Striving Toward Elimination: Advances in Hepatitis C Testing and Treatment

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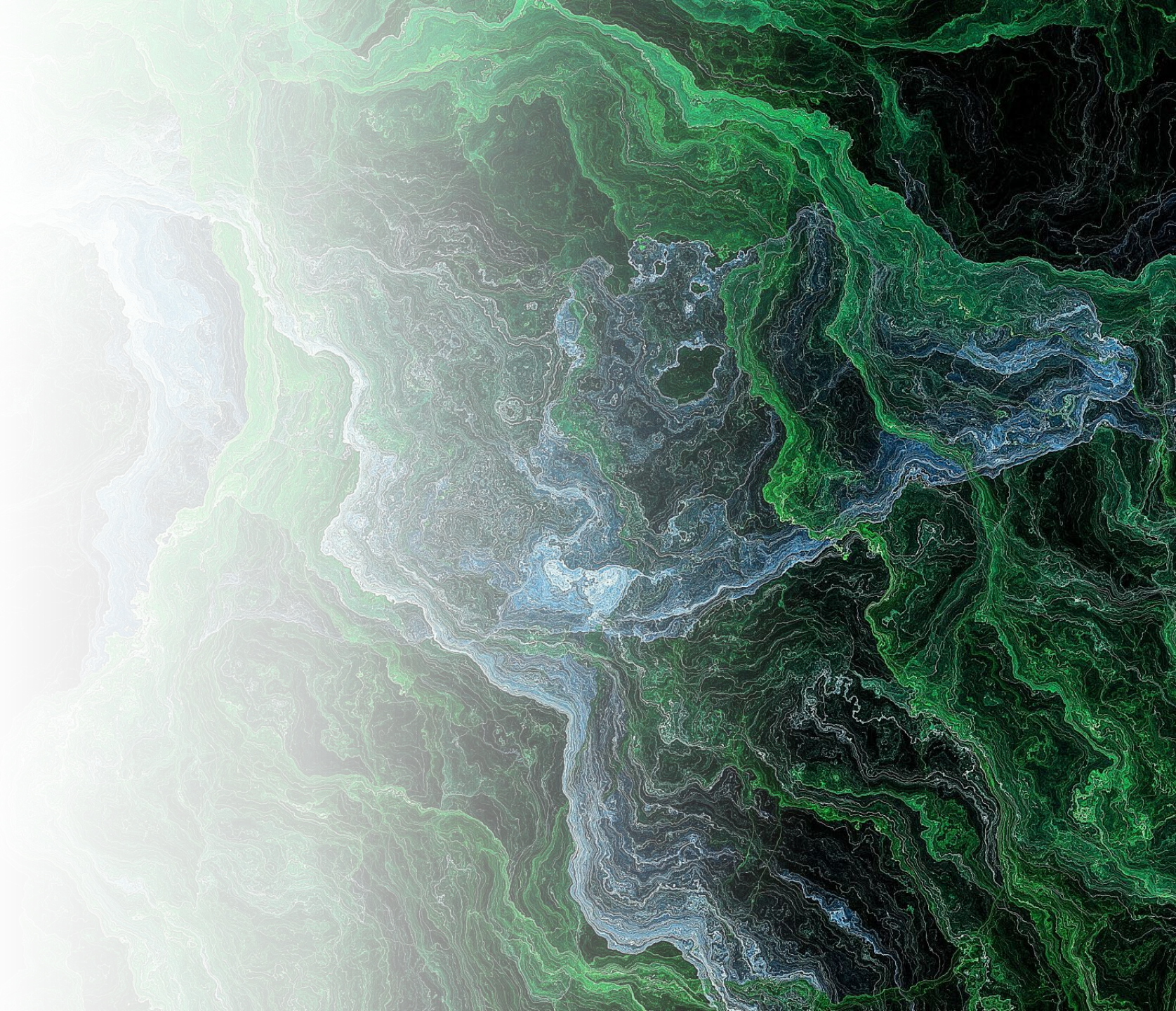
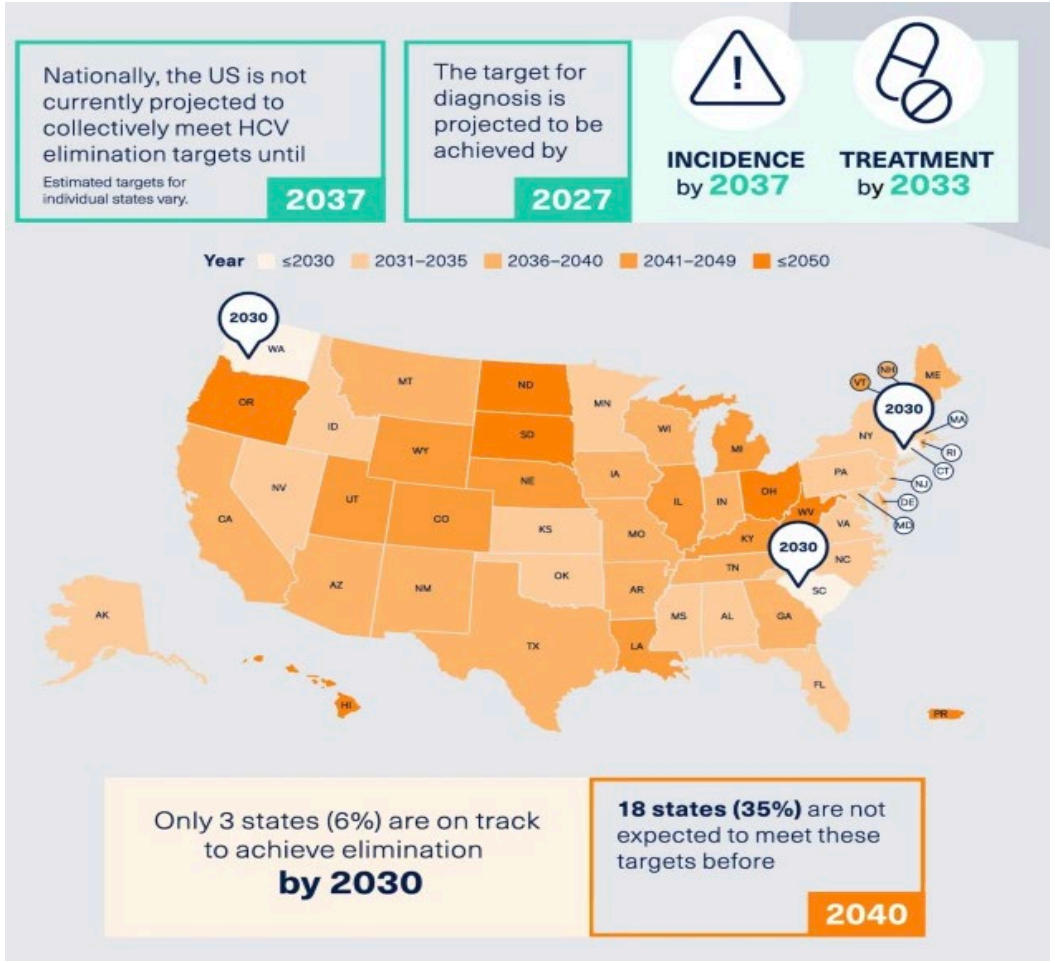


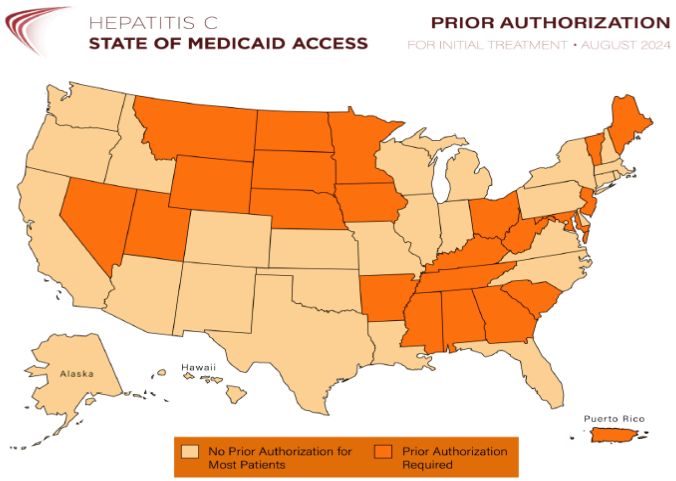
Progress Toward HCV Elimination in the United States



- Elimination progress held back by:
- Sobriety Restrictions
- Prescriber Restrictions
- Retreatment Restrictions
- Need for Prior Authorizations
- Patient readiness models of care
- Stigma

