Hepatitis C Treatment: Meeting Our Patients Wherever They Are

Focus Session

Sarah E. Rowan, MD, Ruth Kanatser, Kevin Kamis, MPH, Hannan Braun, MD

American Society of Addiction Medicine, Annual Meeting, April 2025

Disclosure Information

- Sarah E. Rowan, MD, Public Health Institute at Denver Health
  - No Disclosures
- Ruth Kanatser, Harm Reduction Action Center
  - No Disclosures
- Kevin Kamis, MPH, Public Health Institute at Denver Health
  - No Disclosures
- Hannan Braun, MD, Denver Health, Division of General Internal Medicine and Outpatient Behavioral Health Services
  - No Disclosures

Learning Objectives

- Explain and discuss the simplified approach to hepatitis C testing and treatment as recommended in the U.S. national guidelines.
- Describe nontraditional settings for HCV treatment that increase access for people who use drugs.
- Analyze the challenges of nontraditional approaches and conceptualize solutions to enable implementation of new HCV programs.
- Reflect on patient stories and perspectives on their HCV treatment experience.

Introductions

Hepatitis C: Quick Overview

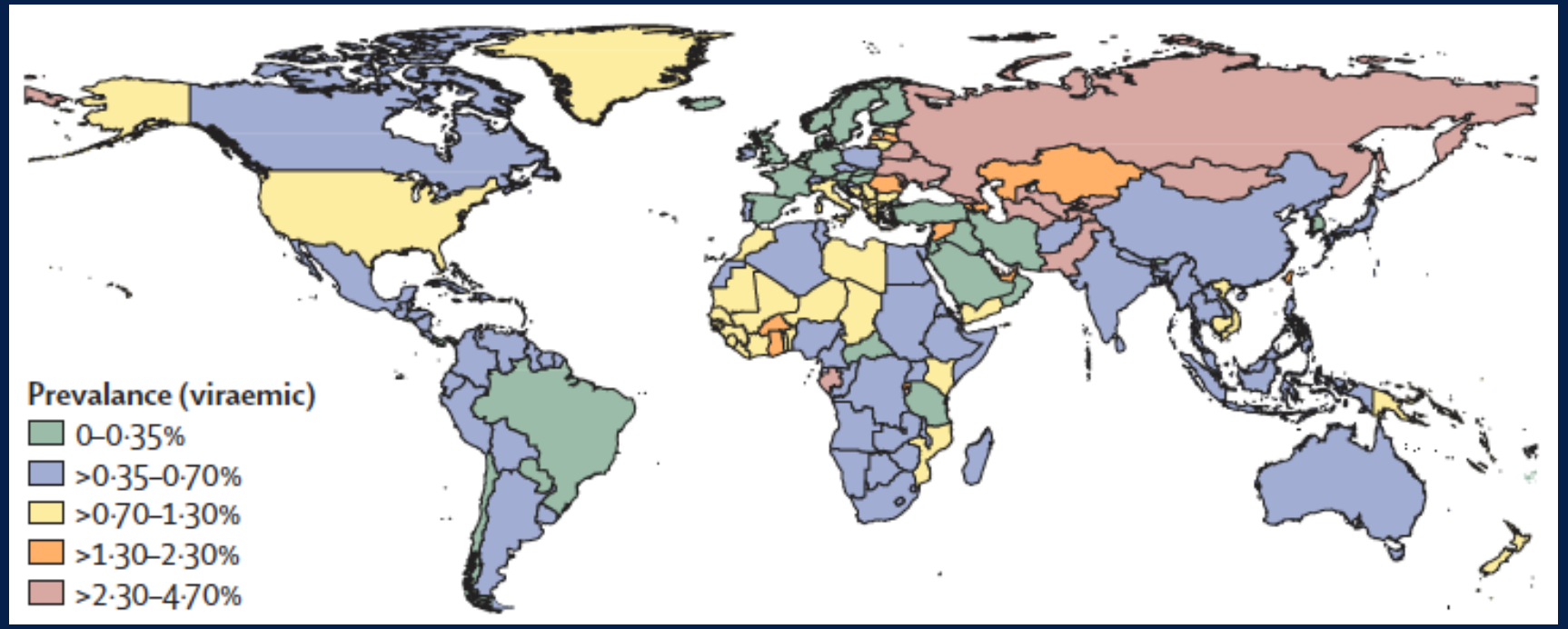
- Epidemiology
- Clinical Characteristics
- Simplified Approach to Treatment

Image: SE Rowan

Global HCV Prevalence: 0.7% (57 million)

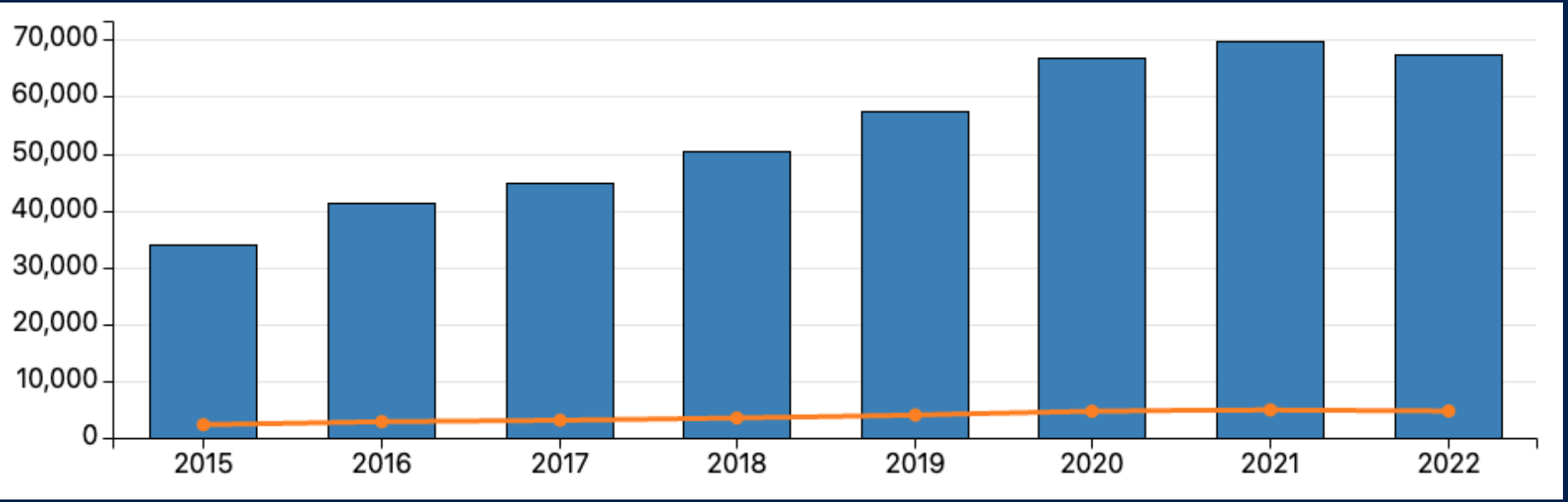
2.5-4 million in U.S. living with HCV

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



Ly R, et al. Clin Infect Dis 2016; Polaris Observatory Collaborators . Lancet Gastroenterol Hepatol 2022.

Incident HCV in the US



	2015	2016	2017	2018	2019	2020	2021	2022
Reported acute cases	2,436	2,967	3,216	3,621	4,136	4,798	5,023	4,848
Estimated acute infections	33,900	41,200	44,700	50,300	57,500	66,700	69,800	67,400

95% CI: 53,300-229,800

New chronic HCV infection diagnosed in 2022: 93,805

2022 CDC Viral Hepatitis Report; CDC 2024

Increased potential for vertical HCV transmission

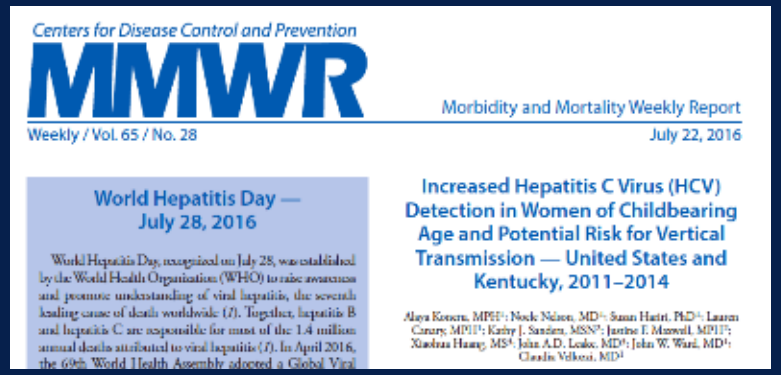
5.8 %

Perinatal Transmission if HCV monoinfection

12%

Perinatal Transmission if HCV-HIV coinfection

Persons of child-bearing potential wishing to become pregnant are a priority group in the AASLD/IDSA guidelines



Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Weekly / Vol. 65 / No. 28 July 22, 2016

World Hepatitis Day — July 28, 2016

Increased Hepatitis C Virus (HCV) Detection in Women of Childbearing Age and Potential Risk for Vertical Transmission — United States and Kentucky, 2011–2014

