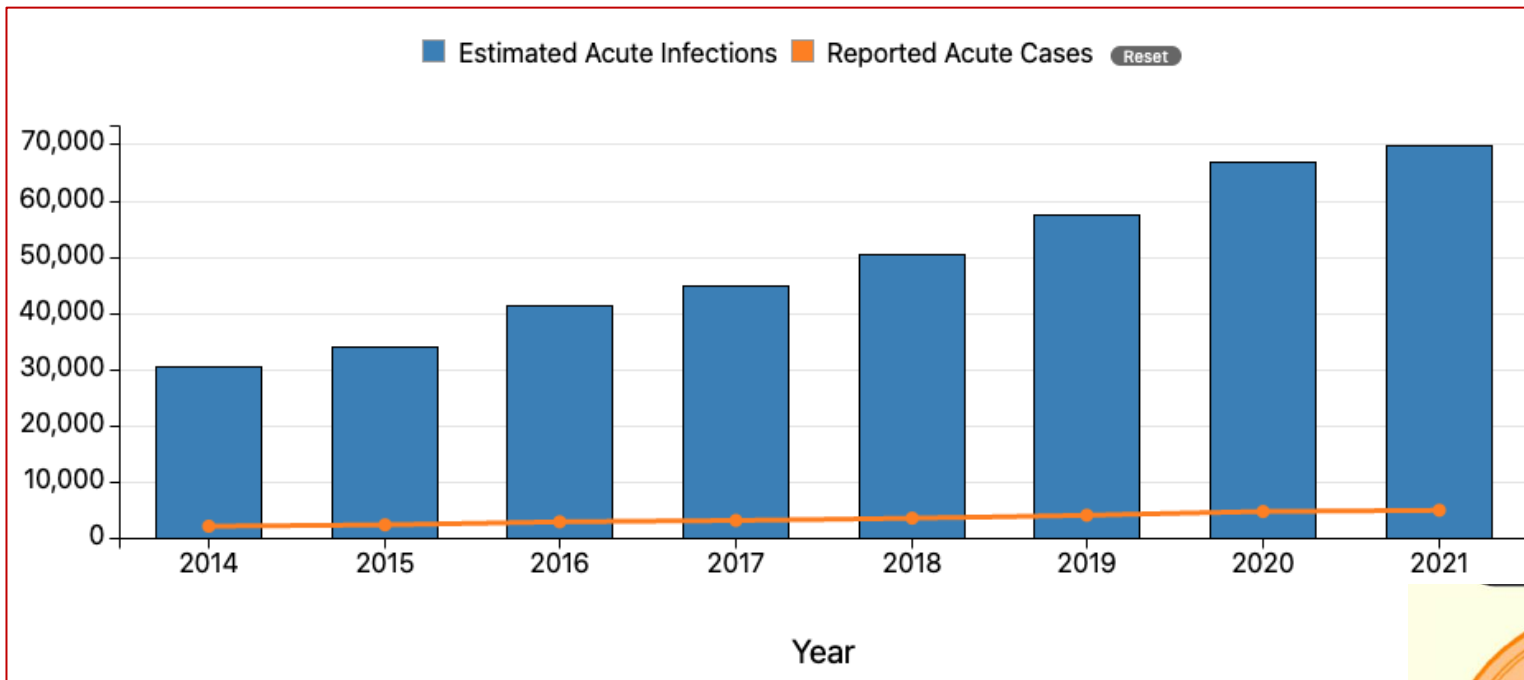
Clinical Course

- Acute infection is often asymptomatic
- Many people clear the virus without meds (50%?)
- **The clinical effects and time course are highly variable**
- **Many people with chronic HCV will develop cirrhosis, liver cancer, liver failure, and death**
- Extrahepatic manifestations also occur such as kidney damage, vasculitis, lymphoma, rash, & others



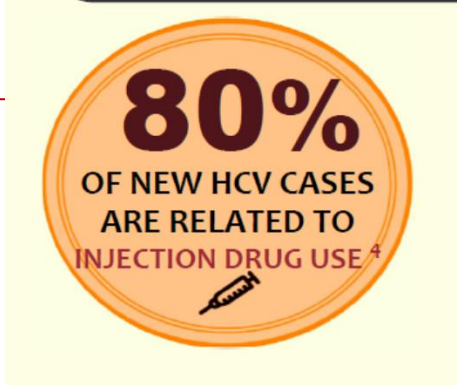
Nature Reviews | Immunology

Transmission Has Increased Significantly in the Past 10 Years



2022
67,000
acute cases
(estimated)

Highest in age groups: 20-29 (2.5/100k) and 30-39 (3.5/100k)



Prevalence of Hep C Remains High

- Globally around 57 million, 0.7%
- US around 2.5 million, 1%



It is estimated that **40 – 74% of people who inject drugs are infected with HCV.** Treatment reduces the risk of ongoing disease transmission. It is impossible to eliminate HCV without addressing the epidemic in this population.

HCV causes more deaths in the U.S. than all other reportable infectious diseases **combined**

(except/after COVID-19)

National HIV Behavioral Surveillance



- Developed and funded by the Centers for Disease Control and Prevention (CDC) to monitor selected behaviors and prevention services among populations disproportionately affected by HIV



19 Metropolitan Statistical Areas (MSAs): selected by high prevalence of HIV

NHBS Denver Hepatitis C Questions

Have you ever been tested for Hep C?

	2018 (n=586)	2022 (n=277)
Yes	507 (87%)	230 (83%)

Have you ever been told you have Hep C?

	2018 (n=507)	2022 (n=230)
Yes	235 (46%)	136 (59%)

Have you ever taken medicine to treat Hep C?

	2018 (n=272)	2022 (n=136)
YES	45 (17%)	50 (37%)

Are you interested in taking medicine to treat Hep C?

	2018 (n=218)	2022 (n=89)
YES	164 (75%)	58 (65%)

National website

<https://www.cdc.gov/hiv/statistics/systems/nhbs/index.html>

Denver website

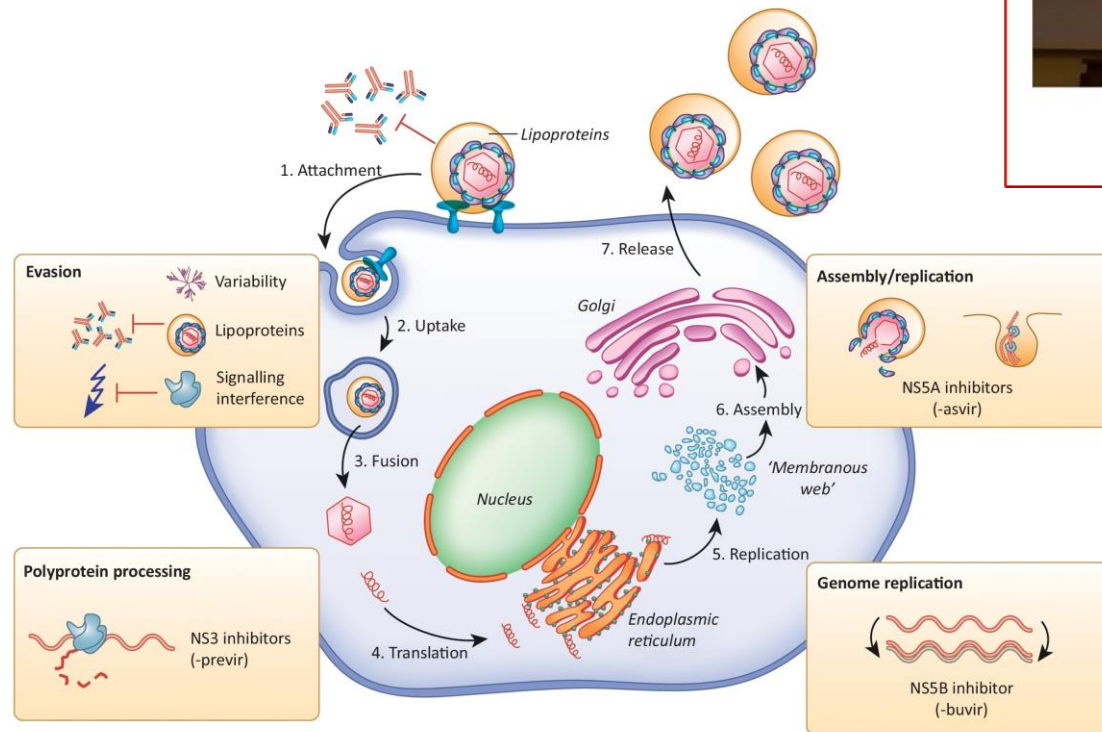
<https://www.phidenverhealth.org/clinics-services/hiv/research/nhbs>

Alia Al-Tayyib, PhD
alia.al-tayyib@dhha.org



The Good News

- Hep C is easily curable!
- How could that be?