Sulkowski, M., Cheng, WH., Marx, S. *et al.* Estimating the Year Each State in the United States Will Achieve the World Health Organization's Elimination Targets for Hepatitis C.*Adv Ther* **38**, 423–440 (2021). https://doi.org/10.1007/s12325-020-01535-3

PRIOR AUTHORIZATION REQUIREMENTS

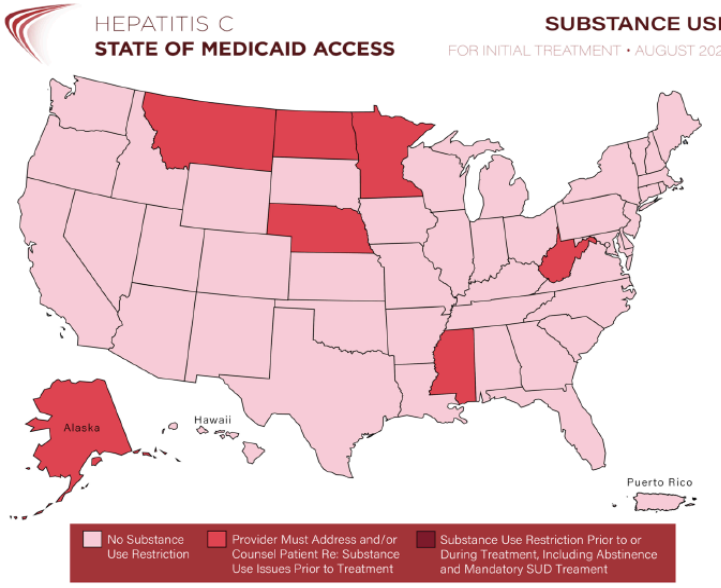


No Prior Authorization for Most Patients (29): Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Missouri, New Hampshire, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, Texas, Virginia, Washington, Wisconsin

Prior Authorization Required (23): Alabama, Arkansas, Georgia, Iowa, Kentucky, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Jersey, North Dakota, Ohio, Puerto Rico, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wyoming

Citation: Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable, Hepatitis C: State of Medicaid Access (2024), www.stateofhepc.org

SOBRIETY RESTRICTIONS



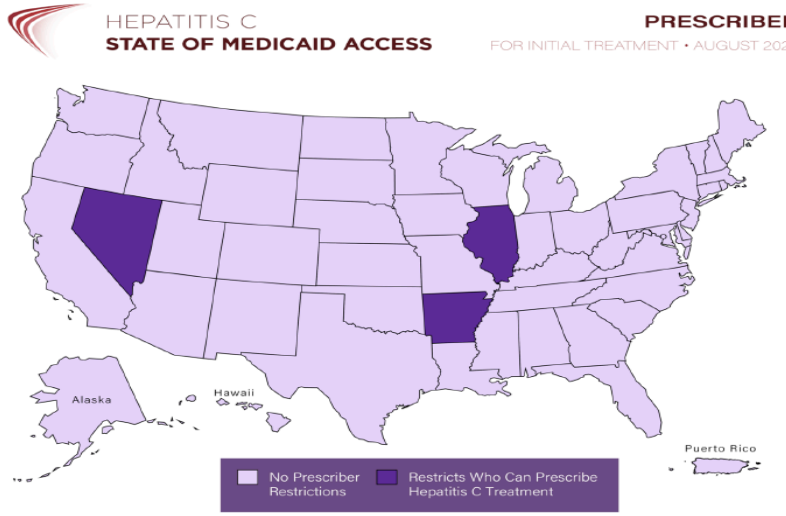
No Substance Use Restriction (45): Alabama, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, Wisconsin, Wyoming

Provider Must Address and/or Counsel Patient About Substance Use Issues Prior to Treatment (7): Alaska, Minnesota, Mississippi, Montana, Nebraska, North Dakota, West Virginia

Citation: Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable, Hepatitis C: State of Medicaid Access (2024), www.stateofhepc.org

Citation: Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable, Hepatitis C: State of Medicaid Access (2024), www.stateofhepc.org

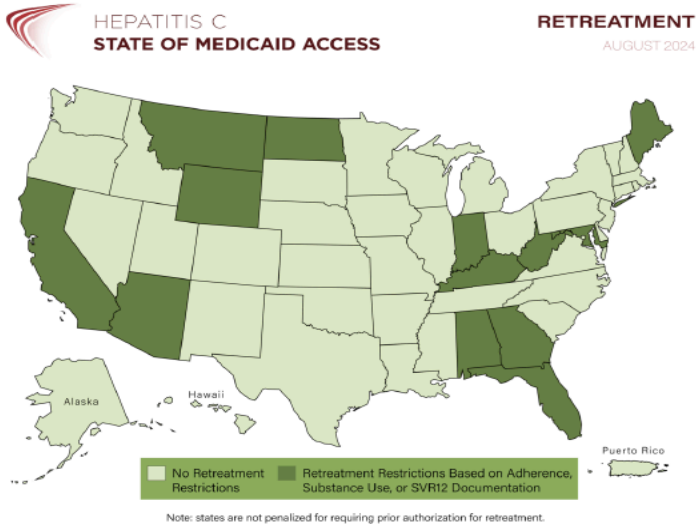
PRESCRIBER RESTRICTIONS



No Prescriber Restrictions for Simplified Treatment (49): Alabama, Alaska, Arizona, California, Colorado, Connecticut, DC, Delaware, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Louisiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming

Prescriber Restrictions (3): Arkansas, Illinois, Nevada

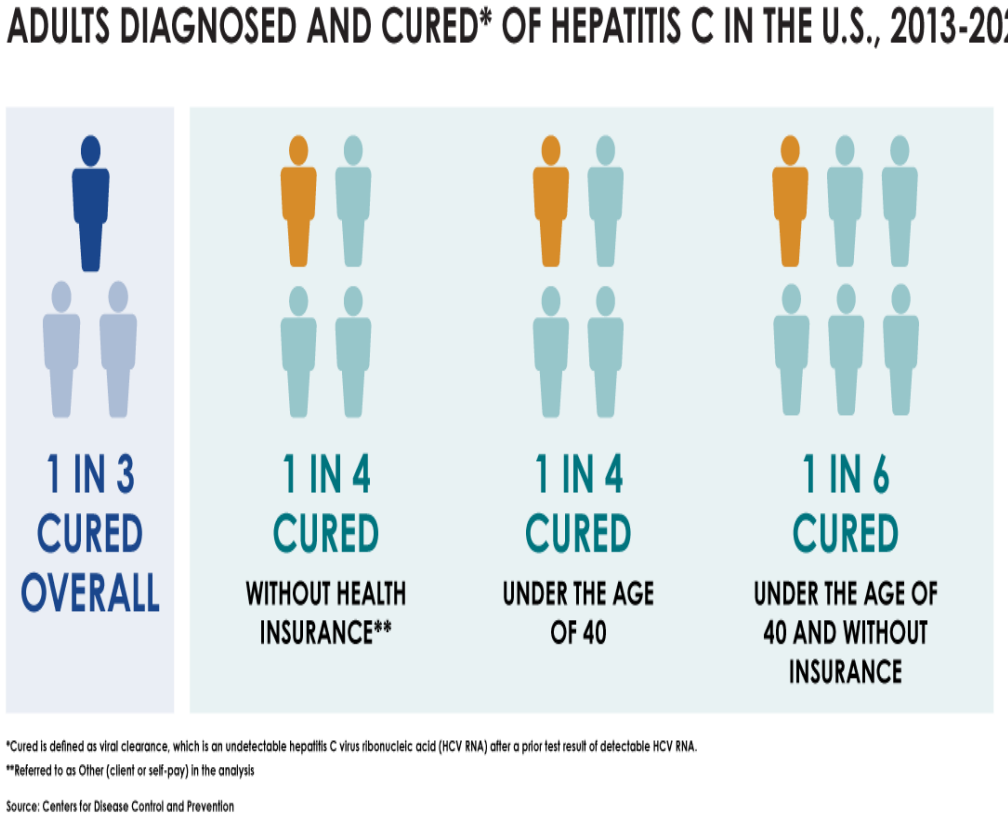
Citation: Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable, Hepatitis C: State of Medicaid Access (2024), www.stateofhepc.org



No Retreatment Restrictions (39): Alaska, Arkansas, Colorado, Connecticut, District of Columbia, Delaware, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, Wisconsin

Retreatment Restrictions based on adherence, substance use, or SVR12 documentation (13): Alabama, Arizona, California, Florida, Georgia, Indiana, Kentucky, Maine, Maryland, Montana, North Dakota, West Virginia, Wyoming

HCV Treatment Rates in the US



Retrospective cohort study of 87,652 US Medicaid enrollees ages 18-64 between 2017-2019[1]

