The Race to 2030: HCV Elimination Progress

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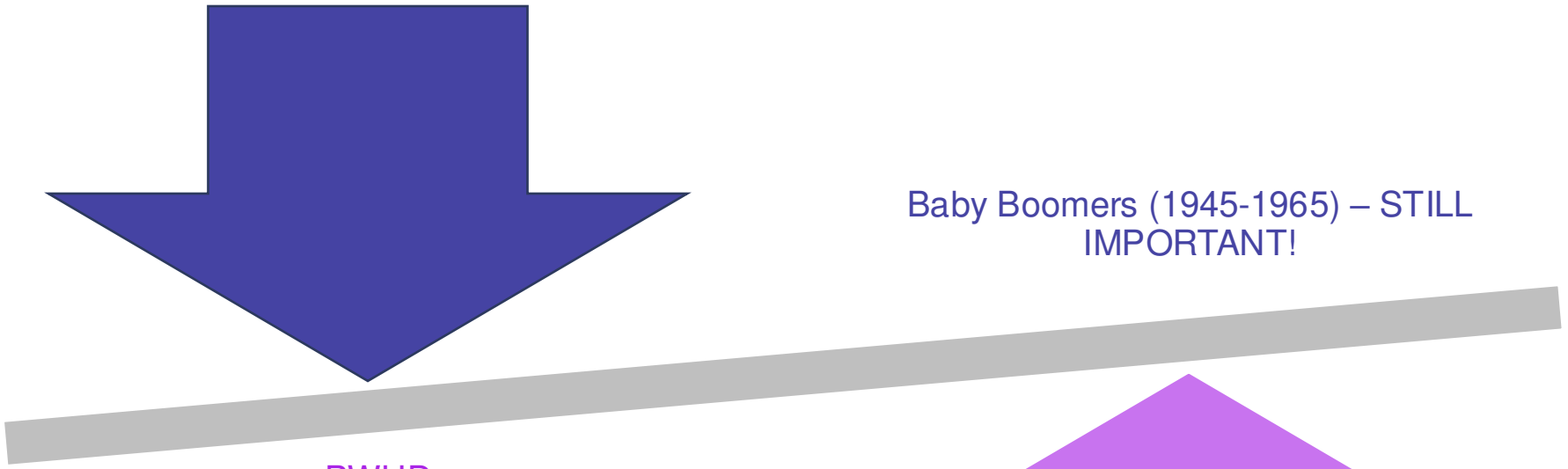
Disclosures

- Consulting – AbbVie, Gilead, Intercept, Eisai, Sirtex, VBI, Arbutus, Altimmune
- Speaking- AbbVie, Gilead, VBI, Braeburn, Madrigal, Ipsen
- Research – AbbVie, Gilead, Allergan, Intercept

HCV In 2024: 2.7-3.9 Million in the US



Baby Boomers (1945-1965) – STILL IMPORTANT!

- PWUD
- Justice Involved
- WOCBA*
- Children born to HCV + mothers
- Indigenous
- Migrants
- Unstably Housed

Injection Drug Use/ Opiate Crisis

* Women of childbearing age

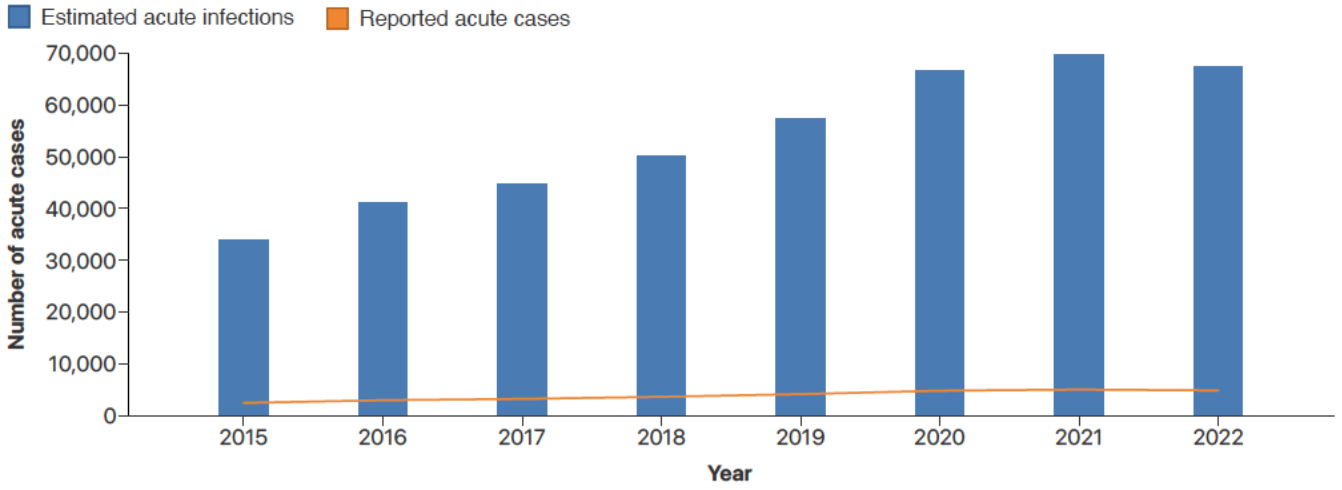
HCV Incidence in the USA

Number of reported cases* and estimated infections† of acute hepatitis C — United States, 2015–2022

ON THIS PAGE

Number of reported cases* and esti...

Summary



Data Table

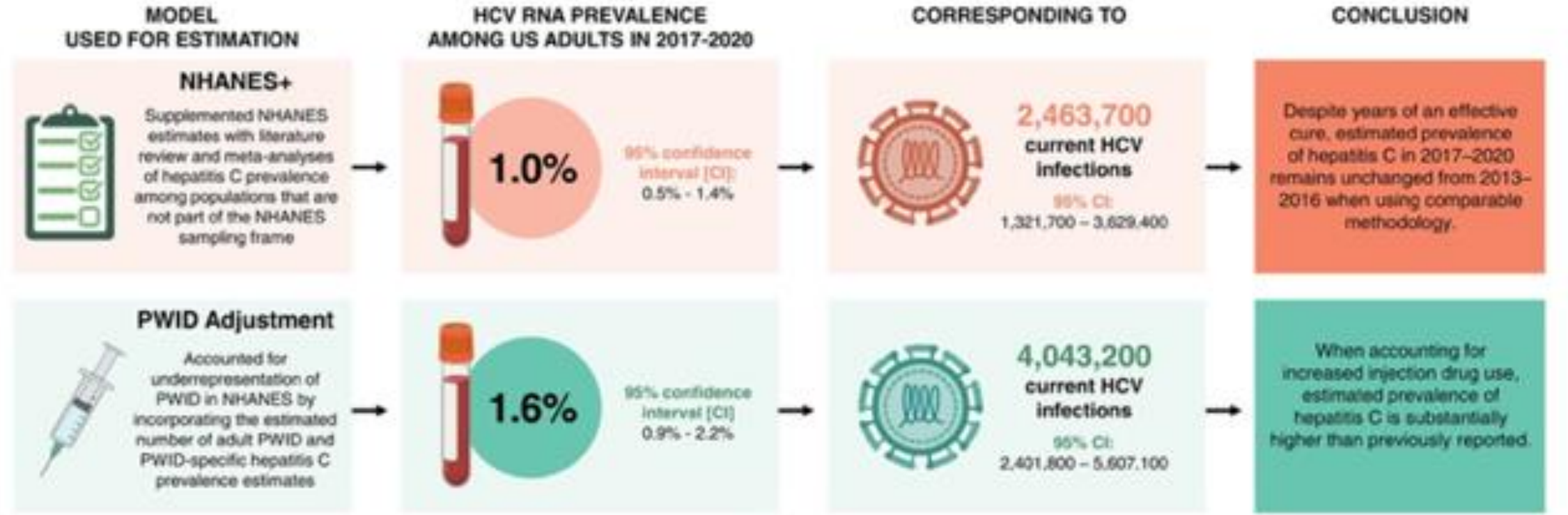
	2015	2016	2017	2018	2019	2020	2021	2022
Estimated acute infections	33,900	41,200	44,700	50,300	57,500	66,700	69,800	67,400
Reported acute cases	2,436	2,967	3,216	3,621	4,136	4,798	5,023	4,848

Source: CDC accessed January 2025

Estimating Hepatitis C Prevalence in the United States, 2017-2020

The National Health and Nutrition Examination Survey (NHANES) underestimates the true prevalence of hepatitis C virus (HCV) infection.

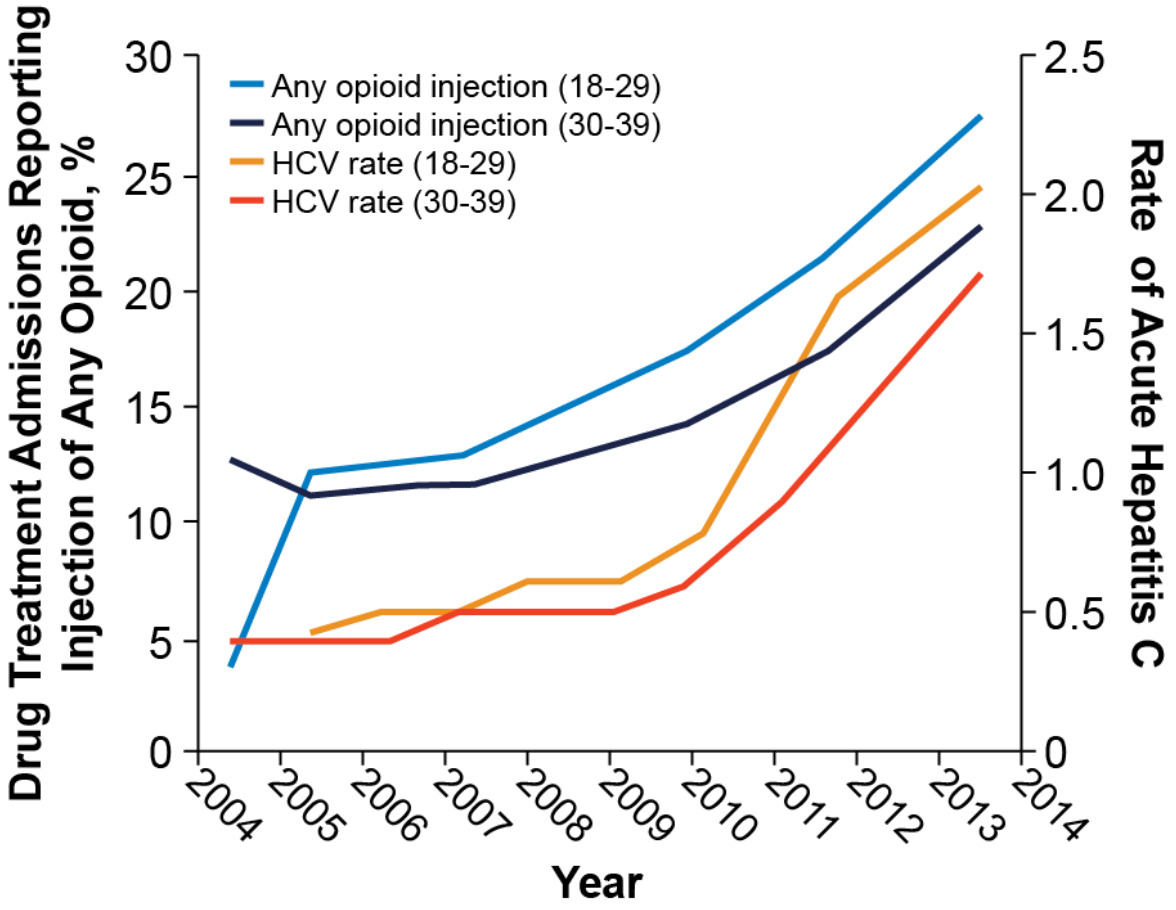
By accounting for populations inadequately represented in NHANES, we **created two models to estimate the national hepatitis C prevalence** among US adults during 2017–2020.



Hall EW, Bradley H, Barker LK, Lewis KC, Shealey J, Valverde E, Sullivan P, Gupta N, Hofmeister MG. Estimating hepatitis C prevalence in the United States, 2017-2020. Hepatology. 2024 May 13. doi: 10.1097/HEP.0000000000000927. Epub ahead of print. PMID: 38739849.