Trends in Microbiology

Nobel Prize for Medicine goes to Hepatitis C discovery

5 October 2020

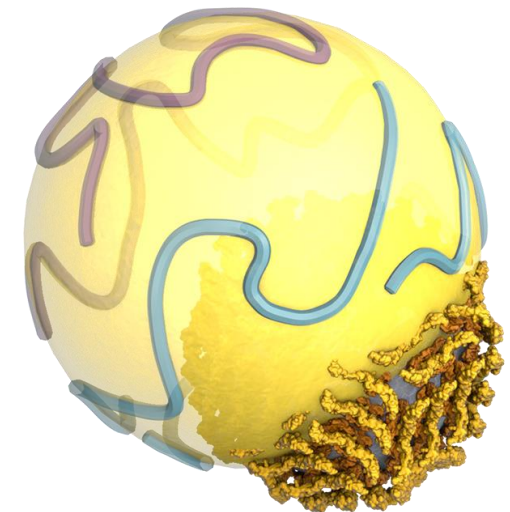
By James Gallagher, Health and science correspondent

Share



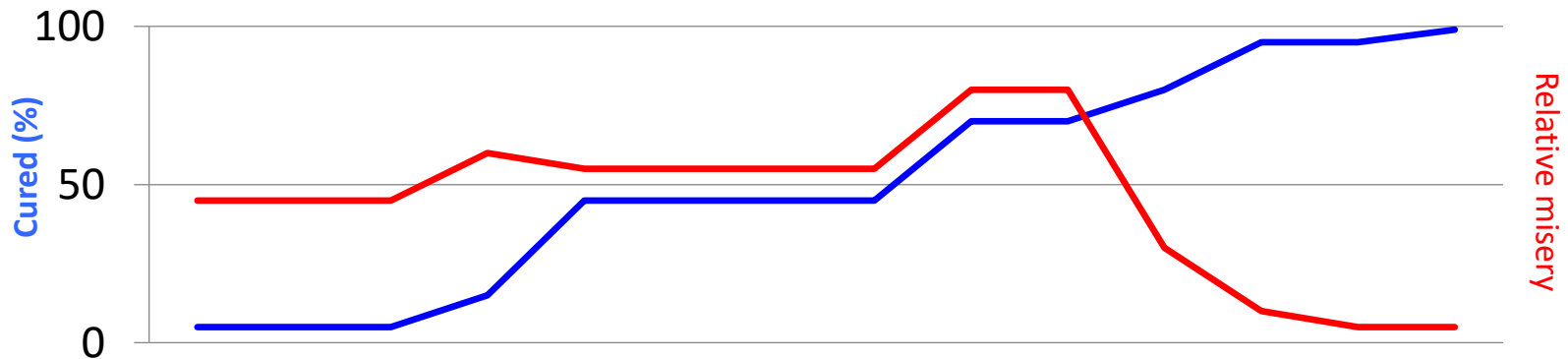
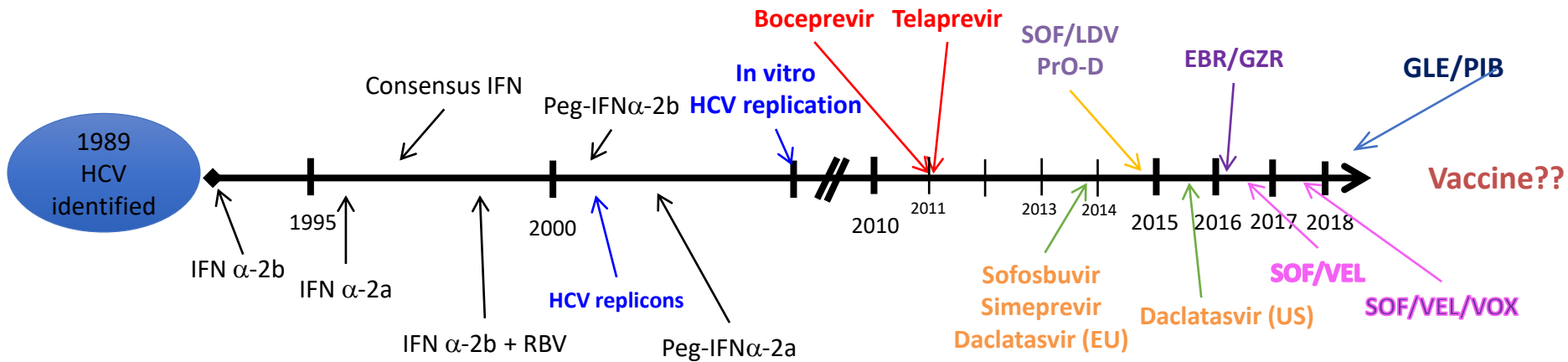
The announcement was made at a press conference at the Karolinska Institute in Stockholm, Sweden

Three scientists who discovered the virus Hepatitis C have won the 2020 Nobel Prize in Medicine or Physiology.