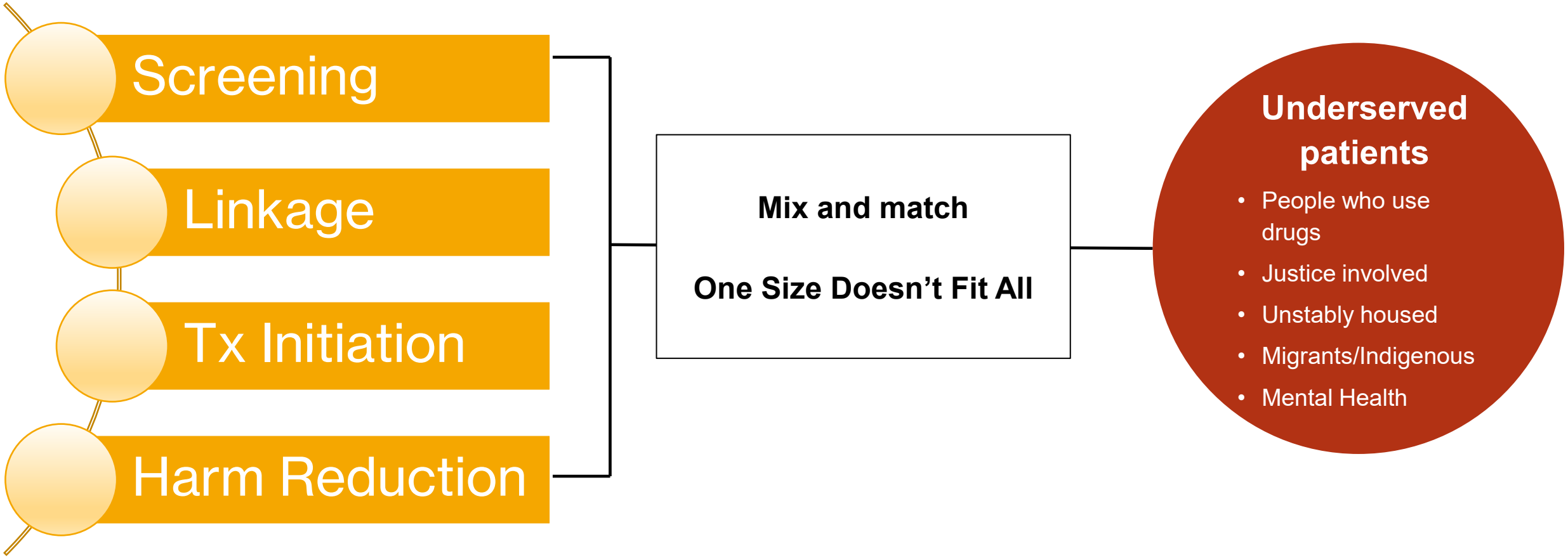
Significantly lower treatment initiation among people younger than 30 years, females, Hispanic and Asian individuals, and people with injection drug use.[1]

Only 20% received DAA treatment within 6 months of initial diagnosis.[1]

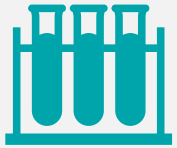
Among Medicaid enrollees with a new diagnosis of HCV from January 2019-October 2020, only 23%received treatment within 1 year after diagnosis.[2]

1.JAMA Network Open. 2023;6(8):e2327326. doi:10.1001/jamanetworkopen.2023.27326
2.ThompsonWW, Symum H, Sandul A, et al; DHSc. Vital signs: hepatitis C treatment among insured adults—United States, 2019-2020. MMWR Morb Mortal Wkly Rep. 2022;71(32):1011-1017. doi:10.15585/mmwr.mm7132e1

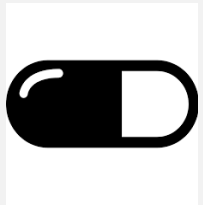
Pillars For HCV Elimination



Test and Treat Model of Care



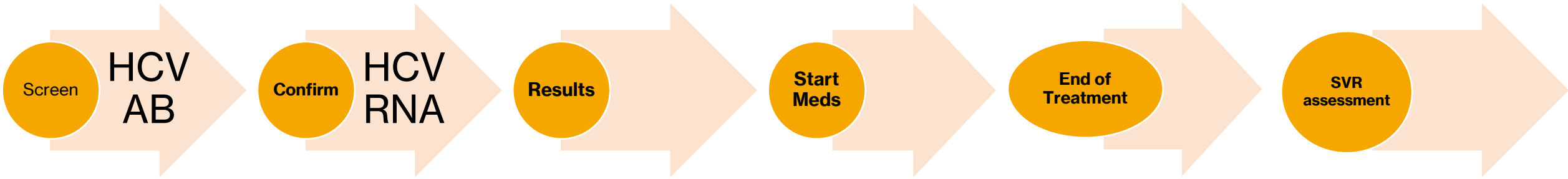
TEST- Simplified HCV screening and Dx

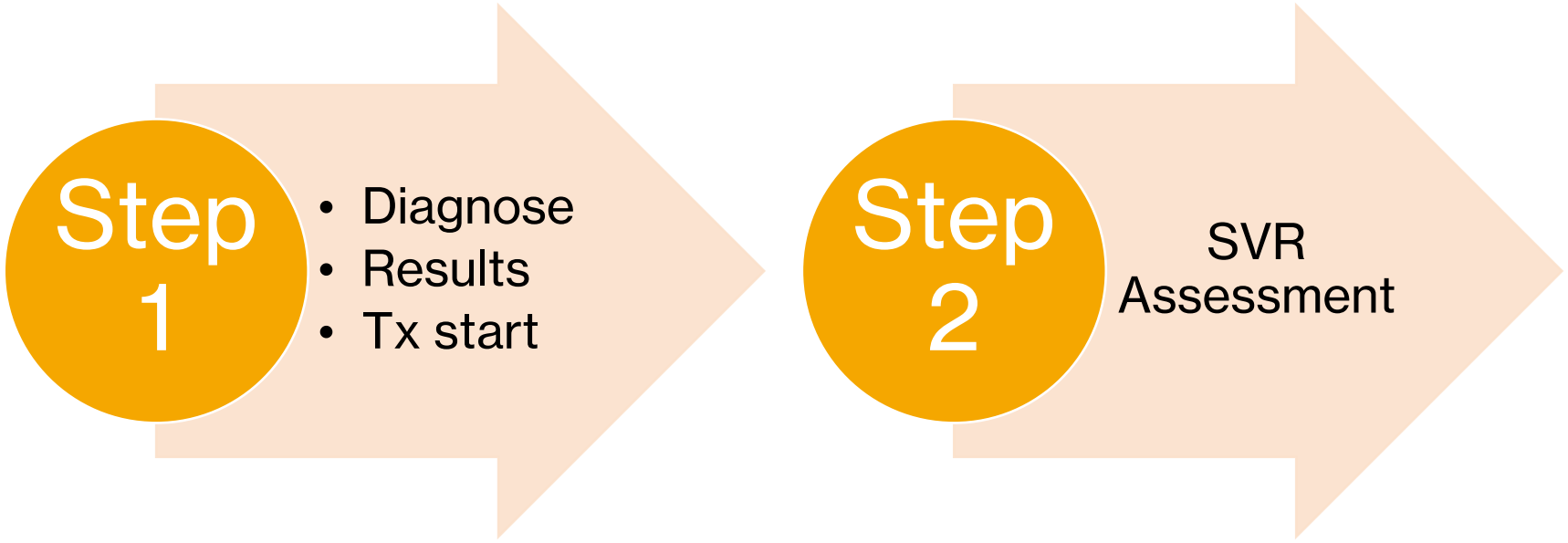


TREAT - Simplified, short-duration, pan-genotypic treatments, immediate initiation