Increase in Hepatitis C Infections Linked to Worsening Opioid Crisis[1]

Hepatitis C and Opioid Injection Rose Dramatically in Younger Americans From 2004-2014



Among people **ages 18-29,** admission for injection opioid use increased by **622%**

HCV incidence increased by **400%** **in the** same cohort

As many as **1 in 2 patients have incomplete testing**[2]

~7% of people who use drugs have received Tx

1. https://www.cdc.gov/nchhstp/newsroom/2017/hepatitis-c-and-opioid-injection-press-release.html. 2. Feld JJ. *J Infect Dis.* Published online October 13, 2023

Syringe Sharing Among People Who Inject Drugs in 23 US Cities, 2018

Sharing needles, syringes, or other drug injection equipment puts people who inject drugs (PWID) at high risk for HIV and other infections.

of PWID shared syringes

Syringe sharing is more common among young people.

of people aged 18 to 24 shared syringes

of people aged 25 to 29 shared syringes

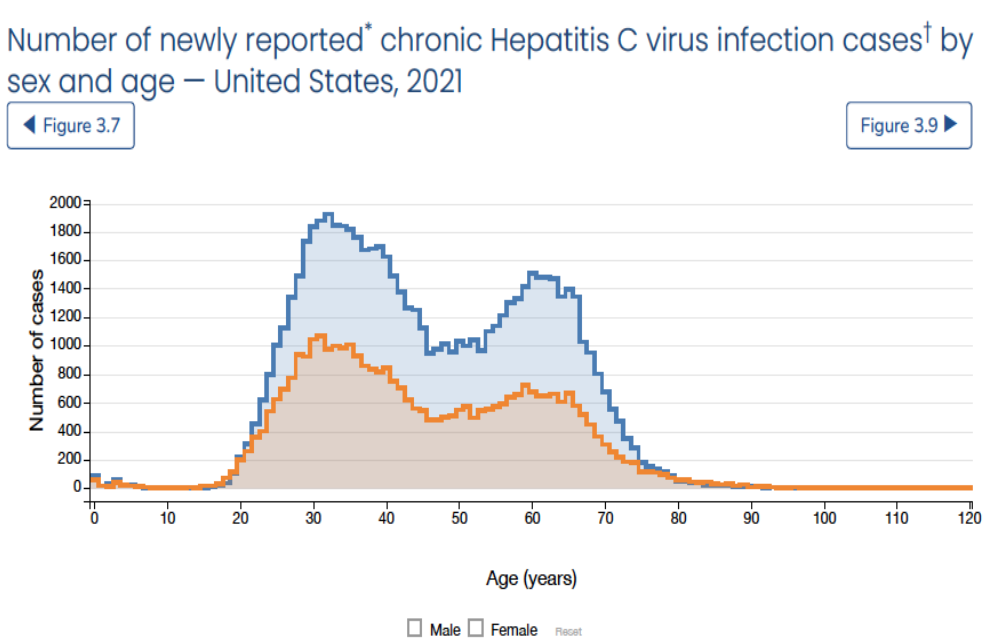
of people aged 30 to 39 shared syringes

of people aged 40 to 49 shared syringes

of people aged 50 and older shared syringes

CDC. HIV Infection risk, prevention, and testing behaviors among persons who inject drugs-National HIV Behavioral Surveillance: Injection drug use – 23 U.S. Cities, 2018. HIV Surveillance Special Report 2020;24.

HCV and Women of Child-Bearing Age (WOCBA)



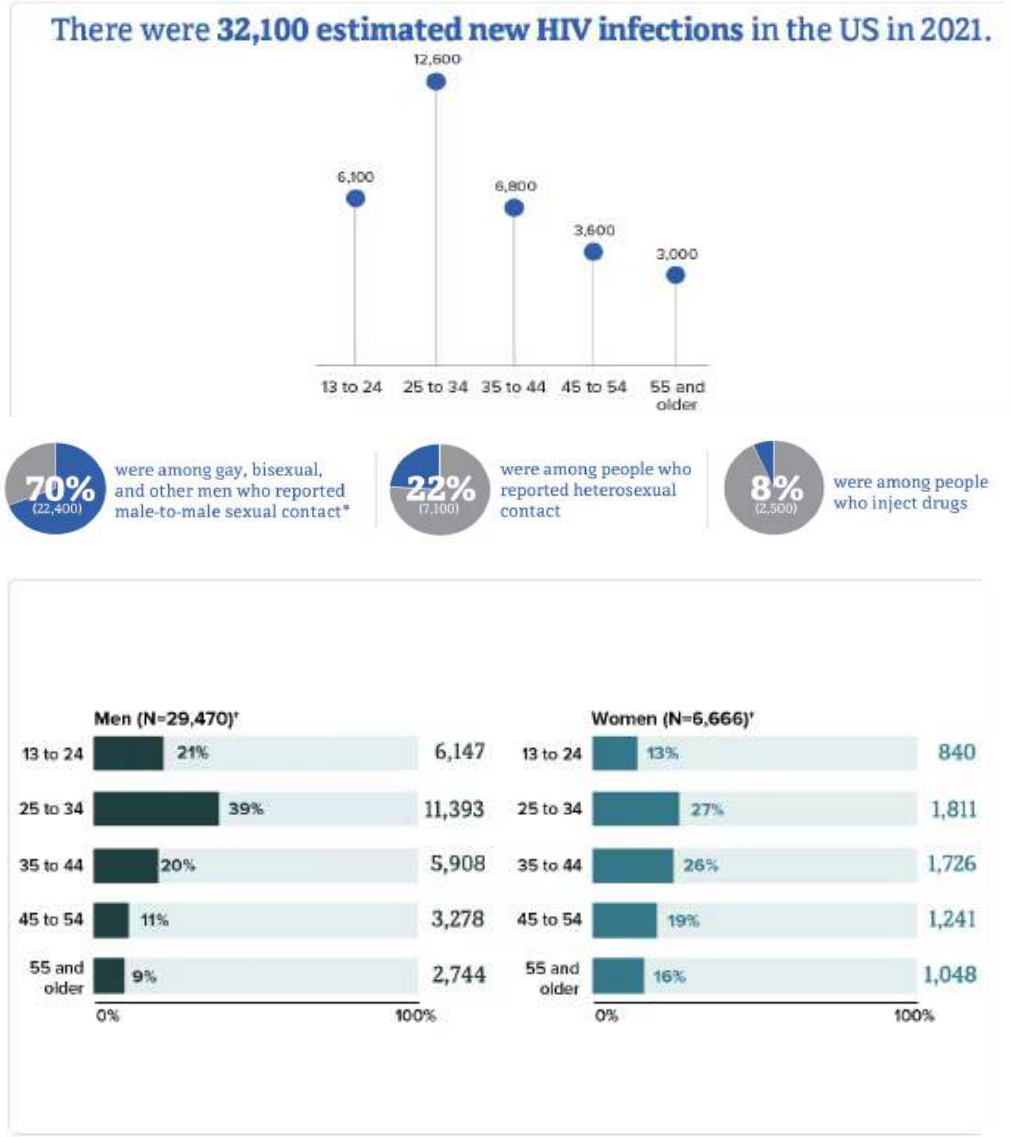
Changing HCV Prevalence Among Pregnant Women[2],

- During 1998–2018, prevalence of HCV diagnosed during pregnancy increased **16 fold** from .34/1000 to 5.3/1000
- Prevalence increased **31-fold** among ages 21-30
- Estimate 725 HCV + children born annually

Meta-analysis of 17 studies looked at HCV vertical transmission risk in women with chronic HCV: risk was 5.8% in HIV-negative women; risk doubled to 10.8% in HIV-positive women[3]

1. Source: CDC accessed June 2024
2. *Arditi et al Deliveries Among Patients With Maternal Hepatitis C OBSTETRICS & GYNECOLOGY VOL. 141, NO. 4, APRIL 2023*
3. Society for Maternal-Fetal Medicine (SMFM). *Am J Obstet Gynecol.* 2017;217(5):B2-B12.

PWUD and HIV



US HIV/HCV coinfection prevalence ~21% but ranges from 6% - 30% with high variability based on the distribution of HIV transmission risk factors.[1,2]

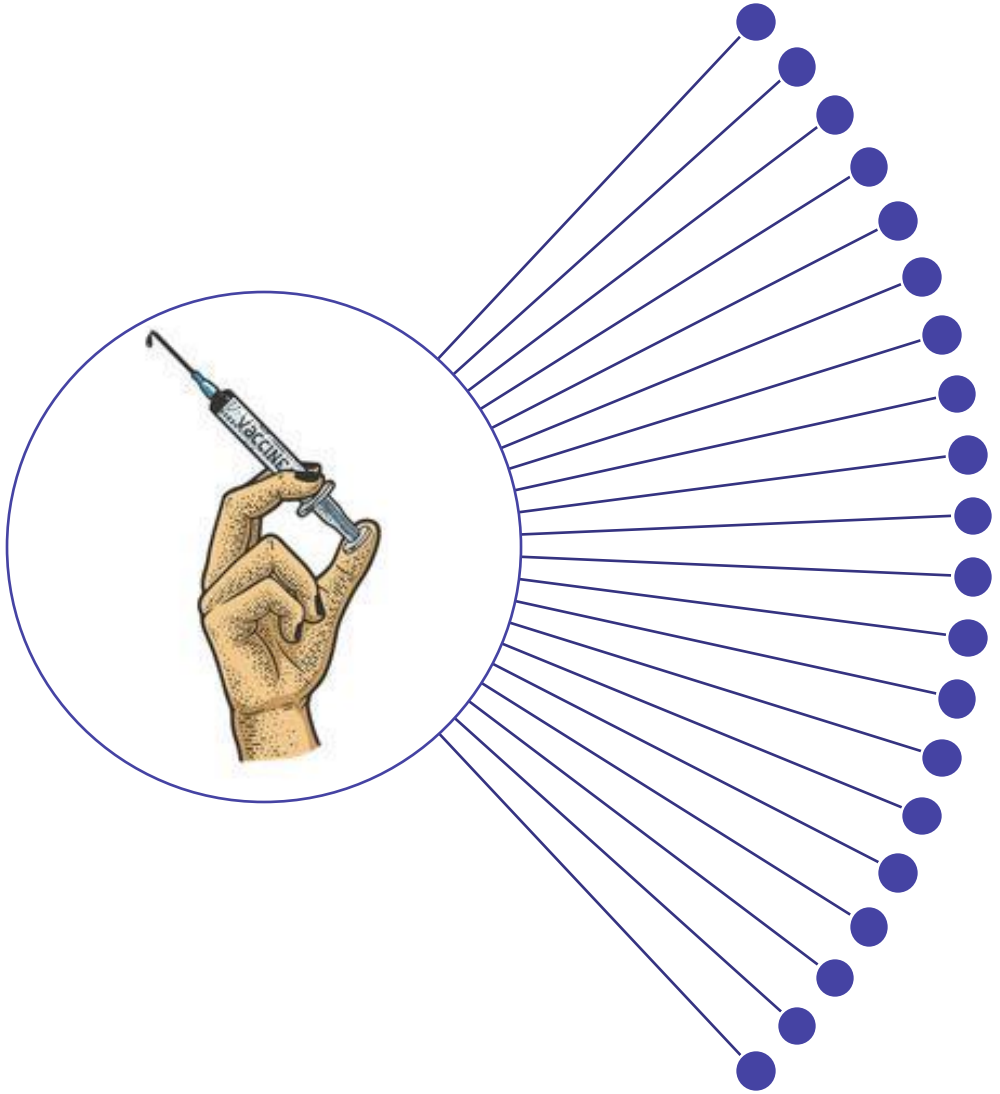
In the United States, it is estimated that 62% to 80% of people who inject drugs who have HIV also have HCV infection.[3]

8% of new HIV infections occur among PWUD[3]

1. Bosh KA, Coyle JR, Hansen V, et al. HIV and viral hepatitis coinfection analysis using surveillance data from 15 U.S. states and two cities. *Epidemiol Infect*. 2018;146(7):920-930. Available at: https://pubmed.ncbi.nlm.nih.gov/29636119.
2. Prussing C, Chan C, Pinchoff J, et al. HIV and viral hepatitis co-infection in New York City, 2000–2010: prevalence and case characteristics. *Epidemiol Infect*. 2015;143(7):1408-1416. Available at: https://pubmed.ncbi.nlm.nih.gov/25170631.
3. Centers for Disease Control and Prevention. 2019 viral hepatitis surveillance report. 2019. Available at: https://www.cdc.gov/hepatitis/statistics/2019surveillance/index.htm.