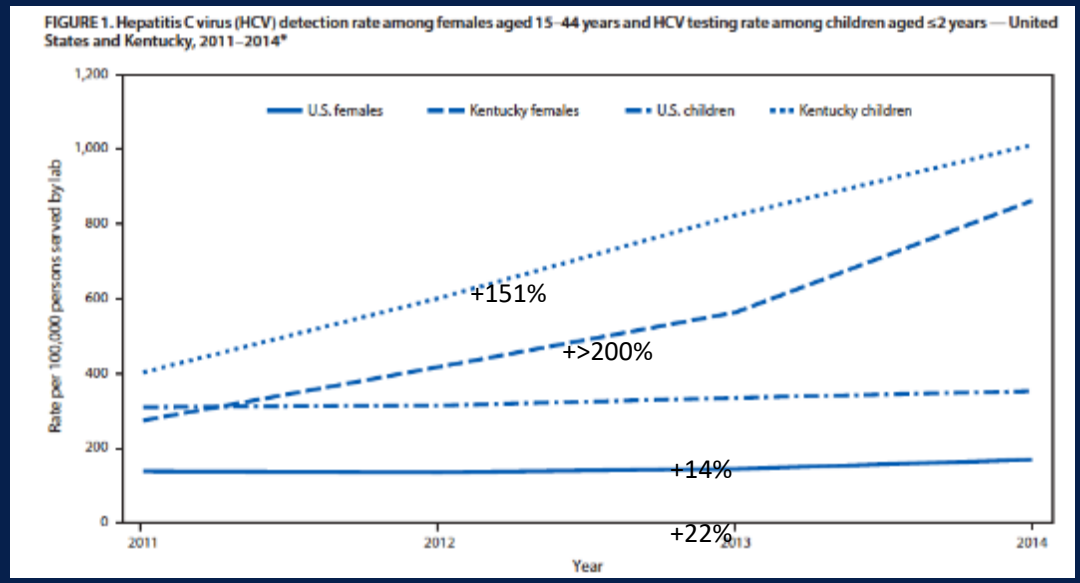


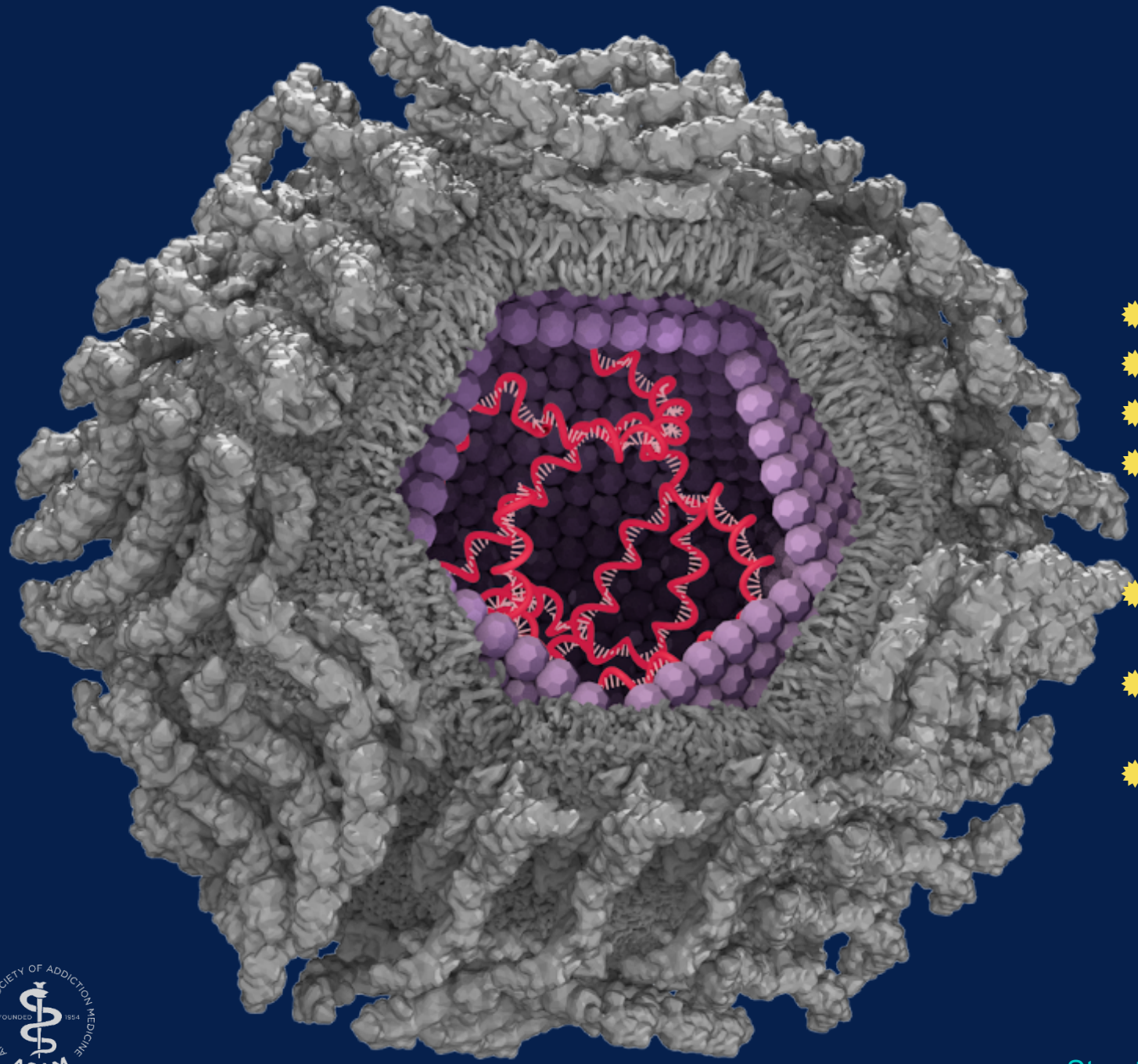
FIGURE 1. Hepatitis C virus (HCV) detection rate among females aged 15–44 years and HCV testing rate among children aged ≤2 years — United States and Kentucky, 2011–2014*

124% increase in infants born to HCV-positive persons

Audience Questions

- Do you treat HCV in your practice?
- What questions do you have about Hep C treatment?

- Discuss with a colleague for 2 minutes.



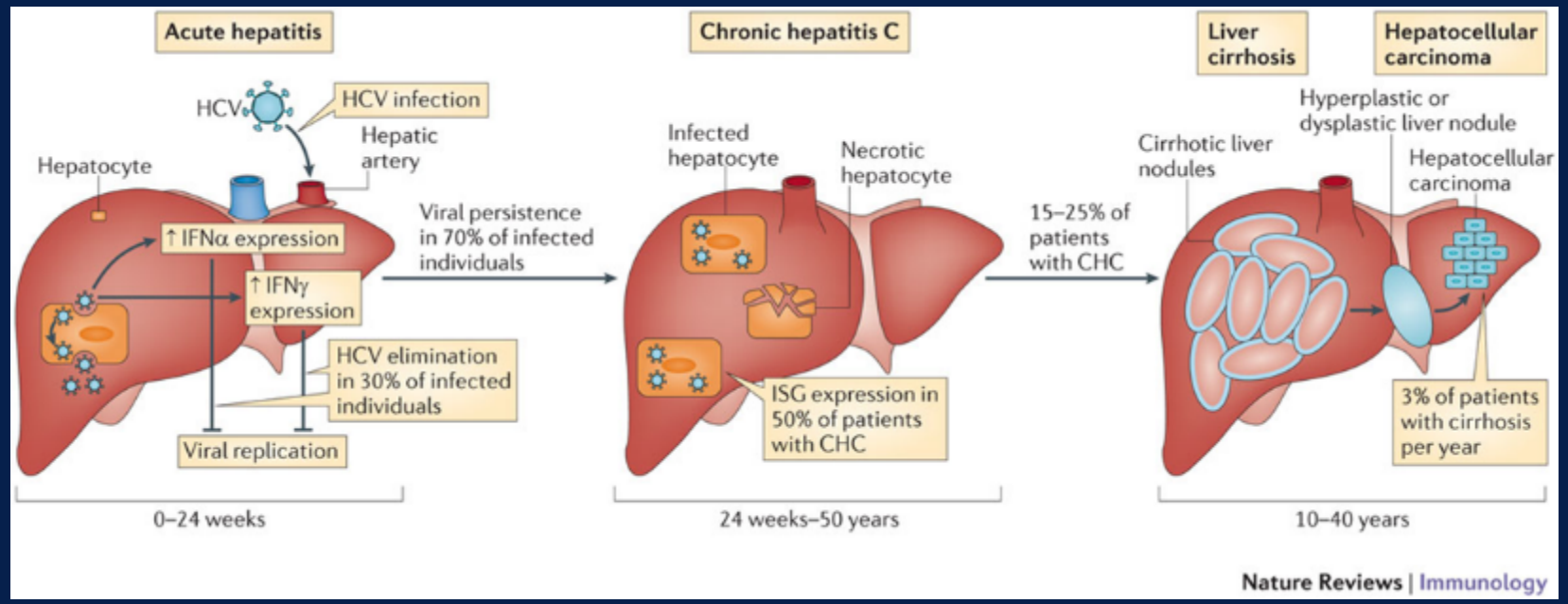
What is Hep C?

- RNA virus
- 7 genotypes
- Blood borne pathogen
- Replicates in hepatic cells and peripheral blood mononuclear cells
- Constitutively active (no latency)
- First identified in 1989; blood supply testing began in 1992
- May survive outside human host on injection equipment for several days

Structure - HCV Biology - Hepatitis C Online (uw.edu)

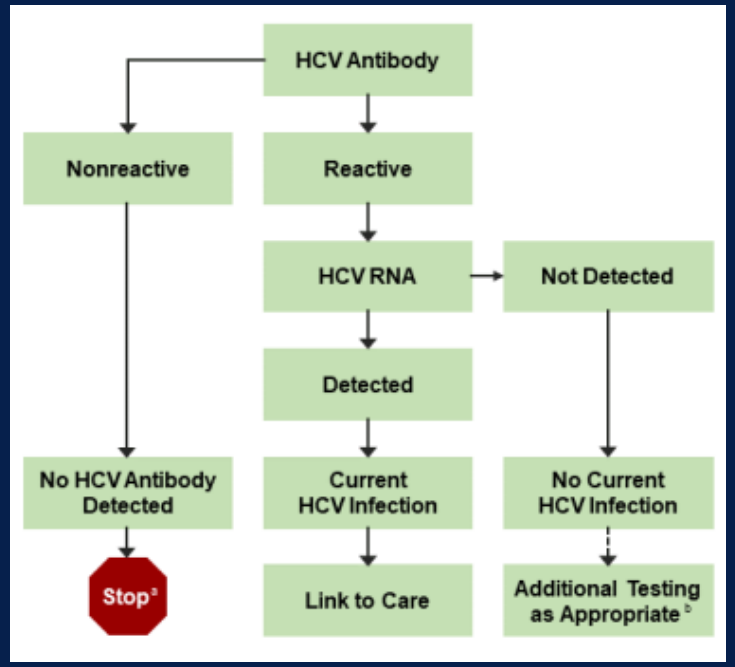
Clinical Course

- 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, HCC, ESLD, and death**
- Extrahepatic manifestations also occur



Seeff LB. Hepatology. 1997

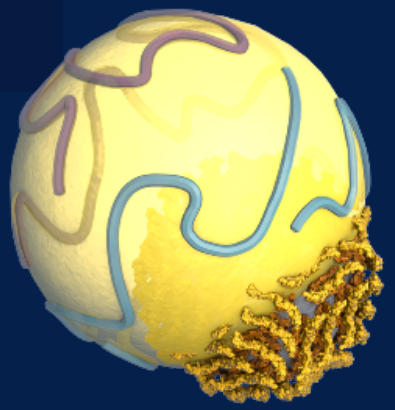
Testing Considerations



- USPSTF 2020 → All adults should be screened for HCV at least once, regardless of risk factors
- CDC 2020 → All pregnant persons should be screened for HCV unless local prevalence is <0.1% *(all states have prevalence rates >0.1%)*
- Best Practice: Reflex testing +AB→ RNA
- Test directly for RNA in the following cases
  - Prior HCV clearance, testing for reinfection
  - Concern for acute HCV; Ab may not appear for 6 mo
  - Immunocompromised

cdc.gov

The good news: HCV is easy to cure!



Nobel Prize for Medicine goes to Hepatitis C discovery

5 October 2020

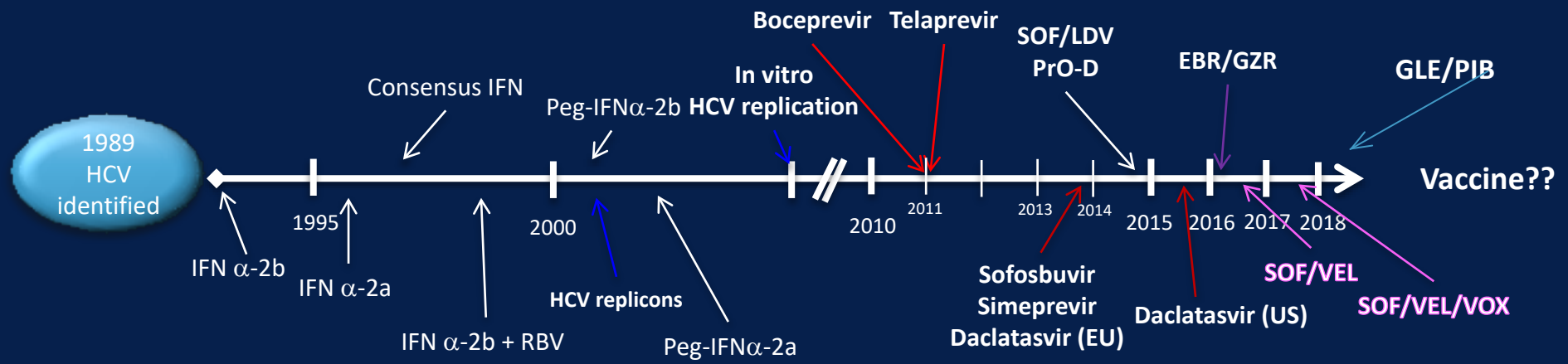
Share

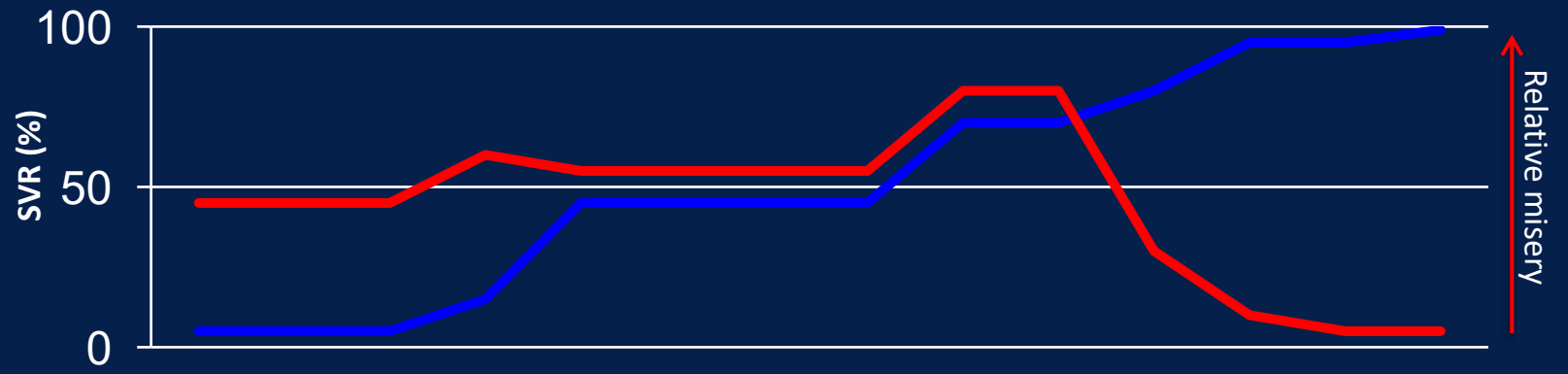
By James Gallagher, Health and science correspondent

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.