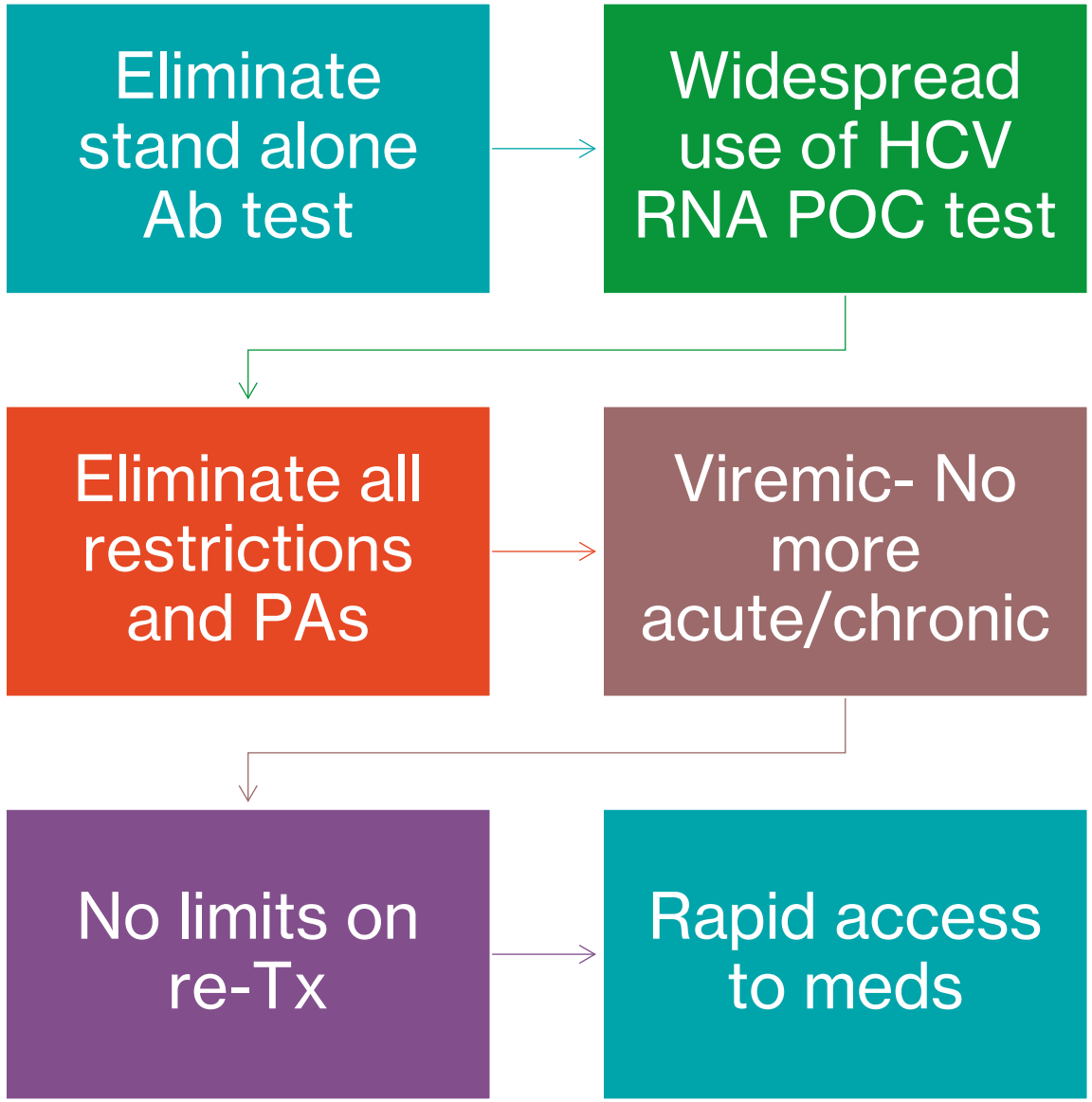
CURE

Speed Is The Key

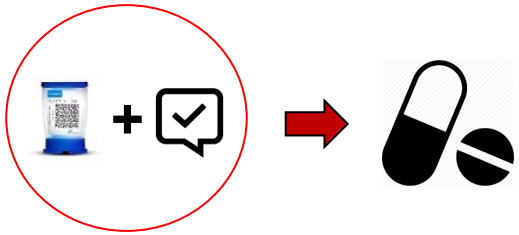




Test And Treat Key Elements

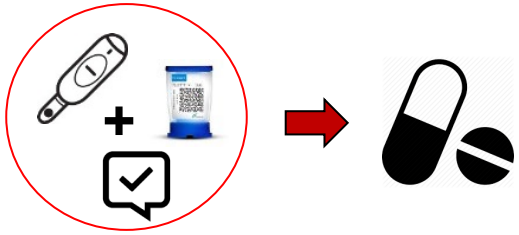


Single-visit strategies to improve testing



Point-of-care HCV RNA and diagnosis (Health care worker)

Point-of-care HCV RNA
(high HCV prevalence setting)



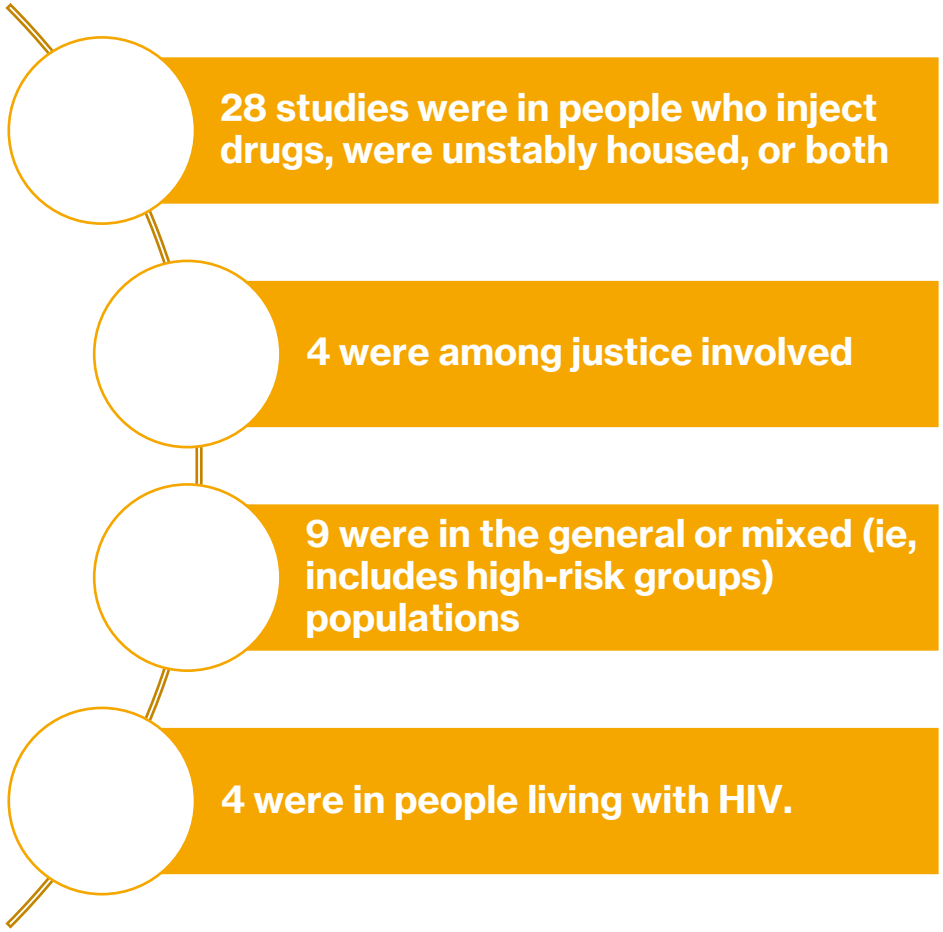
Rapid anti-HCV antibody test, point-of-care HCV RNA and diagnosis (Health care worker)

Rapid HCV antibody testing with reflex point-of-care HCV RNA
(low HCV prevalence setting)

Slide courtesy of Jason Grebley | Head, Hepatitis and Drug Use Research Group, Kirby Institute

Point Of Care Testing

A 2023 Meta-analysis of 45 Studies Evaluating the Impact of Using POC vs SOC Approaches on HCV RNA Viral Load Testing and Treatment[1]



19-day turnaround time

between POC testing and treatment initiation vs **64-67 days with SOC**

32% treatment uptake

for POC vs SOC testing

1. Trickey A, et al. *Lancet Gastroenterol Hepatol*. 2023;8(3):253-270. .

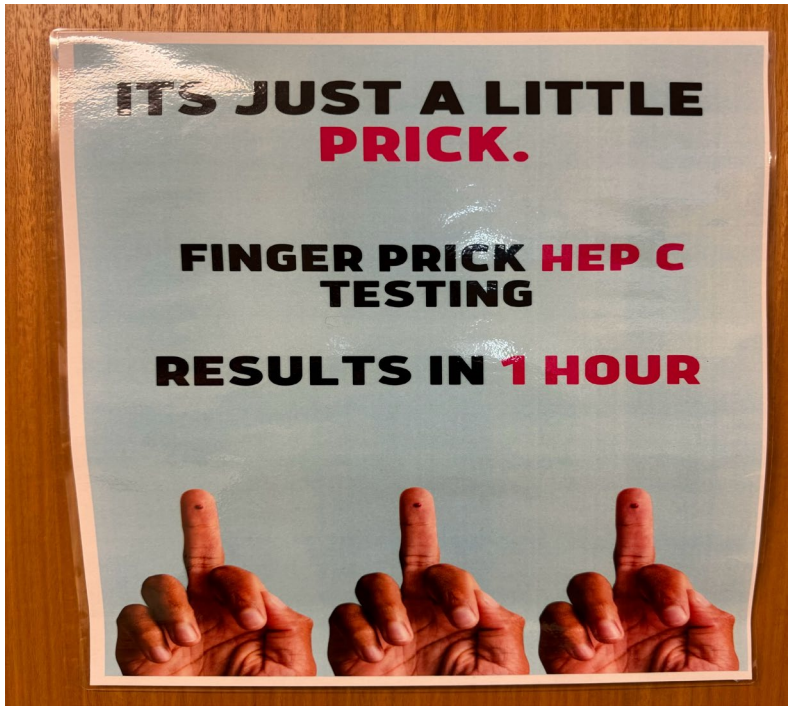
GeneXpert / Xpert HCV

- Fingerstick, CLIA waived
- FDA approved for: Adult (>22) individuals at risk or with signs/symptoms of HCV with or without Ab evidence
- Does not differentiate acute/chronic
- Not intended for on-treatment monitoring or SVR assessment
- No performance characteristics among pregnant people
- Annual calibration
- Limited EMR integration
- Limited communication to state DOH reporting systems