Treatment As Prevention

Left untreated,
one person actively injecting will potentially **infect up to 20 others** with HCV within the first 3 years of diagnosis[1,2]



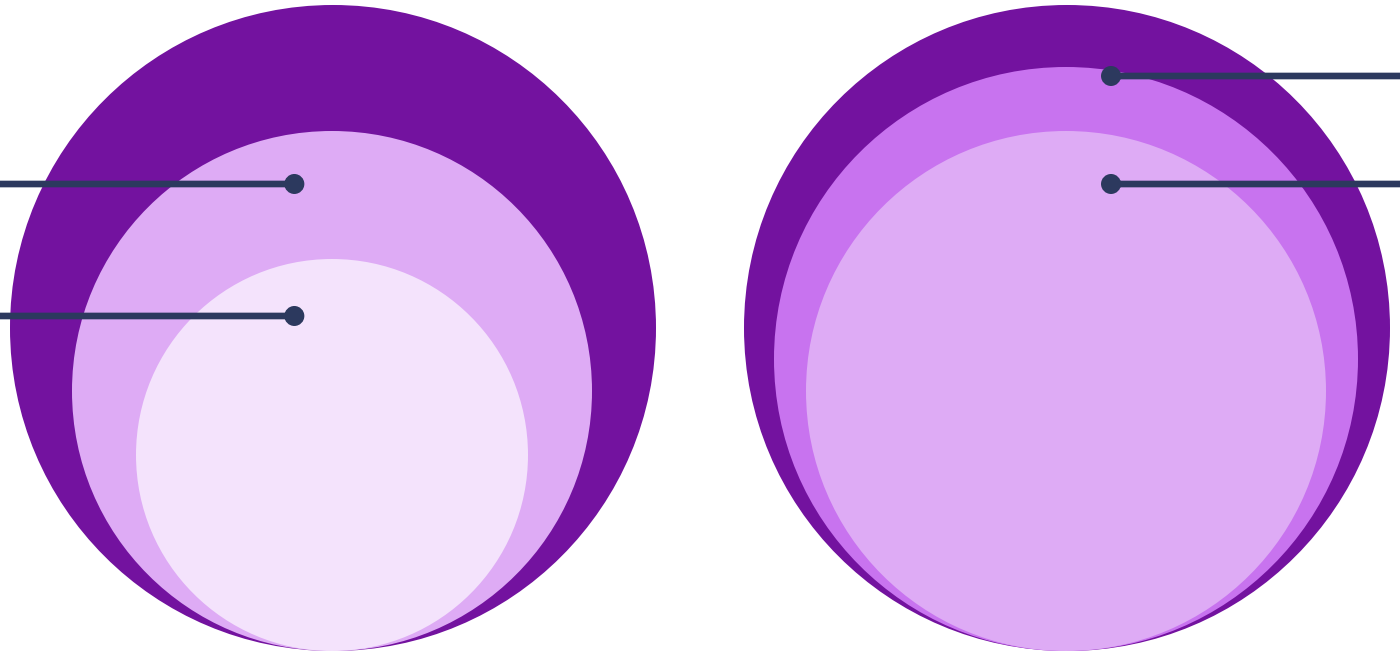
1. NIH National Institute on Drug Abuse. Heroin Research Report. Updated June 2021. Accessed November 2, 2021. https://www.drugabuse.gov/download/37596/heroin-research-report.pdf 2. NIH National Institute on Drug Abuse. Viral Hepatitis—A Very Real Consequence of Substance Use. Updated August 3, 2020. Accessed November 9, 2021. https://www.drugabuse.gov/drug-topics/viral-hepatitis-very-real-consequence-substance-use

WHO Elimination Target

The WHO has developed set targets relative to 2015 benchmark levels with the goal of eliminating HCV as a public threat by 2030:

Reducing new HCV infections by **80%**

Reducing HCV-related deaths by **65%**

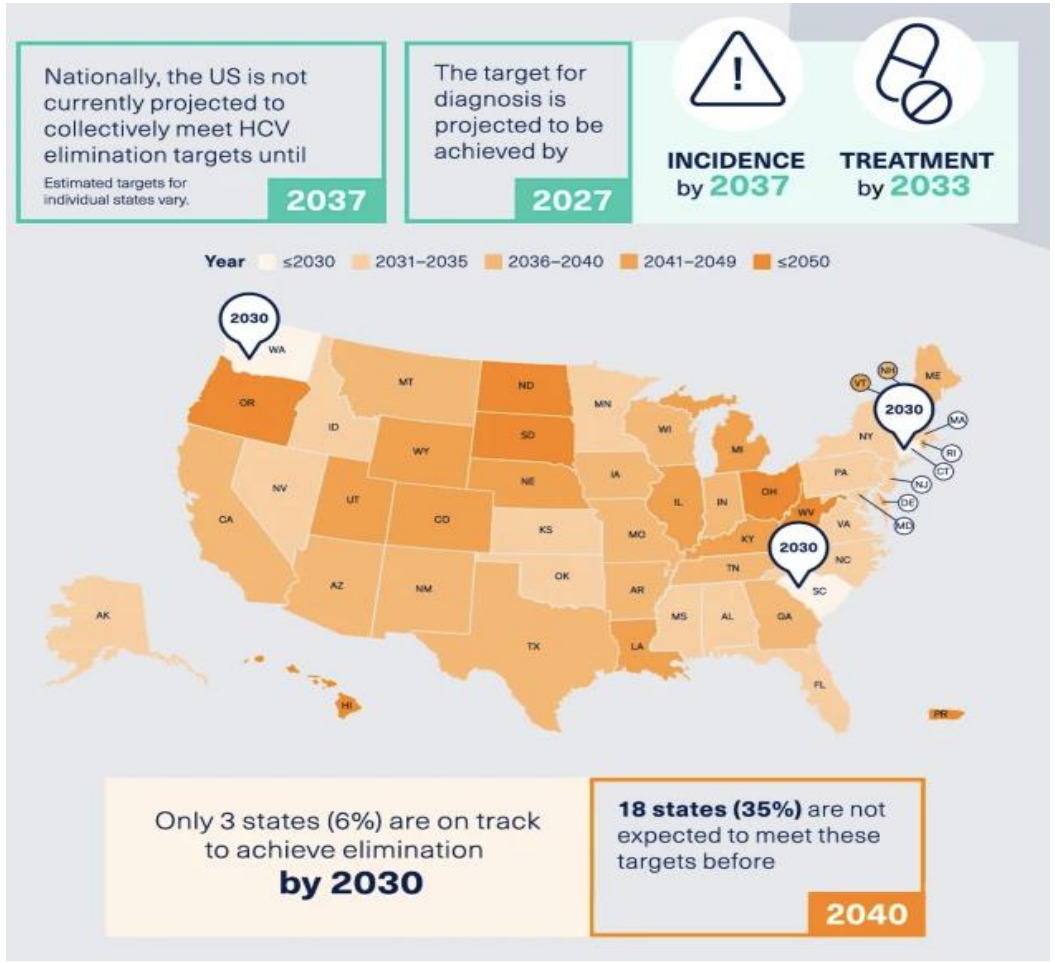


90% **Diagnosing** of the HCV-infected population

80% **Treating** of the eligible population

World Health Organization. Global health sector strategy on viral hepatitis, 2016–2020. WHO REFERENCE NUMBER: WHO/HIV/2016.06

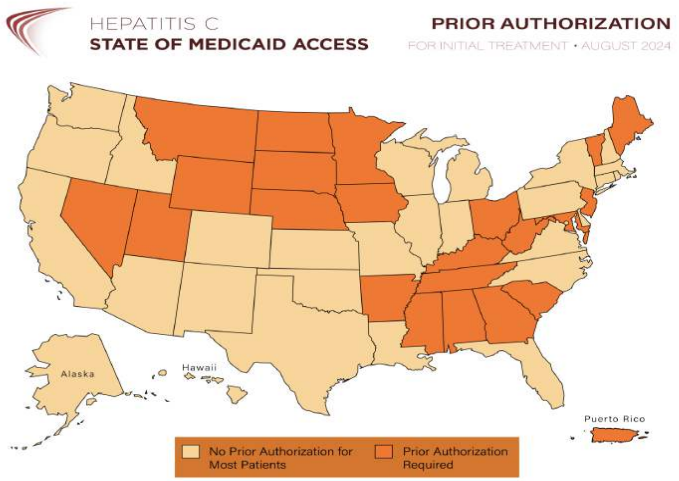
Progress Toward HCV Elimination in the United States



- 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

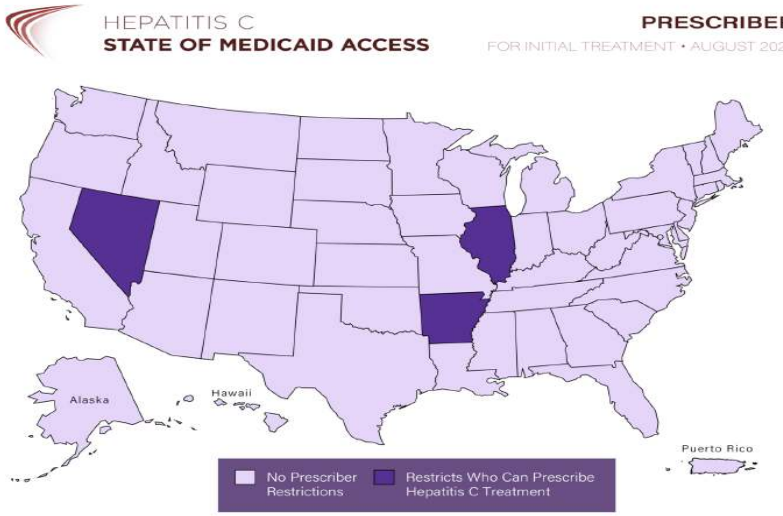


No Prior Authorization for Most Patients (29): Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Missouri, New Hampshire, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania,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

PRESCRIBER RESTRICTIONS

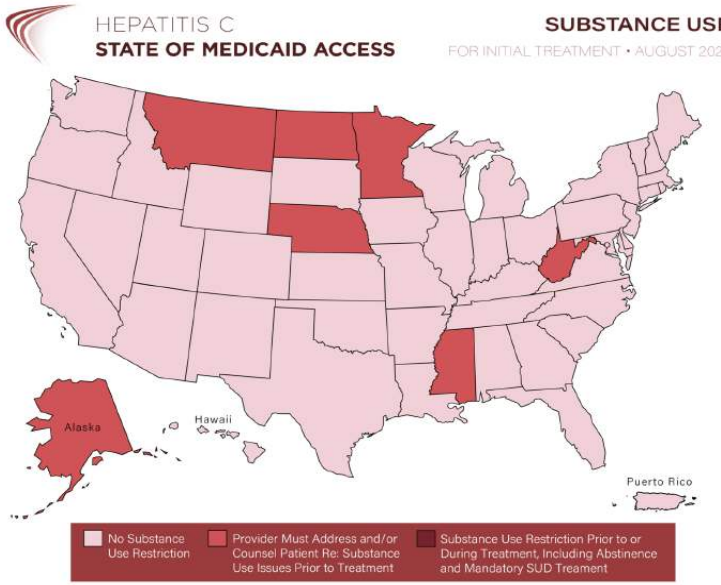


No Prescriber Restrictions for Simplified Treatment (49): Alabama, Alaska, Arizona, California, Colorado, Connecticut, DC, Delaware, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Louisiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, 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

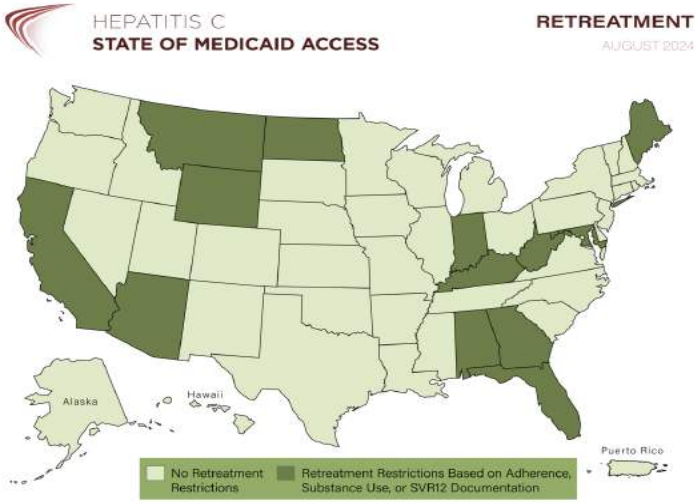
SOBRIETY RESTRICTIONS



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



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

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

What Happens When Restrictions Get Lifted?

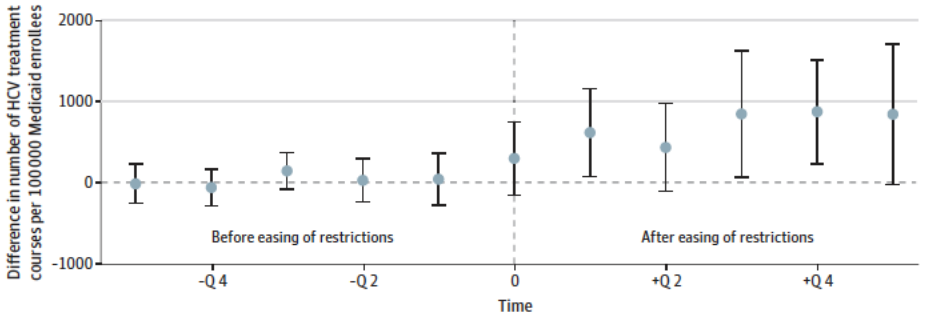
- *39 state Medicaid programs*
- *Medicaid beneficiaries who were prescribed a DAA from January 1, 2015 - December 31, 2019*
- *Of 39 states, 7 (18%) eliminated coverage restrictions*
- *25 (64%) eased restrictions*
- *7 (18%) maintained the same restrictions from 2015 to 2019*
- *After states eased or eliminated restrictions, the use of DAAs increased by 966 (95%CI, 409-1523) treatment courses per 100,000 Medicaid beneficiaries each quarter compared with states that did not ease or eliminate restrictions.*
- *Higher DAA use when DAAs were reimbursed predominantly via fee-for-service Medicaid but not managed care organizations.*

Figure 1. Trends Over Time in Use of Direct-Acting Antivirals Among States That Did Not Ease Restrictions vs Those That Did

	2016, Q1	2016, Q2	2016, Q3	2016, Q4	2017, Q1	2017, Q2	2017, Q3	2017, Q4	2018, Q1	2018, Q2	2018, Q3	2018, Q4	2019, Q1	2019, Q2	2019, Q3	2019, Q4
States that did ease restrictions	5	8	12	13	17	17	19	22	26	27	28	30	28	30	28	28
States that did not ease restrictions	32	30	27	26	22	22	20	17	13	12	10	8	8	7	7	7
Total	37	38	39	39	39	39	39	39	39	39	38	38	36	37	35	35

The brown line shows the mean number of hepatitis C virus (HCV) treatment courses per 100 000 Medicaid enrollees from 2016 to 2019. The blue and orange lines stratify states based on whether they had eased or eliminated coverage restrictions up to that point. States changed from the did not ease restrictions to the did ease restrictions categories in the quarter (Q) when a change was made. The number of states in each group is shown below the x-axis. The average number of HCV treatment courses is an unweighted average of the states.