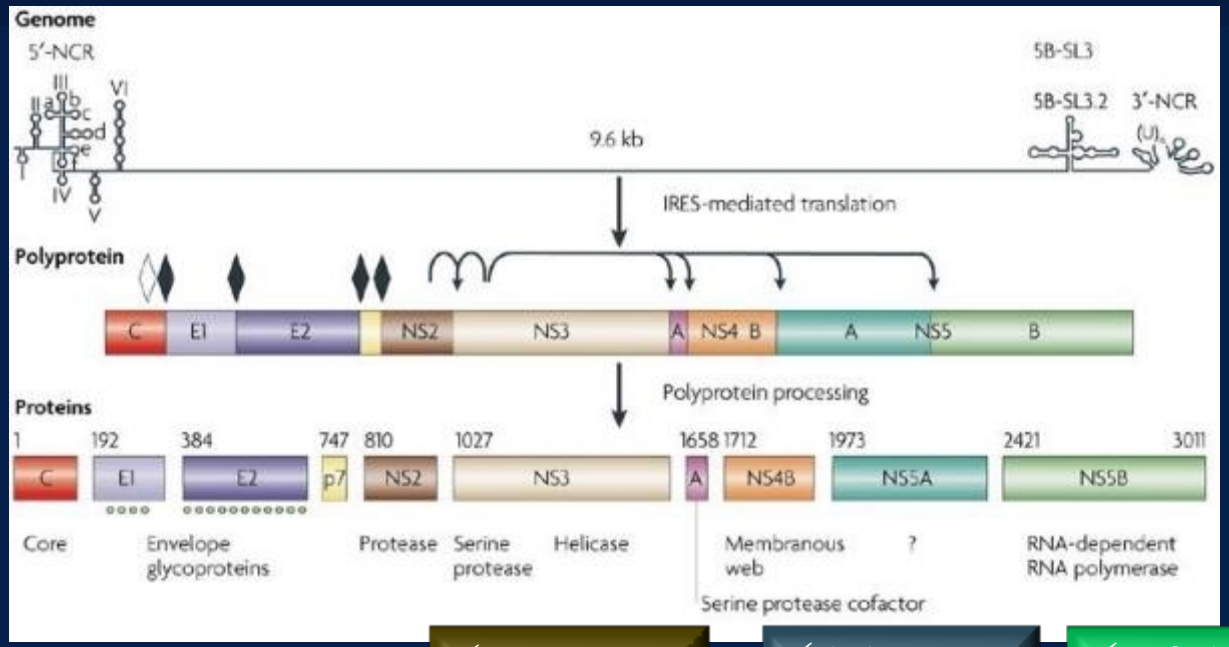
HCV Therapeutics Timeline





Slide courtesy of D. Wyles

HCV antiviral targets



- ✓ simeprevir
- ✓ paritaprevir
- ✓ grazoprevir
- ✓ glecaprevir
- ✓ voxilaprevir

- ✓ ledipasvir
- ✓ ombitasvir
- ✓ daclatasvir
- ✓ elbasvir
- ✓ velpatasvir
- ✓ pibrentasvir

- ✓ sofosbuvir
- ✓ dasabuvir

Maradpour Nature Reviews 2007

No Bad Options in 2025

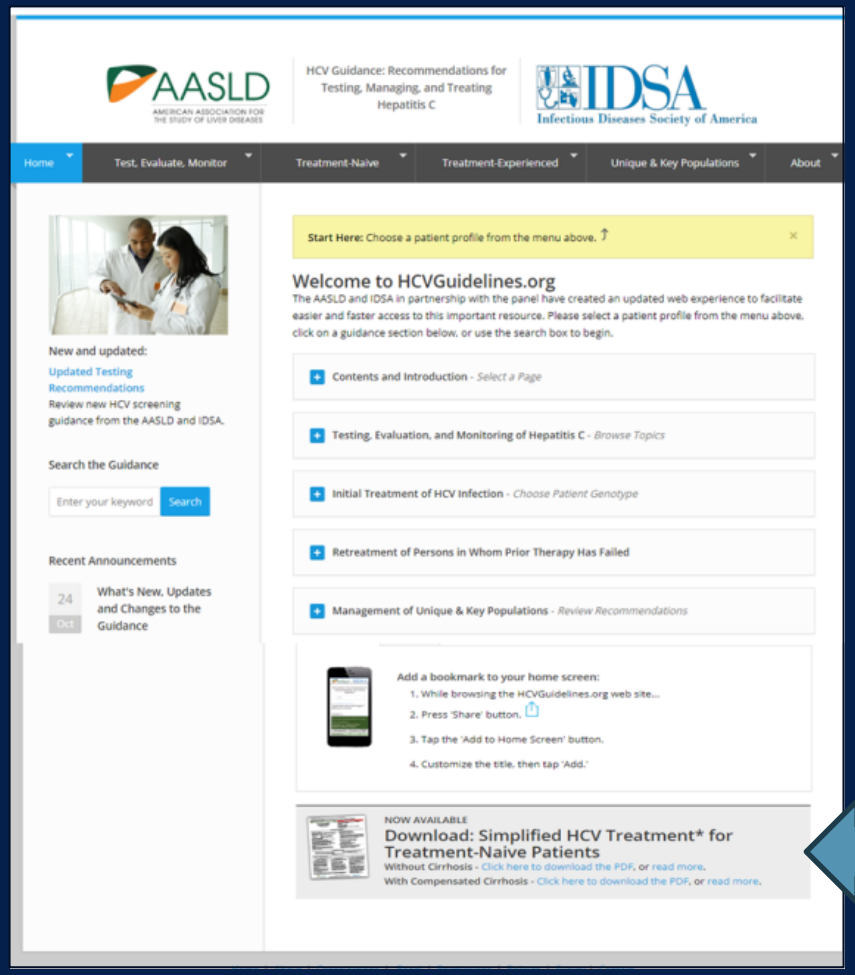
Drug Regimen	Indications in Treatment-Naïve Adults w/o Cirrhosis	Duration of Treatment*
GLE/PIB	**All genotypes**	8 weeks
LDV/SOF	GT1, GT4, GT5, or GT6; Low VL (<6 million) 8-week option	8−12 weeks
SOF/VEL	**All genotypes**	12 weeks

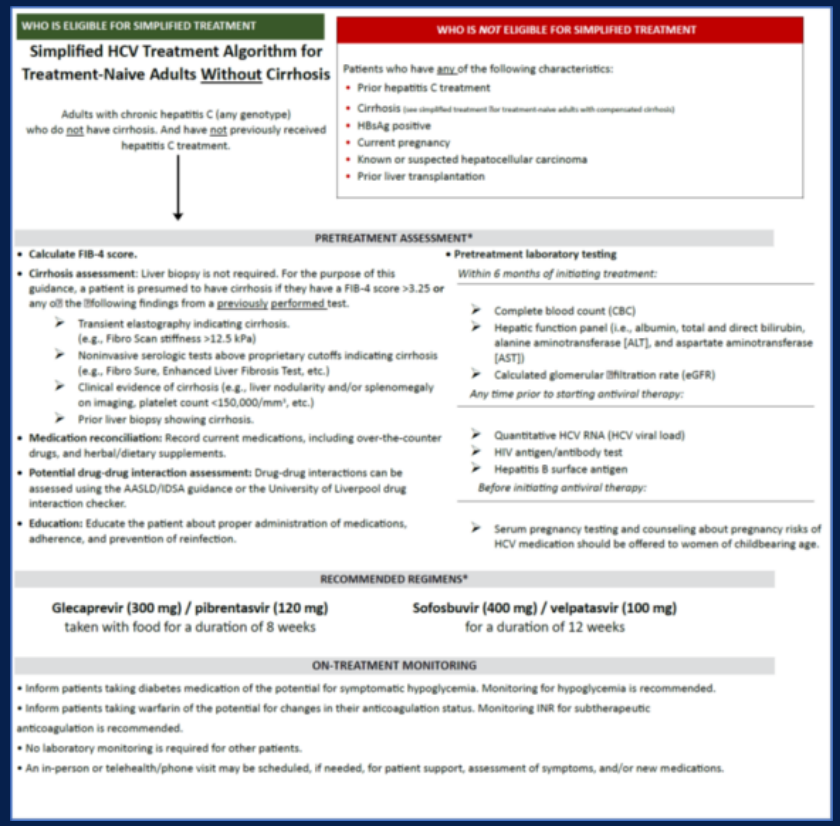
* Guidance recommended regimens; alternative durations in select scenarios but not recommended.

