Implementing HCV Point-of-Care RNA Testing and Test-and-Treat Models

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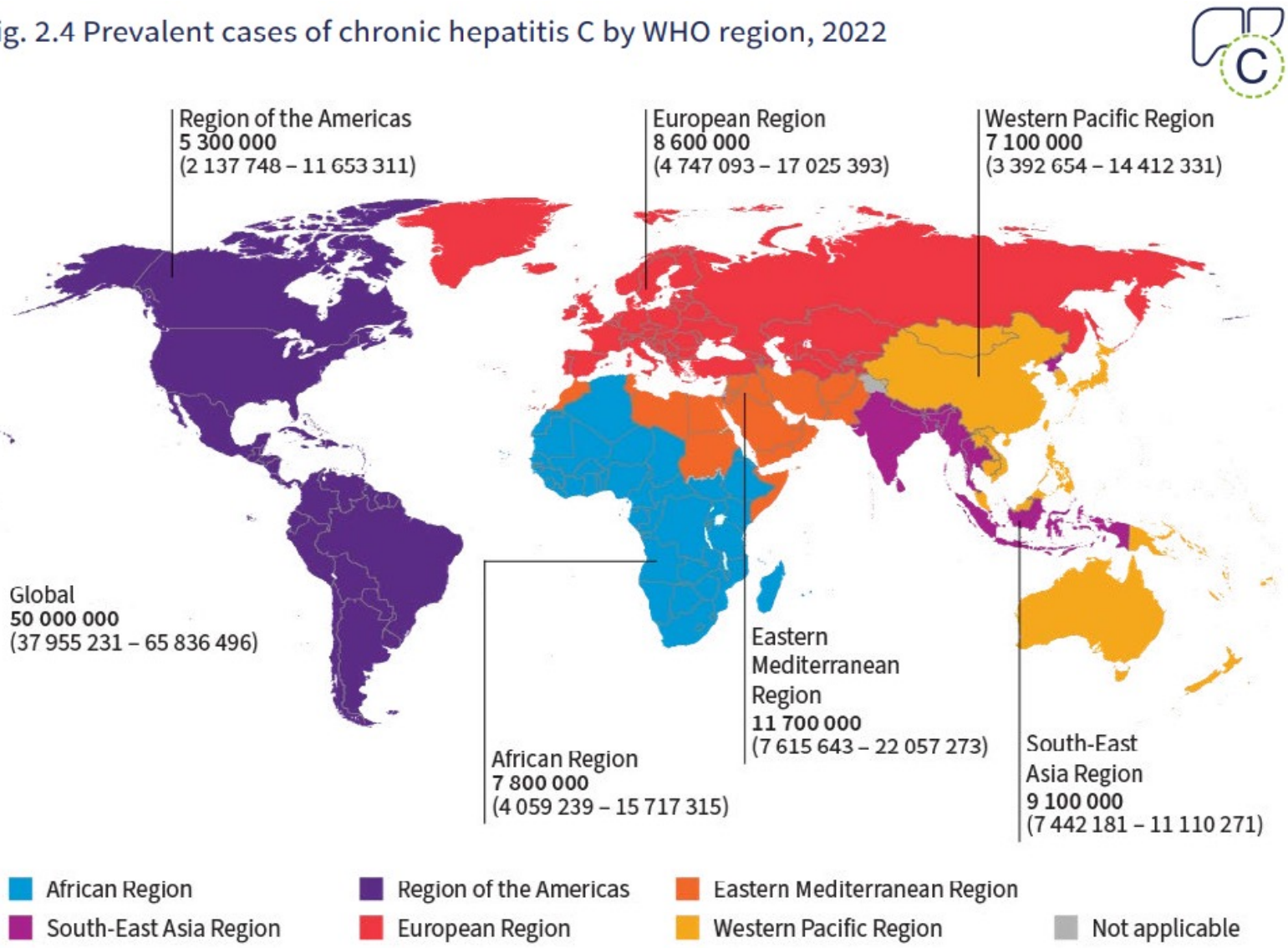
Disclosures

- Grant support: Gilead, AbbVie, VIR, Cepheid, Aligos
- Co-Chair AASLD/IDSA Hepatitis C Guidance

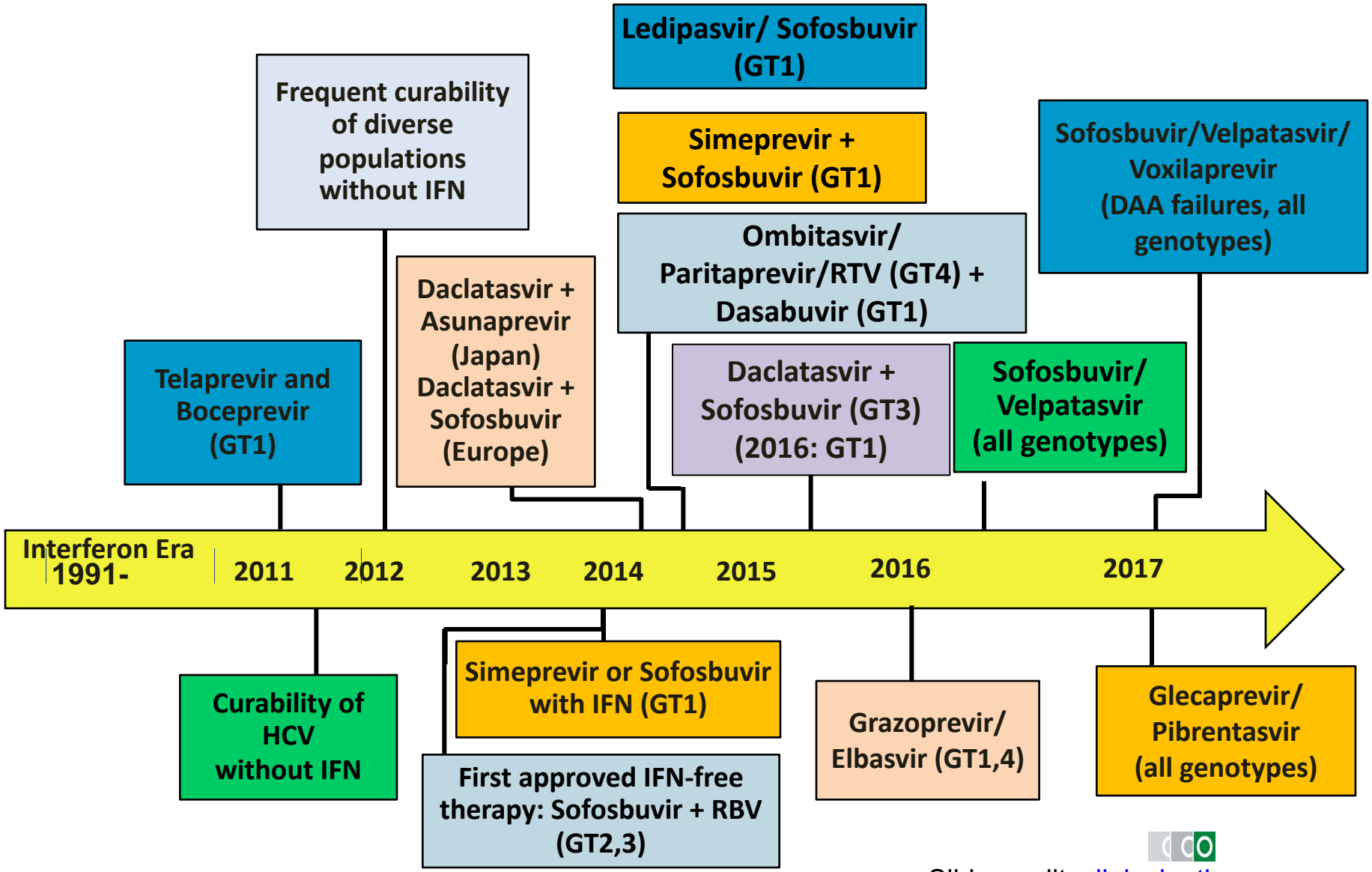
- **50 million chronic hepatitis C cases**
- **1 million new hepatitis C cases per year**
- **240,000 deaths per year**

Fig. 2.4 Prevalent cases of chronic hepatitis C by WHO region, 2022



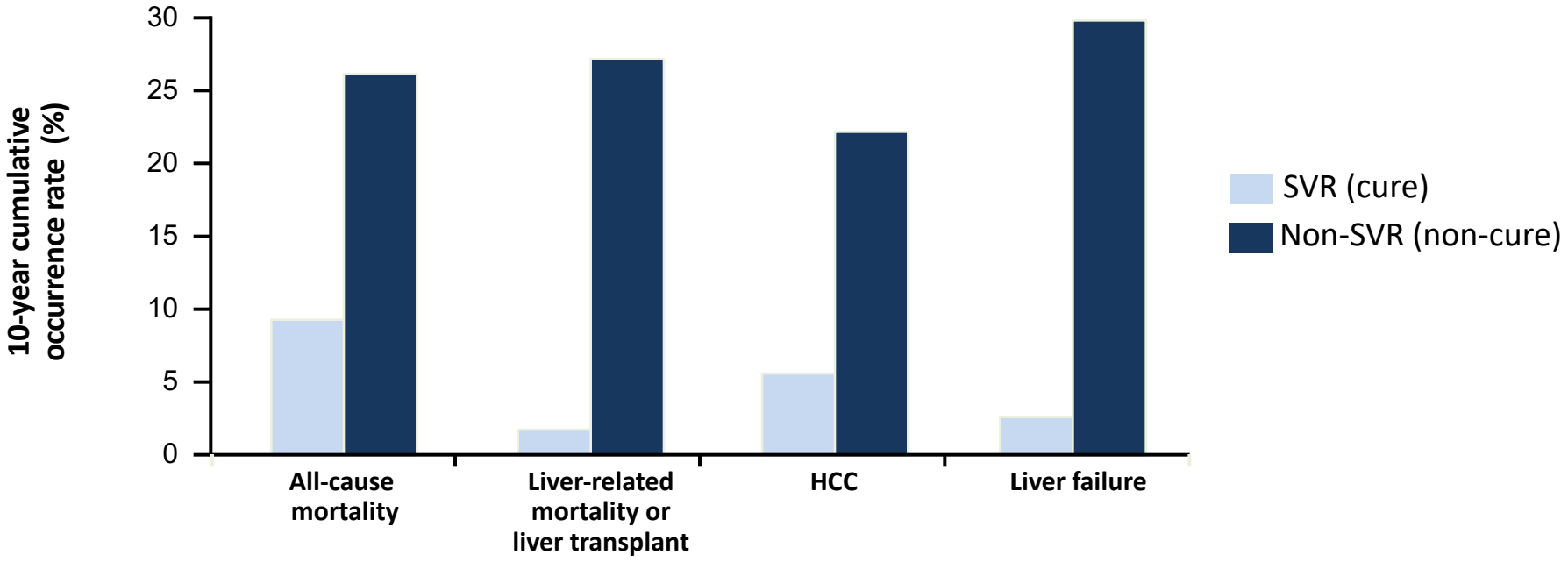
https://www.who.int/publications/i/item/9789240091672

HCV Therapy Evolution in the DAA Era



Slide credit: clinicaloptions.com

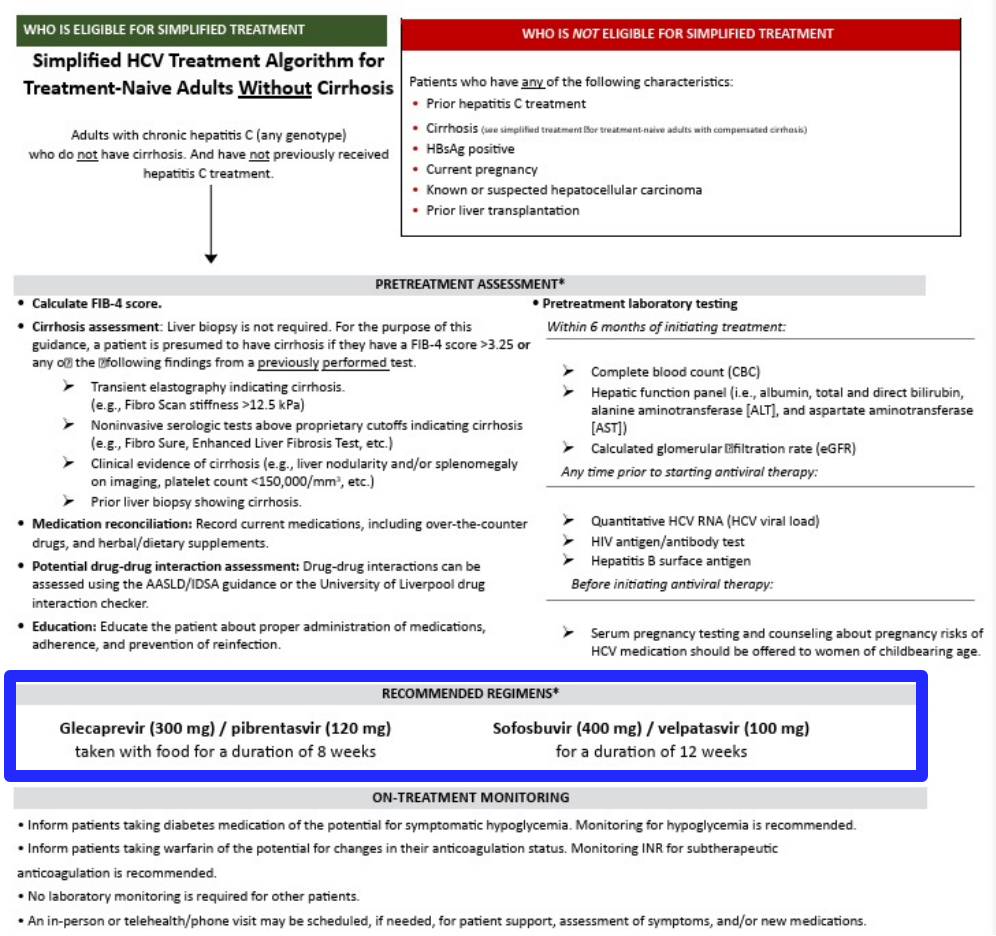
HCV Cure Decreases Mortality and Liver-Related Complications



Van der Meer AJ et al, JAMA, 2012.