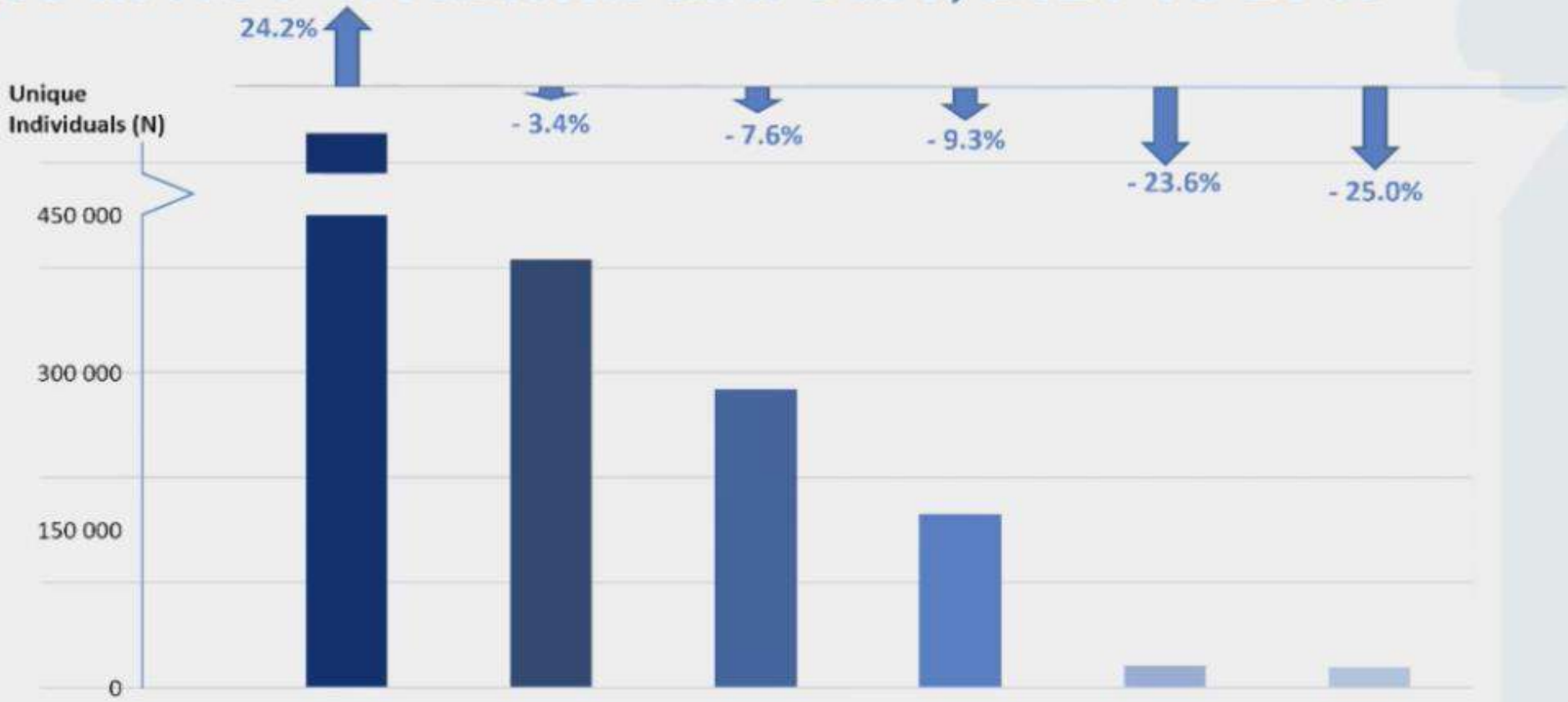
Figure 2. Average Difference in Direct-Acting Antiviral (DAA) Use in States That Eased vs Did Not Ease Coverage Restrictions



Each point shows the average difference in the number of DAA treatment courses per 100 000 Medicaid beneficiaries between states that eased restrictions and those that did not. Values greater than 0 represent higher use of DAAs in states that eased restrictions compared with those that did not. Time 0 is the calendar quarter (Q) during which the restrictions were eased, and the effect estimates in the 5 quarters before vs after this change are averaged across models for states that eased restrictions at different times from 2015 to 2019. Whiskers represent 95% CIs. HCV indicates hepatitis C virus.

JAMA Health Forum. 2024;5(4):e240302. doi:10.1001/jamahealthforum.2024.0302

Changes in HCV Treatment and Cure, 2021 vs 2019



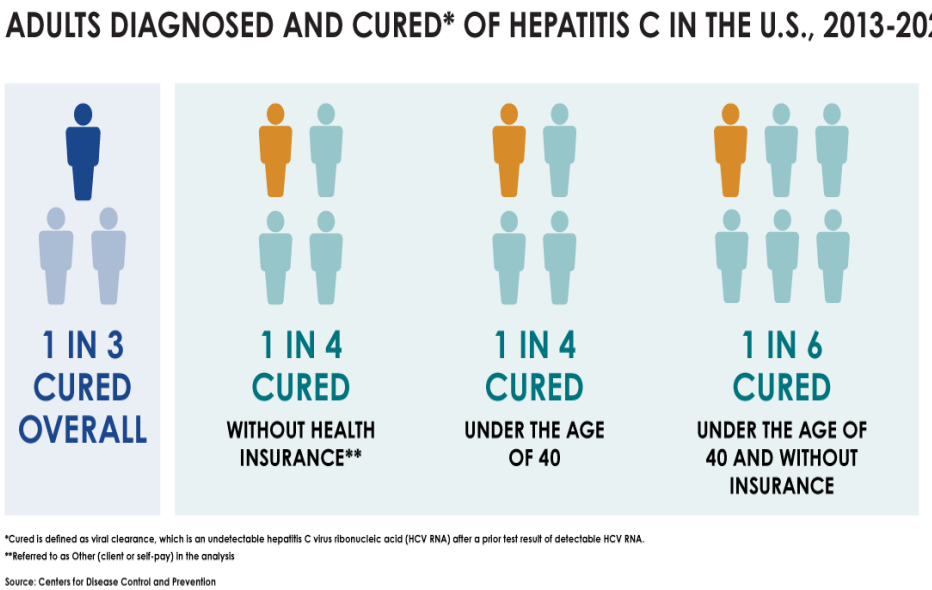
	HCV Ab tested	HCV Ab+	HCV RNA	HCV RNA+	Treated	Cured
Frequency (2021)	10,167,524	407,795	284,220	165,142	21,136	19,584
Proportion	100.0%	4.0% of Ab tested	100.0%	58.1% of RNA tested	12.8% of RNA+	92.7%* of treated

Figure is only showing HCV RNA tested, RNA+, treated (among those tested RNA+ in 2021), and cured individuals who had an Ab+ test in 2021.
HCV Treated and cured individuals were identified using validated imputation algorithms.
*Cure rate may be underestimated because patients diagnosed toward the end of 2021 may not have enough follow-up data to predict treatment initiation and cure.

GLOBAL HEPATITIS SUMMIT 2023

Hepatitis C Care Cascade and Progress Toward Elimination in the United States, 2021, Ward et al; Global Hepatitis Summit 2023
Slide used with permission

HCV Treatment Rates in the US

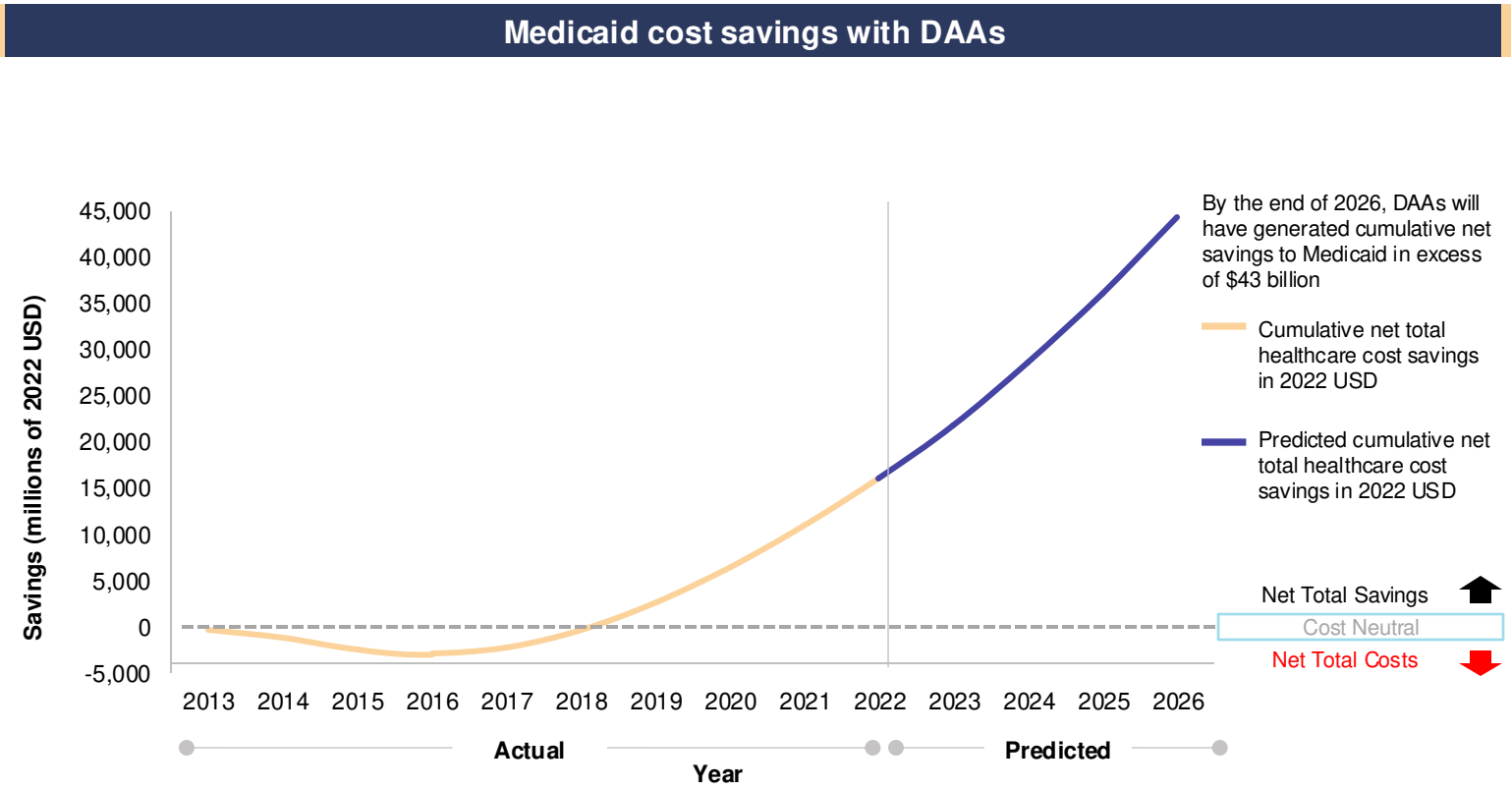


- *Retrospective cohort study of 87,652 US Medicaid enrollees ages 18-64 between 2017-2019[1]*
- *Significantly lower treatment initiation among people younger than 30 years, females, Hispanic and Asian individuals, and people with injection drug use.[1]*
- *Only 20% received DAA treatment within 6 months 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

Impact of DAA Use on Cumulative Net Total Healthcare Savings in Medicaid, 2013-2026

- Within a decade of introduction, DAAs provided Medicaid with a cumulative net total healthcare savings¥ of more than $15 billion, and projected to increase up to $43 billion by 2026.[1,2]



¥Savings included hospitalizations, emergency department visits, physician office visits and prescription drug refills avoided as a result of DAA use

DAA: direct-acting antiviral; $M: dollars in millions; Act; PWID: People who inject drugs.