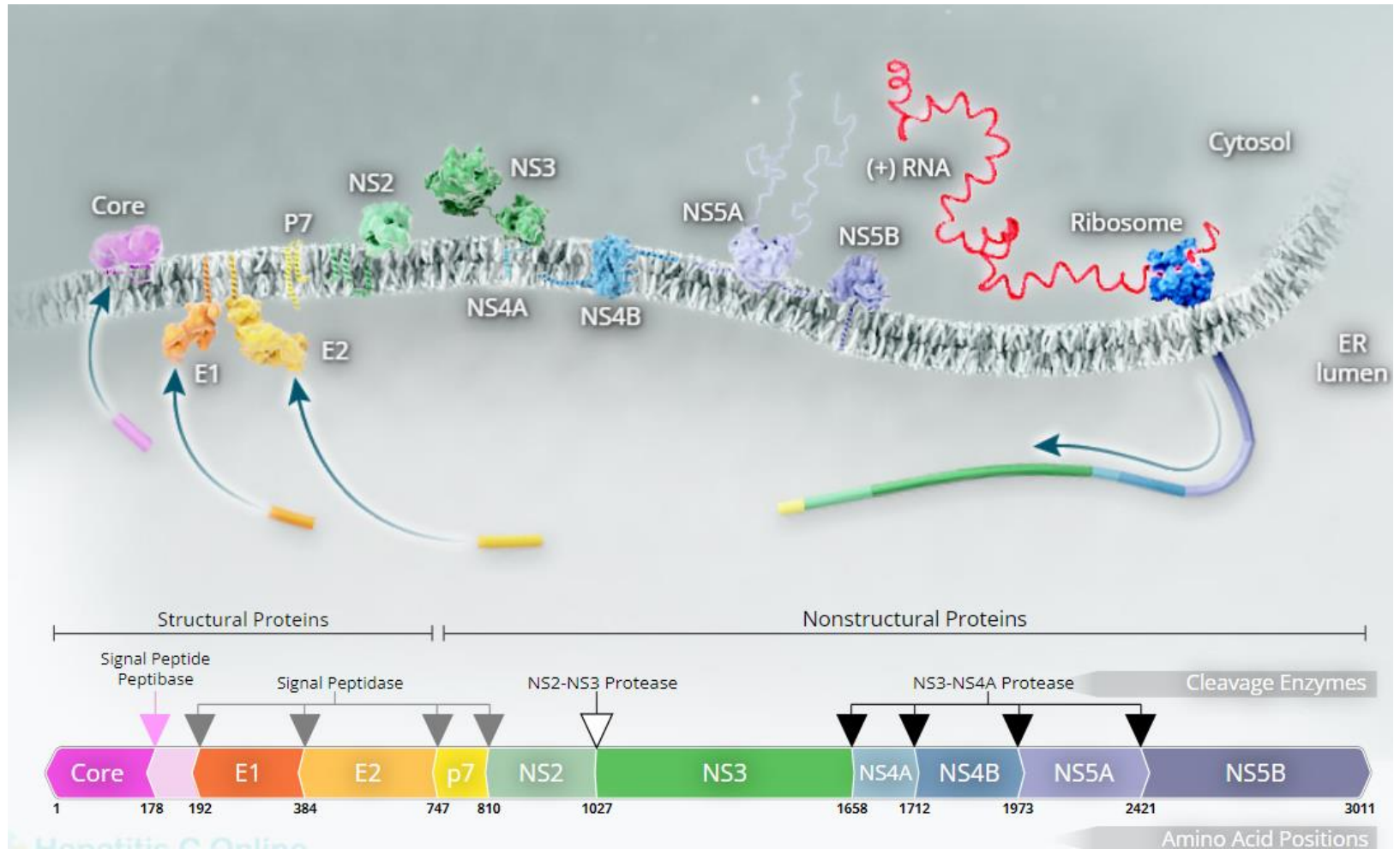


Pietschmann and Brown 2019

HCV Therapeutics Timeline



Proteolytic Processing



Hep C Direct Acting Antivirals No Bad Options



Hepat

1 pill daily X 12 weeks



3 pills daily X 8 weeks

HCV MEDICATIONS

Recommended Regimens

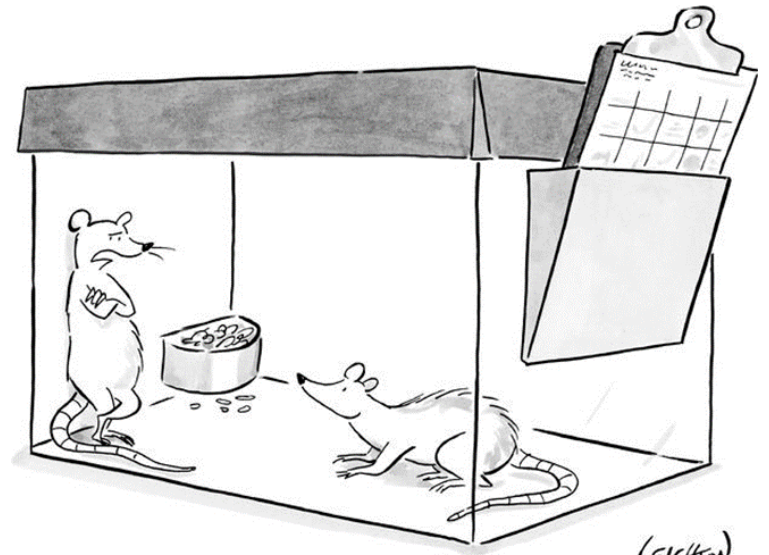
- Epclusa (sofosbuvir-velpatasvir)
- Mavyret (glecaprevir-pibrentasvir)
- Harvoni (sofosbuvir-ledipasvir) (GT1 and 4 only)

All regimens are highly effective: >95% cure rates

Sustained Virologic Response 12 Weeks after the End of Treatment = SVR12 = CURE!

SIDE EFFECTS

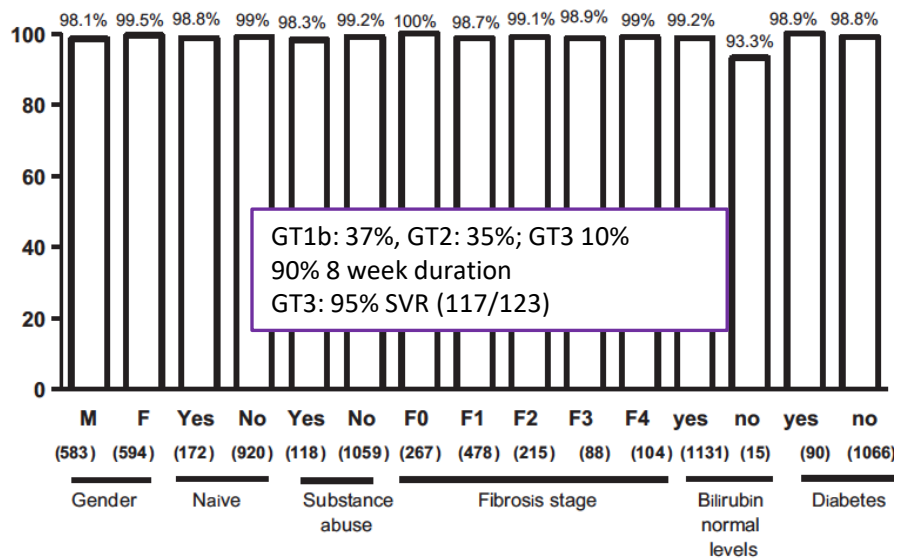
- Headache (13-22%)
- Fatigue (11-15%)
- Nausea (7-9%)
- Diarrhea ($\leq 3\%$)



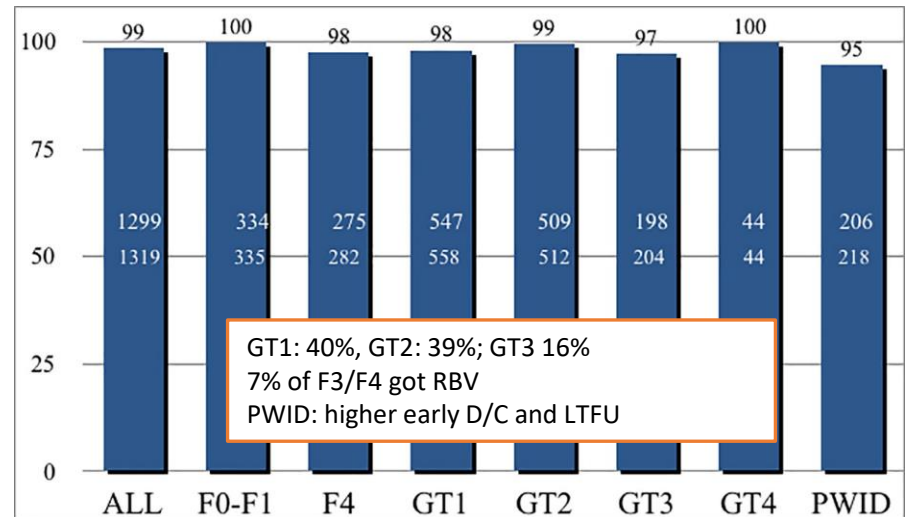
"I hope you work out better than my last roommate. He had backaches, dizziness, and an erection that lasted four hours."

Real-world Efficacy Studies

MISTRAL Cohort (n=1177): GLE/PIB 8-12 weeks



Puglia registry (n=1319): SOF/VEL 12 weeks



HCV Treatment Payment Options

- Medicaid coverage varies by state
- Many state Medicaid programs have eliminated prior authorizations
- Medicare will cover most/all patients but often requires prior auth
- Commercial insurance varies in requirements
- Gilead Support Path & My AbbVie Assist provide cost assistance



39 Hepatitis C Prior Authorization

Prior Authorization No Longer Required for First-Line Preferred Medications Prescribed for Initial Treatment of Hepatitis C.

40 Effective January 1, 2023, prior authorization is **not required** for preferred products prescribed for initial treatment of Hepatitis C. Prior authorization will continue to be required for non-preferred drugs or retreatment regimens. Requests may be submitted by phone, fax, or electronically using the standard [prior authorization request form](#).