Hepatitis C Treatment in 2025

- ✓ Fixed-dose oral DAAs
  - Pan-genotypic
  - Short course
  - >95% SVR across variety of populations
  - Salvage therapy for DAA failures
- ✓ Simplified treatment algorithms
- ✓ Increasing treatment in non-specialty clinics
- ✓ Fewer payer restrictions
  - Varies by state



WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT

Simplified HCV Treatment Algorithm for Treatment-Naive Adults Without Cirrhosis

Adults with chronic hepatitis C (any genotype) who do not have cirrhosis. And have not previously received hepatitis C treatment.

WHO IS *NOT* ELIGIBLE FOR SIMPLIFIED TREATMENT

Patients who have any of the following characteristics:

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

PRETREATMENT ASSESSMENT*

- **Calculate FIB-4 score.**
- **Cirrhosis assessment**: Liver biopsy is not required. For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 or any of the following findings from a previously performed test.
  - Transient elastography indicating cirrhosis. (e.g., Fibro Scan stiffness >12.5 kPa)
  - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (e.g., Fibro Sure, Enhanced Liver Fibrosis Test, etc.)
  - Clinical evidence of cirrhosis (e.g., liver nodularity and/or splenomegaly on imaging, platelet count <150,000/mm³, etc.)
  - Prior liver biopsy showing cirrhosis.
- **Medication reconciliation:** Record current medications, including over-the-counter drugs, and herbal/dietary supplements.
- **Potential drug-drug interaction assessment:** Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.
- **Education:** Educate the patient about proper administration of medications, adherence, and prevention of reinfection.
- **Pretreatment laboratory testing**

Within 6 months of initiating treatment:

- Complete blood count (CBC)
- Hepatic function panel (i.e., albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST])
- Calculated glomerular filtration rate (eGFR)

Any time prior to starting antiviral therapy:

- Quantitative HCV RNA (HCV viral load)
- HIV antigen/antibody test
- Hepatitis B surface antigen

Before initiating antiviral therapy:

- Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.

RECOMMENDED REGIMENS*

Glecaprevir (300 mg) / pibrentasvir (120 mg) taken with food for a duration of 8 weeks

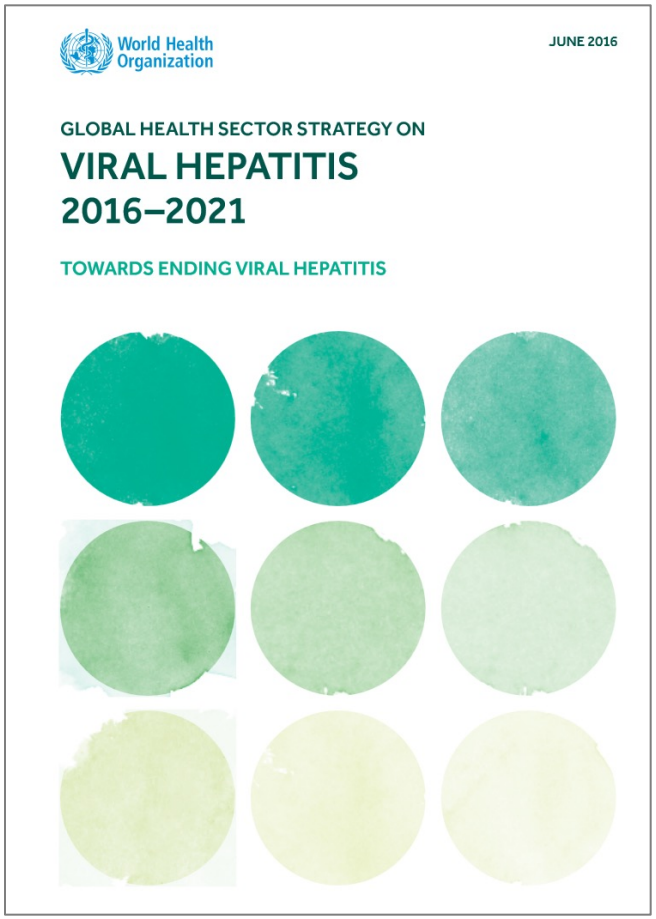
Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks

ON-TREATMENT MONITORING

- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended.
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- No laboratory monitoring is required for other patients.
- An in-person or telehealth/phone visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.

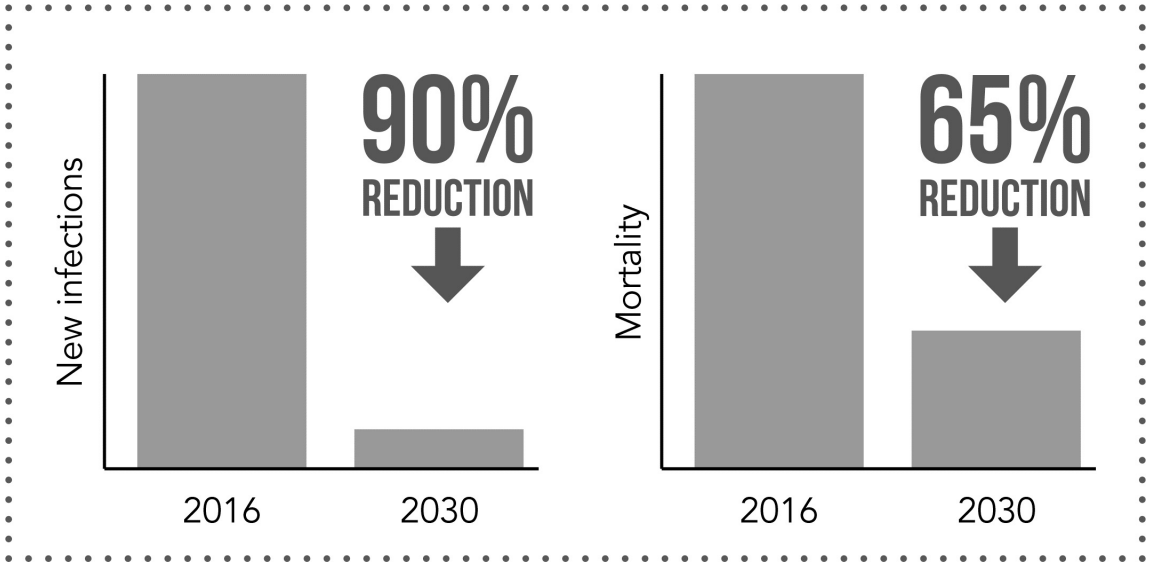
https://www.hcvguidelines.org; https://map.hepvu.org/

Hepatitis C Elimination Goals



Eliminate viral hepatitis as a major **public health threat** by 2030

Calling on all countries to develop **national action plans**



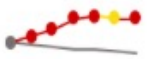
WHO. Global health sector strategy on viral hepatitis 2016-2021. Towards ending viral hepatitis. https://www.who.int/publications/i/item/WHO-HIV-2016.06

2025 Viral Hepatitis National Progress Report

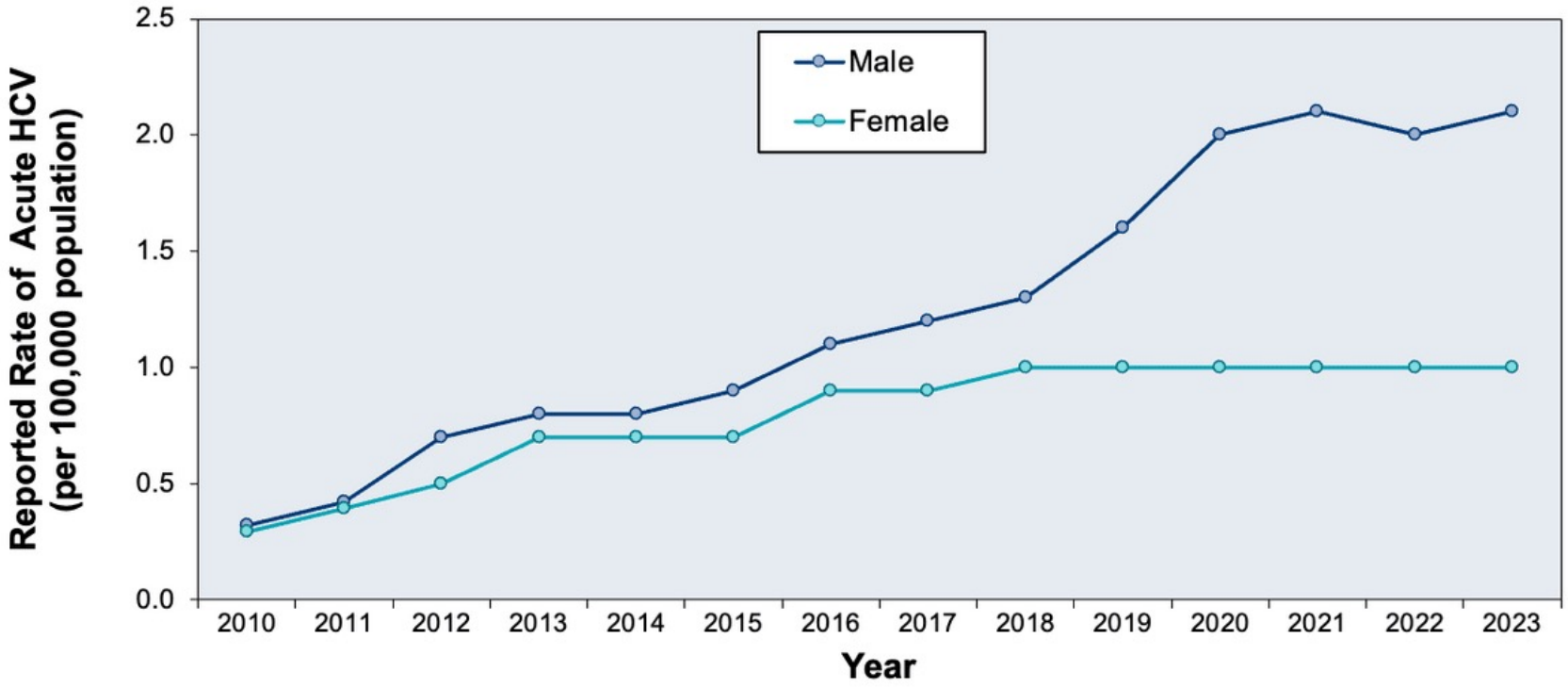
✓ Met or exceeded current annual target

→ Moving ***toward*** annual target, but annual target was not fully met

✗ Has moved ***away*** from annual target or has not changed

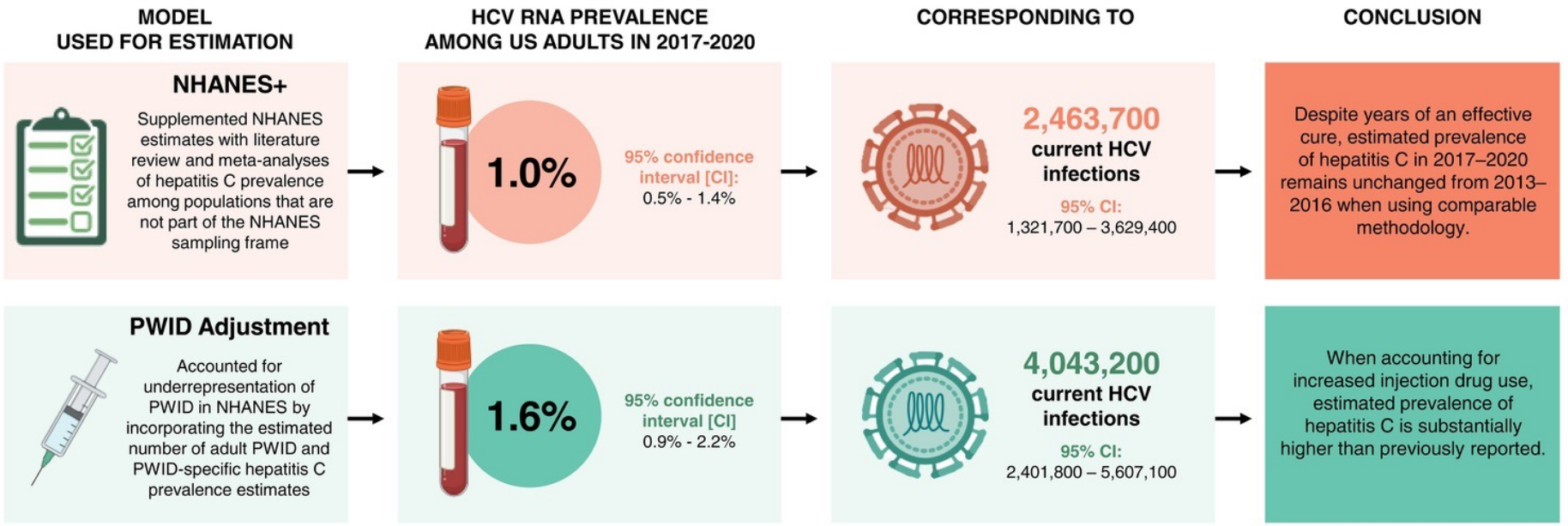
	2017 Baseline Data	2023 Data	2025 Goal/annual target*	Trend	2023 Status
Hepatitis C					
Reduce estimated† new hepatitis C virus infections by ≥20%	44,700	69,000	35,000		✗
Reduce reported rate‡ of new hepatitis C virus infections among persons who inject drugs¶ by ≥25%	2.30	2.60	1.70		→
Reduce reported rate‡ of hepatitis C-related deaths by ≥20%	4.13	2.52	3.00		✓
Reduce reported rate‡ of hepatitis C-related deaths among non-Hispanic American Indian/Alaska Native persons by ≥30%	10.24	7.75	7.17		→
Reduce reported rate‡ of hepatitis C-related deaths among non-Hispanic Black persons by ≥30%	7.03	4.03	4.92		✓