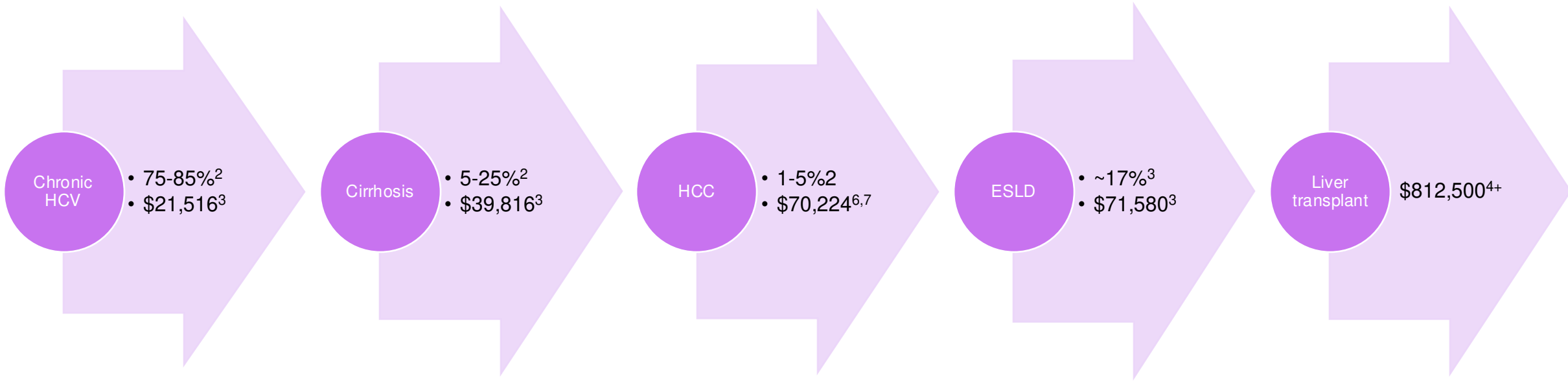
1. Roebuck MC. *Am J Manag Care.* 2022;28(12):630-631.
2. Roebuck MC, Liberman JN. *Am J Manag Care.* 2019;25(8):S131-S139.

*16 states – Alabama, California, Connecticut, Florida, Illinois, Indiana, Louisiana, Michigan, New Hampshire, New Mexico, New York, Ohio, Oregon, Pennsylvania, Virginia, Washington

18

Economic Impact of Hepatic Complications of HCV to Health Systems[1]

Incidence and direct costs of hepatic complications for HCV patients



*Includes costs obtained from 2013 MarketScan data on inpatient and outpatient facilities, professional services, prescription drugs, and other costs for a commercial health plan.[3]
†Includes 2017 charges for pre-transplant and follow-up care, outpatient immunosuppressant and other drugs, and all medical costs associated with the patient during the time period from 30 days pre-transplant through 180 days post-transplant.[4]
‡Includes costs of medications, procedures, and services converted to 2004 US dollars.[5]
ESLD, end-stage liver disease. HCC –hepatocellular carcinoma *PPPY

1. Razavi H et al. Hepatology. 2013;57(6):2164-2170. 2. CDC. https://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#a1. Accessed April 2021.
3. Johnson R, et al. http://us.milliman.com/uploadedFiles/insight/2015/milliman-hcv-burden.pdf. Accessed June 2019.
4. Bentley TS, for Milliman http://us.milliman.com/uploadedFiles/insight/2017/2017-Transplant-Report.pdf. Accessed June 2019.
5. Morrison RS, et al. Arch Intern Med. 2008;168(16):1783-1790. 6. Yin S, et al. Public Health Rep. 2019;134(6):685-694.
6. Younossi Z, Gordon SC, Ahmed A, Dieterich D, Saab S, Beckerman R. Treating Medicaid patients with hepatitis C: clinical and economic impact. *Am j Manag Care*. 2017;23(2):107-112.
7 Younossi ZM, Park H, Saab S, Ahmed A, Dieterich D, Gordon SC. Cost-effectiveness of all-oral ledipasvir/sofosbuvir regimens in patients with chronic hepatitis C virus genotype 1 infection. *Aliment Pharmacol Ther*. 2015;41(6):544-563

US National HCV Elimination Plan

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]

Author Affiliations | Article Information

JAMA. Published online March 9, 2023. doi:10.1001/jama.2023.3692

Highlights of the White House Plan

Proposed a plan to eliminate hepatitis C in five years in the United States through a mandatory authorization:

1. Supporting the development of point-of-care diagnostic tests to enable a test-to-treat model;
2. Broadening access to curative hepatitis C medications, primarily through a national subscription model; and
3. Expanding infrastructure needed to reach, test, and treat all affected individuals.

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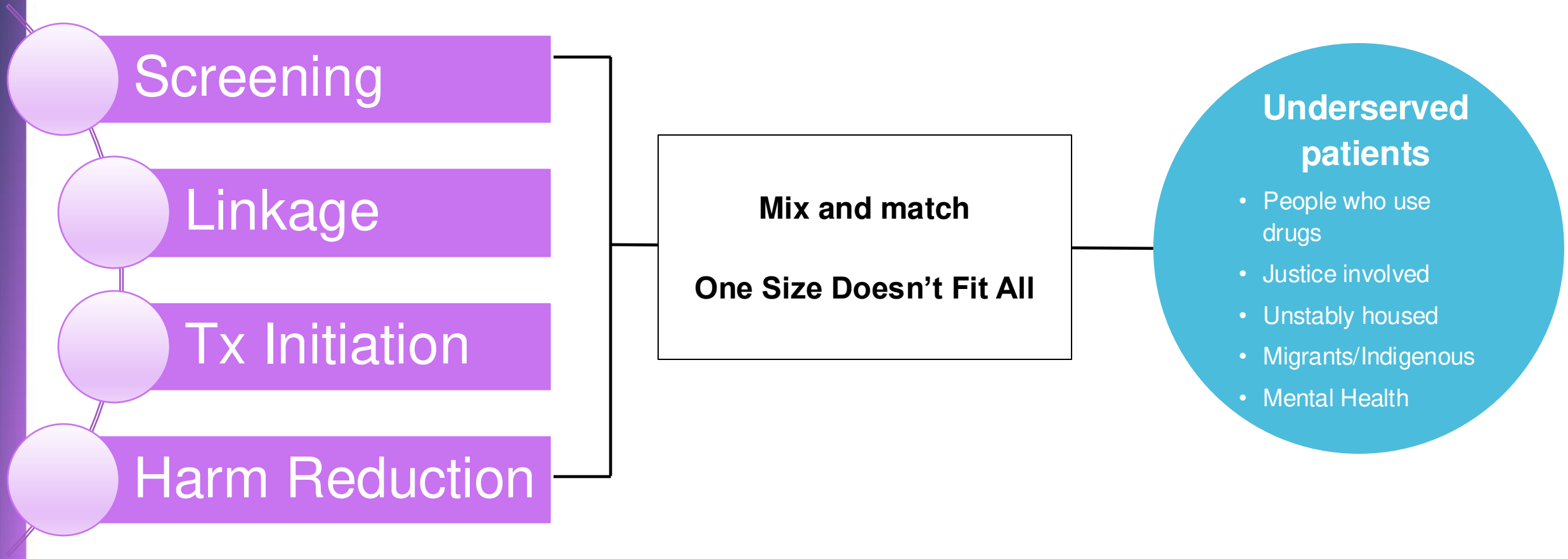
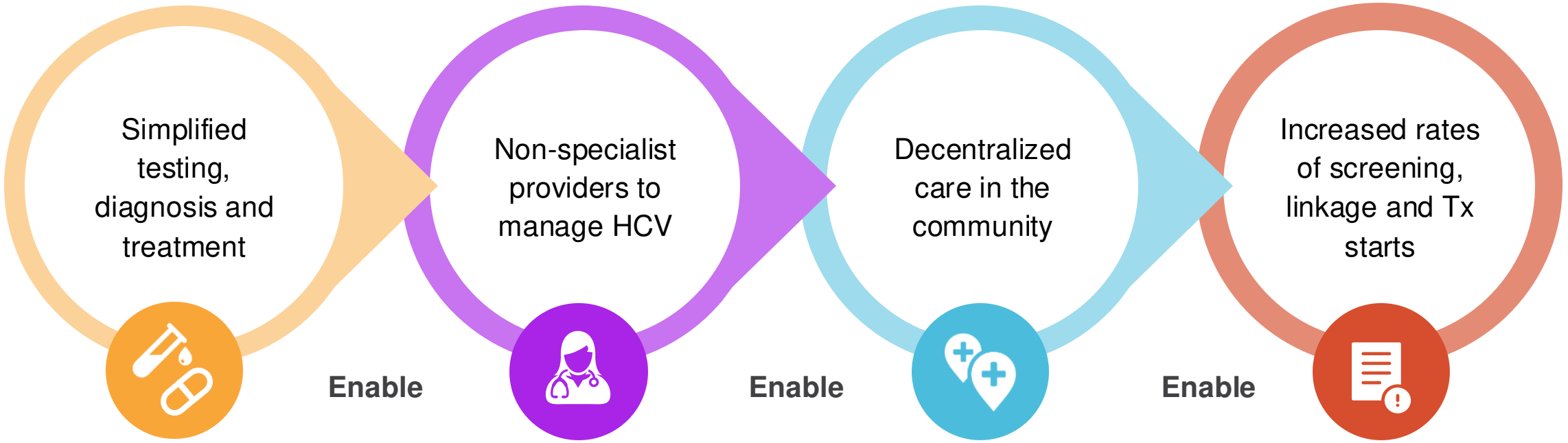
Pillars For HCV Elimination



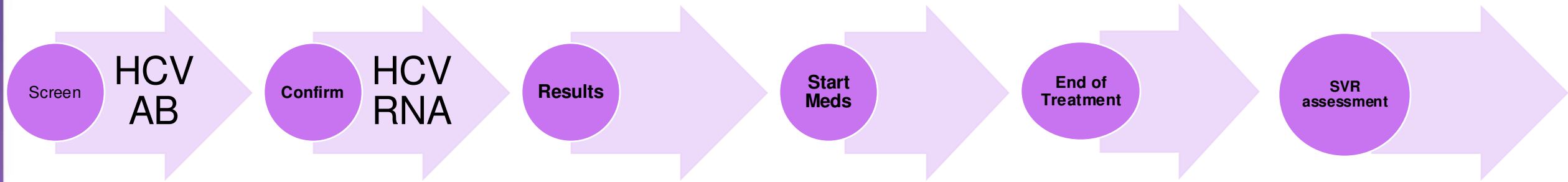
What does Simplified Care Delivery Entail?