Pretreatment Labs

Required

- HCV RNA
- CBC
- LFTs
- Hep B Surface Antigen
- Urine HCG

Recommended

- HCV genotype
- Hep A total Abs
- Hep B core AB and surface AB
- HIV 4th gen

Vaccines

- PCV20
- Hep A and B

Additional Labs

On treatment

- None

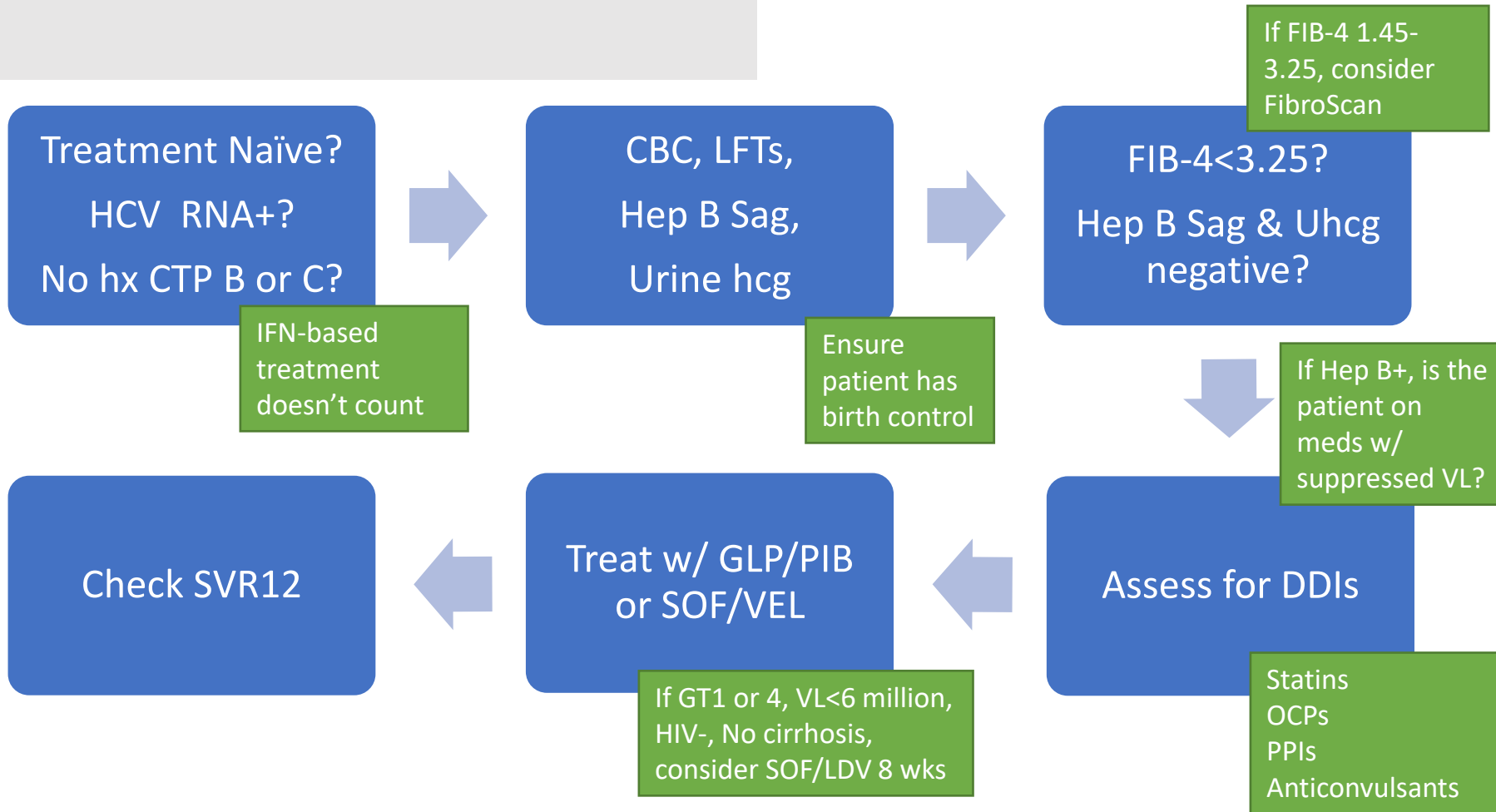
12 weeks after treatment

- HCV RNA
- LFTs
- **HCV RNA 0 = SVR12 = CURE**

Ongoing

- Yearly HCV RNA if risk factors
- If cirrhosis
 - Q6 month US
 - Esophageal varices screening

HCV Treatment



ACTG A5360 (MINMON)

Study Design and Setting

- Phase IV
- Open-label
- Multi-country
 - Brazil, South Africa, Thailand, Uganda, United States*
- Single-arm trial
- 400 participants
- 38 ACTG (DAIDS-certified) sites
- All participants received fixed-dose SOF (400mg)/VEL (100mg) one tablet once daily for 12 weeks

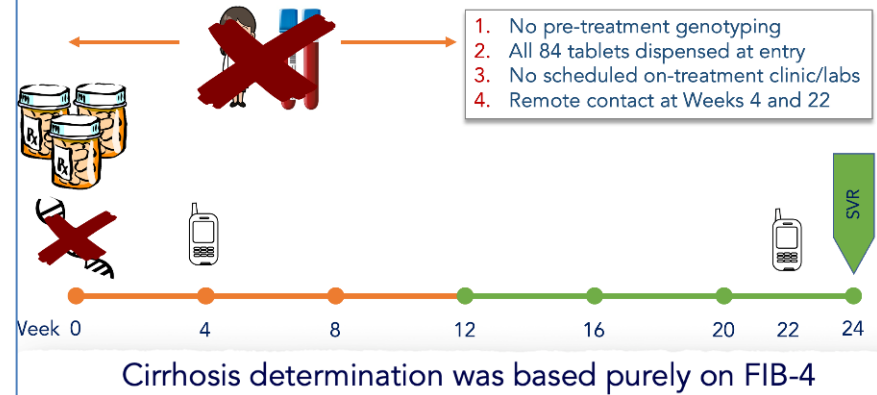


*Recruitment at US sites limited to 132 participants

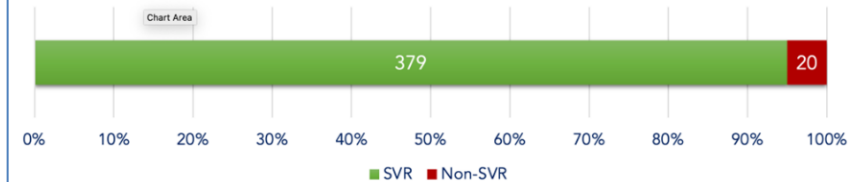


- 399 started therapy
- Cirrhosis 34 (9%)
 - HIV co-infection 166 (42%)
 - 99% on cART HIV RNA <400

The "MINMON" Approach



- HCV RNA data at SVR were available for 396/399 participants
 - 383 samples collected at Week 24 (-2/+4 weeks)



Sustained virologic response: 95% (95% CI: 92.4, 96.7)

Hep C Old Way versus New Way

OLD WAY

- Confirm chronic infection
- Assess for fibrosis w/ a liver biopsy
- Treat if evidence of fibrosis
- WAIT: Make sure your patients stop drinking and using drugs (Utox before referral)
- WAIT: Make sure your patients have a PCP and do not have uncontrolled mental illness before treating HCV



NEW WAY

- Treat acute Hep C
- Assess for cirrhosis w/ blood tests, DO NOT order a liver biopsy
- Treat Hep C regardless of amount of liver damage
- DON'T WAIT: Cure Hep C ASAP, esp for people who use alcohol or drugs
- DON'T WAIT for patients to get their lives in order. Treat Hep C when the opportunity presents itself and patients want treatment.

"This ain't Texas. Ain't no hold em." ~Beyoncé

Logistics



PHONE A FRIEND,
SUBMIT AN ECONSULT
FOR HCV TO DOUBLE
CHECK YOUR PLAN IF
NEEDED



SET A REMINDER IN
FOR WHEN SVR LABS
WILL BE DUE, 4 OR 12
WEEKS AFTER EOT



ENCOURAGE PATIENTS
TO CALL THE CLINIC OR
THE PHARMACY IF THEY
ARE HAVING SIDE
EFFECTS



CHECK WITH
PHARMACY ABOUT
MAILING MEDS



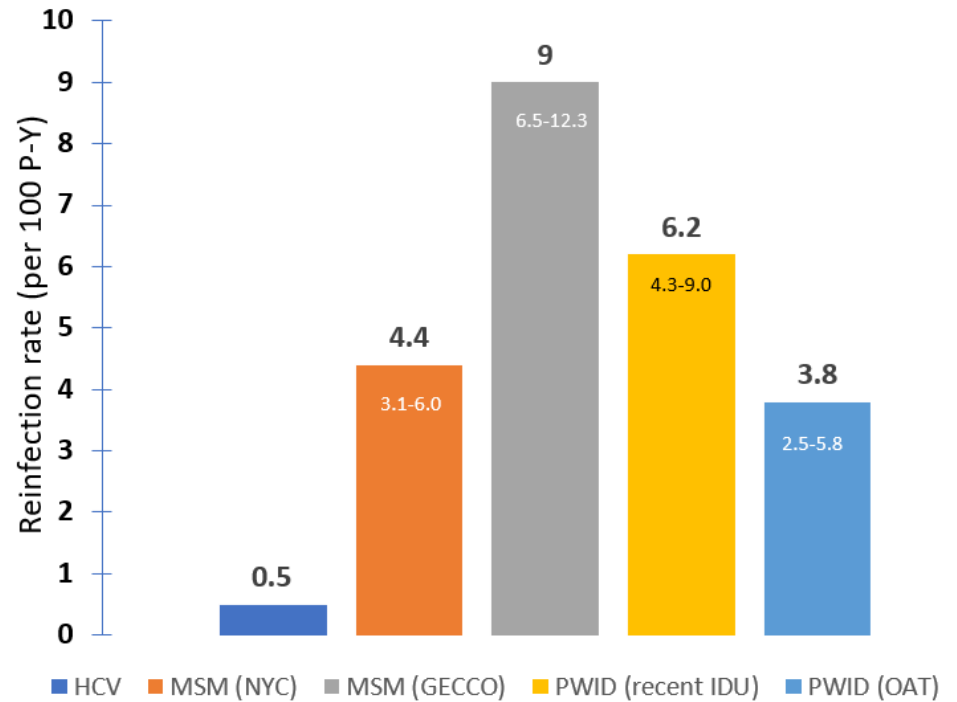
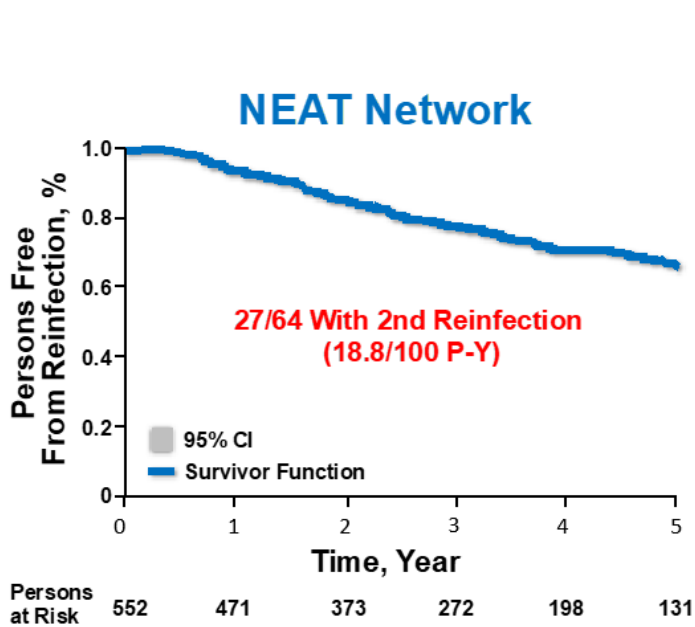
WHAT TO DO ABOUT
MISSED DOSES