HCV Incidence in the US 2010-2023



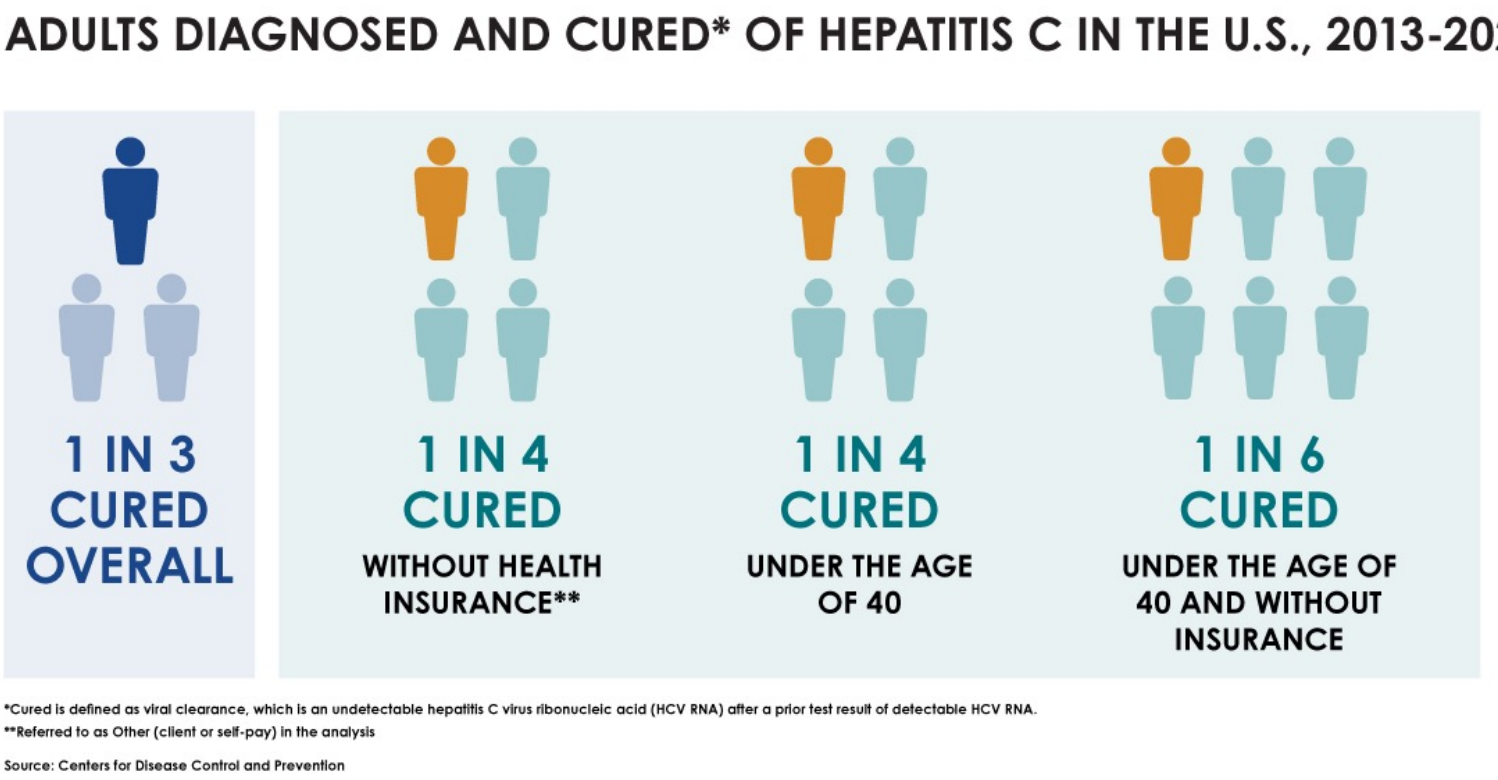
Source: Centers for Disease Control and Prevention (CDC). 2023 Viral Hepatitis Surveillance Report—Hepatitis C. Published April 2025.

HCV Prevalence in the US Has Not Changed



Hall EW et al, Hepatology, 2025.

Most People Living with Hepatitis C are Untreated



Wester C et al, MMWR 2023.

How do we reach people living with hepatitis C?

TABLE 3 Population sizes and hepatitis C prevalence estimates, by population, United States, 2017–2020

Population	Estimated adult population size N (95% CI)	HCV antibody prevalence %	95% CI		HCV RNA prevalence %	95% CI		Source
Noninstitutionalized[10]	249,177,857	2.04	1.36	3.06	0.89	0.55	1.45	[8]
Unsheltered and unhoused[12]	212,090	22.04	10.53	40.44	11.10	5.94	19.78	Meta-analysis
Incarcerated[11]	2,086,600	19.60	14.98	25.23	9.72	7.10	13.18	Meta-analysis
Active duty military[13]	1,326,200	0.22	0.19	0.26	0.02	0.01	0.03	Meta-analysis
Nursing home residents[14]	1,404,421	1.47	0.94	2.01	0.57	0.30	0.85	[8] (age-adjusted)
Persons who injected drugs in past year[39]	3,694,500 (1,872,700–7,273,300)	53.50	47.00	59.90	43.70	40.70	46.70	[43]

Bring hepatitis C testing and treatment to *meet people where they are*

Hall EW et al, Hepatology 2025

Viewpoint

March 9, 2023

A National Hepatitis C Elimination Program in the United States

A Historic Opportunity

Rachael L. Fleurence, MSc, PhD[1]; Francis S. Collins, MD, PhD[1]

Main Priorities of National Program

- **Accelerate availability of Point-of-Care diagnostic tests**
- **Provide broad access to DAAs**
- **Comprehensive public health effort to engage, identify, and treat**

JUNE 4, 2025

CASSIDY, VAN HOLLEN INTRODUCE LIFE-SAVING HEPATITIS C LEGISLATION

Cure Hepatitis C Act of 2025

- $9.7 billion through 2031 to support rapid screening, treatment access, and wraparound services
- CBO estimates $6.5 billion in savings over 10 years

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

For Immediate Release: June 27, 2024

CLIA-Waived GeneXpert® Xpress Platform POC HCV RNA

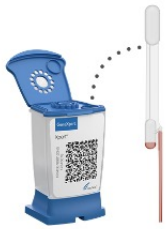
1

Collect 250-500uL fingerstick whole blood in BD Microtainer®^

- Fingerstick using deep lancet
- Valid for clinical use up to 4 hours

2

Transfer 100uL of the sample into the cartridge using the pipette provided



- Load into cartridge with specialized pipette with overflow valve

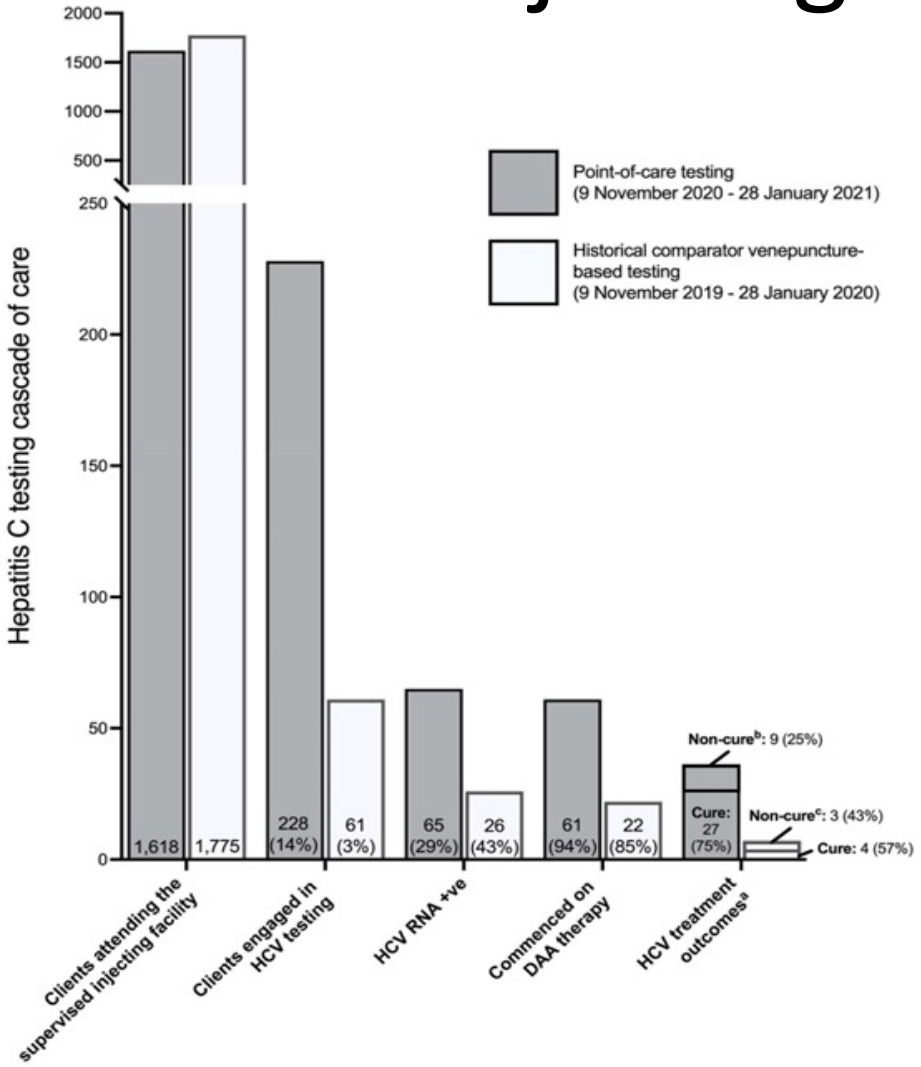
3

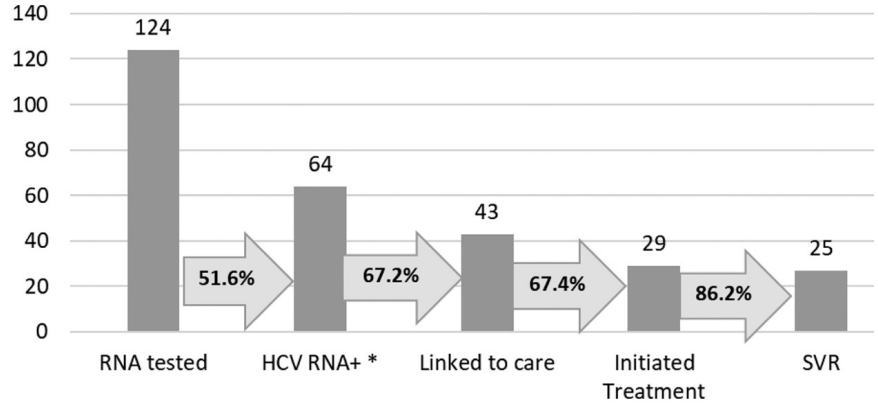
Insert cartridge and start test

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

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

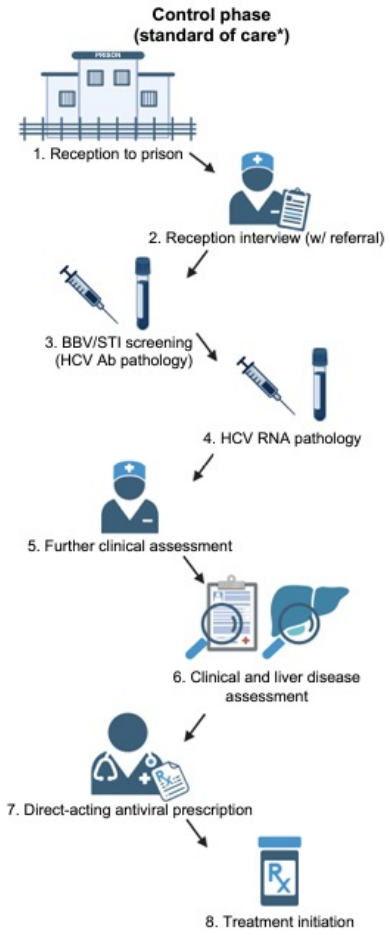
POC HCV Testing in Supervised Injecting Facilities

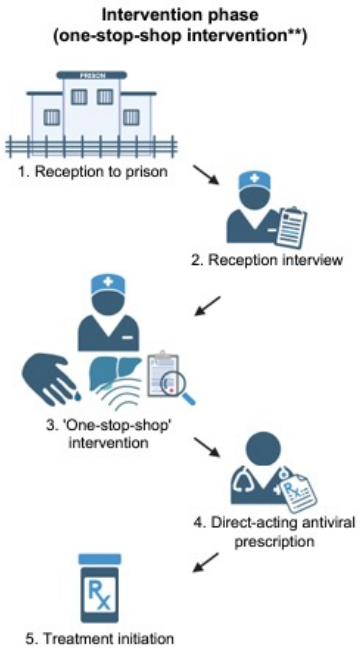




MacIsaac MB et al, Int J Drug Policy, 2024; Lettner B et al, Lancet Reg Health Am, 2023

POC HCV Testing to Enhance Treatment Uptake in Prison





Control: standard of care

Event	Number (%)
Enrolled	239
Ever injected (at risk)	115/239 (48%)
HCV Ab/RNA testing	63/239 (26%)
HCV RNA positive	18/63 (29%)
DAA treatment initiated <12 wks	4/18 (22%)
Treatment completed	Unknown
SVR12 achieved	0/4 (0%)

99 days (median)

'One-stop-shop' intervention

Event	Number (%)
Enrolled	301
Ever injected (at risk)	125/301 (42%)
HCV RNA PoC testing	298/301 (99%)
HCV RNA positive	30/298 (10%)
DAA treatment initiated <12 wks	28/30 (93%)
Treatment completed	15/28 (50%)
SVR12 achieved	11/28 (39%)

6 days (median)