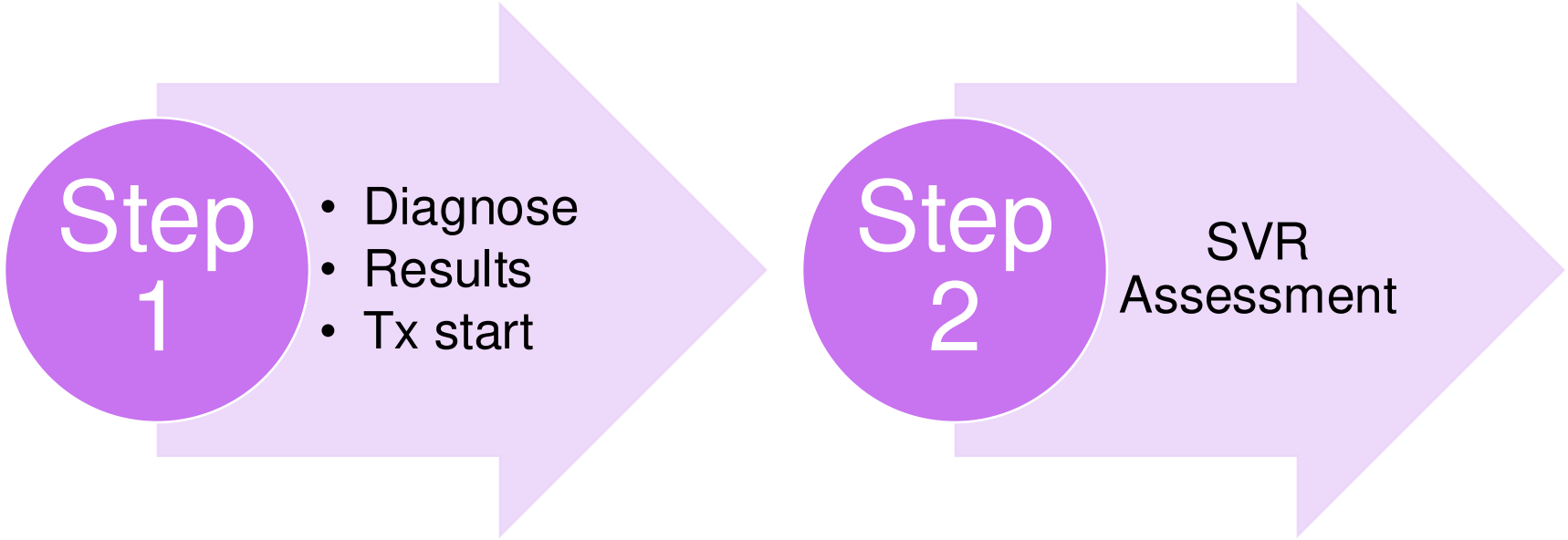
Simplified Care delivery



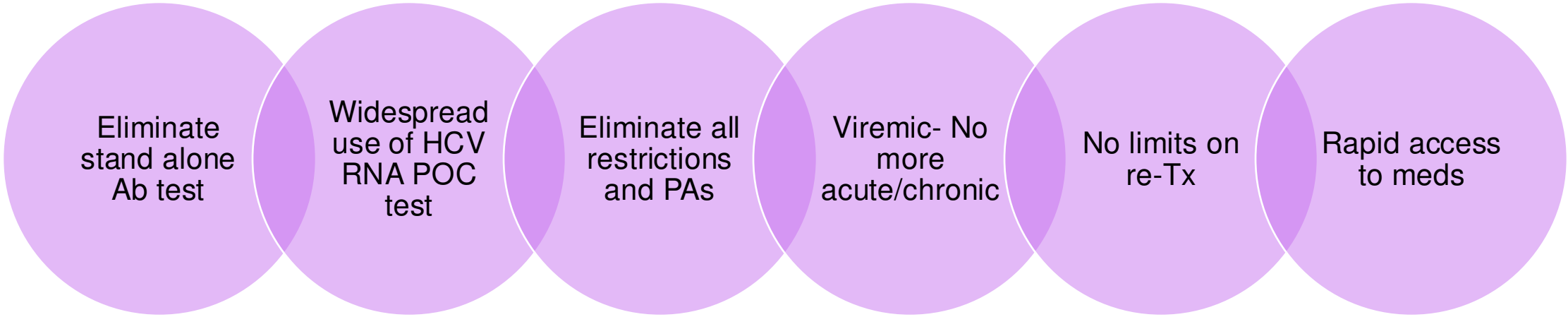
Adapted from World Health Organization. *Updated recommendations on simplified service delivery and diagnostics for hepatitis C infection*, 2022.

Speed Is The Key

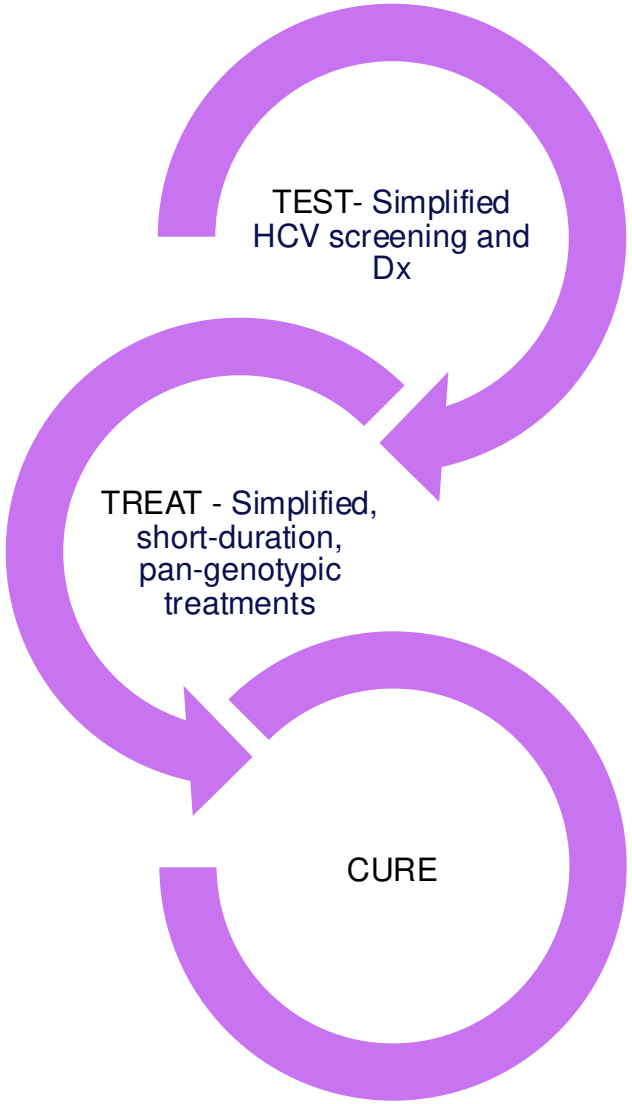




Test And Treat Key Elements



Test and Treat Model of Care



HCV Screening and Initial Evaluation

2020 CDC Recommendations for HCV Screening Among Adults in the United States[1]

Universal screening

Screen at least once in a lifetime for **all adults ≥18 years** (except in settings where HCV RNA-positivity is <0.1%)

Pregnancy

Screen **all pregnant women during each pregnancy** (except in setting where HCV RNA-positivity is <0.1%)

Exposure

One-time testing among people with recognized conditions or exposures, regardless of age or setting prevalence)

Periodic testing

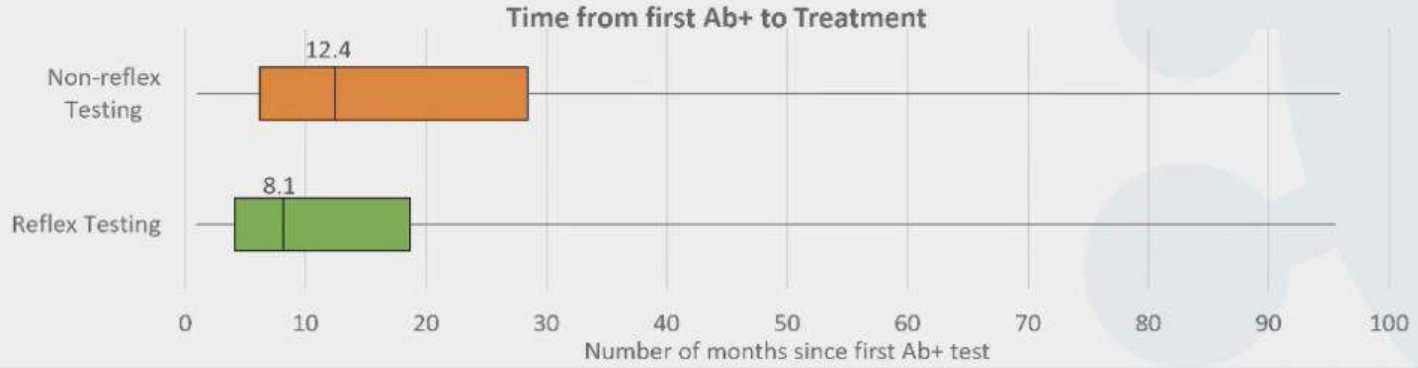
Routine **periodic testing** for people with ongoing risk factors

1. Schillie S, et al. *MMWR Recomm Rep*. 2020;69:1-17.

Association of Reflex Testing and Receipt of HCV Treatment, 2014-2021

- Received HCV treatment
  - 30% among persons having reflex HCV RNA testing
  - 8% among persons for whom HCV Ab and RNA testing were ordered separately

- Median time from first HCV Ab+ test to treatment
  - 8.1 mos. median, 14.5 mos. mean among persons having reflex HCV RNA
  - 12.4 mos. median, 19.9 mos. mean HCV Ab and RNA testing ordered separately

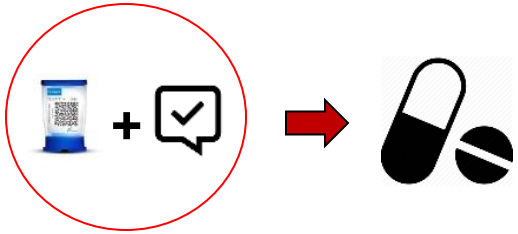


*Percent treated for individuals for whom Ab and RNA testing were ordered separately may be underestimated due to inclusion of those who may not have a confirmed RNA+ test result. Reflex testing (HCV Antibody with reflex to RNA test) was identified by matching the test date (date the specimen was drawn) of the Antibody test with that of the RNA test. Reflex testing analyses are only available with data from one large US national laboratory.
Receipt of treatment was determined based on a viral load decline of at least 1.2 × log10 units since the first positive HCV RNA test, indicating that treatment was initiated in the immediate period prior to the decline. Time to treatment analysis was limited to individuals with an Ab+ test at least 28 days prior to the viral load decline.

GLOBAL HEPATITIS SUMMIT 2023

Hepatitis C Care Cascade and Progress Toward Elimination in the United States, 2021, Ward et al; Global Hepatitis Summit 2023
Slide used with permission.

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)

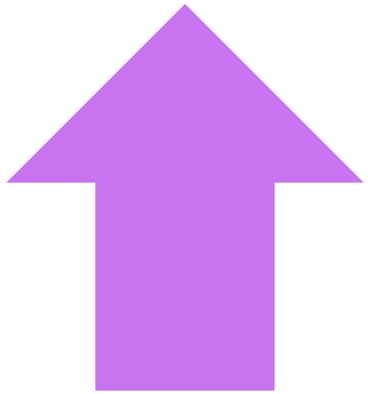
Rapid HCV antibody testing with reflex point-of-care HCV RNA
(low HCV prevalence setting)

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

Point Of Care Testing

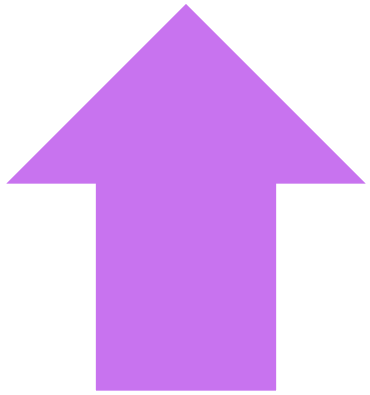
A 2023 Meta-analysis of 45 Studies Evaluating the Impact of Using POC vs SOC Approaches on HCV RNA Viral Load Testing and Treatment[1]

- 28 studies were in people who inject drugs, were unstably housed, or both
- 4 were among justice involved
- 9 were in the general or mixed (ie, includes high-risk groups) populations
- 4 were in people living with HIV.



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

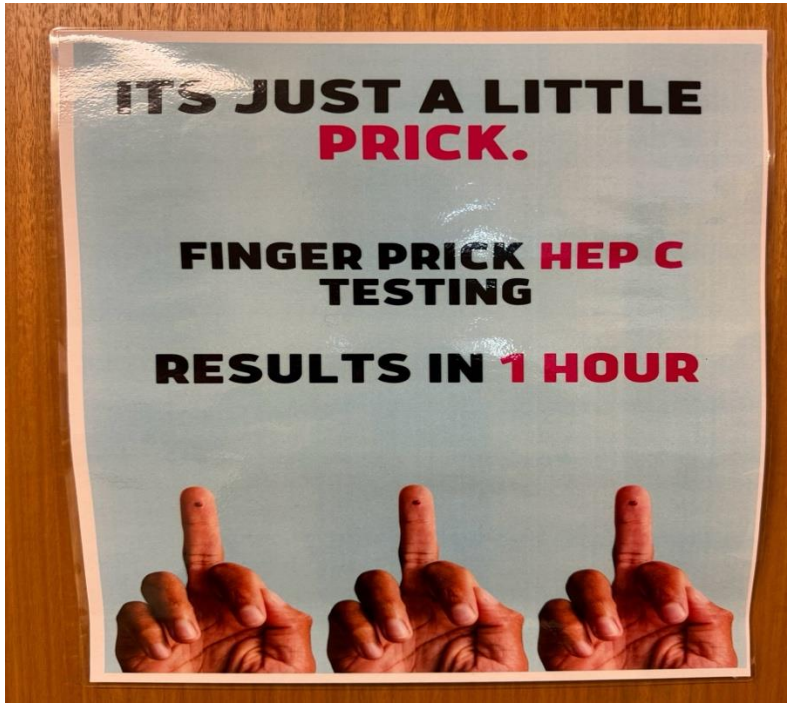
Evaluation of Time to HCV RNA Detection Using the Xpert HCV Viral Load Fingerstick Assay[1]

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

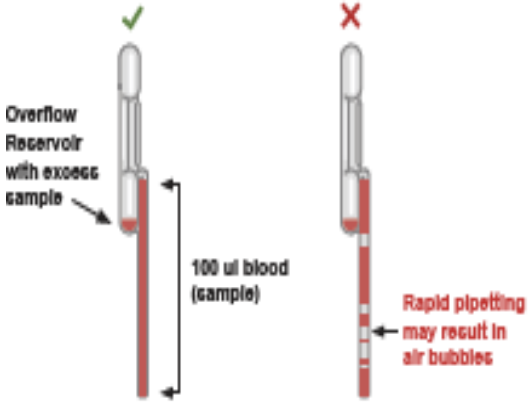
GeneXpert / Xpert HCV

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)