Evaluation of Time to HCV RNA Detection Using the Xpert HCV Viral Load Fingerstick Assay[1]

Overall median time to result:
32 minutes for people with detectable HCV RNA vs **57 minutes** for people with undetectable HCV RNA

Results in ≤40 minutes among 80% of participants with detectable HCV RNA



Grebely J, et al. *J Infect Dis.* 2020;221(12):2043-2049.

What's included

6 Materials Provided

The Xpert HCV test kit (GXHCV-10) contains sufficient reagents to process 10 specimens or quality control samples. Each kit contains the following:

Xpert HCV cartridges with integrated reaction tubes	**10 per kit**
• Bead 1, Bead 2 and Bead 3 (freeze-dried)	1 of each per cartridge
• Lysis Reagent (Guanidinium Thiocyanate)	1.0 mL per cartridge
• Rinse Reagent	0.5 mL per cartridge
• Binding Reagent	1.5 mL per cartridge
• Elution Reagent	1.5 mL per cartridge
Disposable 100 µL Transfer Pipettes	**20 per kit**
Instructions for Use	**1 per kit**
(For use with the GeneXpert Xpress System)	
Quick Reference Instructions	**1 per kit**
(For use with the GeneXpert Xpress System)	
CD	**1 per kit**
• Assay Definition File (ADF)	
• Instructions to import ADF into GeneXpert Xpress System	

What's Not Included

Bleach
Ethanol / denatured alcohol
Absorbent pad
High flow lancet
Capillary collection tubes
Alcohol wipes
Gauze
Bandage
Warm packs

- Positive quality controls
- Negative quality controls
- Carrying case
- Printer

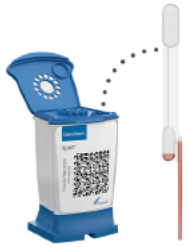
GeneXpert / Xpert HCV

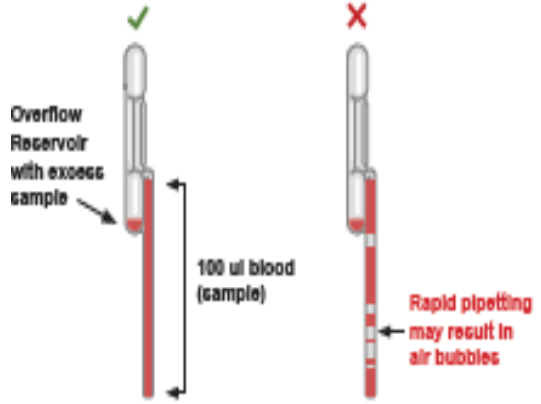
1

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

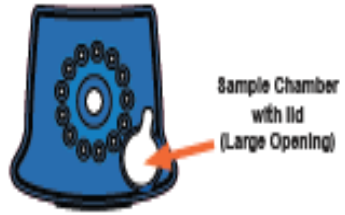
2

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





- Place the pipette tip deep into the Sample Chamber of the cartridge.



3

Insert cartridge and start test

La Bodega POC Testing Program

- N = 60
- Past Ab (n =14)
- POC RNA + (n = 10)
- Insufficient sample / error (n = 5)
- SVR assessment (n=10)
- Serum SVR correlation 100%
- HIV (n=1), Pregnant (n=2)

Key Learnings

Handwarmer is key
Gravity is your friend (hang the arm)
Position hand against firm surface
Get high-flow lancets
Use the ring finger
Use the nondominant hand (avoid calluses, etc.)
Among people who use drugs via inhalation, use the opposite hand that they hold the stem with
Patients very willing to be tested
Still need HBV testing / POC test

Costs

- 2 bay machine $21,000, 4 bay $39,000 (before discounts)
- ~ $30.00 per cartridge
- Controls:

Item	Primary Description	Catalog	Category	EOC	Vendor #	Vendor	UOM	UOM Cost	Comments
0081837	NATROL HEP C VIRUS NEG CTRL	NATHCVNEGGCIVD	LAB	1150	E88918A2	CEPHEID	EA	$ 339.0000	COBBLESTONE CONTRACT 8957
0081838	NATROL HEP C VIRUS POS CTRL	NATHCVGCIVD	LAB	1150	E88918A2	CEPHEID	EA	$ 241.0000	COBBLESTONE CONTRACT 8957

ZeptoMetrix

NATtrol Hepatitis C Virus Positive Control (6 x 0.25 mL)

SKU: NATHCV-6C-IVD

Have a question?

$349.00 / EA

AVAILABLE

1 ADD TO CART

ZeptoMetrix

NATtrol Hepatitis C Virus Negative Control (6 x 0.25 mL)

SKU: NATHCVNEG-6C-IVD

Have a question?

$248.00 / PK

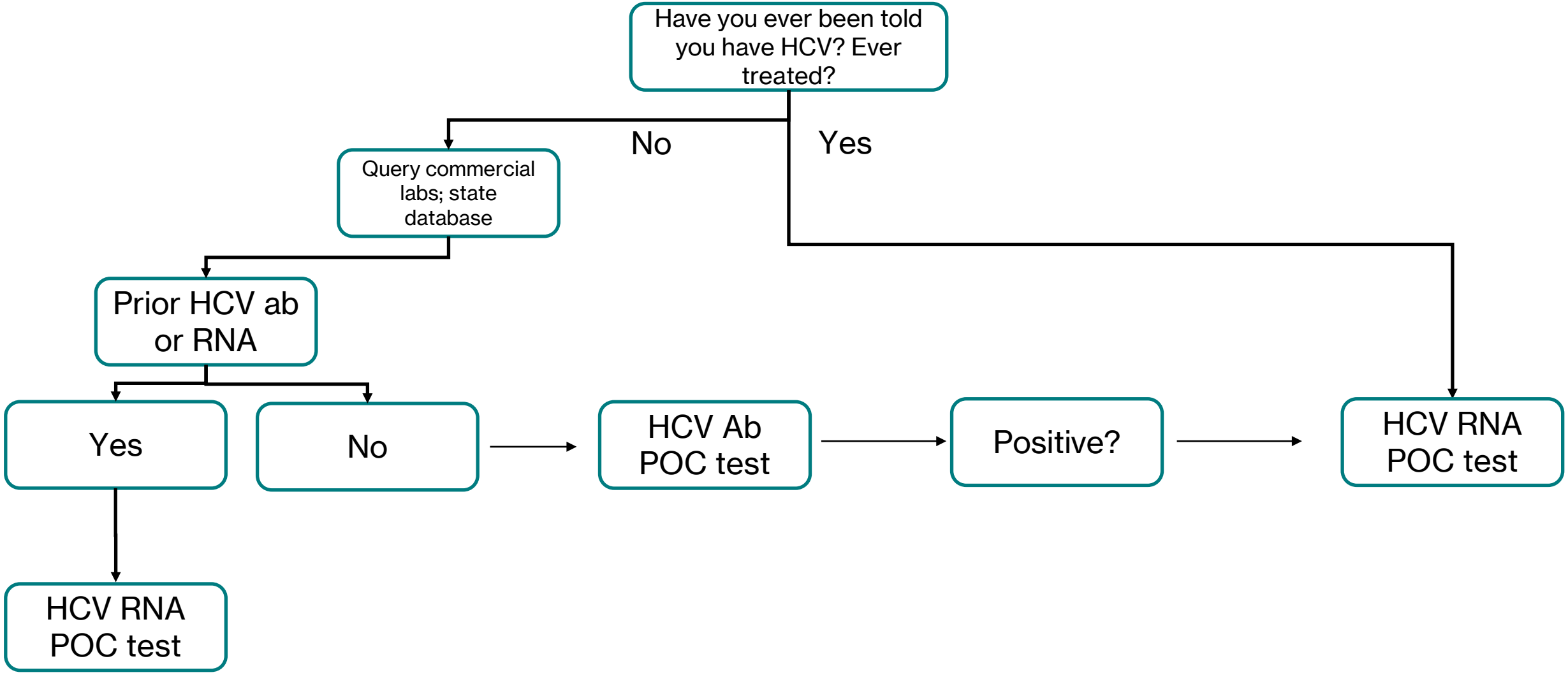
AVAILABLE

1 ADD TO CART

- Lancets:

ONE-CARE Opti+ Adjustable Safety Lancets 23G x 3 Depth Setting (1.3 I 1.8 I 2.3mm), Preloaded, Gentle, Sterile,100/bx

La Bodega HCV POC Testing Algorithm



Can we shorten the time to cure?