Sheehan Y et al, Journal of Hepatology 2023

Clinical Infectious Diseases

VIEWPOINTS

IDSA Infectious Diseases Society of America

hivma hiv medicine association

OXFORD

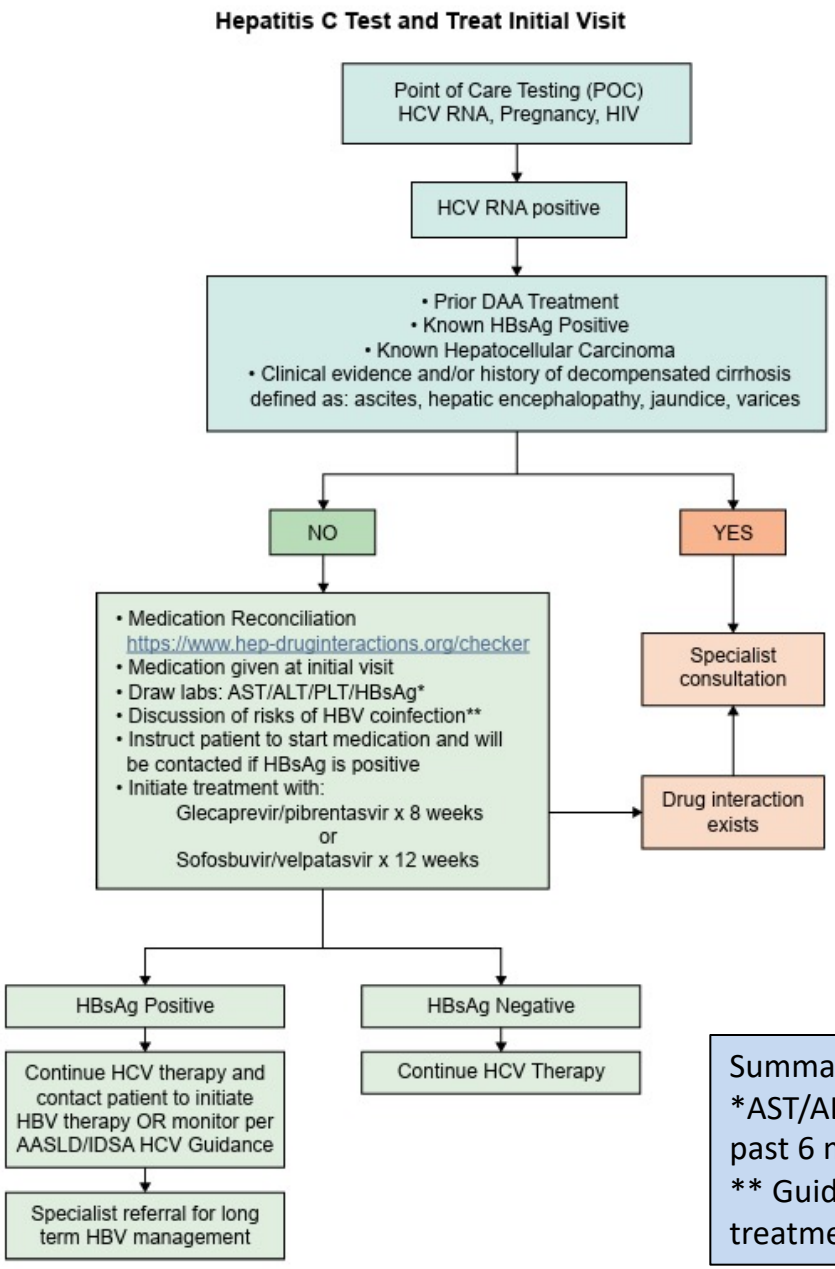
The Urgent Need to Implement Point-of-Care RNA Testing for Hepatitis C Virus to Support Elimination

Shashi N. Kapadia,[1] Ashly E. Jordan,[2] Benjamin J. Eckhardt,[3] and David C. Perlman[2,4]

[1]Division of Infectious Diseases, Weill Cornell Medicine, New York, New York, USA; [2]Center for Drug Use and HIV/HCV Research, New York, New York, USA; [3]Division of Infectious Diseases, New York University School of Medicine, New York, New York, USA; and [4]Division of Infectious Diseases, Icahn School of Medicine at Mt Sinai, New York, New York, USA

- A federal HCV elimination plan should include a funding model for community-based testing programs that use POC tests, including consideration of staffing, overhead, and logistical costs.
- Insurance reimbursement for POC testing should be encouraged via development of specific billing codes for this purpose and incorporation into the Medicare fee schedule.
- State and local public health departments should incorporate POC testing into their surveillance plans by determining standards for reporting POC tests.
- Federal agencies should fund rigorous clinical research to evaluate the safety and effectiveness of POC testing in innovative care models, such as rapid-treatment start models or all-POC strategies. Professional societies should prepare to incorporate POC RNA testing into clinical guidance based on available evidence.

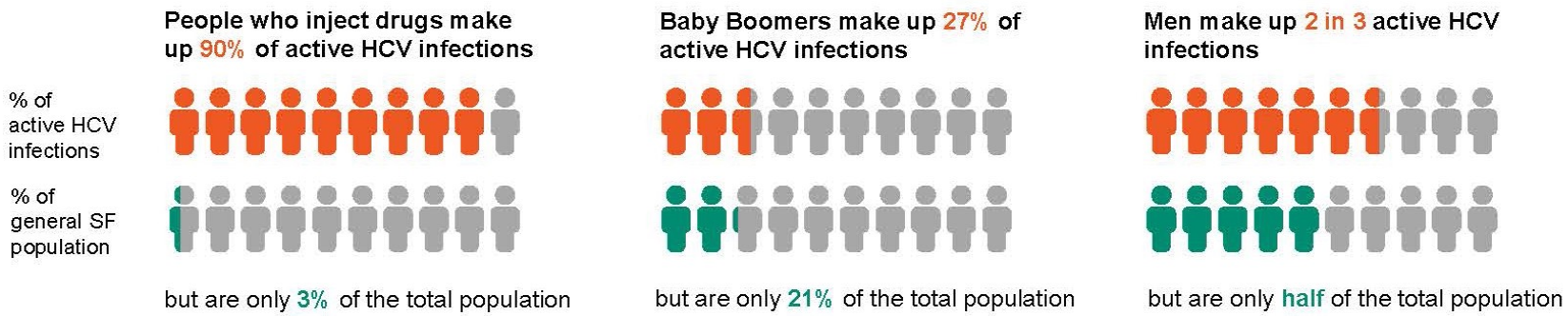
AASLD/IDSA HCV Test and Treat Algorithm



Summary of Footnotes:
*AST/ALT and PLT can be deferred if drawn in past 6 months or if TE done
** Guidance for immediate treatment or treatment after HBSAg results are obtained

https://www.hcvguidelines.org/

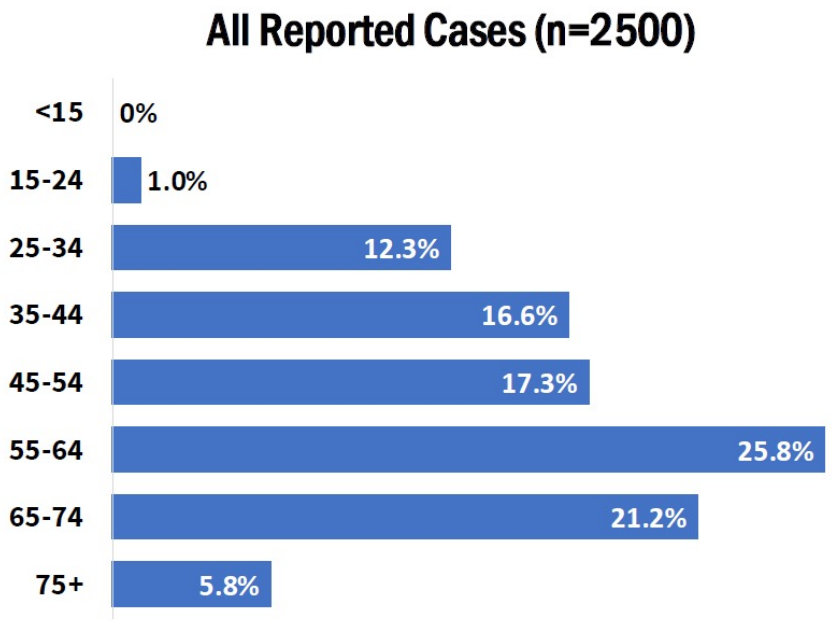
Hepatitis C Virus Prevalence in San Francisco

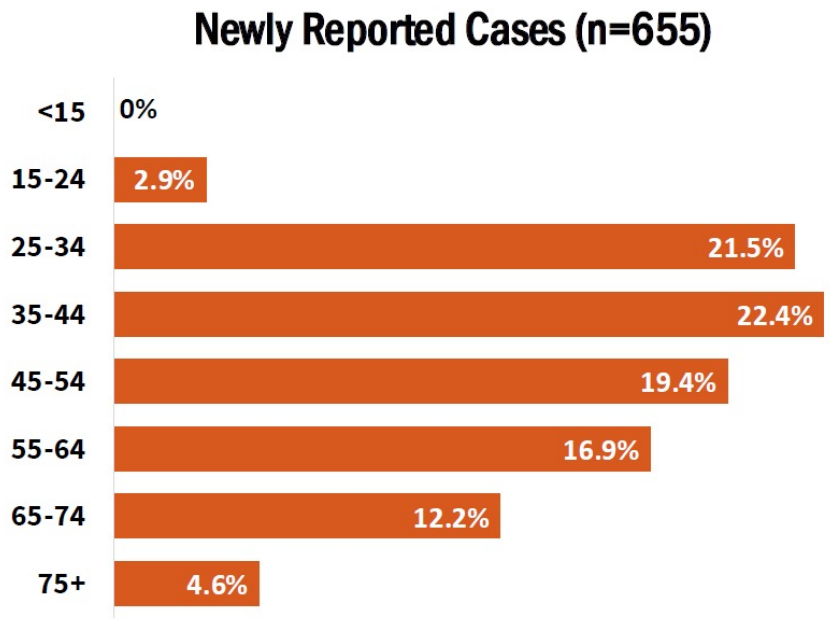


Approximately 11,500 people are living with active, untreated hepatitis C virus (HCV) in San Francisco; an estimated 90% of those are people who inject drugs (PWID).

Facente SN et al, PLOS One, 2022

San Francisco Viral Hepatitis C Surveillance Report, 2023

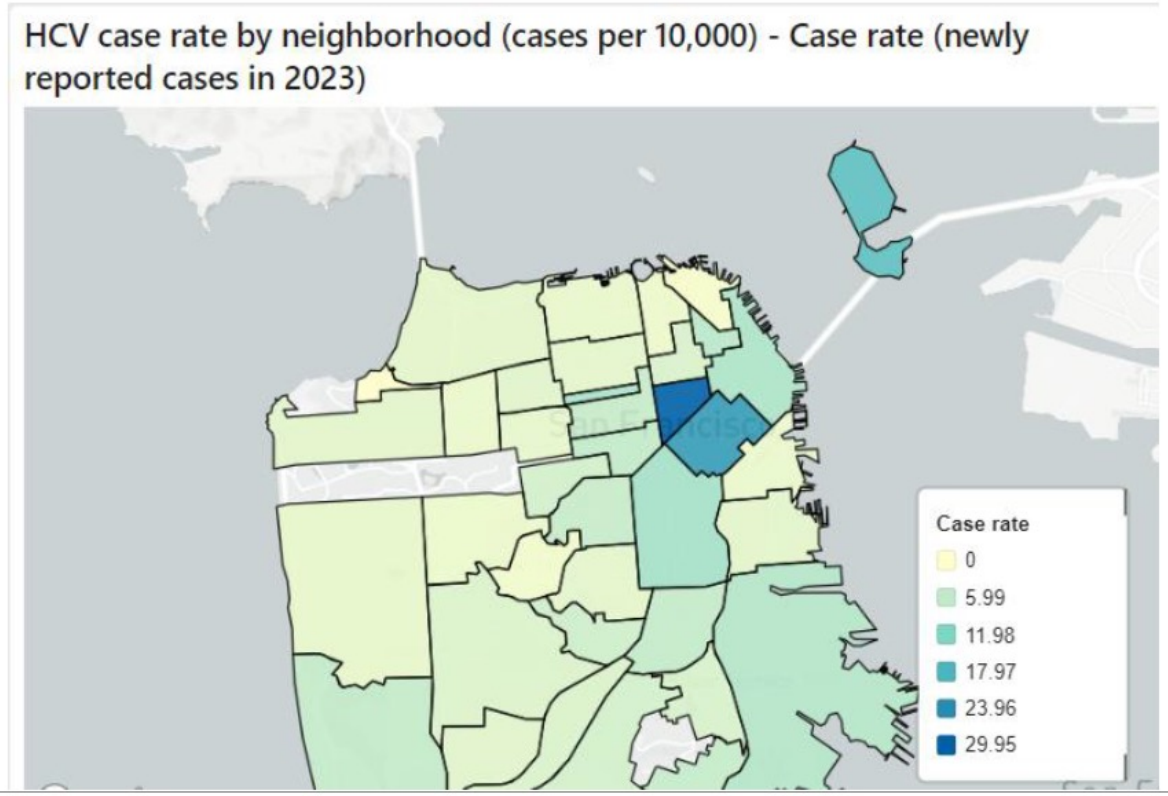




The age groups with the highest proportion of cases were 55-64 years among all reported cases and 35-44 years among newly reported cases

https://www.sf.gov/resource/2024/viral-hepatitis-reports

Newly Reported Chronic Hepatitis C Cases by Neighborhood, 2023



Newly reported HCV cases were highest in the Tenderloin (29.9) and South of Market (21.6) neighborhoods

- 181/655 (27.6%) of newly reported cases could not be geocoded and are not shown.
- Case counts and rates are not shown for neighborhoods with fewer than five cases or for neighborhoods with a population fewer than 1,000 people.
- San Francisco Population data source: American Community Survey 5-year 2017-2022

https://www.sf.gov/resource/2024/viral-hepatitis-reports

Mobile Hepatitis C Screening and Treatment

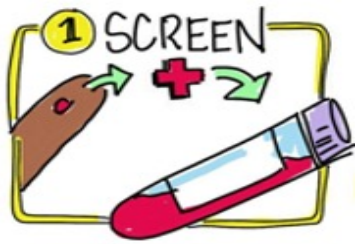
1 week | 1 week | 1 week

- OraQuick® Rapid HCV Ab reactive
- Venipuncture for confirmatory HCV RNA testing performed