GLE/PIB- glecaprevir/pibrentasvir; LDV/SOF- ledipasvir/sofosbuvir; SOF/VEL- sofosbuvir/velpatasvir

Simplified Approach

- Hcvguidelines.org





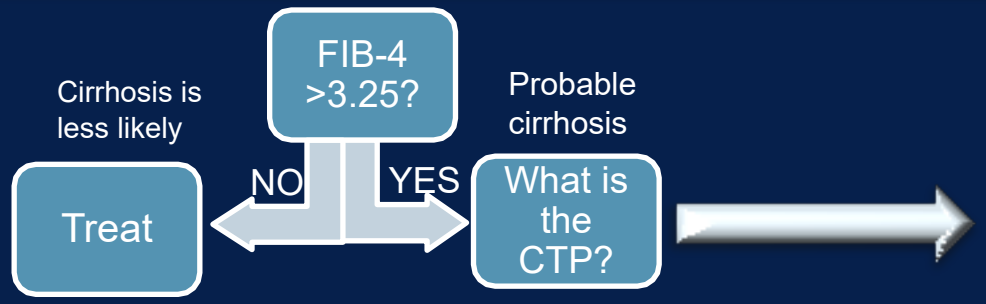
Pretreatment

History & Physical Exam	Required	Consider	Vaccines
• Treatment hx • Alcohol use • Drug use • HIV? HBV? • Current Meds • Evidence of liver disease	• HCV RNA • CBC • LFTs • Hep B Surface Antigen • Urine HCG	• HCV Genotype* • Hep A total Abs • Hep B core AB and surface AB • HIV 4th gen • STI testing	• Prevnar20 • Hep A and B

*Useful if compensated cirrhosis and planning to treat with sof-vel

Cirrhosis Calculations

$$\text{FIB 4} = \frac{\text{Age (yrs)} \times \text{AST (U/L)}}{\text{Platelet count } (10^9/\text{L}) \times \text{ALT (U/L)}^{1/2}}$$



Finding	1 point	2 points	3 points
Encephalopathy	None	Mild	Severe
Ascites	None	Mild	Severe
Albumin (g/dl)	>3.5	2.8 – 3.4	<2.8
Bilirubin (mg/dl)	<2	2 – 3	>3
INR	<1.7	1.7 – 2.2	>2.2
Child Pugh class A = 5-6 points; class B = 7-9 points; class C = 10-15 points			

Class A – compensated liver disease => Treat

Class B or C – decompensated liver disease =>Refer to liver specialist

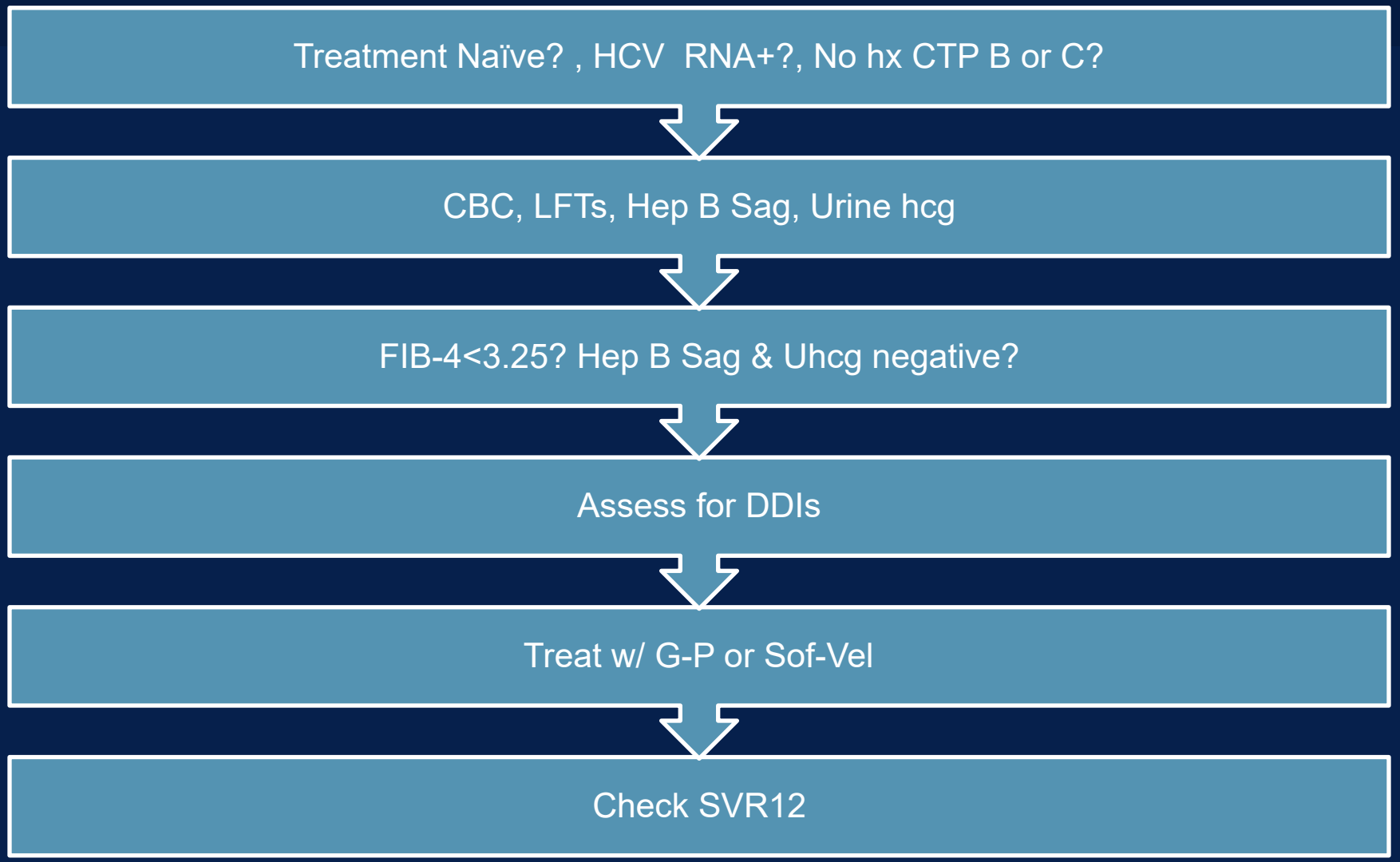
Additional Labs

On treatment	12 weeks after treatment	Ongoing

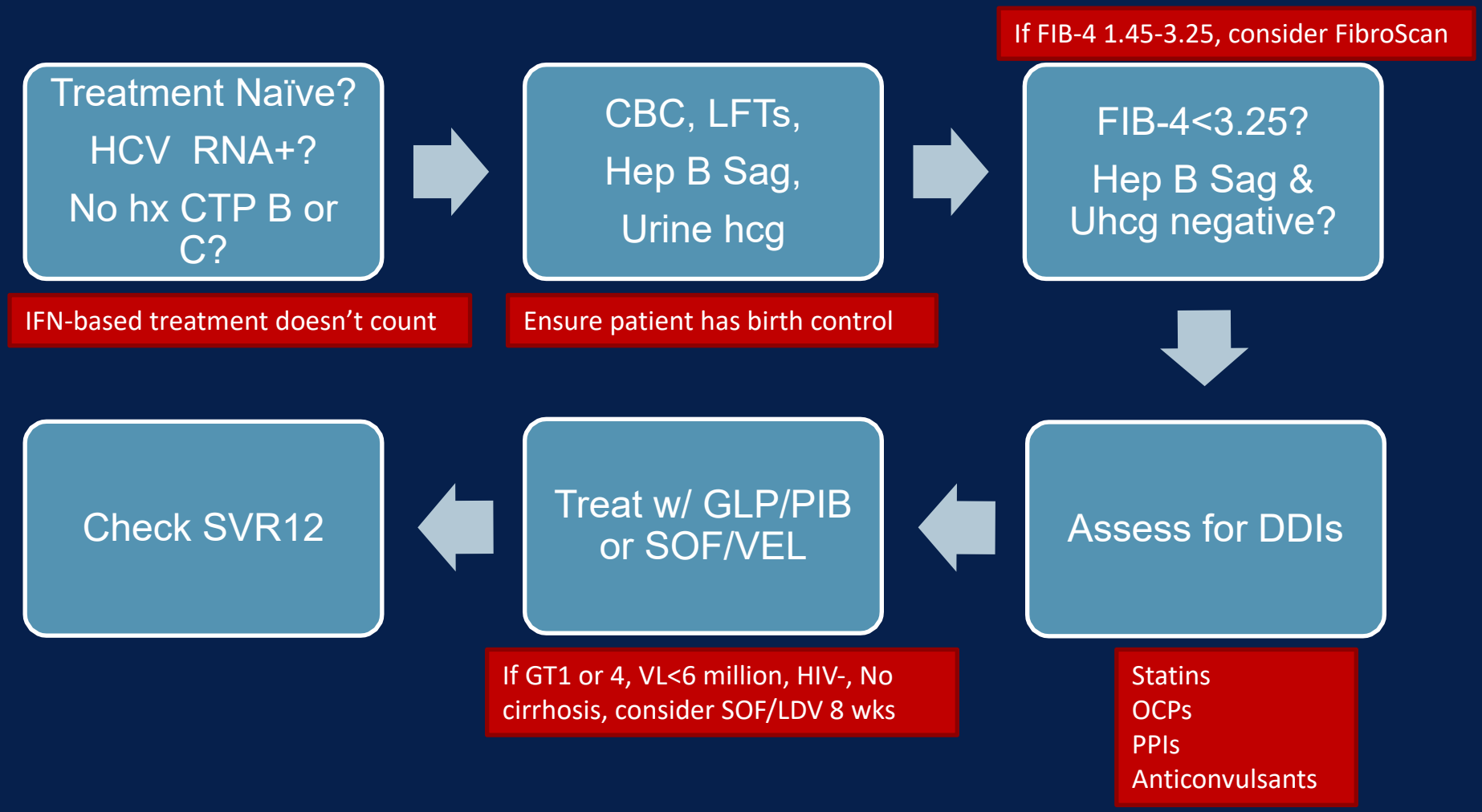
• None
• Glc & INR if DM or taking warfarin
	• HCV RNA
	• LFTs
	➢ **HCV RNA 0 = SVR12 = CURE**
		• Yearly HCV RNA if risk factors
		• If cirrhosis
		  • Q6 month US
		  • Esophageal varices screening