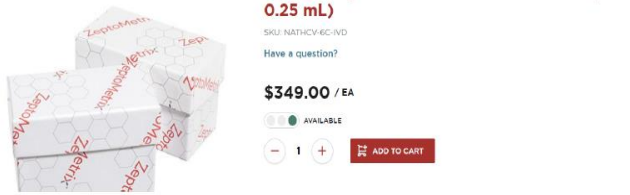
Key Learnings

- 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	E88891842	CEPHEID	EA	$ 339.0000	COBBLESTONE CONTRACT 8957
0081838	NATROL HEP C VIRUS POS CTRL	NATHCVGCIVD	LAB	1150	E88891842	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

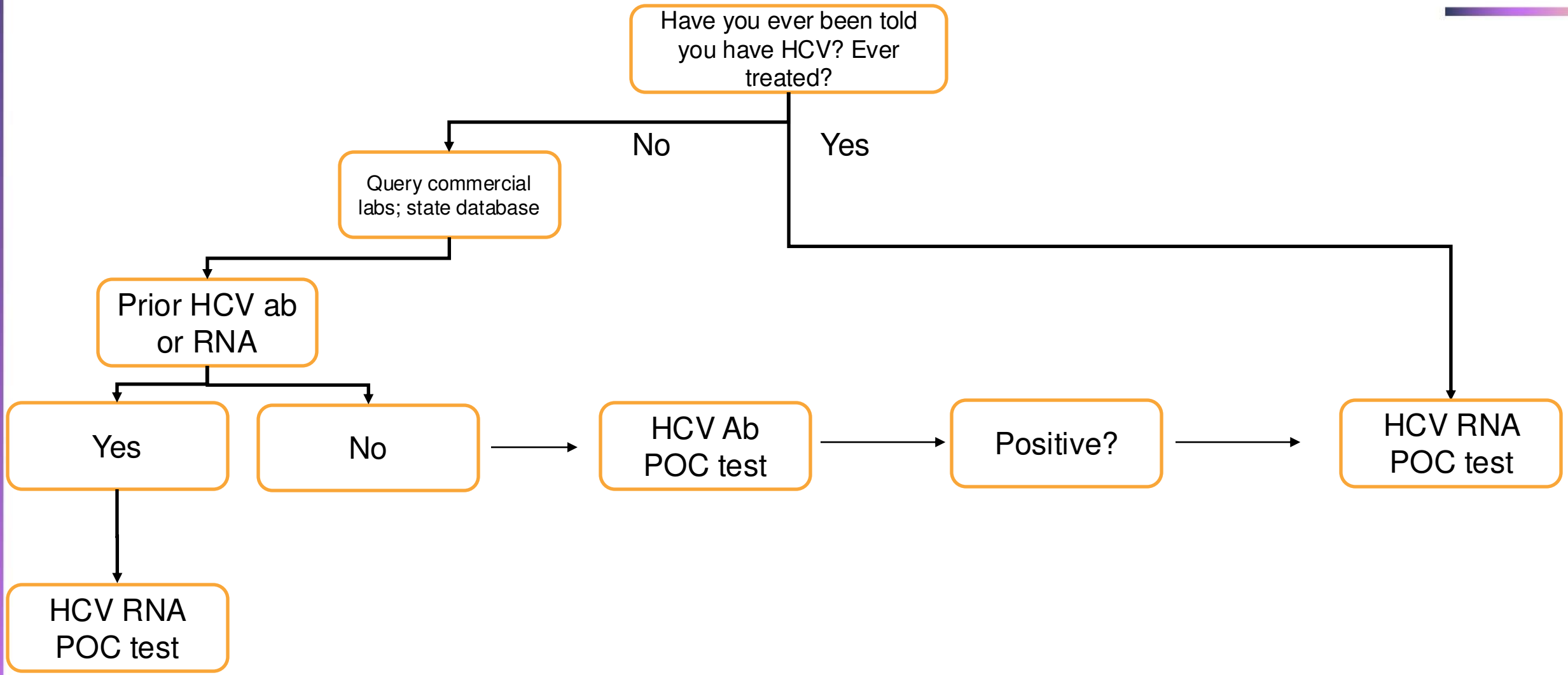
AVAILABLE

1 ADD TO CART

- Lancets:

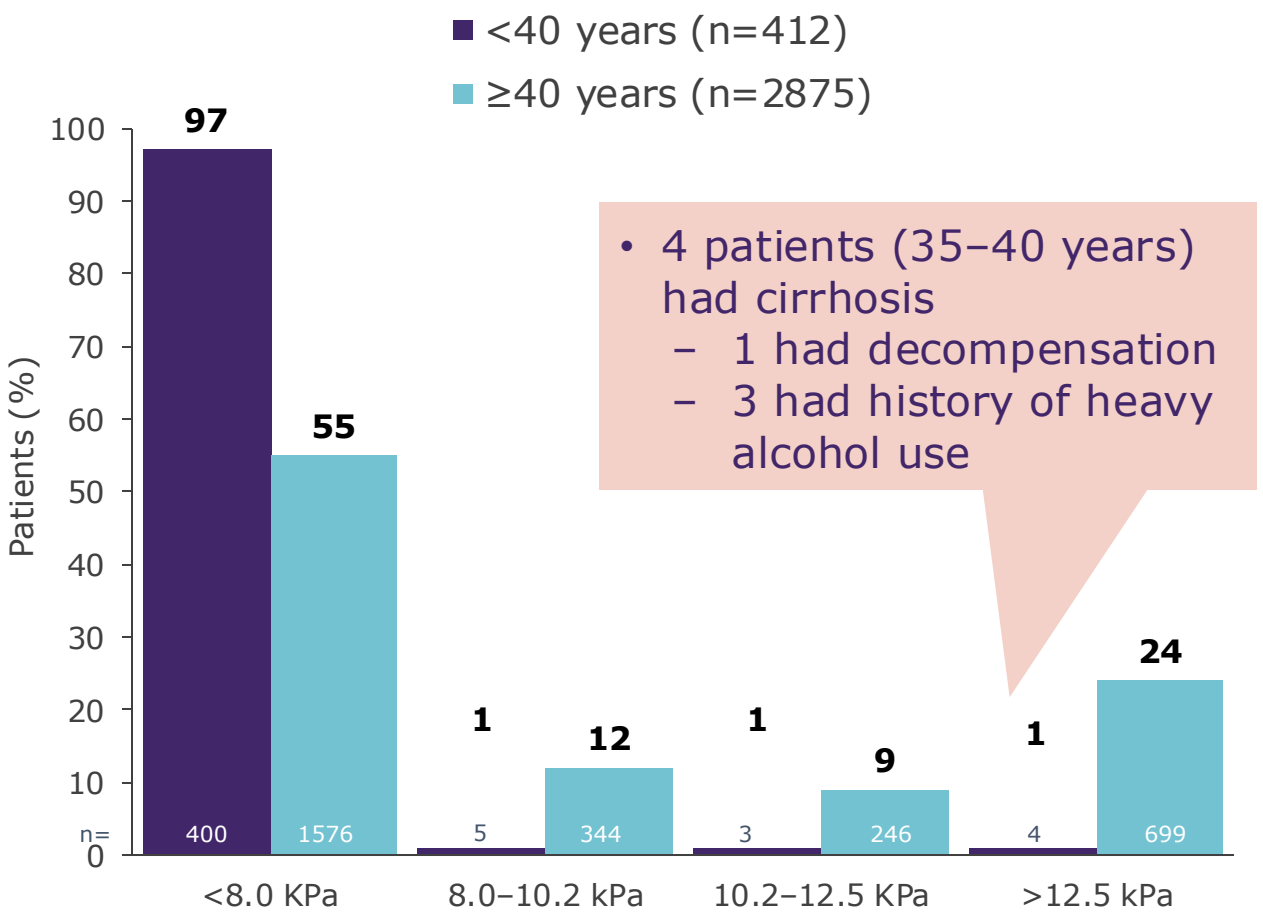
ONE-CARE Opti+ Adjustable Safety Lancets 23G x 3 Depth Setting (1.3 I 1.8 I 2.3mm), Preloaded, Gentle, Sterile,100/bx

La Bodega HCV POC Testing Algorithm



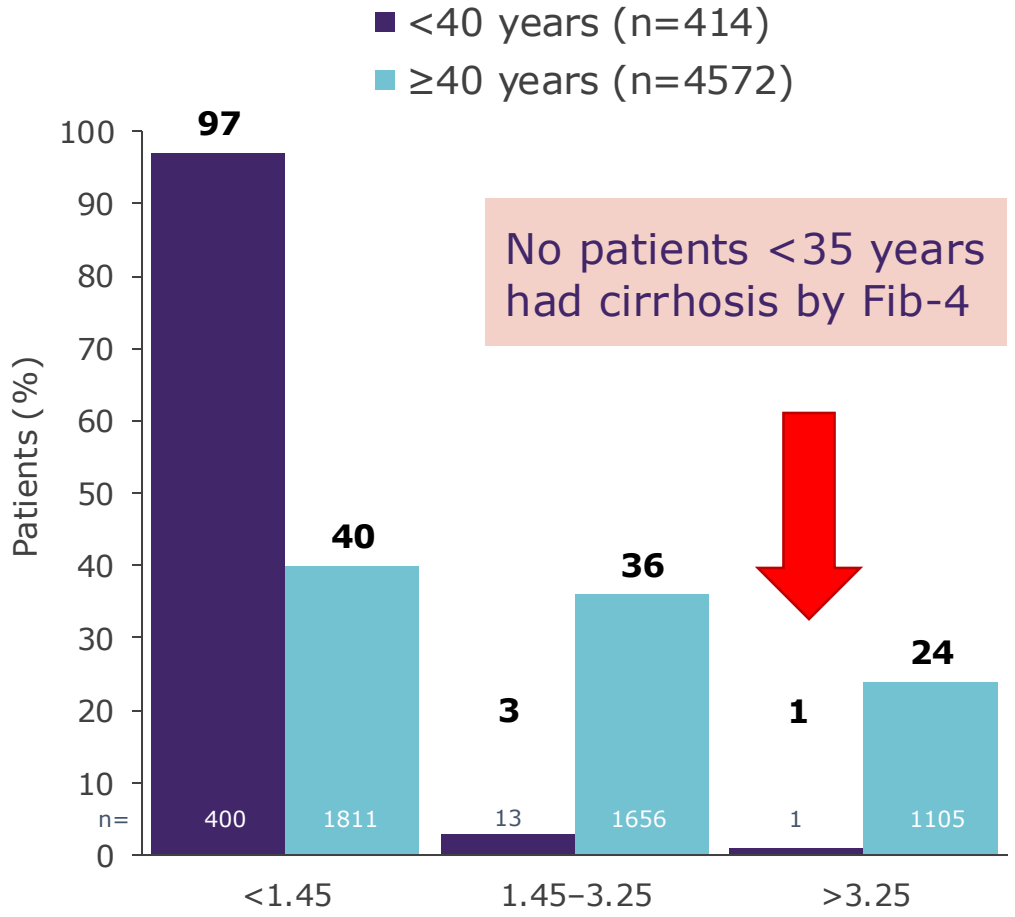
Transition Away From A “Liver” Disease

Fibrosis by transient elastography



- 4 patients (35–40 years) had cirrhosis
  - 1 had decompensation
  - 3 had history of heavy alcohol use

Fibrosis by Fib-4



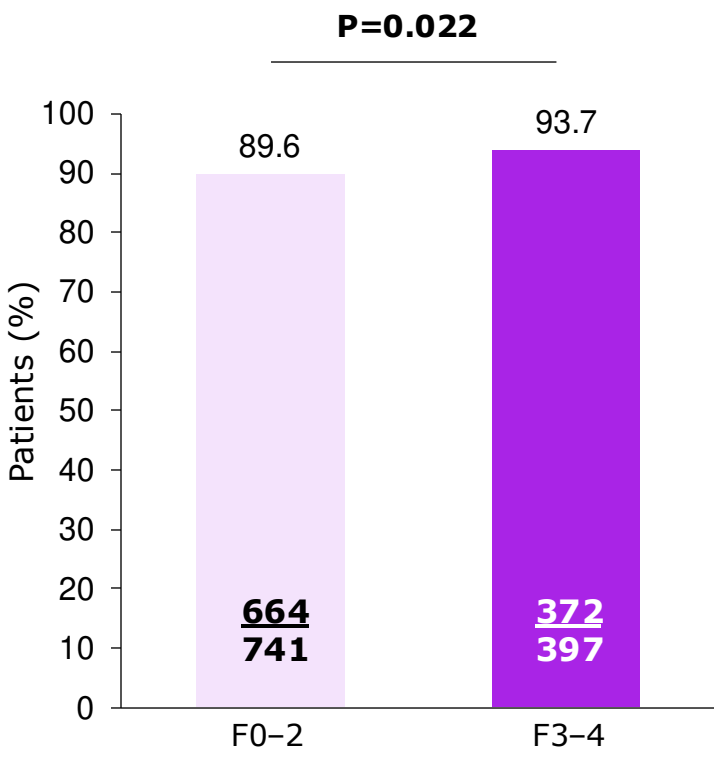
No patients <35 years had cirrhosis by Fib-4