SVR 12

- Many get lost to follow up
- Hard to track people down for SVR 12 assessment
- Potential to relapse and reinfect
- Heightened anxiety while waiting could be a trigger for relapse

SVR 4

- Shortens care cascade by 2 months
- Easier to retain in care for a month
- Knowledge of cure can serve as reinfection/relapse deterrent
- Entire patient journey reduced to 3 months start to finish (for 8-week G/P regimen)

Positive Predictive Value of SVR4 for SVR12 in Pts Treated with G/P

- Patients receiving G/P in clinical trials
- **>99% of patients that achieved SVR4 achieved SVR12**
- All patients that did not achieve SVR4 did not achieve SVR12 (NPV=100%; sensitivity=100%)
- Specificity was 79.5%, indicating the majority of patients relapsing do so by post-treatment week 4

	Overall	All	8-wk G/P	12-wk G/P	16-wk G/P
PPV	99.8	99.8	99.8	99.5	100.0
NPV	100.0	100.0	100.0	100.0	100.0
Sensitivity	100.0	100.0	100.0	100.0	100.0
Specificity	79.5	81.3	79.2	50.0	100.0

SVR, sustained virologic response; SVR4, SVR at post-treatment Week 4; SVR12, SVR at post-treatment Week 12; PPV, positive predictive value; NPV, negative predictive value

- Achieving SVR4 was highly predictive of long-term SVR for patients treated with G/P, regardless of treatment duration
- All measures of concordance were similar between the overall group and the 8-week treatment duration group, demonstrating the high effectiveness of the shortest treatment regimen

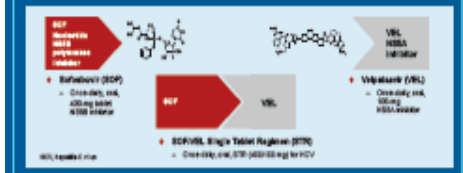
Gane E, *et al*. *J Viral Hepat*. 2021;28(11):1635-1642.

Concordance Between SVR4, SVR12, and SVR24 in HCV-Infected Patients Who Received Fixed-Dose Combination Sofosbuvir/Velpatasvir in Phase 3 Clinical Trials

M. SULKOWSKI[1], J. FELD[2], N. REAU[3], S. SCHERBAKOVSKY[4], C. HERNANDEZ[4], K. VANSTRAELEN[4], K. HAMMOND[4], B. KRETER[4], V. SURI[4], L. NI[4], M. BOURLIERE[5], A. MANGIA[6]

[1]Johns Hopkins University School of Medicine, Baltimore, MD, USA; [2]Toronto Centre for Liver Disease, Toronto General Hospital, University Health Network, Canada; [3]Rush University Medical Center, Chicago, IL, USA; [4]Gilead Sciences, Inc., Foster City, CA; [5]Hôpital Saint Joseph, Marseilles, France; [6]Fondazione "Casa Sollievo Della Sofferenza" IRCCS, San Giovanni Rotondo, Italy

INTRODUCTION



- The SOF/VEL Phase 3 ASTRAL-1, -2, and -3 program evaluated SOF/VEL in treatment-naïve (TN) and treatment-experienced (TE) patients both with and without compensated cirrhosis.
- SOF/VEL has been shown to be safe and effective (sustained virologic response 12 weeks after treatment completion [SVR12] >90%) in TN and TE patients, and was the first pangenotypic single-tablet regimen for the treatment of chronic HCV.[1-2]
- As HCV treatment expands to resource limited populations or beyond tertiary care, simplistic algorithms require clarification when SVR can be determined. SVR concordance with SOF/ supports this shift to a minimal monitoring strategy.[3]

OBJECTIVE

To evaluate the concordance of SVR 4 weeks after treatm completion (SVR4) with SVR12, and SVR12 with SVR 24 eks after treatment completion (SVR24) in patients receiving SOF/ in the Phase 3 ASTRAL-1 (GS-US-342-1138; NCT02201940), A AL-2 (GS-US-342-1139; NCT02220998), and ASTRAL-3 (GS-U 2-1140; NCT02201953) studies.

METHODS

Sofosbuvir/Velpatasvir Phase 3 Program

- HCV RNA data from patients in ASTRAL-1, ASTRAL-2, and ASTRAL-3 were evaluated.
- SVR was defined as patients with HCV RNA < lower limit of quantitation (15 IU/mL) at the aforementioned post-treatment visits, using the COBAS® TaqMan® HCV Test v2.0.
- Only patients with both SVR4 and SVR12 or SVR12 and SVR24 data were included in this concordance analysis.
- No data were imputed.

RESULTS

Demographics: Phase 3 ASTRAL Studies

	Total, N=1558	SOF/VEL, N=1035
Mean age, y	53	53
Men, n (%)	944 (61)	630 (61)
Black, n (%)	85 (6)	61 (6)
Hispanic, n (%)	107 (7)	68 (7)
Mean BMI, kg/m² (SD)	26.9	26.8
HCV GT	393(25)/391(25)/552(35)/ 138 (9)/25(2)/49(3)	328(32)/238(23)/277(27)/ 116(11)/35(3)/41(4)
baseline HCV RNA, log_{10} IU/mL (SD)	0.70)	6.3 (0.70)
Cirrhosis, n (%)	343	220 (21)
Treatment-experienced, n (%)	415 (27	291 (28)

SVR4 and SVR12 Concordance

		SVR12, n	
		Yes	No
SVR4	Yes	1002	3
	No	0	10

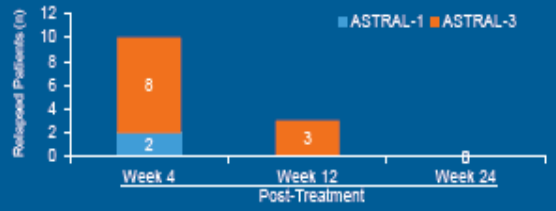
- 99.7% positive predictive value
- 100% negative predictive value

SVR12 d SVR24 Concordance

		SVR24, n	
		Yes	No
SVR12	Yes	991	0
	No	0	2

- 100% ive predictive value
- 100% ative predictive value

Timing of Viral Relapse or Reinfection



Patient Details on Viral Relapse or Reinfection

Patient #	GT	SVR4	SVR 12	SVR 24	Relapsed	Previous Regimen	Cirrhosis	Previous Outcome
1	3a	Yes	No	No	Between SVR4 & SVR12	PEG + RBV	Yes	Nonresponder
2	3a	Yes	No	No	Between SVR4 & SVR12	None (TN)	Yes	N/A
3	3a	Yes	No	No	Between SVR4 & SVR12	PEG +RBV	No	Relapse/breakthrough
4	1a	No	No	No	Before SVR4	None (TN)	No	N/A
5	1b	No	No	No	Before SVR4	PEG + RBV	Yes	Nonresponder
6	3a	No	No	No	Before SVR4	None (TN)	Yes	N/A
7	3a	No	No	No	Before SVR4	PEG + RBV	No	Relapse/breakthrough
8	3a	No	No	No	Before SVR4	None (TN)	No	N/A
9	3a	No	No	No	Before SVR4	PEG + RBV	Yes	Relapse/breakthrough
10	3	No	No	No	Before SVR4	PEG +RBV	No	Relapse/breakthrough
11	3a	No	No	No	Before SVR4	PEG+RBV	Yes	Nonresponder
12	3a	No	No	No	Before SVR4	None (TN)	Yes	N/A
13	3a	No	No	No	Before SVR4	PEG+RBV	Yes	Nonresponder

RESULTS

- There were 20 patients from ASTRAL-1, -2, an who received SOF/VEL (n=1015/1035) and did not achieve SVR12
  - 13 patients who experienced virolo apse or reinfection
  - follow-up
  - 1 discon
  - 1 withdrew consent
  - 1 death – unrelated to treatment
- Of 13 patients who relapsed or reinfected, 10 occurred at post-treatment Week4, and 3 occurred at post-treatment Week 12:
  - 2 were GT1; 11 were GT3
  - 8 had compensated cirrhosis
  - 6 had been previously been treated with peg-interferon + ribavirin
- There was 1 GT3a patient with confirmed GT1a reinfection between post-treatment Week 4 and post-treatment Week 12
  - This would potentially change the PPV for SVR4 and SVR12 concordance from 99.7% to 99.8%.