SVR12 = Sustained virologic response 12 weeks after the end of treatment

General Approach

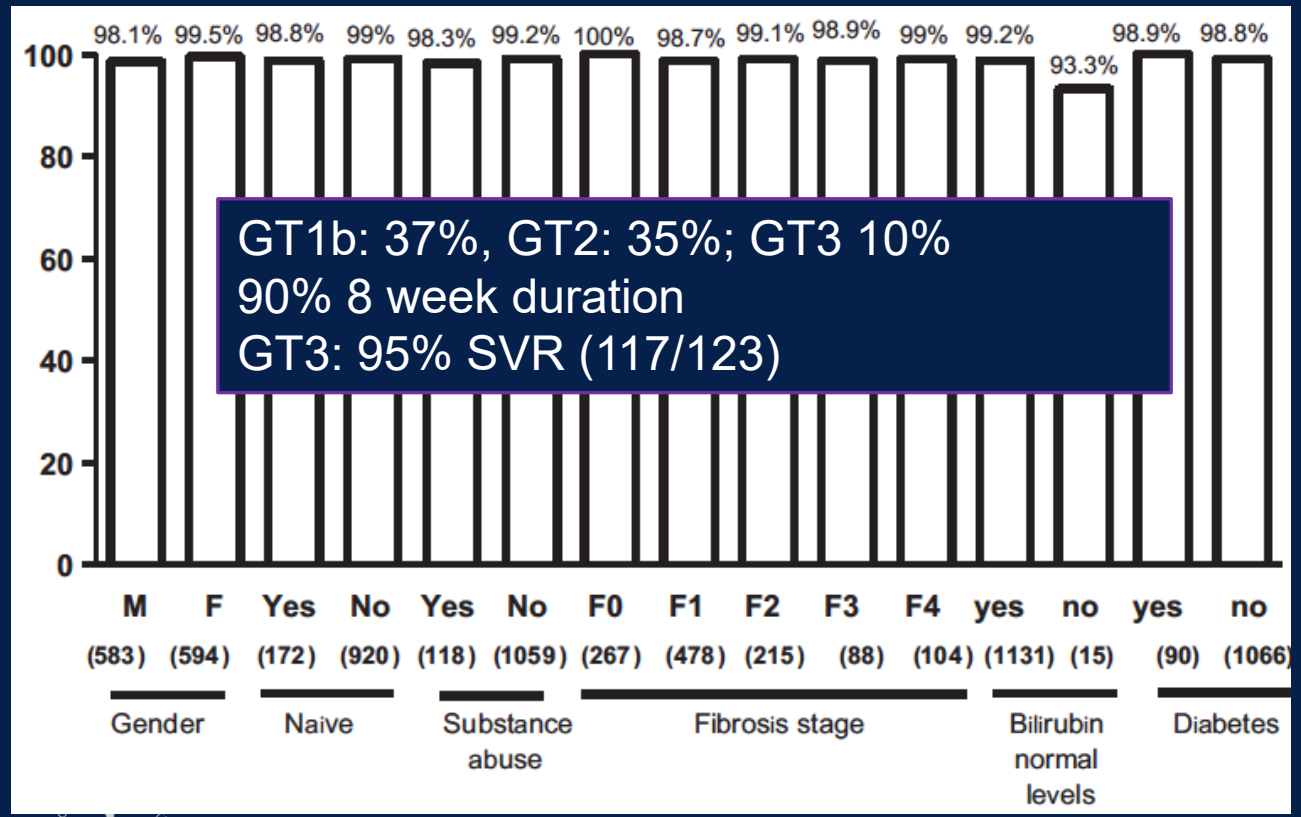


Additional Considerations

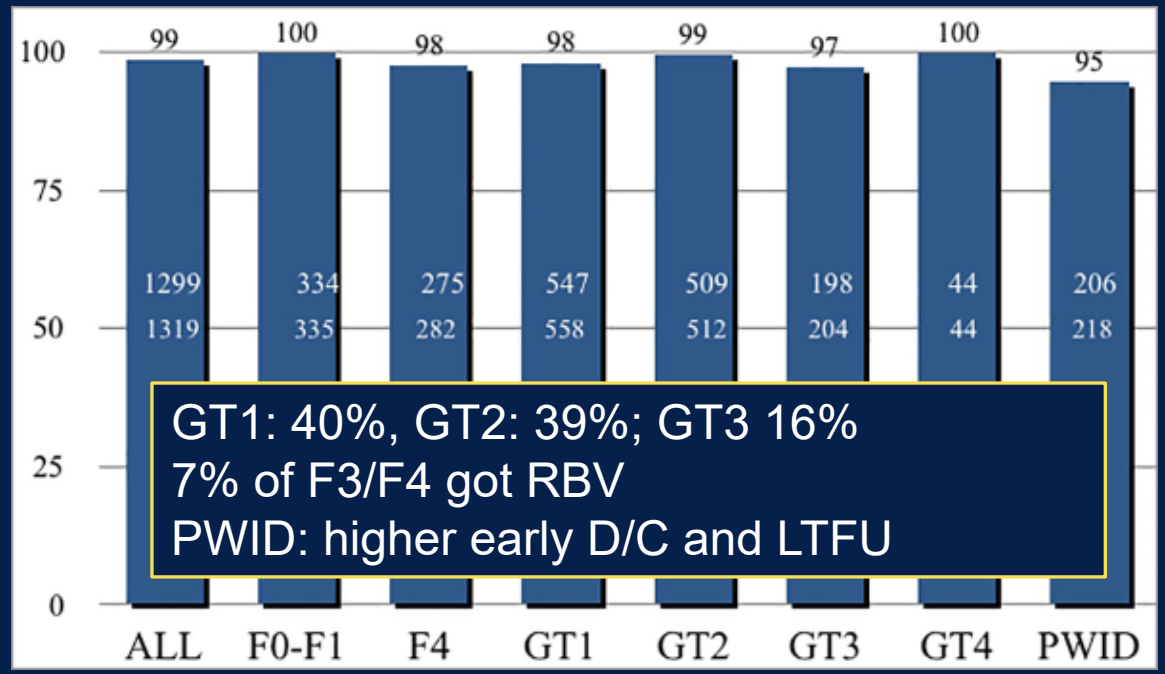


Lights out efficacy in the "real-world"

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



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



Persico M. Liver Inter 2019. Mangia A. PLosONE 2019

Counseling: Liver Health & Prevent Transmission

- **Alcohol (none)**
- APAP <2g/day if cirrhosis
- Avoid NSAIDs if cirrhosis
- Herbals & Supplements
  - Milk thistle results mixed
  - Coffee may decrease cirrhosis risk
- Transmission
  - Don’t share toothbrushes or razors
  - Sterile drug equipment
  - Condoms (higher risks if MSM)
  - Not immune after treatment

Case

32 y/o living with HIV and substance use disorder in residential treatment program.

MSM and history of IDU.

Review of outside records:

- HCV Ab negative JAN 2017
- HCV Ab + DEC 2019 -> RNA 3.7 million

Exam WNL

ALT 74 AST 47 ALB 4.2 TB 0.6 Cr. 0.57 PLT 215 [FIB-4: 0.81]

Current HCV RNA 12.2 million IU/mL

HBV +sAb, negative core total Ab and sAg. HAV immune

What additional testing is medically needed prior to HCV treatment?

A. HCV Genotype
B. Baseline abdominal ultrasound
C. Further fibrosis staging with elastography
D. Urine drug screen
E. Repeat HIV RNA to document suppression
F. No additional testing is required

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Back to our patient

- Glecaprevir/pibrentasvir for 8 weeks was delivered to the patient
  - He left sober living after about 5 weeks of therapy
  - Lost medications after leaving
  - Called the pharmacy 5d after losing medication
- Pharmacy reaches out to you for guidance on how to approach.

What would you do next?

A. Restart G/P, finish last 4 weeks
B. Restart G/P, extend therapy for another 8 weeks
C. Stop and assess for SVR12
D. Check HCV RNA, if <LLOQ restart G/P to complete current 8 week course
E. Something else

What would you do next?

A. **Restart G/P, finish last 4 weeks**
B. Restart G/P, extend therapy for another 8 weeks
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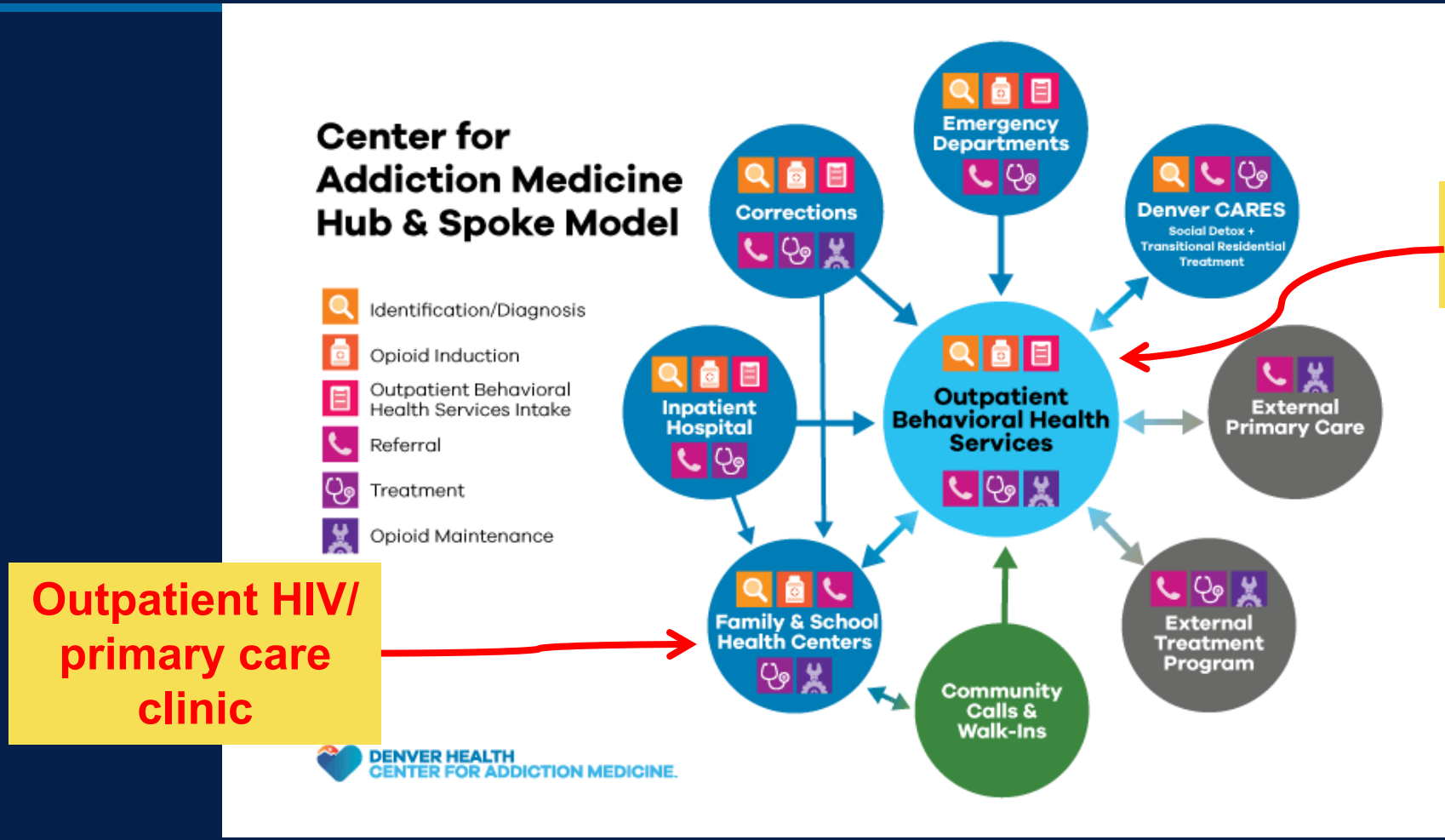
E. Something else

HCV Treatment at Denver Health OBHS

Treating ID@SUD OTP and outpatient SUD
Denver Health's Center Addiction Medicine (CAM)



OTP outpatient SUD clinic

Outpatient HIV/ primary care clinic

DENVER HEALTH
CENTER FOR ADDICTION MEDICINE

Treating HBV, HCV, HIV and syphilis at the OTP

<u>Only one blood draw for intake, labs reflex quantitative</u>

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 →confirmatory → RPR titre

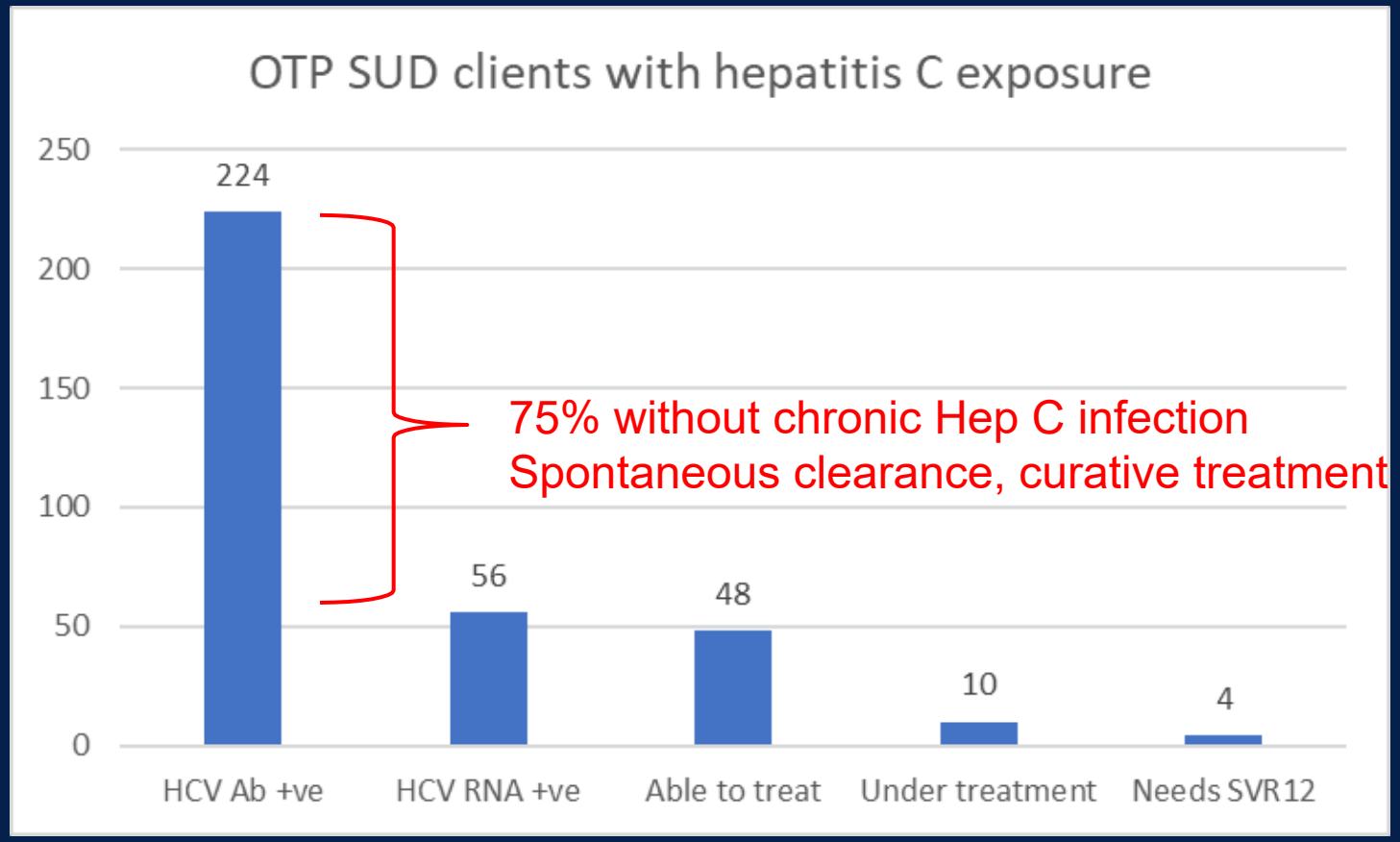
Hepatitis C is our most common blood borne infection in outpatient substance treatment