- HCV RNA + results disclosed
- Fibroscan performed
- Insurance information obtained and clinic forms completed

- **Clinician telehealth visit**
- Pre-treatment labs drawn (CBC, CMP, HIV, HBV serologies)
- Prescription sent to pharmacy

- DAA's brought to pt
- **Clinician treatment start visit**
- Review individualized treatment plan



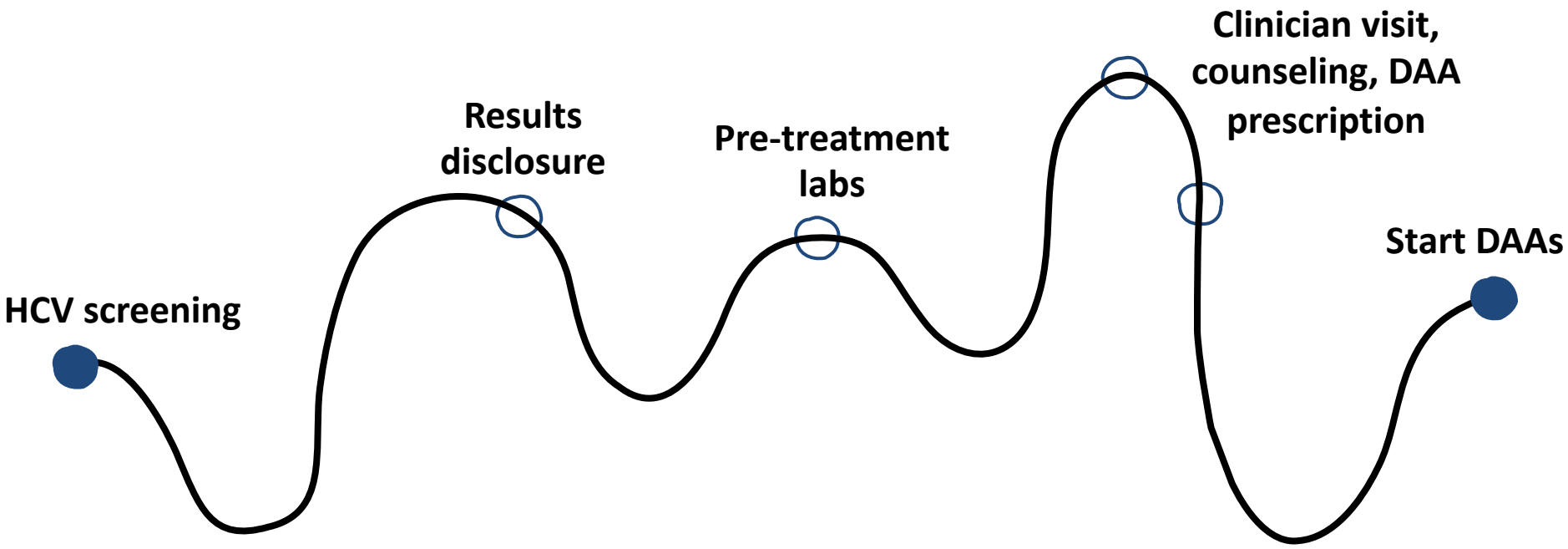
“How do you feel about completing treatment?”

“I think this is a fantastic program. **I don't think I would have sought it out**…. To be cured is huge.”

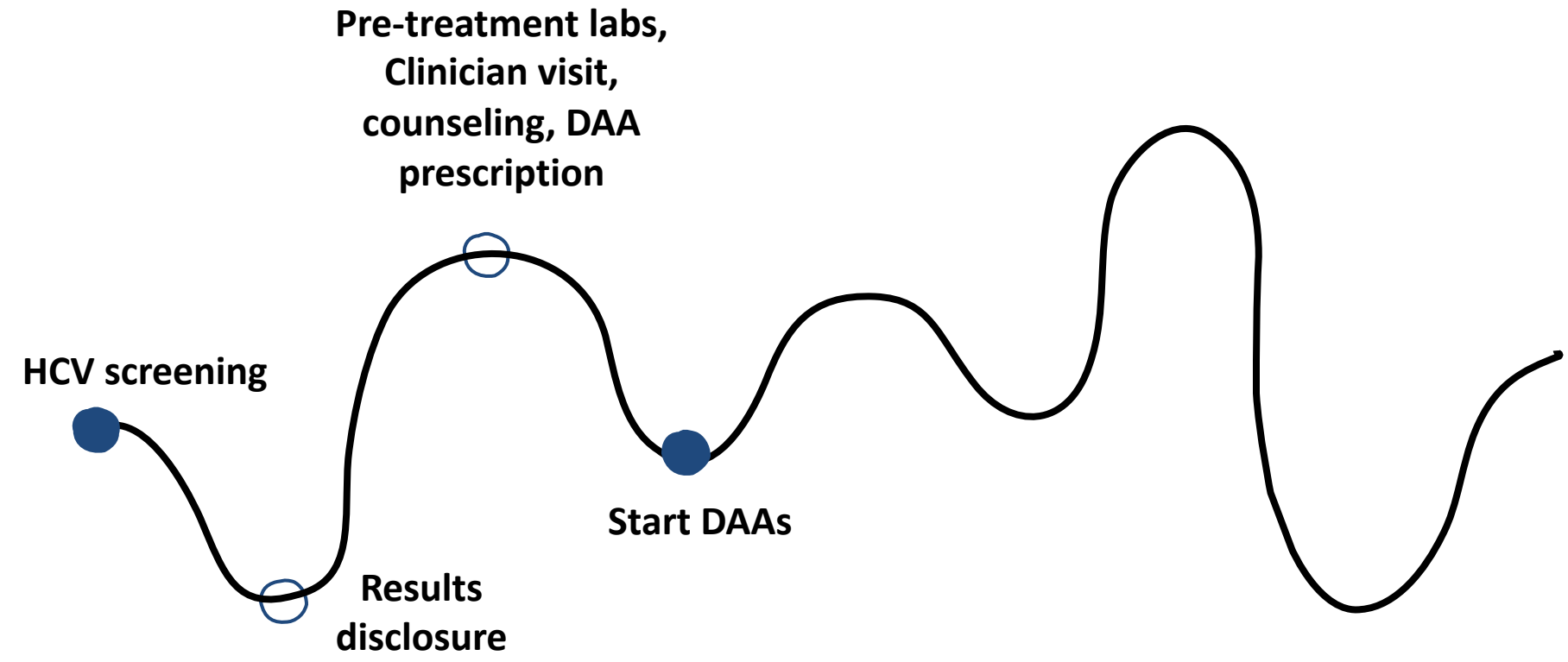
“I liked it. **It was convenient** and normally when I go to a doctor's office I wait an hour or 45 minutes, but I am seen sooner at the van.”

“I was touched that UCSF has come to me **because I would have not been able to go to them**…”

Traditional Path From Testing to Treatment



DeLIVER Care Path From Testing to Treatment



POC HCV RNA Implementation Considerations

Regulatory

1. Federal CLIA Certification of Waiver
2. California State Laboratory Registration of Licensing
3. Result Reporting
   - Positive HCV RNA results must be reported to local health authorities within one working day of identification as mandated by Title 17 of the California Code of Regulations (CCR) Section 2505
4. Personnel Training and Scope of Practice
   - Authorized Personnel: Trained healthcare professionals, including MDs, APPs, RNs, LVNs, and MAs
   - Non-Medical Personnel: Must complete appropriate training approved by the California Department of Public Health
5. Quality Assurance

OraQuick HCV Antibody Testing Quality Assurance Guidelines for Non-Healthcare Settings

California Department of Public Health
Office of AIDS

Instructions for Use
For Use with GeneXpert Xpress System
CLIA Complexity: Waived

IVD

13.1 Starting the GeneXpert Xpress System

This section lists the basic steps for running the test. For detailed instructions, see the *GeneXpert Xpress System User's Guide*.

1. Put on a new pair of gloves.
2. Turn on the GeneXpert Xpress IV instrument (in two or four modules configuration).
3. Turn on the Hub computer. The Windows Lock screen appears.
4. Swipe up to continue. The Windows Password screen appears.
5. Touch **Password** to display the keyboard, and then type your Windows password.
6. Touch the arrow button at the right of the password entry area. The GeneXpert Xpress Software starts, and a login screen appears.
7. If enabled, you may log in by scanning a barcode on your institutional ID, using the barcode scanner (located behind the right side of the touchscreen). Then proceed to Step 10. Otherwise, follow the steps below to login manually.
8. Enter your User Name and Password (the virtual keyboard appears once you touch the entry fields).
9. Touch the **X** in the upper right of the virtual keyboard. The keyboard disappears and the **LOGIN** button appears at the bottom of the screen. Touch the **LOGIN** button to continue.
10. The Database Maintenance Reminder screen and the Archive Tests Reminder dialog boxes may appear, depending on your system configuration. For more information, see the *GeneXpert Xpress System User's Guide*.

14.7 Running External Controls

It is recommended that external controls be tested at the frequency listed below:

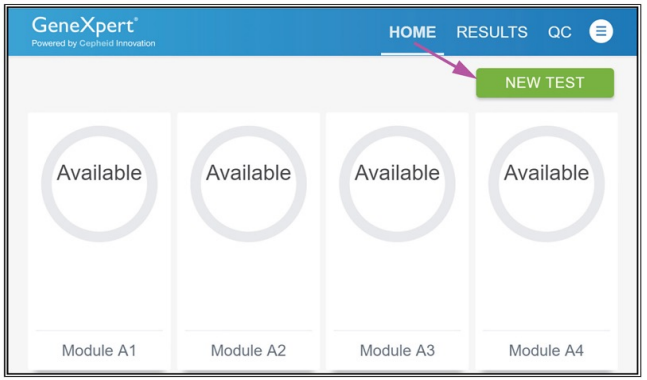
- Each time a new lot of Xpert HCV kits is received.
- Each time a new shipment of Xpert HCV kits is received even if it is the same lot previously received.
- Each time a new operator is performing the test (i.e., operator who has not performed the test recently).
- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your institution's standard Quality Control (QC) procedures.

14.1 Starting a Test

Note Before you start the test, make sure that the system is running GeneXpert Xpress software version 6.4a or higher and that the Xpert HCV Assay Definition File is imported into the software.

The following instructions showing how to prepare the sample and the cartridge are shown on-screen in a video and are also described in the *Quick Reference Instructions* (QRI).

1. Put on a new pair of gloves if performing a new test.
2. Touch the **NEW TEST** button on the Home screen (see Figure 1).



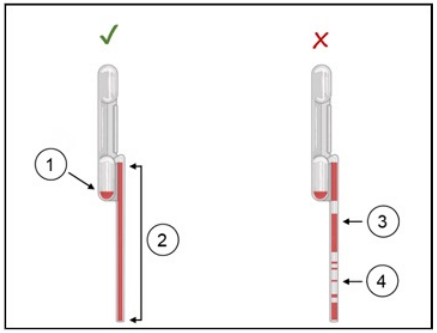


Figure 5. Xpert HCV Test 100 µL Transfer Pipette (Correct and Incorrect Use)

Staff Training

- Key components
  - Background on HCV
  - Safety and quality assurance
  - Specimen collection/fingerstick
  - Test procedures
  - Result interpretation
  - Results disclosure
  - Compliance with local regulatory requirements
  - Practice runs (hands-on)
  - Proficiency testing
- Desired components
  - Co-design with end users
  - Flexibility of training options
  - Provide SOPs
  - Ongoing operator support
  - Post-training review and re-training

Hepatitis C History

Have you ever been tested and told you have Hepatitis C?	○ Yes ◉ No reset

Recent Hepatitis C Exposure History

Has the patient mentioned recent HCV exposures? **(2 weeks to 6 months)**	

Patient Eligible for Antibody Testi

- A drop of blood will be collected via finger prick
- Results will be available in approximately 20 minutes

Hepatitis C History

Have you ever been tested and told you have Hepatitis C?	◉ Yes ○ No reset

Hepatitis C Treatment History

Are you currently on Hep C medication **OR** **Have you finished/stopped meds <4 weeks**	○ Yes ◉ No reset

Patient Eligible for RNA testing!!

There are two options for HCV RNA testing:

1. Option A: Point-of-Care RNA Test (A small vial of blood will be collected via finger prick. Results may take up to 1 hour)
2, Option B: Venipuncture/Blood draw RNA Test (A small tube of blood will be collected via blood draw. Results will be available in approximately 1 week)

☐ Option A: Point-of-Care RNA Test
☐ Option B: Venipuncture/Blood draw RNA Test

Evaluation

- HCV RNA POC Pilot Evaluation Goals
  - Assess progress
  - Identify opportunities for quality improvement
  - Document implementation lessons learned to inform similar programs
- Formative Evaluation
  - Interview staff and community partners

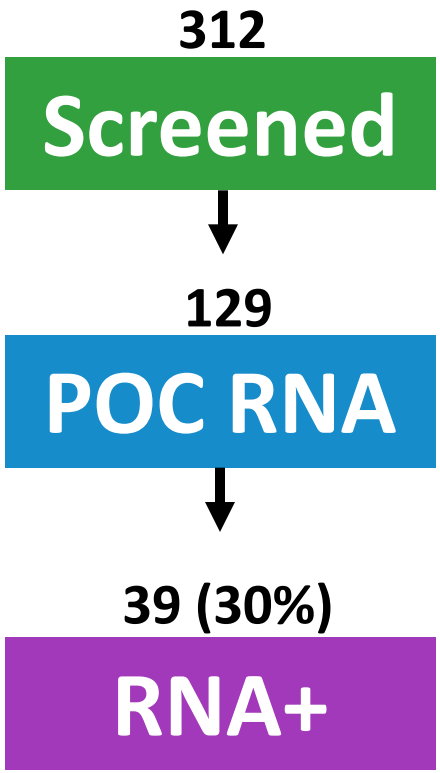
Interviewees included:

- 6 UCSF staff
- 1 San Francisco Department of Public Health staff
- 1 California Department of Public Health staff
- 1 End Hep C SF staff

FACENTE CONSULTING
UNDERSTAND - IMPLEMENT - TELL YOUR STORY

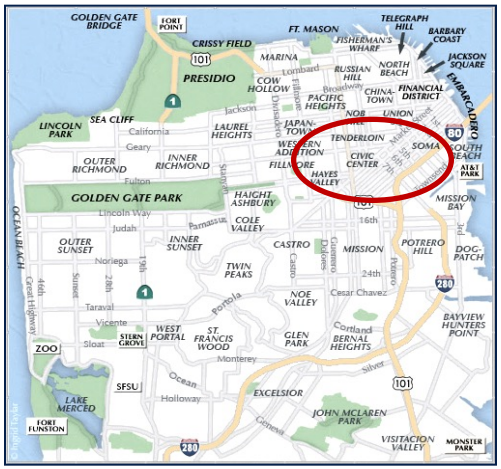
Initial Experience

- ✓ Full run-through before first shift
- ✓ On-site run-through of new workflow at each shift site
- ✓ Planned for low-volume first 2-4 weeks
- ✓ Adjust survey instruments based on feedback
- ✓ Manual result reporting while working on automated process



Same Day Test-and-Treat: Is it now feasible?