Counseling: Liver Health

- Alcohol
- Obesity
- Diabetes
- Smoking
- Medications
- Herbals & Supplements
- Transmission

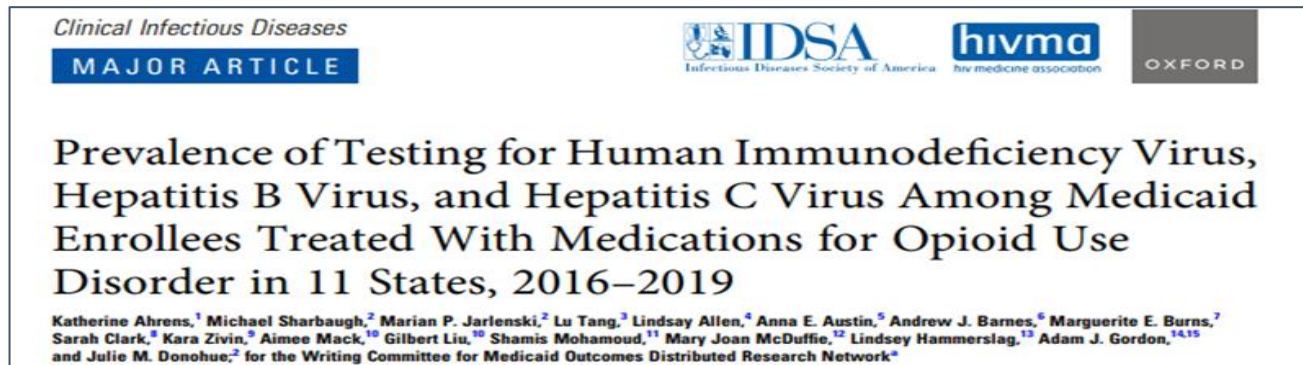


HCV RE-INFECTION IS RELATIVELY RARE. RETREATMENT IS SIMPLE (MEDICALLY).

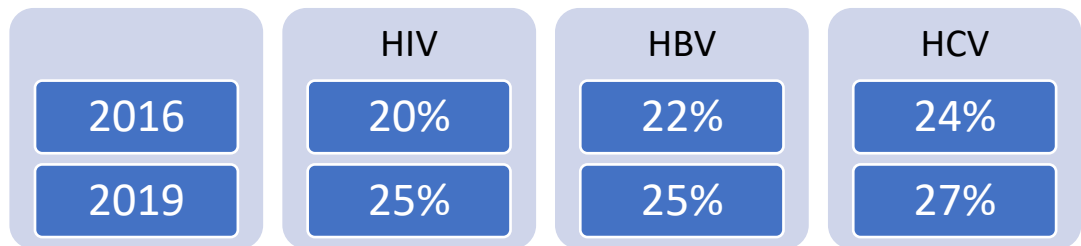


Screening for re-infection requires HCV RNA testing

Despite how simple and effective hep C treatment has become, we are still not reaching people who need it the most.



- Only 27% of 360,000 individuals starting OUD treatment were tested for HCV in 2019



Initiation of Hep C Treatment for PWID is Low



Navigation is Superior to Clinician Referral for Linkage to HCV Care

Sarah E. Lyle, Robert...

BACKGROUND

Emergency departments (EDs) serve clinical settings for hepatitis C (HCV) and care, yet optimal methods of linkage for HCV-diagnosed individuals remain unclear.

We aimed to test the effectiveness of navigation (LN) and clinician referral (CR) for ED patients identified with untreated HCV. Our primary hypothesis was that LN plus CR would be superior to CR alone.

METHODS

Design & Setting: Prospective two-group comparative effectiveness research at Denver Health Medical Center (DHMC) ED patients with untreated HCV.

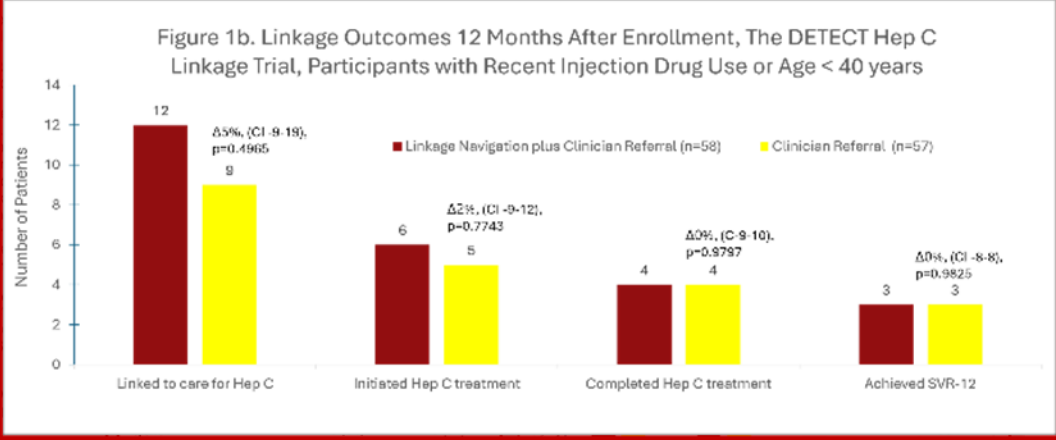
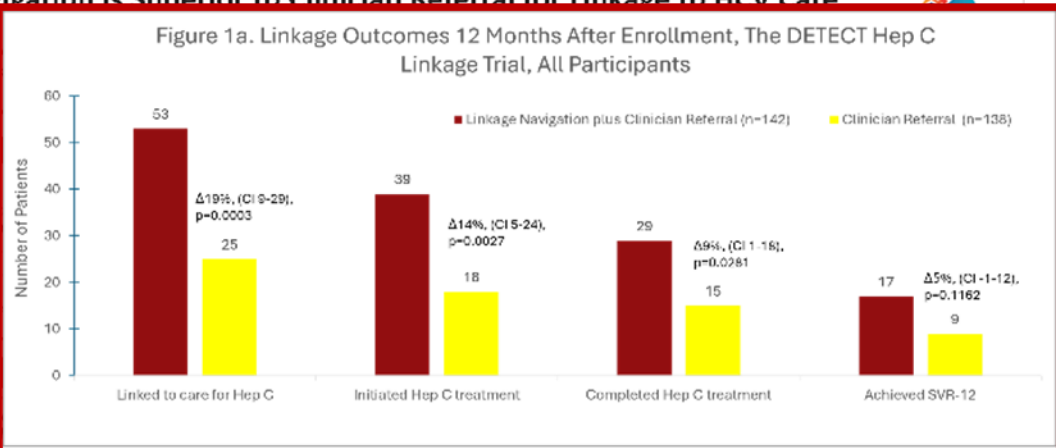
Population: Patients ≥ 18 years of age at DHMC ED with evidence of untreated HCV.

Exclusions: Critical illness, inability to reside out of state, pregnancy, or other conditions.

Interventions: Participants randomized to LN or CR. In the LN arm, individuals were educated about HCV by their primary care clinician and given information to access care verbally and in discharge instructions. Individuals in the LN arm met with a navigator in the ED or by phone after enrollment. In the CR arm, individuals received reiterated basic HCV education, help with insurance, and facilitated HCV treatment appointment.

Outcomes: **Primary** - Initiation of HCV treatment. **Secondary** - Appointment with an HCV specialist, completion of treatment, and sustained virologic response 12 weeks after treatment (SVR-12) 12 months post-enrollment.

Analyses: Intention-to-treat with difference in proportions, 95% confidence intervals, and bivariate hypothesis testing.



Supported by the National Institute on Drug Abuse (R01DA042982). Contact: Sarah.Rowan@dhha.org

Abbreviations: IQR, interquartile range; ED, emergency department.