- Hepatitis C Ab positive: 253 of 1190 (21.3%)
  - Hepatitis C RNA detectable: 46 of 253 (18.2%)
- HIV Ab/Ag positive: 34 of 1190 (2.9%)
  - 3 with HIV viremia > 200 copies/ml
- Hepatitis B Surface Ag positive: 5 of 1190 (0.4%)

Viral infection report run on 4/5/2025

Outpatient Treatment Program (OTP) current clients

631 with intake labs, 224 (35.5%) hepatitis C Ab +



Viral infection report run on 06/24/24

DENVER HEALTH
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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 active withdrawal
- The quality of your care navigator is critical
- Substance treatment is often run by psychiatry not medicine
- Be careful to decouple offerings, need non punitive approach
- Many clients know people treated in ‘dark days’ of interferon
- Some clients may be cautious about potential for reinfection

Partnership with Public Health Immunization to provide vaccination at OTP for clients, staff, family

Vaccines	Personal Considerations
• COVID-19 • Influenza • Hep A • Hep B • Tdap • MenACWY/B • Mpox • HPV • PCV20	• Injection drug use • Young person • Elderly person • Homelessness • Smoking • Transactional sex work • MSM

DENVER HEALTH
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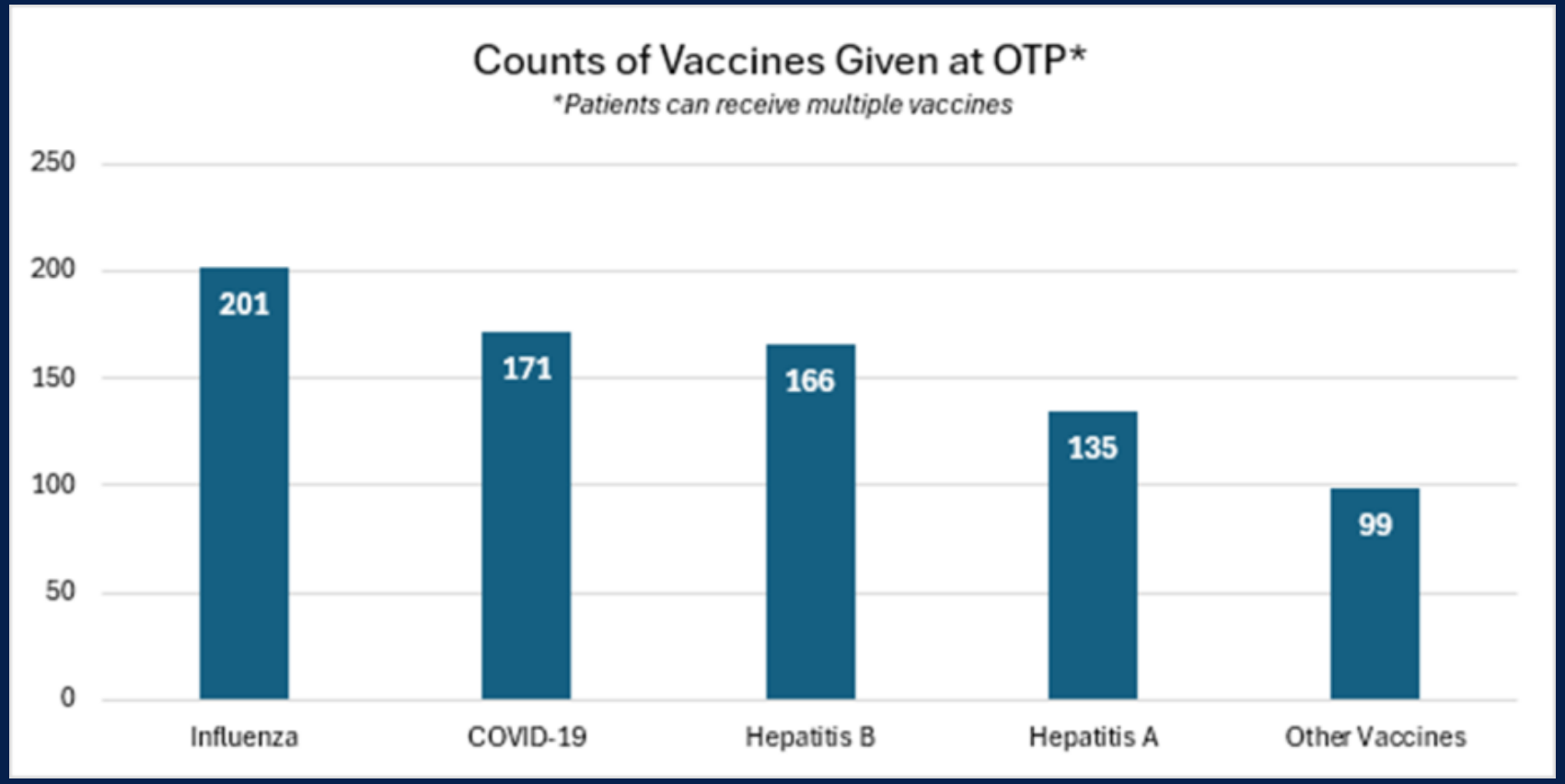
Adapted from AICP 2023 recommendations

Quantitative analysis of vaccinations 2019-2024

Total 772 vaccinations to 321 OTP patients



28% of people only received vaccinations at the OTP vaccination clinic

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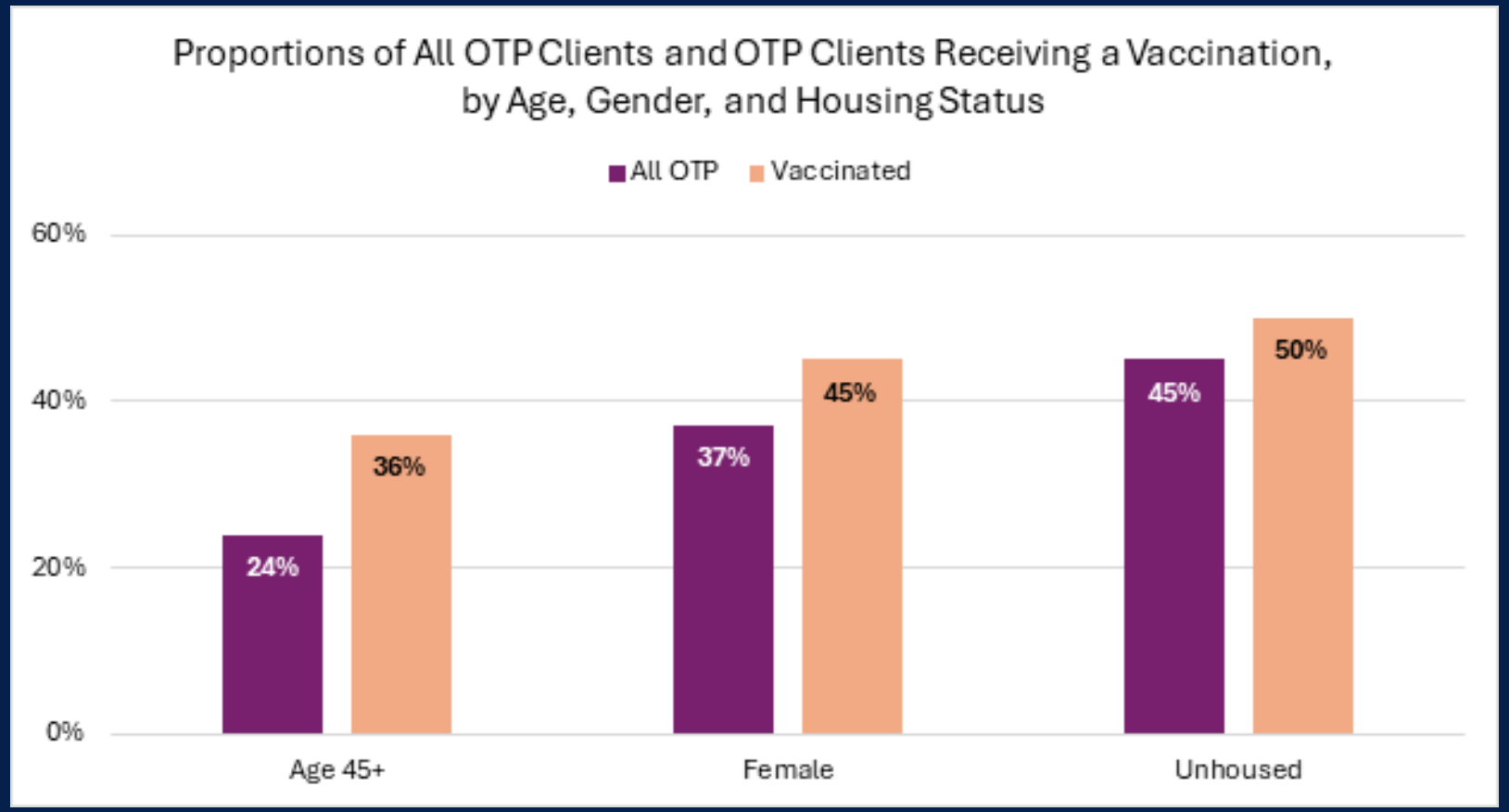
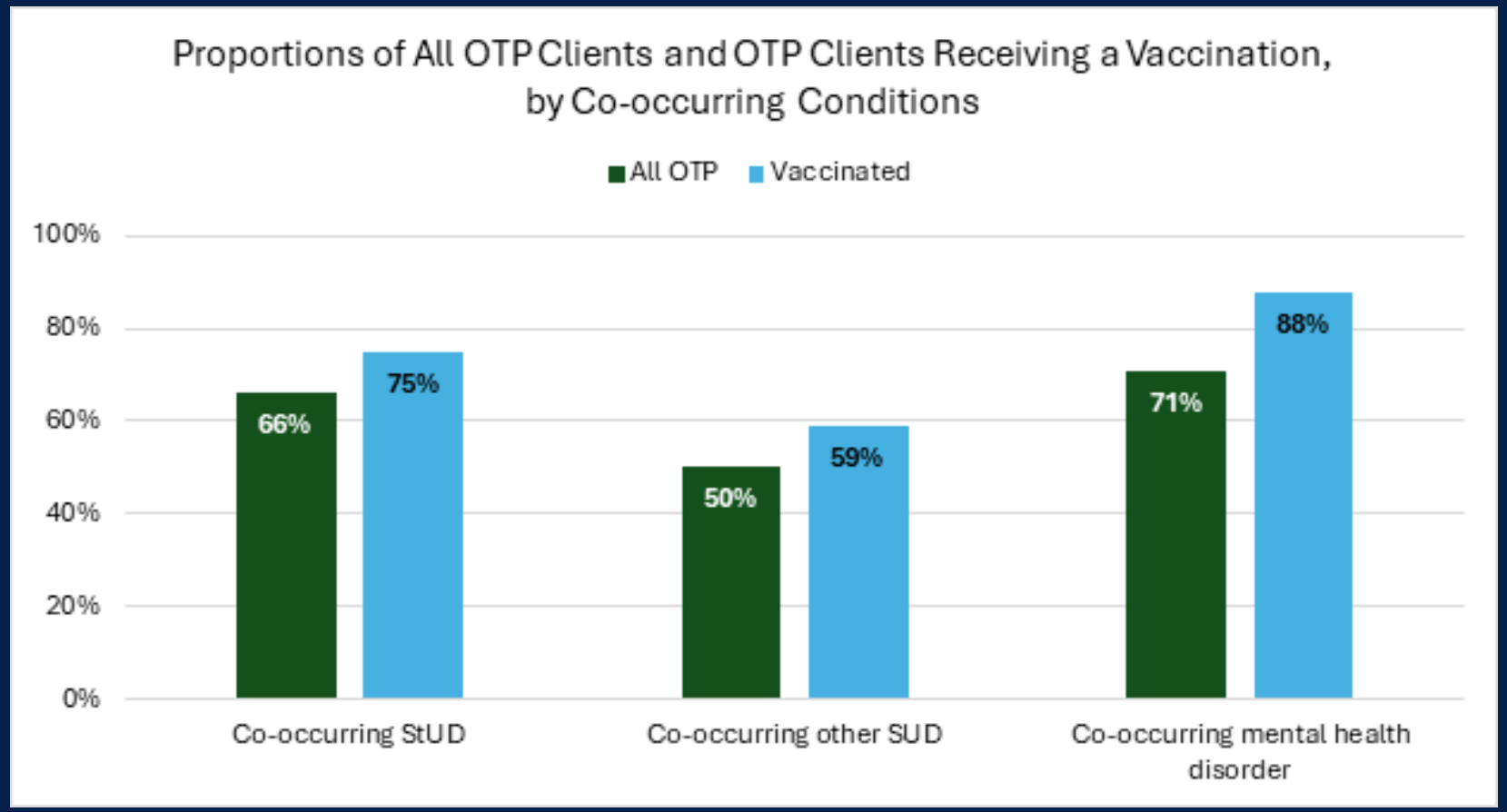
Compared to OTP population, people accepting vaccination were more likely 45+, female, or unhoused