The No One Waits (NOW) Study



Screening	Treatment	Follow-up
• 2-step testing (POC Ab, venipuncture HCV RNA)	• **SAME-DAY** treatment initiation using **donated SOF/VEL**	• Follow-up check-ins every 2 weeks
• Results disclosure ~1 week after screening	• Insurance authorization for remainder of treatment	• SVR (cure) testing after treatment completion

Morris MD & Price JC et al, JAMA Netw Open 2023

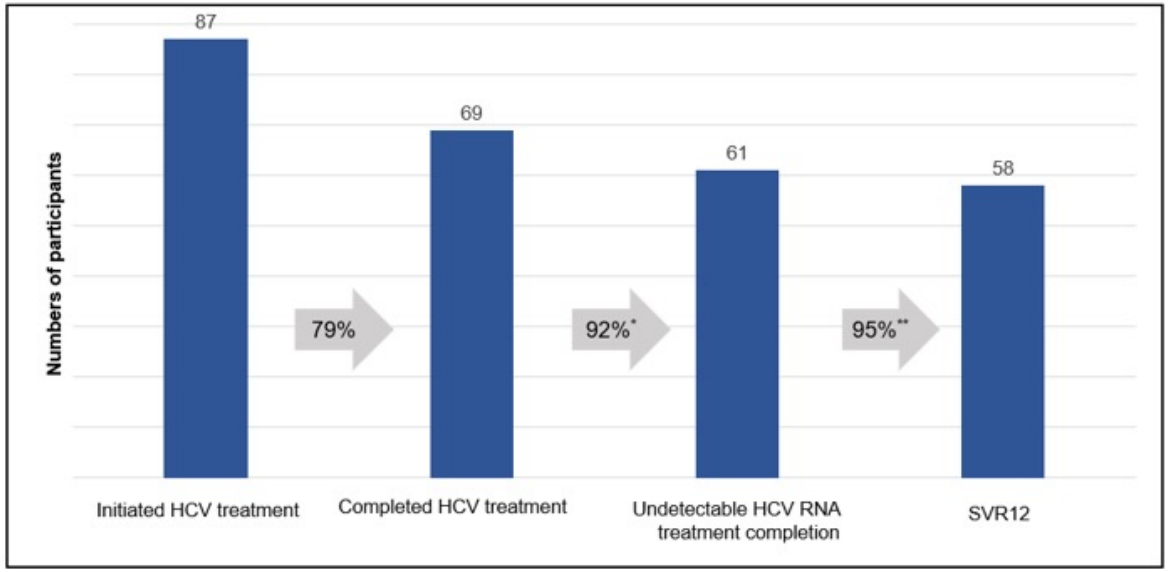
NOW Study Population

	N=87
Median years of age (IQR)	48 (37, 58)
Male	71%
Race and ethnicity	
African American and Black	25%
Latino/a/e/x	10%
Asian, Native Hawaii, Pacific Islander, Mixed	6%
White	56%
Not specified	2%
Slept outside or in vehicle in past 12 months	61%
Current housing	
Outdoors or vehicle	43%
Shelter	9%
SRO or hotel	17%
With friend or family	3%
Treatment or transitional	10%
Rent or own	17%
Income below the national poverty line	97%
Any injection drug use in past 3 months	80%

	N=87
Insured at time of enrollment	94%
Type of insurance	
Medi-Cal/SFHP	95%
VA	1%
Blue Cross	3%
Kaiser	1%
Primary care provider	48%
Time it took to get to study location	
Less than 15 min	52%
15 min - 30 min	29%
More than 30 minutes	17%

Morris MD & Price JC et al, JAMA Netw Open 2023

Hepatitis C Treatment Outcomes



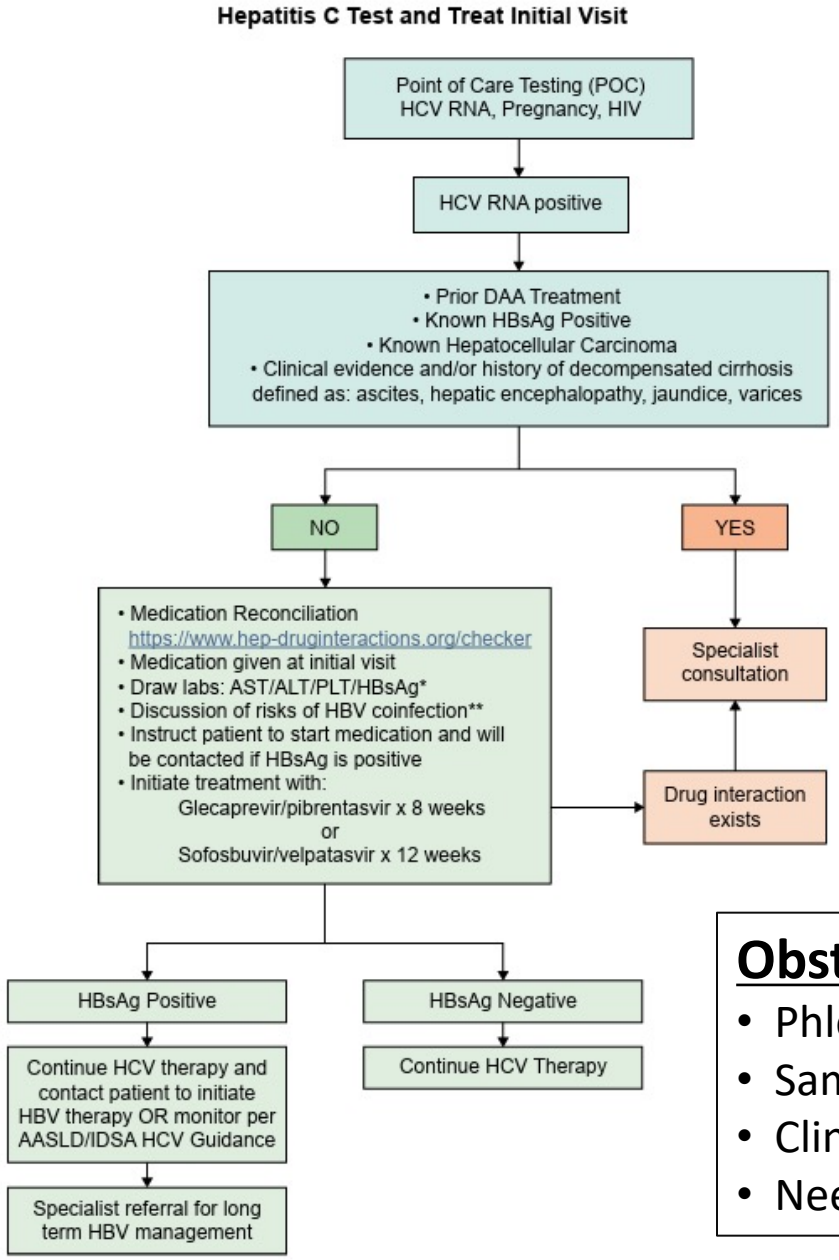
*excludes 3 people with incomplete blood draws at end of treatment
**includes 2 people with presumed reinfection post-treatment

- ITT SVR12: 67%
- PP SVR12: 84%
- No adverse events causing premature tx discontinuation
- No alterations in treatment based on pre-treatment labs drawn day of SOF/VEL start

Median time from antibody screening to treatment initiation: 7 days (IQR: 6, 14 days)

Morris MD & Price JC et al, JAMA Netw Open 2023

AASLD/IDSA HCV Test and Treat Algorithm

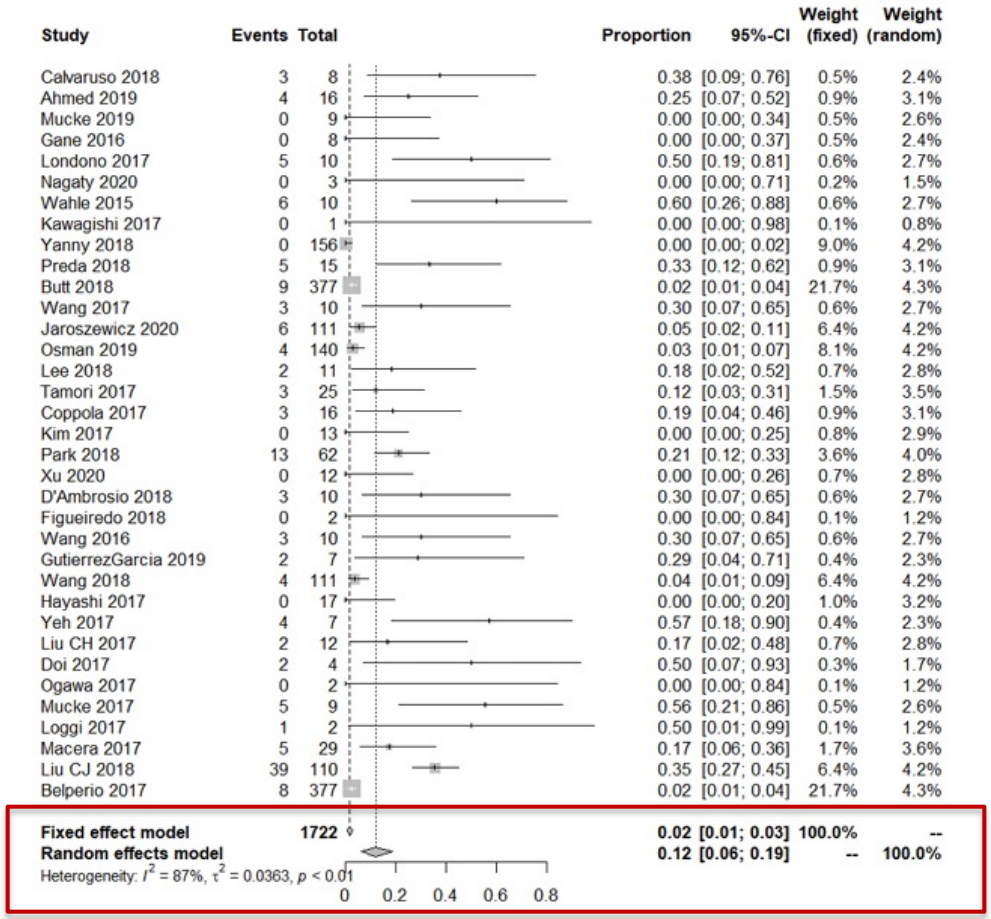


Obstacles:

- Phlebotomy for HBsAg
- Same day medication
- Clinician availability
- Need for fibrosis staging

https://www.hcvguidelines.org/

DAAs and Hepatitis B Reactivation



Study	Events	Total	Proportion	95%-CI	Weight (fixed)	Weight (random)
Calvaruso 2018	3	8	0.38	[0.09; 0.76]	0.5%	2.4%
Ahmed 2019	4	16	0.25	[0.07; 0.52]	0.9%	3.1%
Mucke 2019	0	9	0.00	[0.00; 0.34]	0.5%	2.6%
Gane 2016	0	8	0.00	[0.00; 0.37]	0.5%	2.4%
Londono 2017	5	10	0.50	[0.19; 0.81]	0.6%	2.7%
Nagaty 2020	0	3	0.00	[0.00; 0.71]	0.2%	1.5%
Wahle 2015	6	10	0.60	[0.26; 0.88]	0.6%	2.7%
Kawagishi 2017	0	1	0.00	[0.00; 0.98]	0.1%	0.8%
Yanny 2018	0	156	0.00	[0.00; 0.02]	9.0%	4.2%
Preda 2018	5	15	0.33	[0.12; 0.62]	0.9%	3.1%
Butt 2018	9	377	0.02	[0.01; 0.04]	21.7%	4.3%
Wang 2017	3	10	0.30	[0.07; 0.65]	0.6%	2.7%
Jaroszewicz 2020	6	111	0.05	[0.02; 0.11]	6.4%	4.2%
Osman 2019	4	140	0.03	[0.01; 0.07]	8.1%	4.2%
Lee 2018	2	11	0.18	[0.02; 0.52]	0.7%	2.8%
Tamori 2017	3	25	0.12	[0.03; 0.31]	1.5%	3.5%
Coppola 2017	3	16	0.19	[0.04; 0.46]	0.9%	3.1%
Kim 2017	0	13	0.00	[0.00; 0.25]	0.8%	2.9%
Park 2018	13	62	0.21	[0.12; 0.33]	3.6%	4.0%
Xu 2020	0	12	0.00	[0.00; 0.26]	0.7%	2.8%
D'Ambrosio 2018	3	10	0.30	[0.07; 0.65]	0.6%	2.7%
Figueiredo 2018	0	2	0.00	[0.00; 0.84]	0.1%	1.2%
Wang 2016	3	10	0.30	[0.07; 0.65]	0.6%	2.7%
GutierrezGarcia 2019	2	7	0.29	[0.04; 0.71]	0.4%	2.3%
Wang 2018	4	111	0.04	[0.01; 0.09]	6.4%	4.2%
Hayashi 2017	0	17	0.00	[0.00; 0.20]	1.0%	3.2%
Yeh 2017	4	7	0.57	[0.18; 0.90]	0.4%	2.3%
Liu CH 2017	2	12	0.17	[0.02; 0.48]	0.7%	2.8%
Doi 2017	2	4	0.50	[0.07; 0.93]	0.3%	1.7%
Ogawa 2017	0	2	0.00	[0.00; 0.84]	0.1%	1.2%
Mucke 2017	5	9	0.56	[0.21; 0.86]	0.5%	2.6%
Loggi 2017	1	2	0.50	[0.01; 0.99]	0.1%	1.2%
Macera 2017	5	29	0.17	[0.06; 0.36]	1.7%	3.6%
Liu CJ 2018	39	110	0.35	[0.27; 0.45]	6.4%	4.2%
Belperio 2017	8	377	0.02	[0.01; 0.04]	21.7%	4.3%
Fixed effect model		**1722**	**0.02**	**[0.01; 0.03]**	**100.0%**	--
Random effects model			**0.12**	**[0.06; 0.19]**	--	**100.0%**