Calls for integrated SUD and HCV Care

- US Hep C Elimination Program
 - Substance use disorder treatment clinics among the sites where rapid diagnosis and prompt initiation of treatment could substantially advance efforts to eliminate hep C
- Recommendations from expert panel
 - Interventions must be implemented at settings where people who inject drugs are already accessing services.
 - Significant role for OST providers in OTPs, pharmacies, and primary care

VIEWPOINT

A National Hepatitis C Elimination Program
in the United States
A Historic Opportunity

Fleurence R, Collins F. JAMA 2023



Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo



Review

Interventions to increase linkage to care and adherence to treatment for hepatitis C among people who inject drugs: A systematic review and practical considerations from an expert panel consultation



Tanja Schwarz^{a,*}, Ilonka Horváth^a, Lydia Fenz^a, Irene Schmutterer^a, Ingrid Rosian-Schikuta^a, Otilia Mårdh^b

Examples of Successful Hep C / SUD Treatment Integration

- Denver Health Outpatient Behavioral Health

Rowan et al. JID 2020

- In 2018, HIV, HCV, HBV screening for all patients at intake was implemented
- Hep C patient navigator embedded in OTP provided education and support for linkage to treatment and treatment adherence
- 108 of 532 individuals had + HCV RNA tests
- 60 additional patients identified as previously HCV-diagnosed but not yet treated
- 69 individuals (42%) completed HCV treatment during the follow-up period

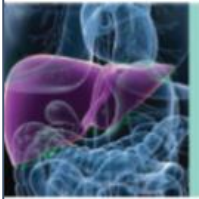
- New York State

Talal et al. JAMA 2024

- RCT at 12 OTPs -facilitated telemedicine integrated into opioid treatment programs (n = 290) vs standard-of-care off-site referral (n = 312).
- SVR12 85% vs 34%

Table 2. Hepatitis C Virus Care Cascade

	No. (%)		Log odds estimate (95% CI)
	OTP-integrated facilitated telemedicine (n = 290)	Referral (n = 312)	
Visit 1*	280 (96.6)	297 (95.2)	0.1 (-0.8 to 1.0)
Treatment initiation	268 (92.4)	126 (40.4)	2.8 (2.3 to 3.3)
Treatment completion	261 (90.0)	116 (37.2)	2.7 (2.2 to 3.1)
Sustained virologic response assessed	251 (86.6)	108 (34.6)	2.4 (2.0 to 2.9)
Observed sustained virologic response	246 (84.8)	106 (34.0)	2.3 (1.9 to 2.7)



Colocalization in Hepatitis C Virus Infection Care: The Role of Opioid Agonist Therapy Clinics

Lynn E. Taylor, M.D., F.A.A.S.L.D. *†‡☺

Clin Liver Dis 2020



FIG 1 Arud, Switzerland. Colocated HCV and OUD care: a representative model of ideal, comprehensive, whole-person health care for PWID under one roof.

Denver NHBS PWID Cycles: Where would it be easiest to receive medicine to treat your Hep C?

	2018 (n=163)	2022 (n=58)
Primary Care	59 (36%)	18 (31%)
Pharmacy	26 (16%)	7 (12%)
Specialty Clinic	17 (10%)	2 (3%)
Methadone/Suboxone Clinic	53 (33%)	12 (21%)
Syringe Access Program	Not Asked	17 (29%)

Emergency
Department?



Treating and preventing viral infections in an OTP

Treatment, harm reduction and how to integrate hepatitis services

Mountain Plains ATTC Webinar – June 26th 2024

Hermione Hurley, MBChB
Infectious Disease, Addiction Medicine

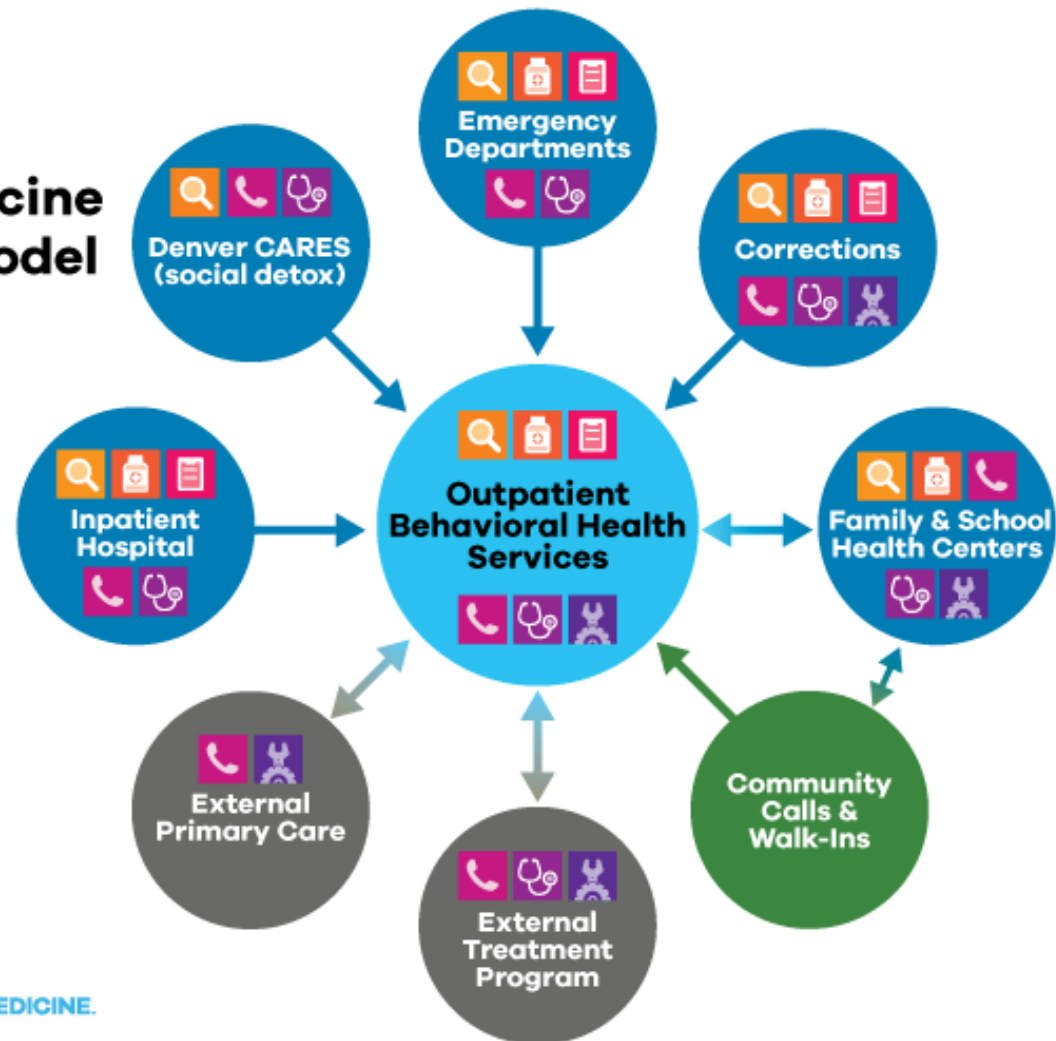


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Denver Health Center for Addiction Medicine (CAM) is based on a “Hub & Spoke Model”

Center for Addiction Medicine Hub & Spoke Model

- Identification/Diagnosis
- Opioid Induction
- Outpatient Behavioral Health Services Intake
- Referral
- Treatment
- Opioid Maintenance



The “hub” specialty clinics provide dispensed medications (OTP) and prescribed (DHARC)

Only one blood draw for intake, labs reflex quantitative

Complete blood count

Hepatic panel

Hepatitis A total Antibodies

Hepatitis B Surface Antigen, Surface Antibodies

Hepatitis C Antibodies → HCV RNA → genotype

HIV 4th generation Antibodies/Antigen → HIV viral load

Treponemal Antibodies → RPR → RPR titer

Hepatitis C is our most common blood borne infection among individuals enrolled in outpatient substance treatment.