CONCLUSIONS

- For SOF/VEL, there was high concordance (99.7% positive predictive value) between SVR4 and SVR12.
  - 3 of 1025 patients (0.3%) who achieved SVR4 subsequently did not achieve SVR12. All were GT3a.
  - The 1 GT1a reinfected patient would potentially change the PPV from 99.7% to 99.8%.
- There was 100% concordance between SVR12 and SVR24.
- These results suggest SVR4 may be utilized to predict long-term SVR, as opposed to SVR12 and SVR24. This approach could be valuable in patients with high risk (PWID or incarcerated individuals released) of not attending SVR12 assessment.
- This data supports alternative approaches to SVR assessment. In addition, this supports EASL guidance that testing for SVR can be omitted in certain patients.

REFERENCES: 1. Feld JJ et al. N Engl J Med 2015; 373: 2599-2607; 2. Foster GR et al. N Engl J Med 2015; 373: 2608-2617; 3. Solomon S et al. AASLD 2020 LOT.

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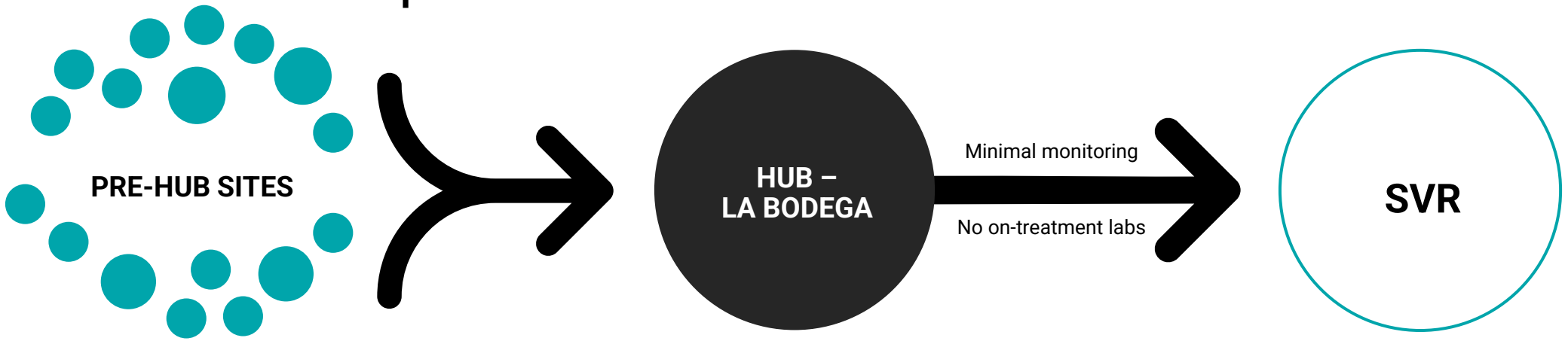
La Bodega Buffalo, New York: Modified Rapid-Start/Test-and-Treat Model[1]

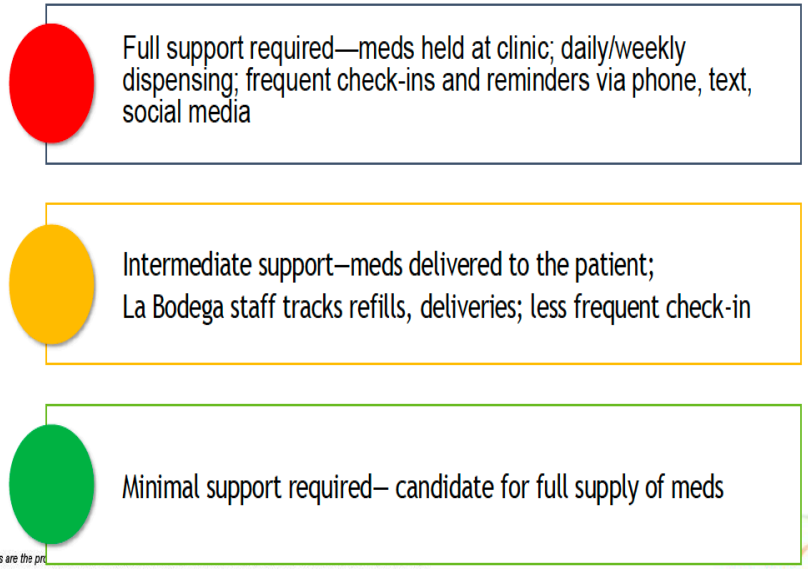


- Community addiction clinics; SSPs
- High-risk OB/peds (foster care system)
- Prison/jail
- STI clinics
- Emergency department
- Primary care
- Street medicine

- Individualized screening protocol: POC Ab test; conventional Ab with PCR reflex
- Single phone number and email for referral
- La Bodega staff schedules, and navigates patient to, appointments

- On-site lab draw
- Colocalized MAT—rapid start
- Immediate HCV treatment
- On-site pharmacy
- Counseling services
- PrEP, HIV, primary care

La Bodega Triage System



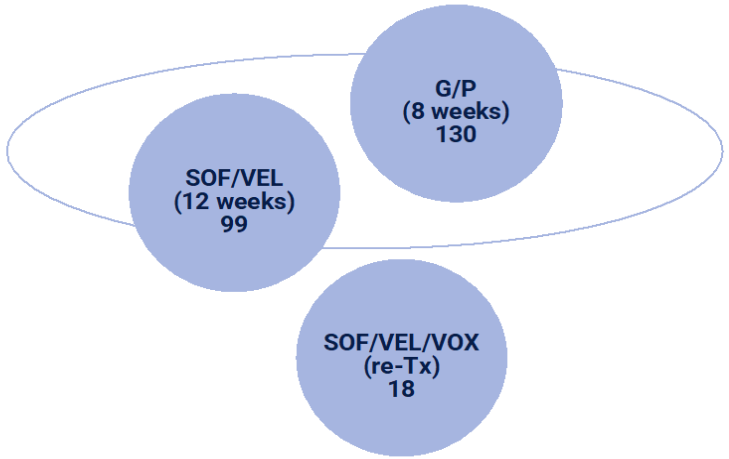
Ab=antibody; HCV=hepatitis C virus; HIV=human immunodeficiency virus; MAT=medication-assisted treatment; PCR=polymerase chain reaction; POC=point of care; PrEP=pre-exposure prophylaxis; OB=obstetrics; SSP=syringe service program; STI=sexually transmitted infection; SVR=sustained virologic response.

Reference: 1. Data on file, La Bodega.

Rapid Start Model[1]

April 2023 – April 2024

- All regimens at parity
- No longer payer driven
- Patients able to choose regimen
- Meds kept on site
- Started same day with rapid start vs next-day start for Medicare or telemedicine patients
- N=247



27 PATIENTS RECEIVED FULL SUPPLY OF MEDS AT THE INITIAL VISIT

Results

Regimen Preference

- 51% preferred a shorter duration of therapy
- 30% preferred fewer pills
- Active substance use, or the total number of concomitant medications did not affect patient preference
- Patients receiving MAT preferred a shorter duration of treatment (59% vs 41%, *P*<0.05)

Adherence Results

- Overall full adherence rate, 59%
- Adherence was the greatest but not significant in those receiving fewer pills compared to shorter duration (67% vs 59%)
- Overall loss to follow-up rate, 32%
- Those receiving telemedicine had significant follow-up loss (68%, *P*<0.01)

Efficacy Results

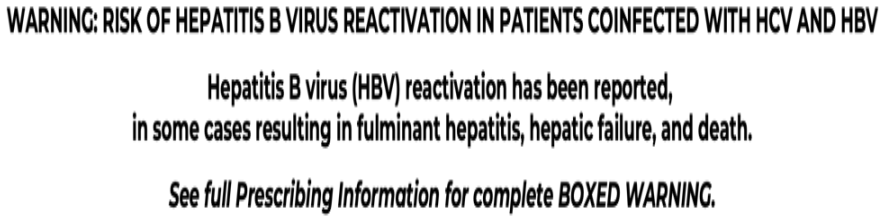
- Overall SVR: 97% mITT (124/128)
- Telemedicine achieved the lowest percentage of SVR (67%, *P*<0.01, per protocol)
- 94% SVR among active substance users

G=glecaprevir; MAT=medication-assisted treatment; mITT=modified intention to treat; P=pibrentasvir; SOF=sofobusvir; SVR=sustained virologic response; Tx=treatment; VEL=velpatasvir; VOX=voxilaprevir.