Heterogeneity: $I^2 = 87\%$, $\tau^2 = 0.0363$, $p < 0.01$

- 35 articles (1673 patients) with HBsAg+
- HBV reactivation defined as:
  - reappearance of HBV DNA;
  - HBV DNA ≥1-2 log increase from baseline
- Pooled HBV reactivation risk 12% (95% CI 6-19)

HBV prevalence in US:
HCV: 0.7-5.8%
IDU: 4-12%

Oh JH et al, J Pers Med, 2022 Lim JK et al, Am J Gastroenterol, 2020

Time to Insurance-Provided DAAs

- 70% transitioned to insurance-covered SOF/VEL within two weeks
- 90% transitioned prior to completing treatment

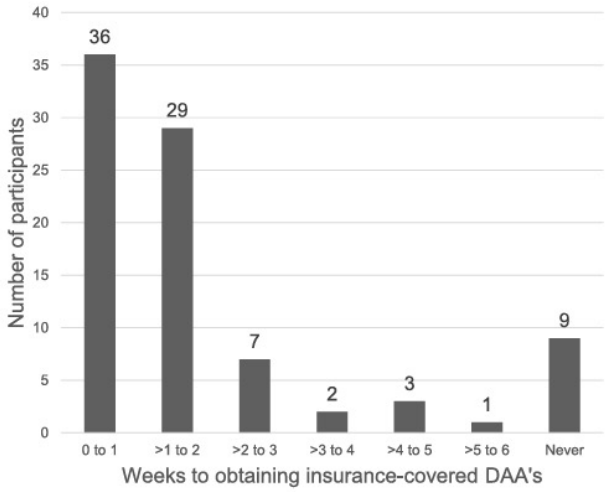


Fig. 1. Weeks required for transition to insurance-covered DAAs.

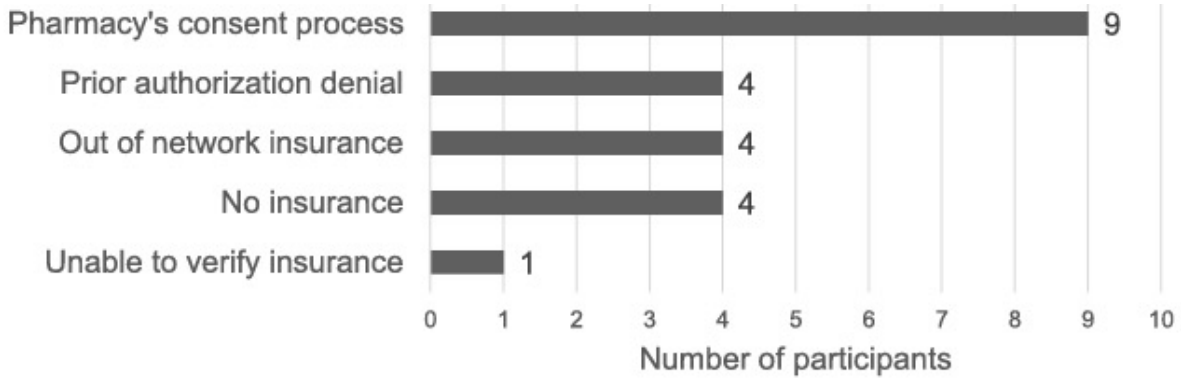


Fig. 2. Reasons for delay in transition to insurance-covered medication (n = 22 participants).

McGourty CA et al, Int J Drug Policy, 2025.

UNIVERSITY OF LIVERPOOL

Unitaid
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LONGEVITY CELT

A novel long-acting solid injectable of **glecaprevir / pibrentasvir** displayed **sustained** therapeutic concentrations for more than 8 weeks *in vivo*

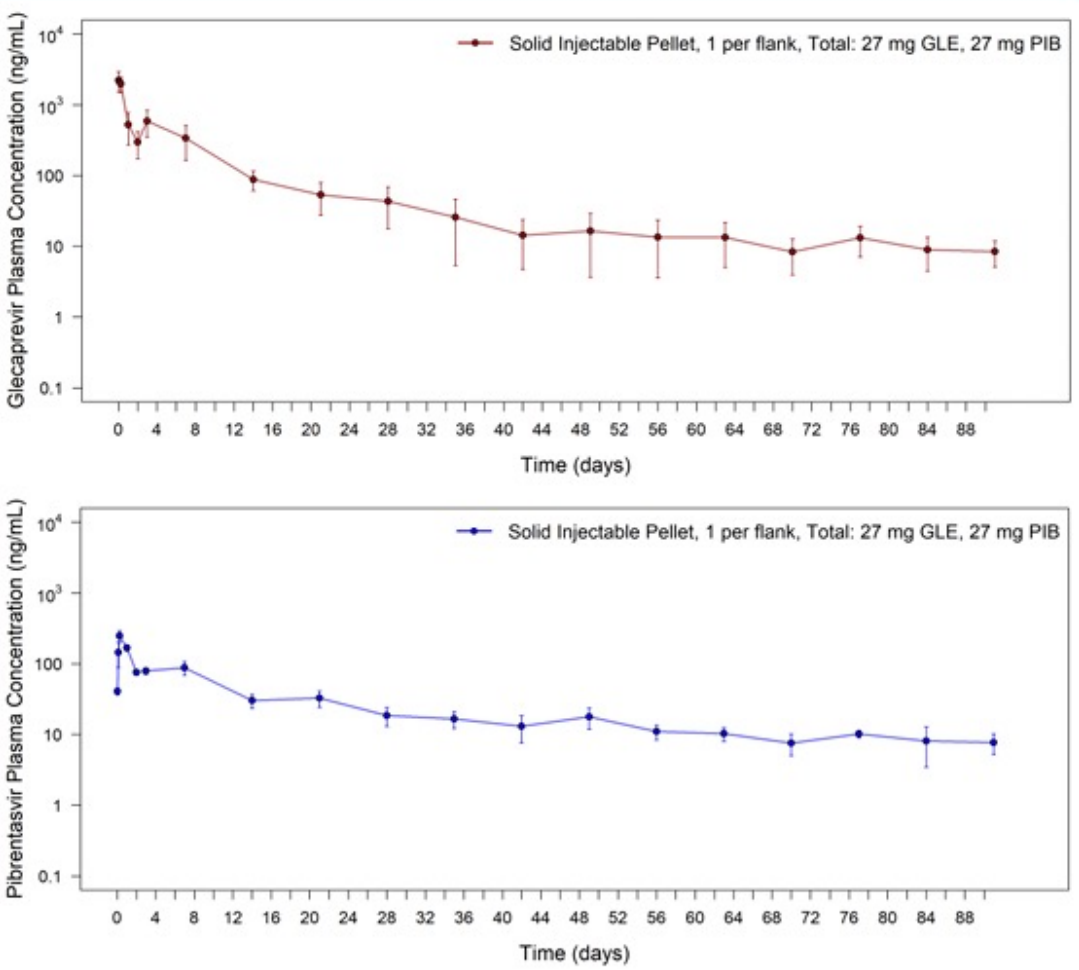


Figure 1. Plasma concentration-time curve in Sprague Dawley rats following administration of a glecaprevir/pibrentasvir solid injectable. Data are expressed as the mean ± SD (n = 4).

Arshad U et al, CROI 2024

JAMA | Original Investigation

Integrated Hepatitis C–Opioid Use Disorder Care Through Facilitated Telemedicine
A Randomized Trial

Andrew H. Talal, MD, MPH; Marianthi Markatou, PhD; Anran Liu, MS; Ponni V. Perumalswami, MD, MS; Amreen M. Dinani, MD; Jonathan N. Tobin, PhD; Lawrence S. Brown, MD, MPH

Table 2. Hepatitis C Virus Care Cascade

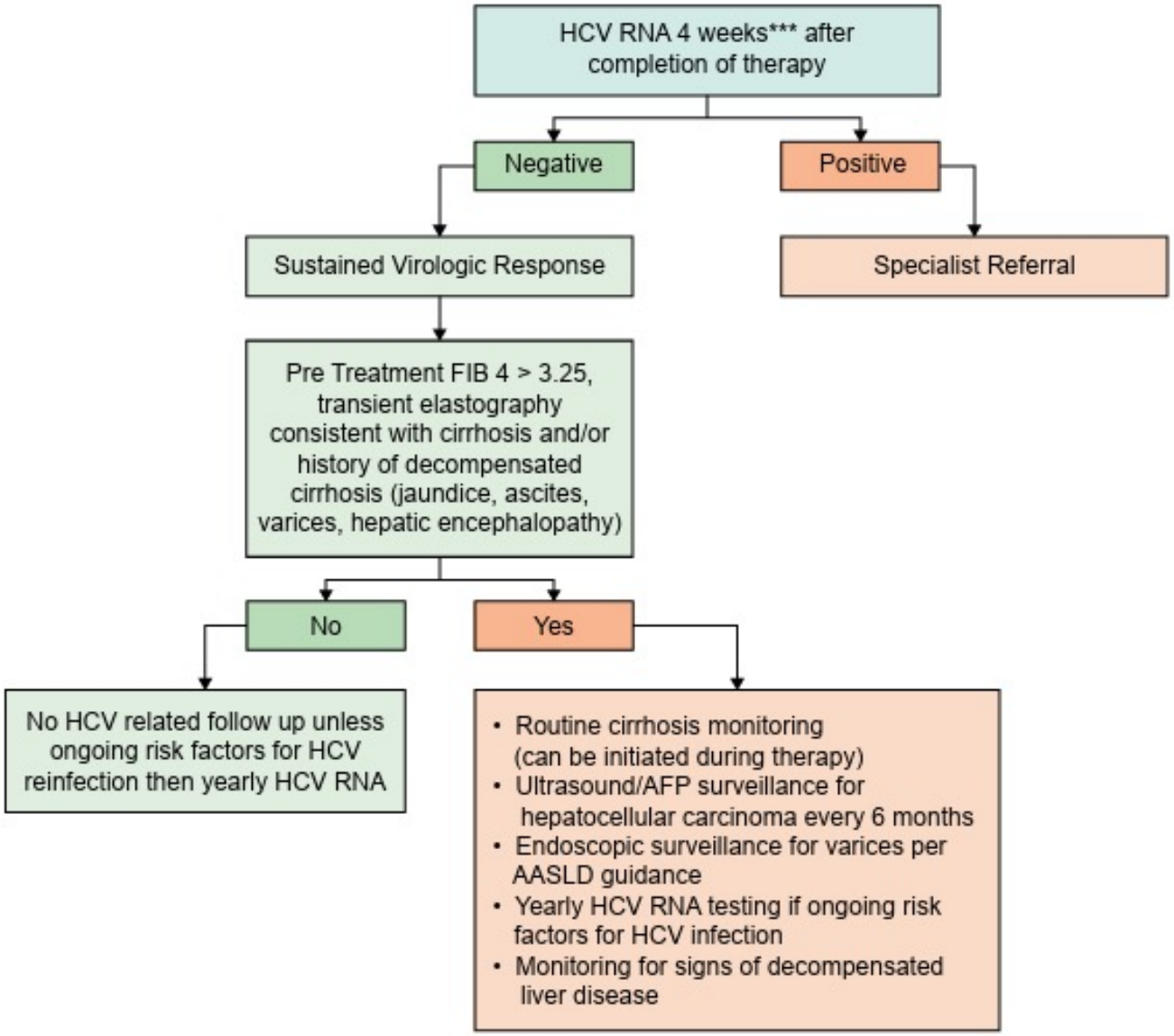
	No. (%)		
	OTP-integrated facilitated telemedicine (n = 290)	Referral (n = 312)	Log odds estimate (95% CI)
Visit 1[a]	280 (96.6)	297 (95.2)	0.1 (−0.8 to 1.0)
Treatment initiation	268 (92.4)	126 (40.4)	2.8 (2.3 to 3.3)
Treatment completion	261 (90.0)	116 (37.2)	2.7 (2.2 to 3.1)
Sustained virologic response 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)

Abbreviation: OTP, opioid treatment program.