Compared to OTP population, people accepting vaccination more likely StUD, SUD in addition to OUD, or co-occurring mental health disorder



Harm Reduction Action Center

Slides: HRAC

HCV Treatment Partnership with HRAC

Client visits SSP for supplies & services

Offered drop-in video visit w/ physician if history of HCV

Gets labs drawn & receives gift card for labs

If HCV RNA+, meds delivered to SSP

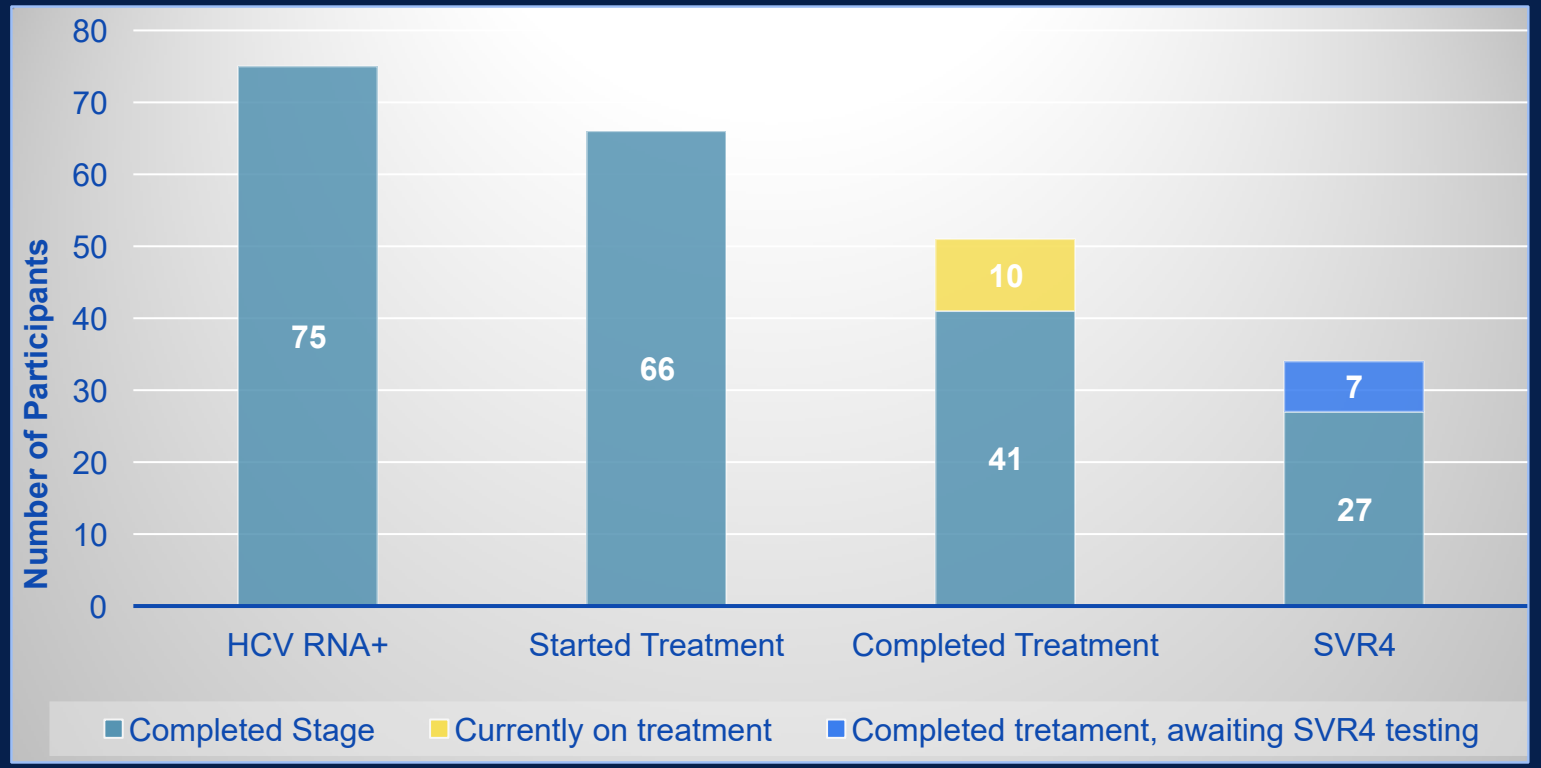
Client picks up meds from SSP in quantity needed; remainder safely stored at SSP

Meds completed, follow-up SVR4 labs drawn, gift card issued for lab check

Images: Sarah Rowan

Syringe Service Program
HCV Treatment Care Continuum
November 2022-April 2025

46 years median age	66% Recent IDU	68% RNA+	91% Medicaid



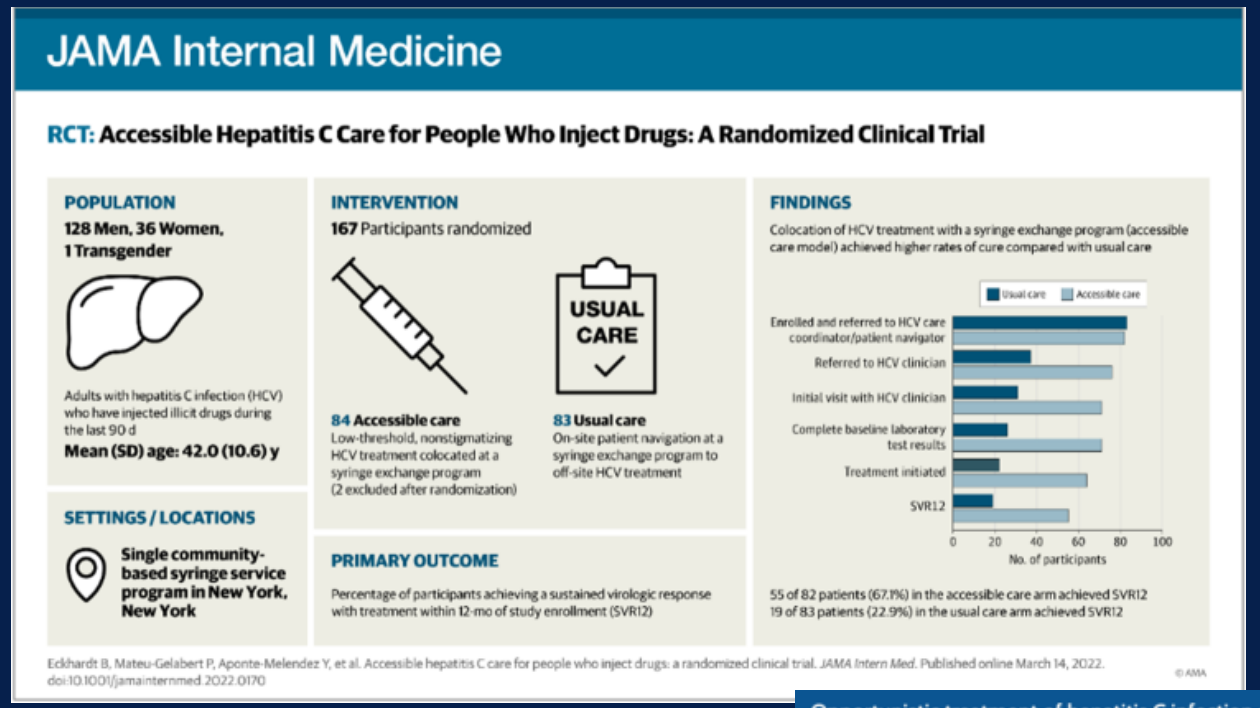
Rowan SE. INHSU 2024.

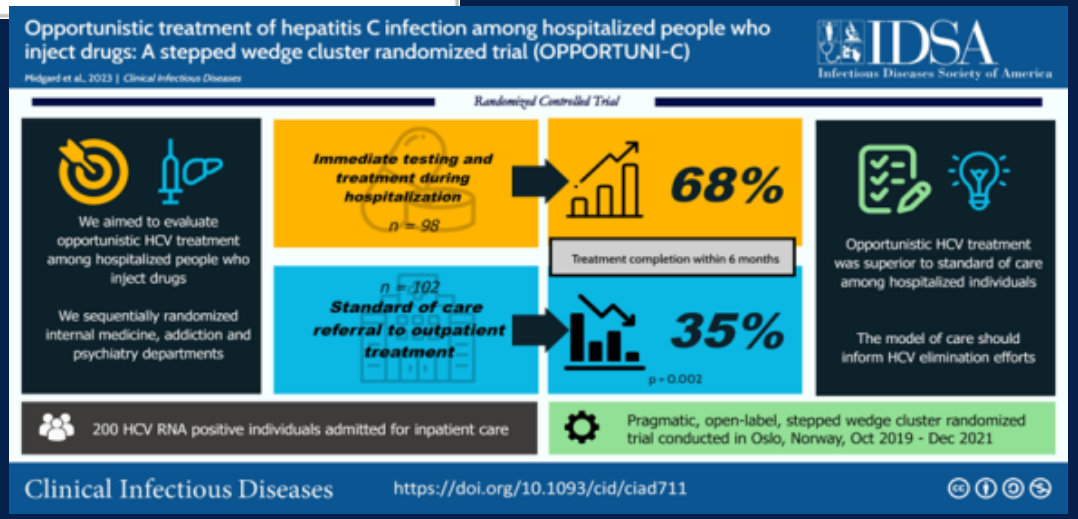
Questions so far?