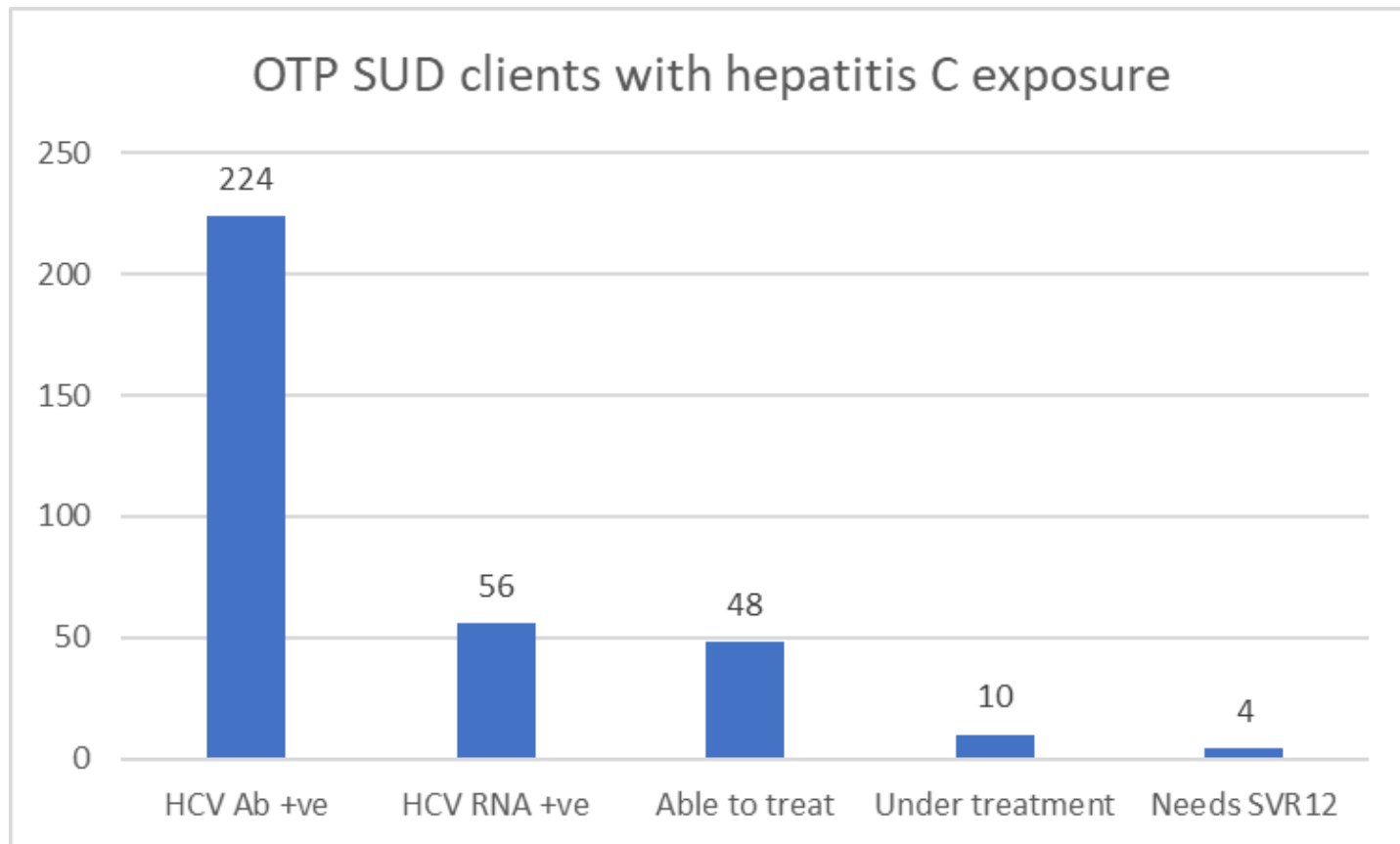
- Hepatitis C Ab +ve - 259 of 1018 (25%)
 - Hepatitis C RNA >0 – 63 of 259 (24%) (6.2% of all tested)
- HIV Ab/Ag +ve – 15 of 1018 (1.5%)
 - 14 undetectable, 1 suppressed HIV VL 36
 - 1 with concurrent HCV, in week 4 of treatment
- Hepatitis B Surface Ag +ve 3 of 1018 (0.3%)
 - None consistently on suppressive medication, 1 with HCV

HCV RNA Detectable	
Grand Total	1121
Detectable	62
Within last Month	6

Viral infection report
run on 06/24/24

Outpatient Treatment Program (OTP)

631 with intake labs, 224 (35%) hepatitis C Ab +ve



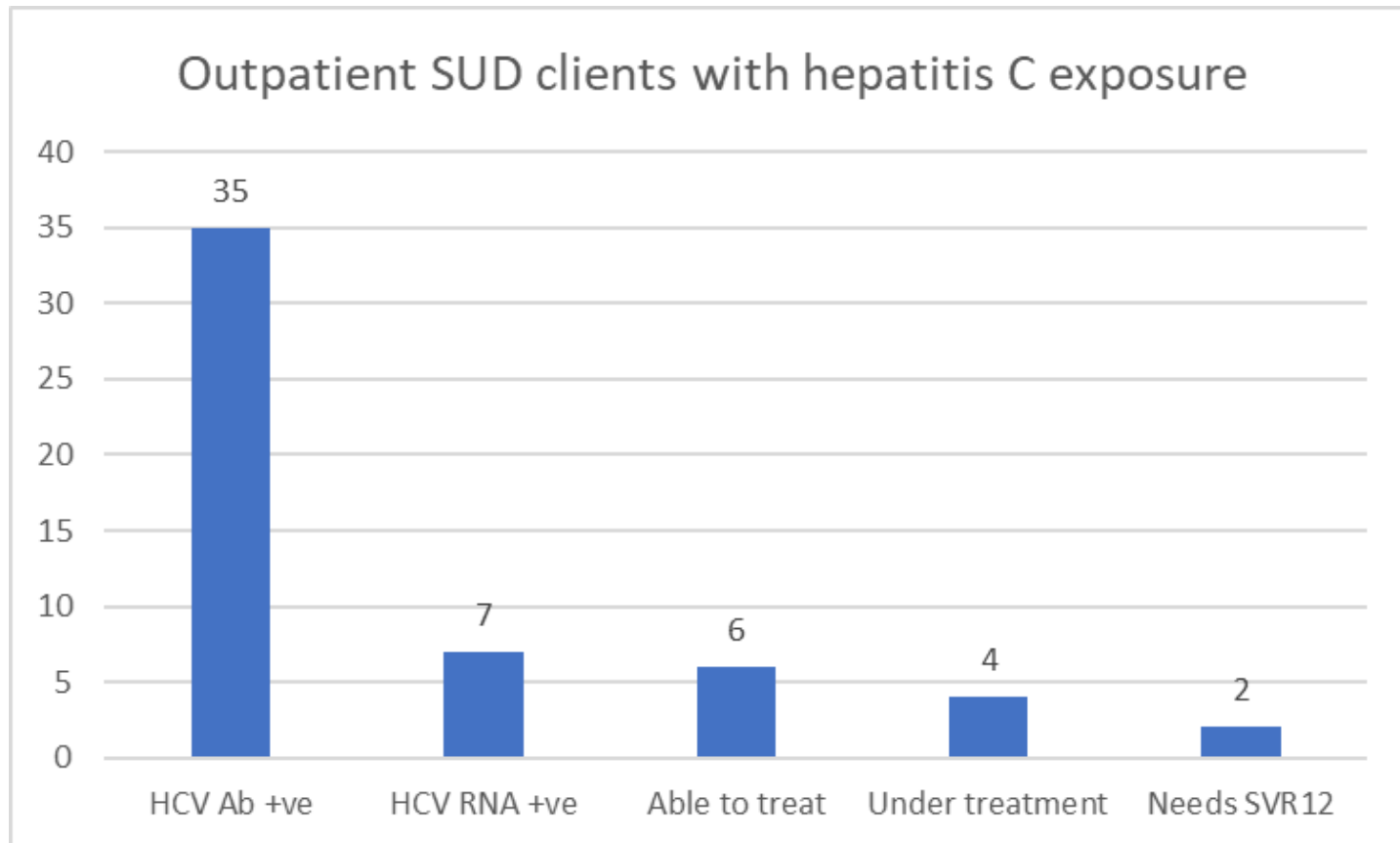
4 no longer in care, 2 incarcerated in jail, 2 pregnant, 2 died prior to treatment



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Denver Health Addiction Recovery Center (DHARC)