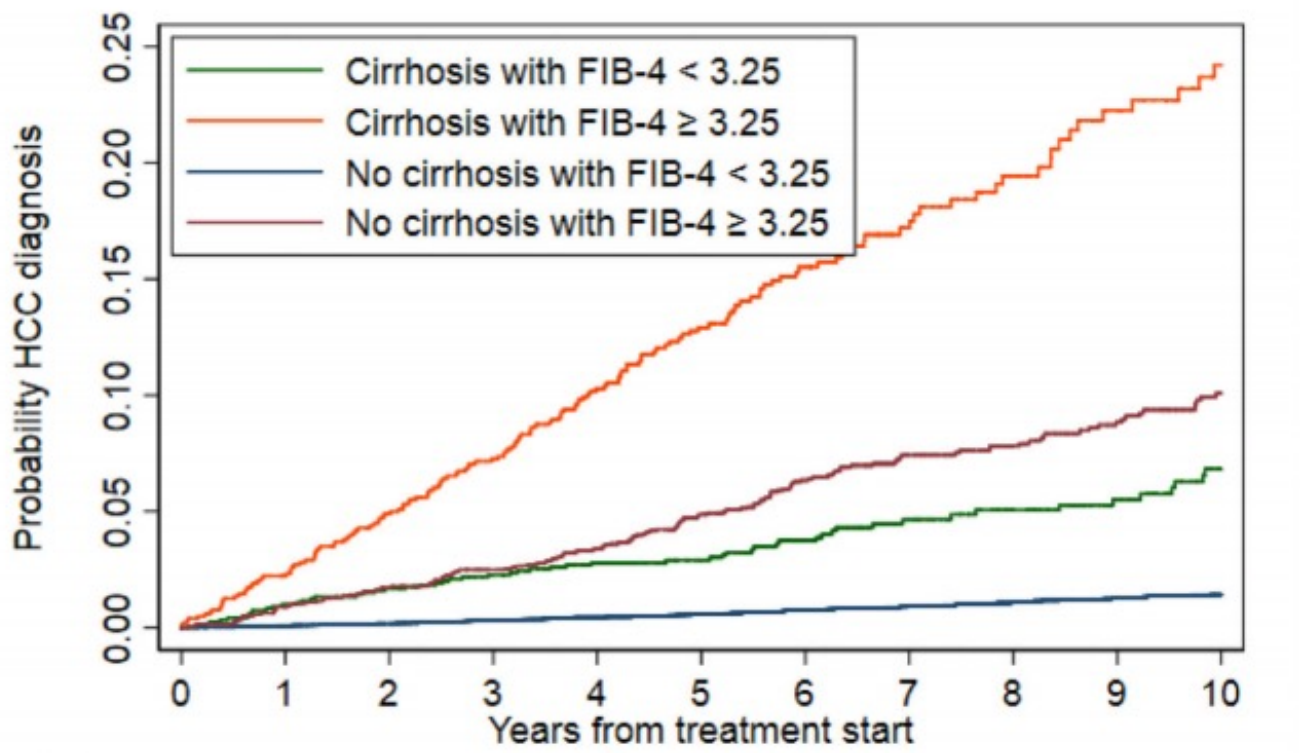
[a] The percentage of study participants in both groups who attended the initial visit with the case manager to provide blood for testing for the initial telemedicine encounter or to obtain a referral to an off-site hepatitis C virus clinician. The log odds estimates and associated 95% CIs for comparing the proportions in the 2 groups were obtained by fitting a linear mixed model incorporating the study group effect and a random effect to account for clustering.

- Hepatitis C clinician off-site
- Case manager on-site facilitated the telemedicine encounter

Hepatitis C Test and Treat Follow Up Visit



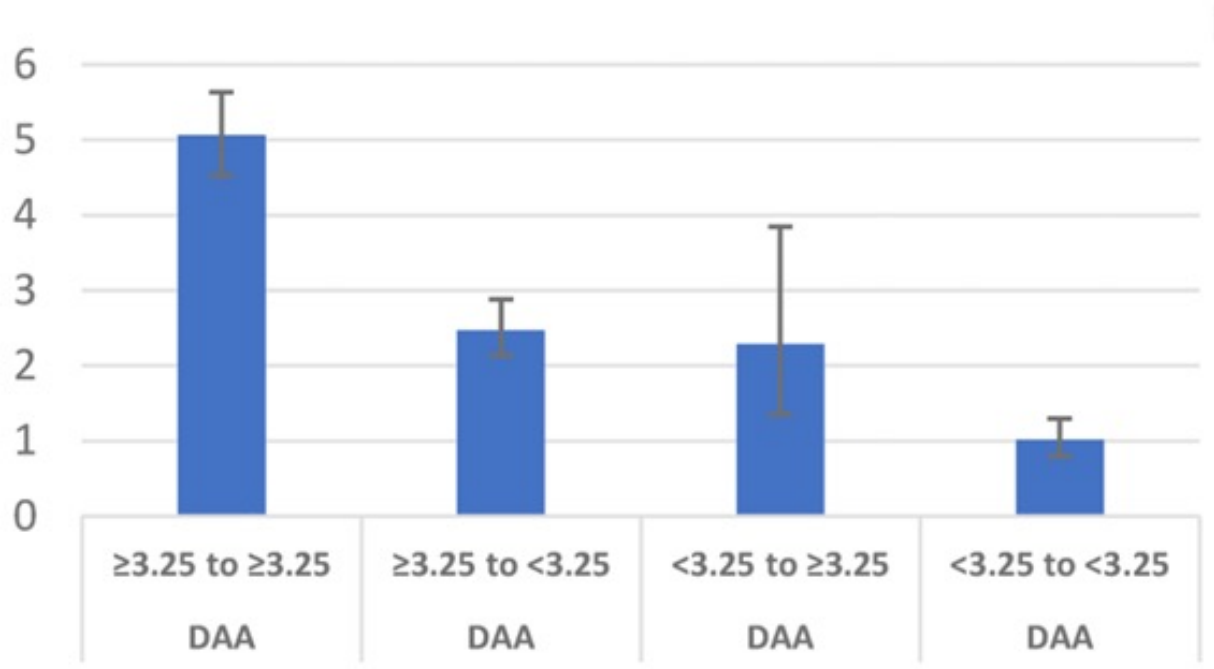
HCC After SVR: Pre-Treatment Cirrhosis and FIB-4 Predict Risk



Ioannou GN et al, Gastroenterology 2019

High FIB-4 Before or After Cure is Associated with Elevated HCC Risk

HCC risk according to pre and post treatment FIB-4



EASL

Early post-SVR decreases in FIB-4 (or liver stiffness) reflect decreased necroinflammation rather than true fibrosis regression

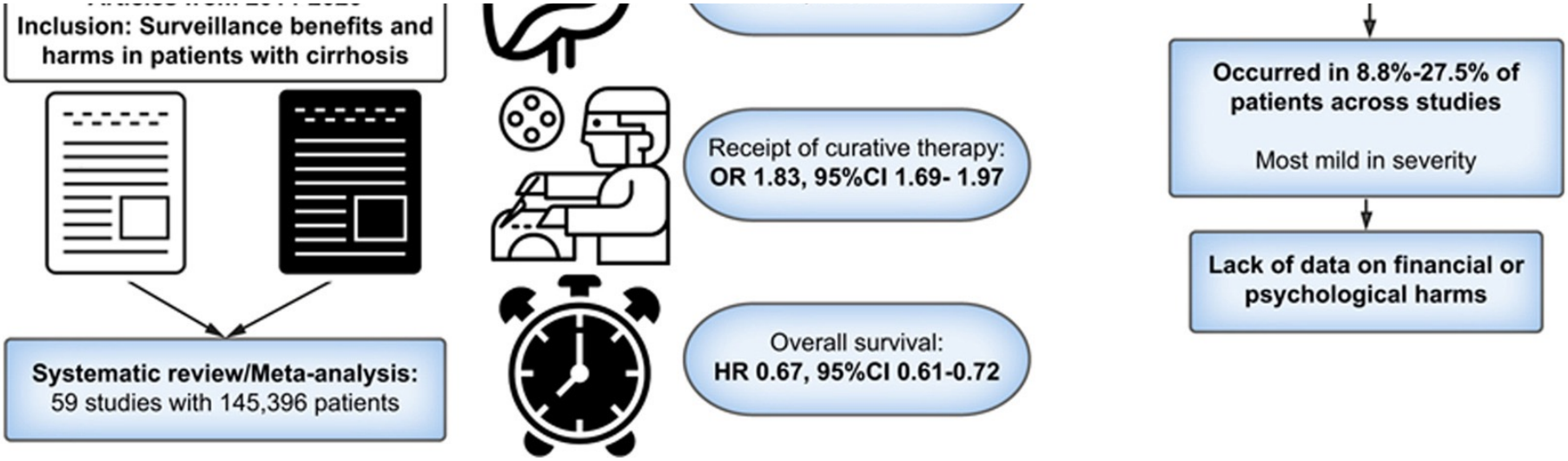
Ioannou GN et al, Gastroenterology 2019, Reiberger T et al, J of Hepatol 2024

Meta-Analysis of HCC Surveillance in Cirrhosis

Original Investigation | Gastroenterology and Hepatology

Screening for Hepatocellular Carcinoma and Survival in Patients With Cirrhosis After Hepatitis C Virus Cure

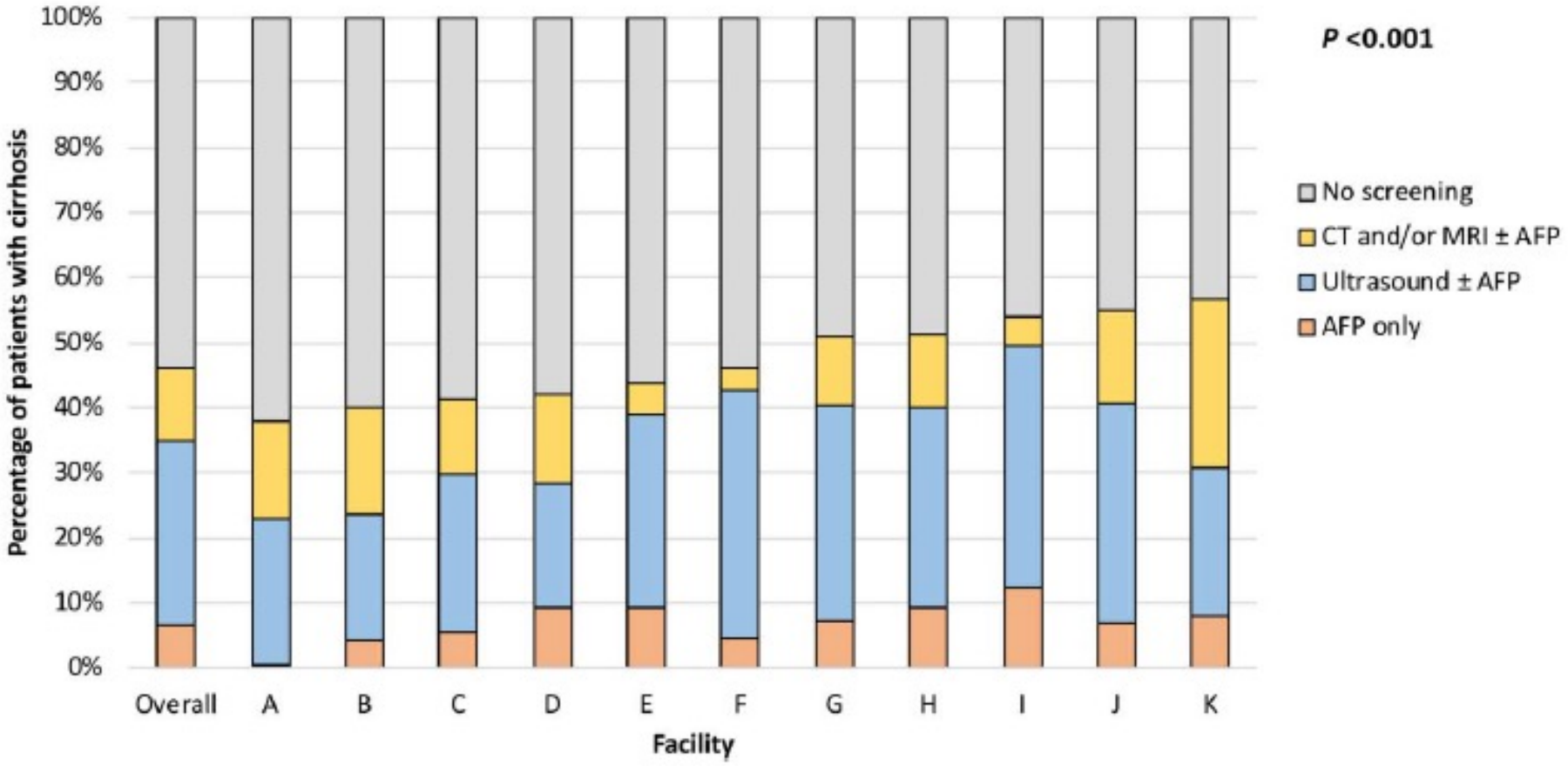
Catherine Mezzacappa, MD; Nicole J. Kim, MD; Philip Vutien, MD; David E. Kaplan, MD; George N. Ioannou, MD; Tamar H. Taddei, MD



Few studies evaluated surveillance outcomes in post-SVR setting

AG Singal et al, J of Hepatol 2022 Mezzacappa C et al, JAMA Network Open 2024

HCC Surveillance Rates Are Suboptimal



Kim NJ et al, AJG 2020

Unmet Needs in Post-SVR HCC Surveillance

- Better screening methods
- Better HCC risk prediction models post-SVR
  - Patients several years post-cure
  - Patients with pre-treatment indeterminate staging and risk factors for liver disease progression
  - Patients with unclear fibrosis stage at time of HCV treatment
  - Patients with metabolic comorbidities
- Better pre-treatment risk stratification
  - Alternatives to venipuncture

Summary

- HCV is a significant cause of death globally; **cure is lifesaving**
- Treatment is **much simpler** than it was 10 years ago
- Reaching people with HCV requires thinking **beyond a one-size-fits-all approach**
- **Approaches to POC HCV RNA will vary** based on setting needs and infrastructure
- Same day **test-and-treat is feasible** with POC HCV RNA
  - Still requires venipuncture for HBV screening if not already done
  - Still requires fibrosis staging

Summary

- More **resources are needed**
  - DAA access
  - Staffing and support for
  - counseling, clinician visits, and navigation while on treatment
- Additional **tools are needed**, including new innovations
  - Long-acting injection formulations of DAA
  - HCV vaccine

Thank you!

UCSF

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DeLIVER Care Van

NOW Study

End Hep C SF

NOW Study participants