- What has this meant to our clients/patients?
- What are the pros and cons of these approaches?
- What are the barriers?

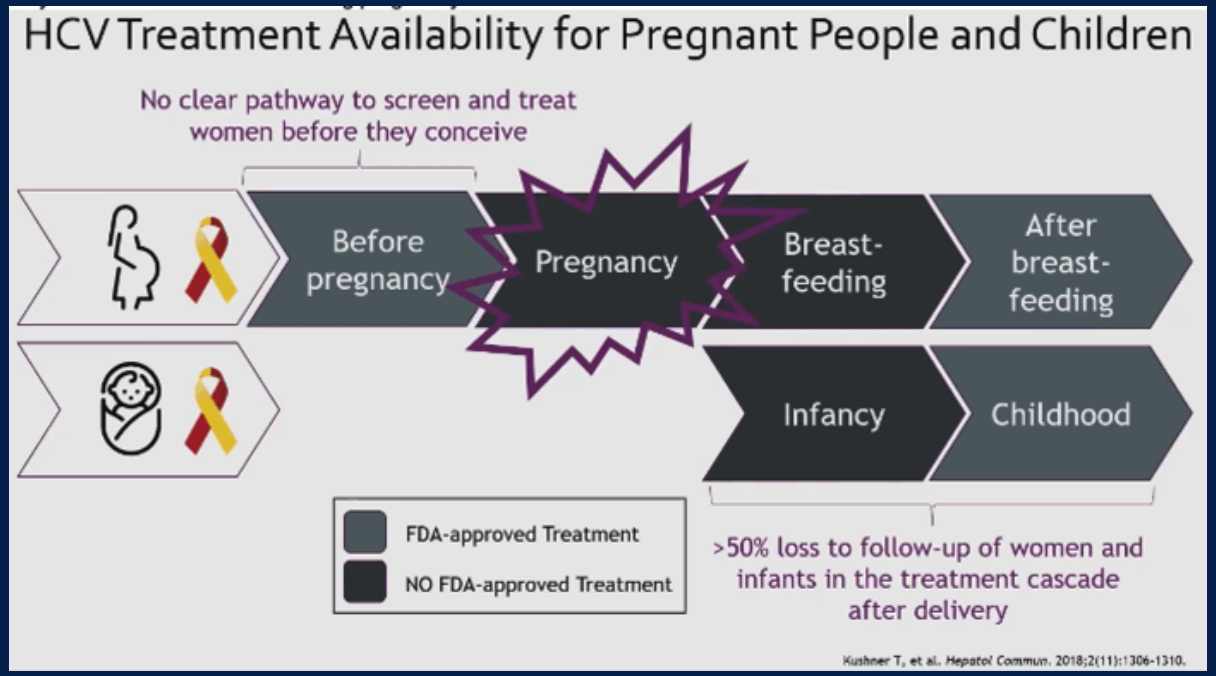
HCV Treatment in Other Non-Traditional Settings

- Emergency Departments
- Sexual Health Clinics
- Inpatient Hospital Admissions
- Street Medicine
- Pharmacies

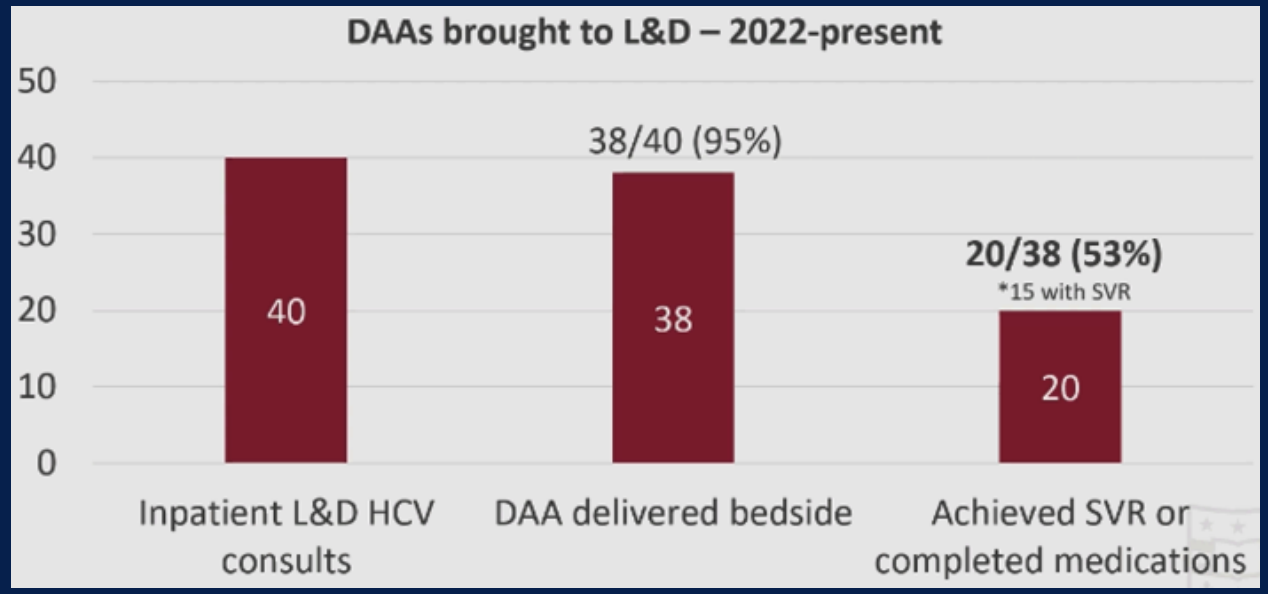




Treatment during pregnancy



IDSA/AASLD support a shared-decision making approach to HCV treatment during pregnancy
https://www.hcvguidelines.org/unique-populations/pregnancy



SOF/LDV or SOF/VEL in studies:

- 35/35 women achieved SVR
- No drug related adverse fetal/infant outcomes

Chappell C. ID Week 2024. McCrary M. ID Week 2024.

Additional Considerations

- Point of care HCV RNA testing
- Medicaid prior authorization requirements
- Injectable HCV treatment
- Elimination Goals

FDA NEWS RELEASE

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

Test Enables Single-Visit Testing and Treatment for Hepatitis C

Share | Post | Linkedin | Email | Print

For Immediate Release: June 27, 2024

Español

Today, the U.S. Food and Drug Administration granted marketing authorization to Cepheid for the Xpert HCV test and GeneXpert Xpress System, the first hepatitis C virus (HCV) test that can be used to bring diagnosis to appropriately certified point-of-care settings for individuals at risk for hepatitis C. The test may be performed in settings operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, such as certain substance use disorder treatment facilities, correctional facilities, syringe service programs, doctor's offices, emergency departments and urgent care clinics. Rather than requiring a sample to be sent to a central lab for testing, the test detects HCV RNA and delivers results in about an hour using a blood sample from the fingertip.

https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-point-care-hepatitis-c-rna-test

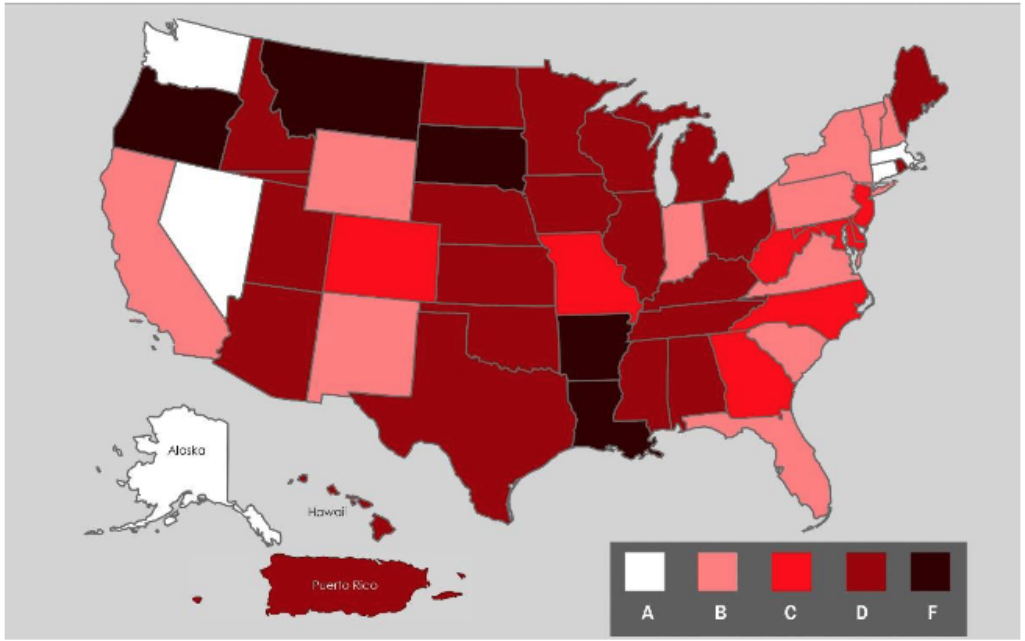
CHLPI CENTER for HEALTH LAW and POLICY INNOVATION
HARVARD LAW SCHOOL

NVHR National Viral Hepatitis Roundtable

https://stateofhepc.org/

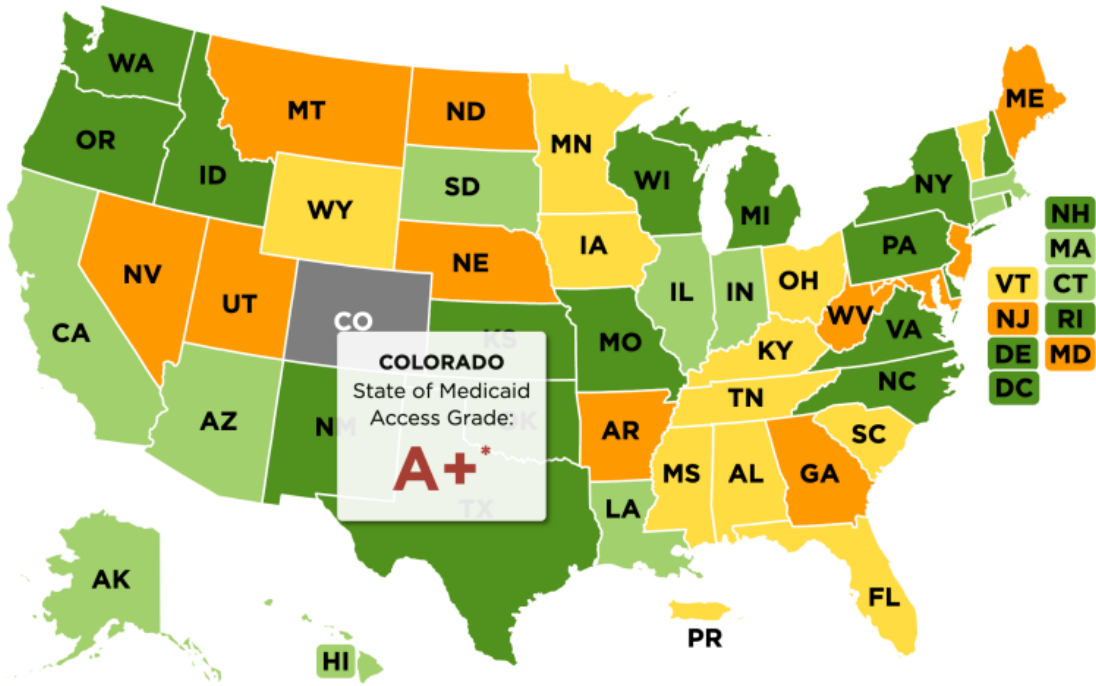
State of HepC:
Evolution of HCV treatment restrictions over time

OCT 2017



A	B	C	D	F
10%	21%	17%	42%	10%

OCT 2024



A	B	C	D	F
54%	25%	21%	0	0

Final Takeaways

Thank You

Additional References

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