387 with intake labs, 35 (9%) hepatitis C Ab +ve



1 no longer in care



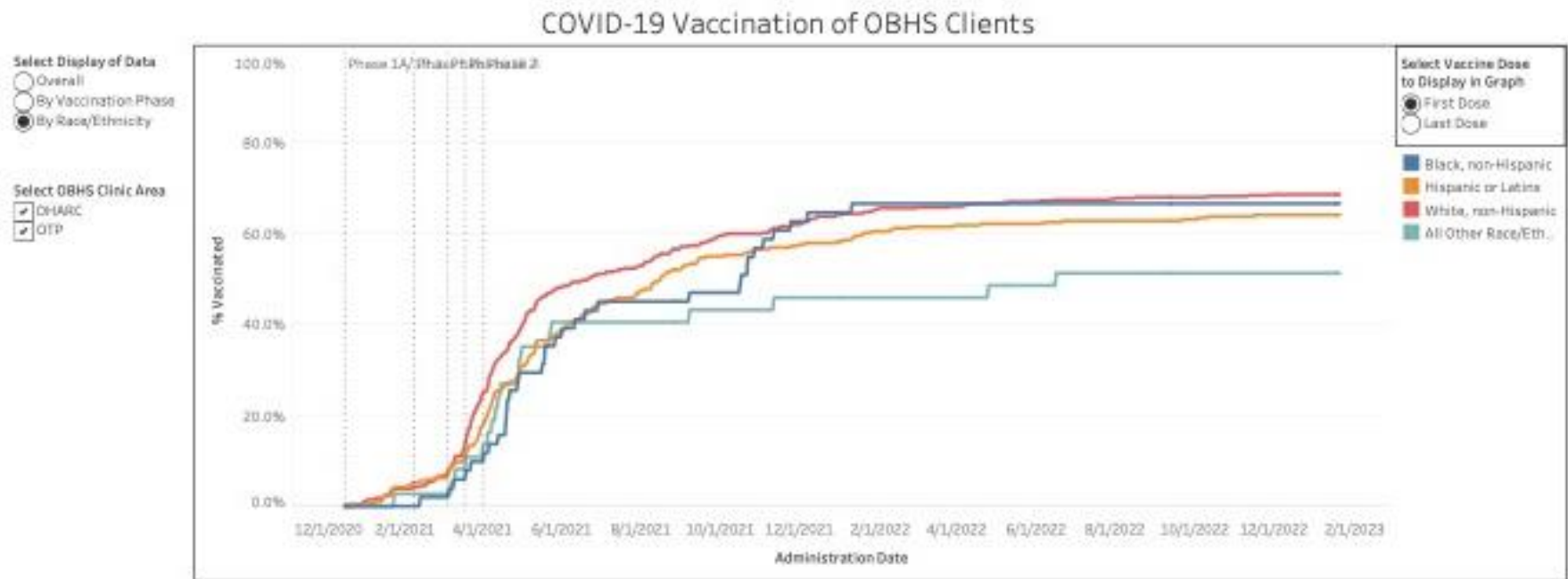
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We offer collocated vaccinations

Vaccine	Everyone with substance use disorder	Person who injects drugs	Person who experiences homelessness	Young people Transactional sex work, MSM	Elderly or people who smoke
COVID-19	●				
Influenza	●				
Hep A	●	●	●		
Hep B	●	●	●		
Tdap/Td		●	●		
MenACWY/B		●	●		
HPV				●	
PCV20					●

Adapted from AICP 2023 recommendations

Vaccines accepted in trusted clinical environment, respects time of clients



Targeted outreach by non provider staff closed race and ethnicity gaps

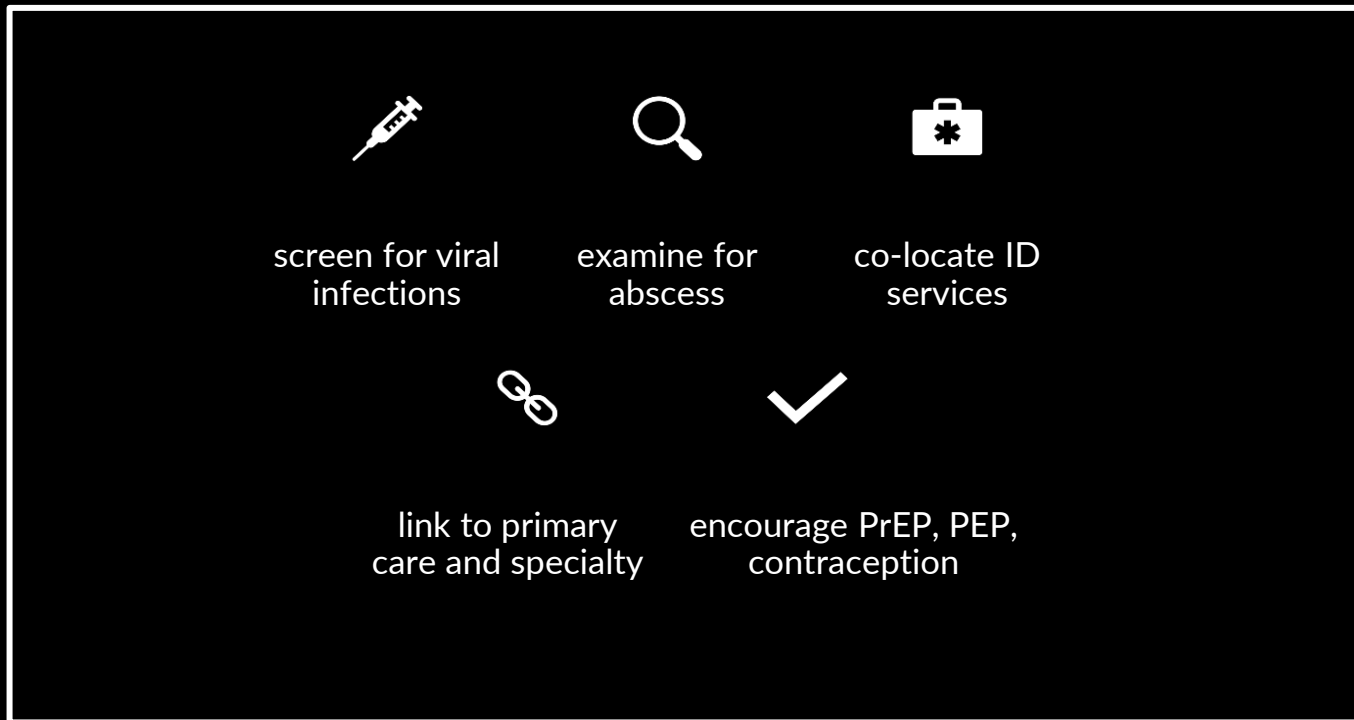
Top tips to treating viral infections in outpatient substance clinics

- Intake labs with single blood draw are critical
- Embedded care navigators increase treatment
- Insurance or lack thereof can complicate medications
- Find the window of opportunity to treat
- Involve counselors include engagement as treatment
- OTP dispensary can assist with medication delivery

Barriers to treating viral infections in outpatient substance clinics

- Most people are not ready if still in withdrawal
- The quality of your care navigator is critical
- Substance treatment is often run by psychiatry not medicine
- Be careful to decouple offerings, non punitive approach
- Many clients know people treated in difficult interferon times
- Some clients may be cautious about potential for reinfection

Remember five strategies - you can make a start



Provide infectious disease treatment at SUD clinics

Thank you

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**HEP C TREATMENT
HAS CHANGED**

~~24-48 weeks~~ **8 weeks**

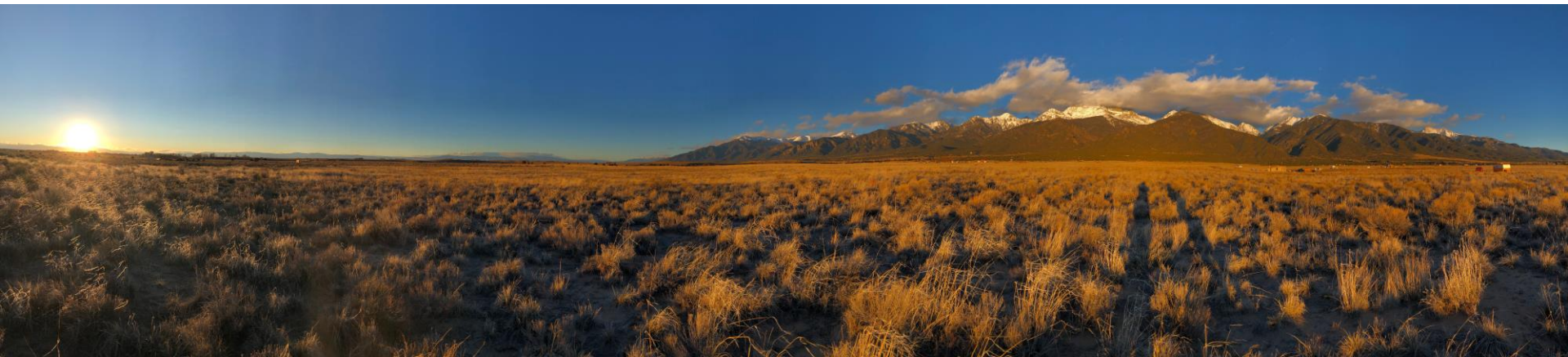
~~Sobriety~~ **not** required

~~30-50% effective~~ **95% effective**

~~I'm afraid to~~ **Get treated today**

Call 303-602-4215
to get started.

 **DENVER
PUBLIC HEALTH.**
denverpublichealth.org/hepc



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