Reference: 1. Data on file, La Bodega.

So What About HBV?

- 29 cases worldwide (5 in the US) of HBV reactivation



- Born after 1991 in the US, should be immunized

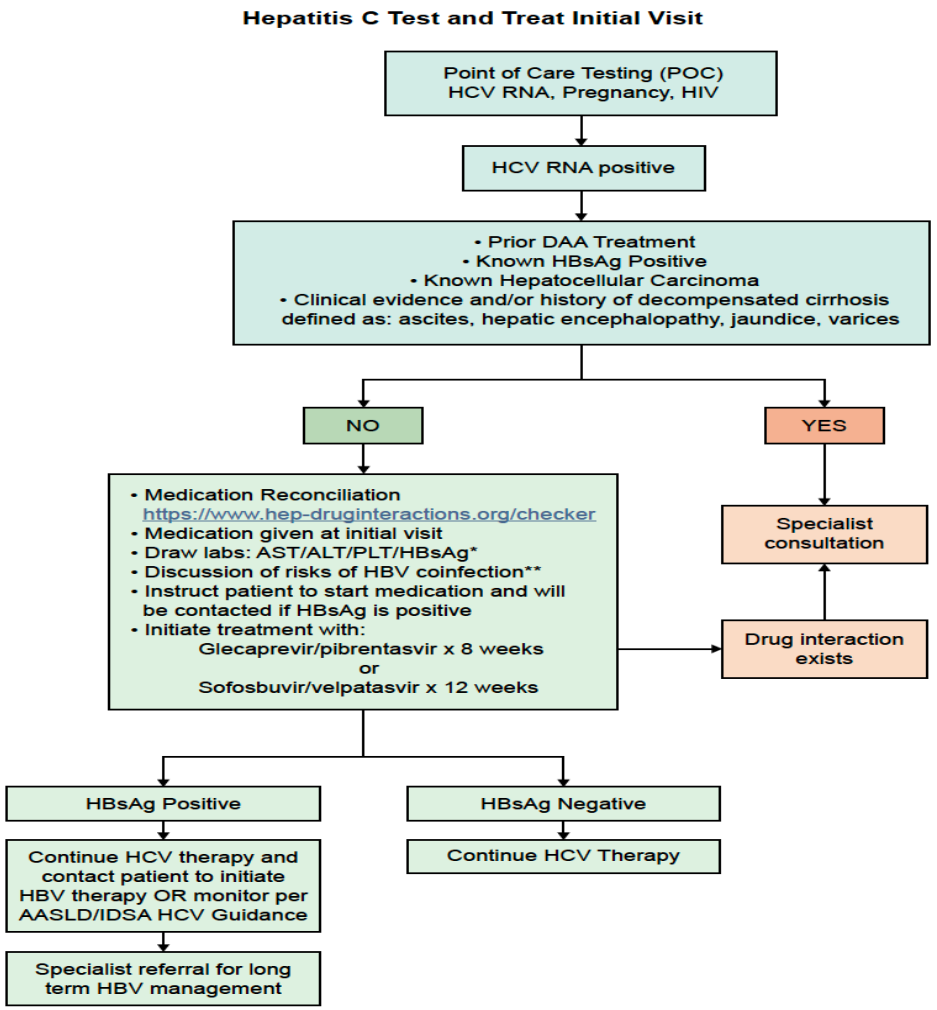
Prevalence (Median) = 1.2%[1] in US

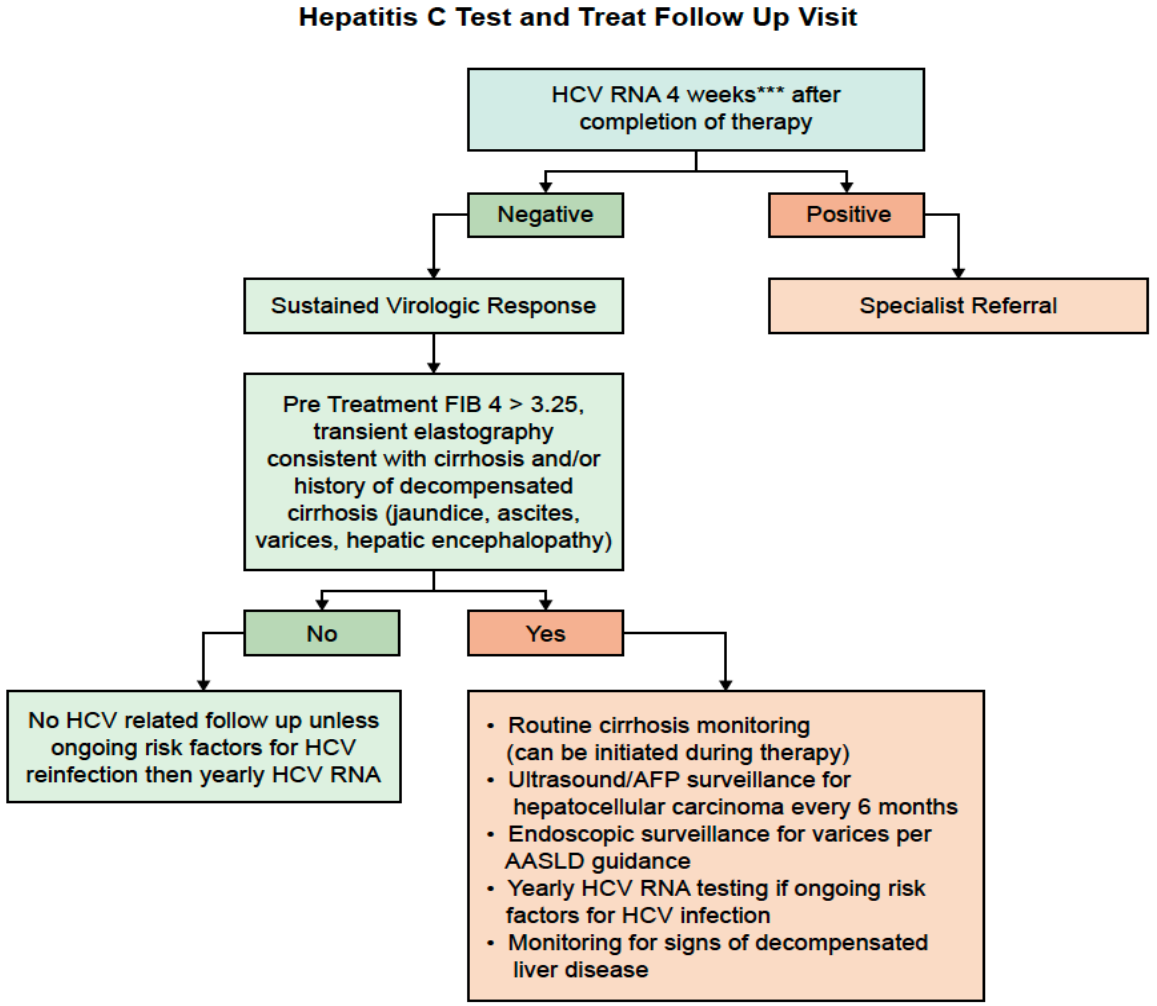
HBV reactivation in patients on HCV DAA Tx = 0-0.1%[1]

Time to HBV reactivation after starting HCV treatment[2] = 4-8 weeks. Mean 52 days

1. Conners EE, et al. *MMWR Recomm Rep*. 2023;72(1):1-25. **2.** FDA. October 12, 2016. Accessed February 6, 2025. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-about-risk-hepatitis-b-reactivating-some-patients-treated

Updated AASLD / IDSA Guidelines 2025





Conclusions

- Shortening the patient journey from diagnosis to cure is essential for elimination.
- Test and treat models of care are critical and feasible among high-risk populations.
- Need to move away from liver disease to infectious disease.
- POC test utilization will be key for test and treat adoption.
- Implementation of SVR4 where appropriate, has major impact on shortening the care cascade.
- SVR rates are high despite imperfect adherence regardless of regimen.
- Full supplies of medication at the time of diagnosis are key.
- Move from ”patient readiness” to “provider readiness.”

Final Thoughts

- **It's all about the people**: The best programs are built *of* the community, *for* the community

- **It's all about the people:** The right provider for the right person at the right time with the right tools at their disposal