Ramji N, et al. AASLD 2022. Poster P1293

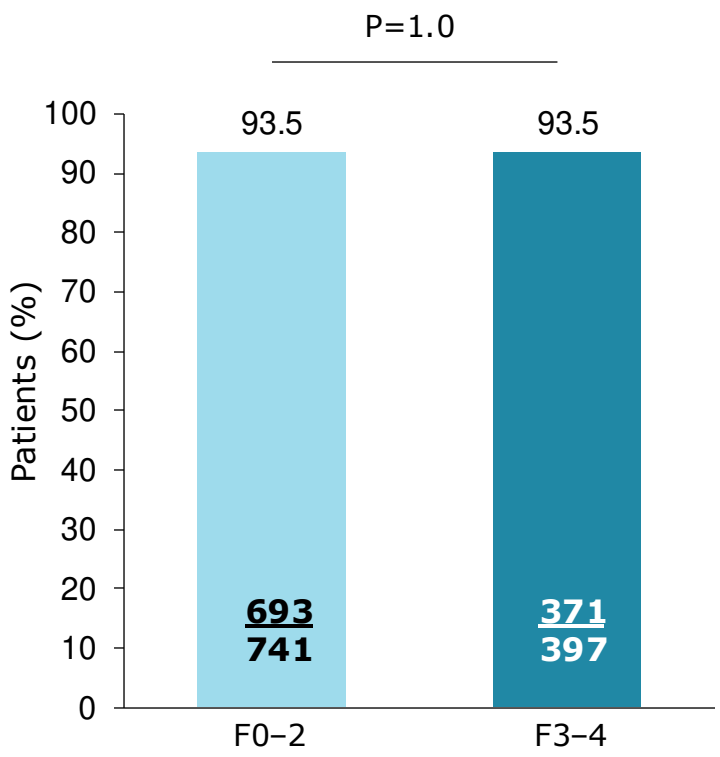
Treatment adherence and fibrosis in PWID: La Bodega

Adherence and SVR12

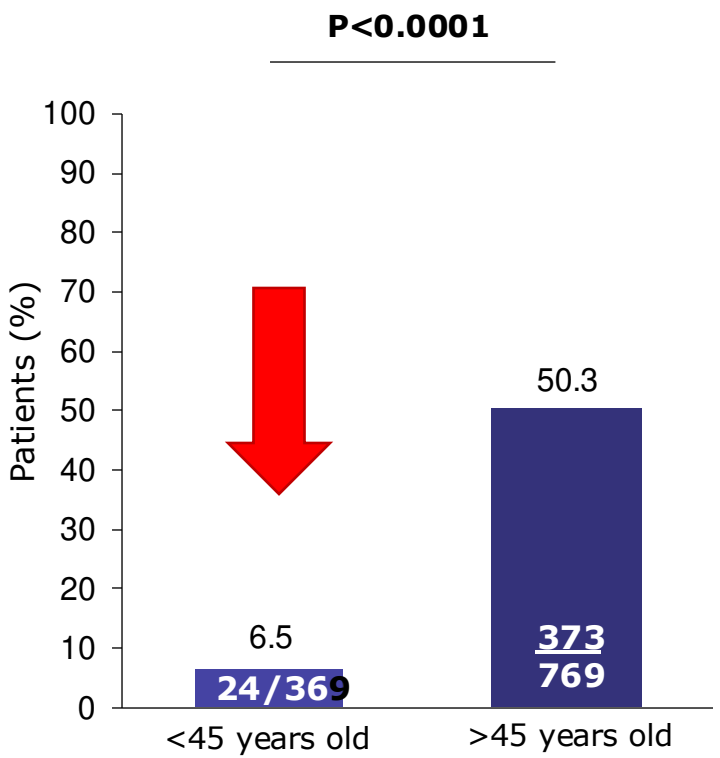
Full adherence



SVR12



Patients with fibrosis F3–4



PWID, people who inject drugs; SVR12, sustained virologic response at post-treatment Week 12.

Moga T, et al. AASLD 2022. Poster P1327

Baseline Workup

< age 40?

+ RNA

Screen HIV, HBV

Start HCV Tx

> Age 40

+ RNA

Screen HIV, HBV

Start Tx

CBC

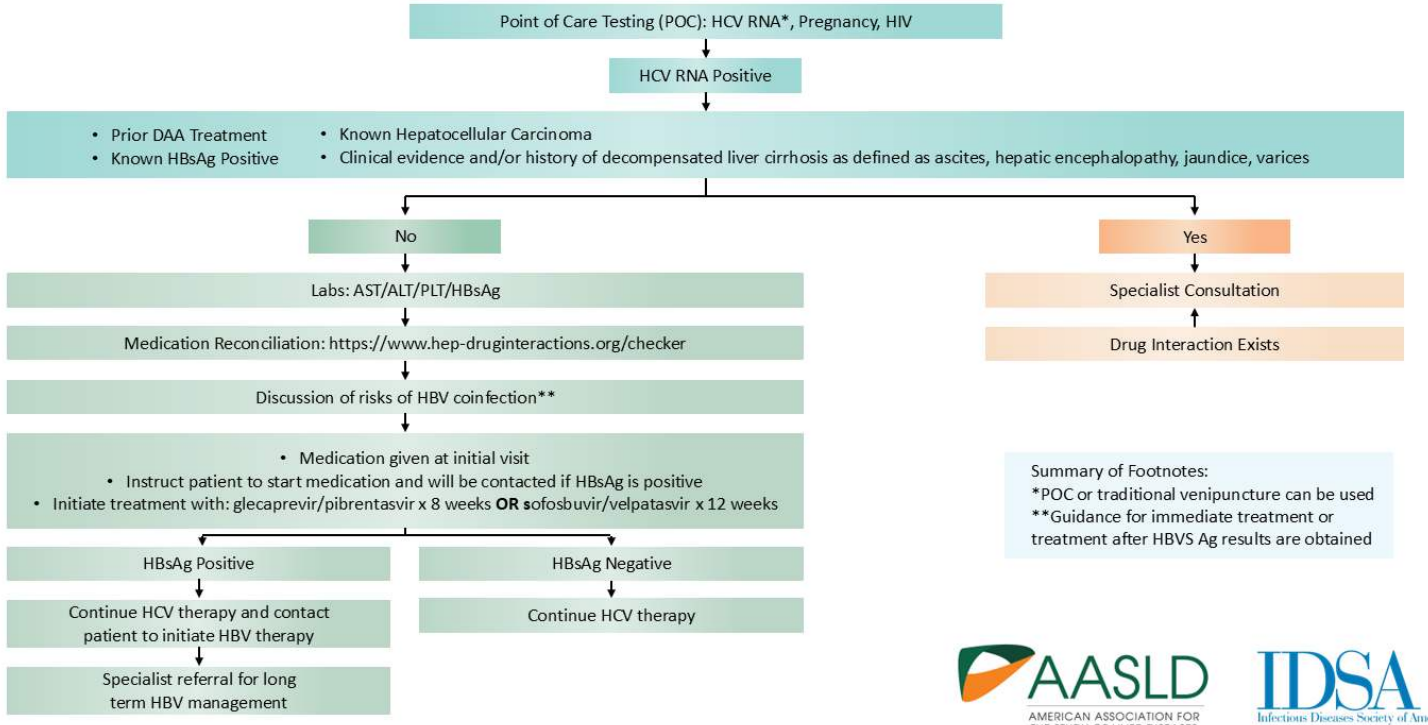
CMP

If: low platelets, low albumin, elevated bilirubin

Ultrasound Fibroscan

- Still need HBV POC SAg test
- DBS HBV SAg available
- Theoretically if born after 1991 → immunized

NEW HCV TEST AND TREAT ALGORITHM PRESENTED AT AASLD CONFERENCE



AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

IDSA
Infectious Diseases Society of America

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

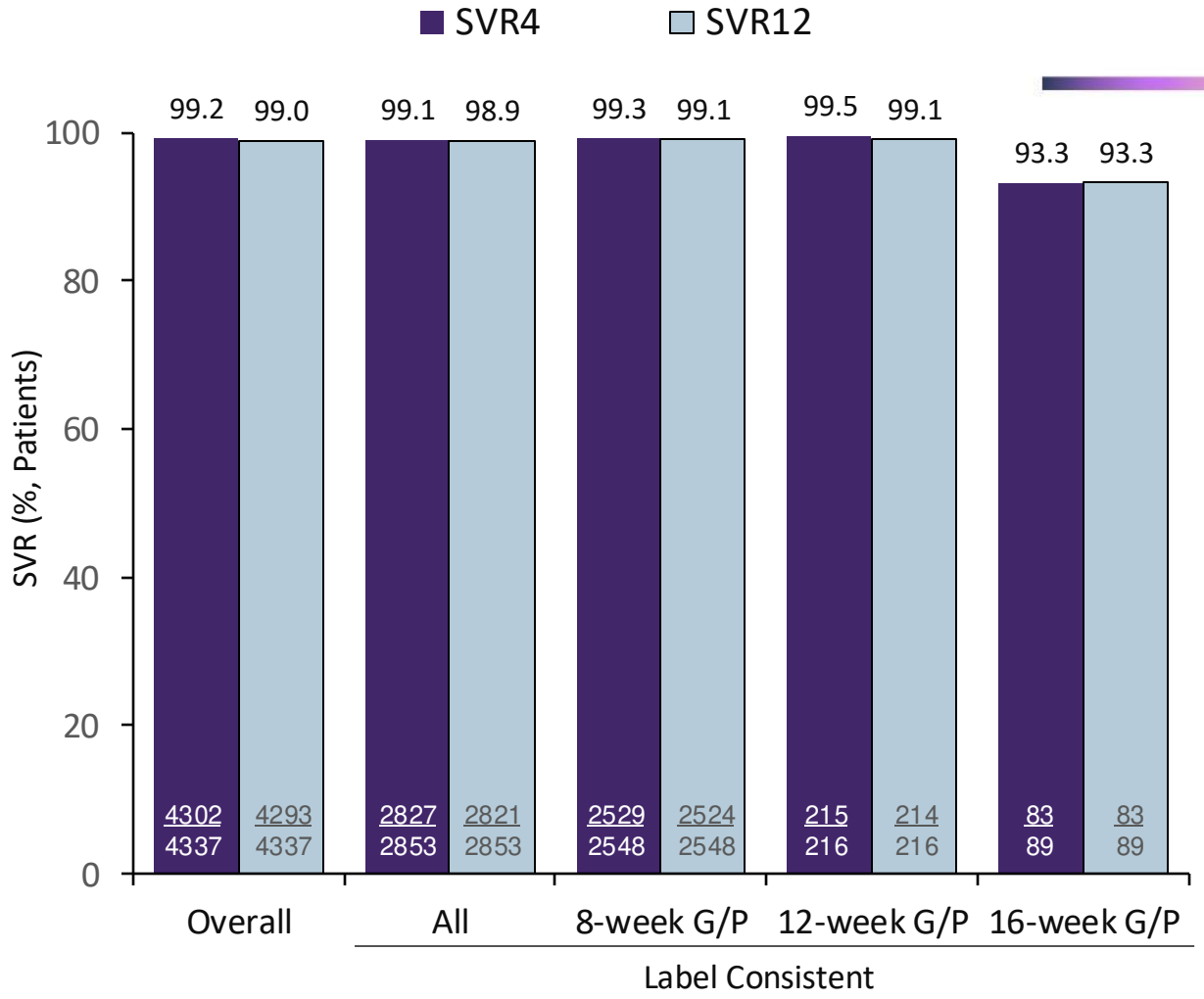
SVR 4

- 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

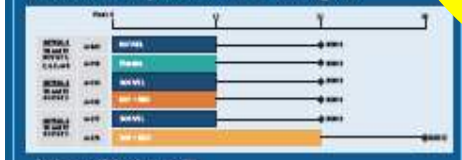
- The SOF/VEL Phase 3 ASTRAL-1, -2, and -3 program evaluated SOF/VEL in treatment-naïve (TN) and treatment-experienced (TE) patients both with and without compensated cirrhosis.
- SOF/VEL has been shown to be safe and effective (sustained virologic response 12 weeks after treatment completion [SVR12] >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 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 42-1140; 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

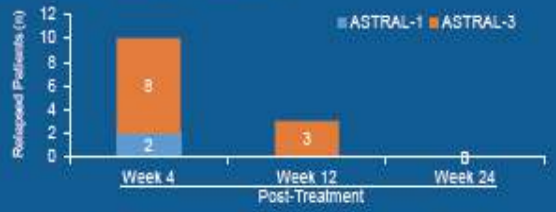
- 99.7% positive predictive value
- 100% negative predictive value

SVR12 d SVR24 Concordance

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

- 100% p ive predictive value
- 100% tive 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 virolog pse or reinfection
  - follow-up
  - 1 disco
  - 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
  - 8 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 LO7.

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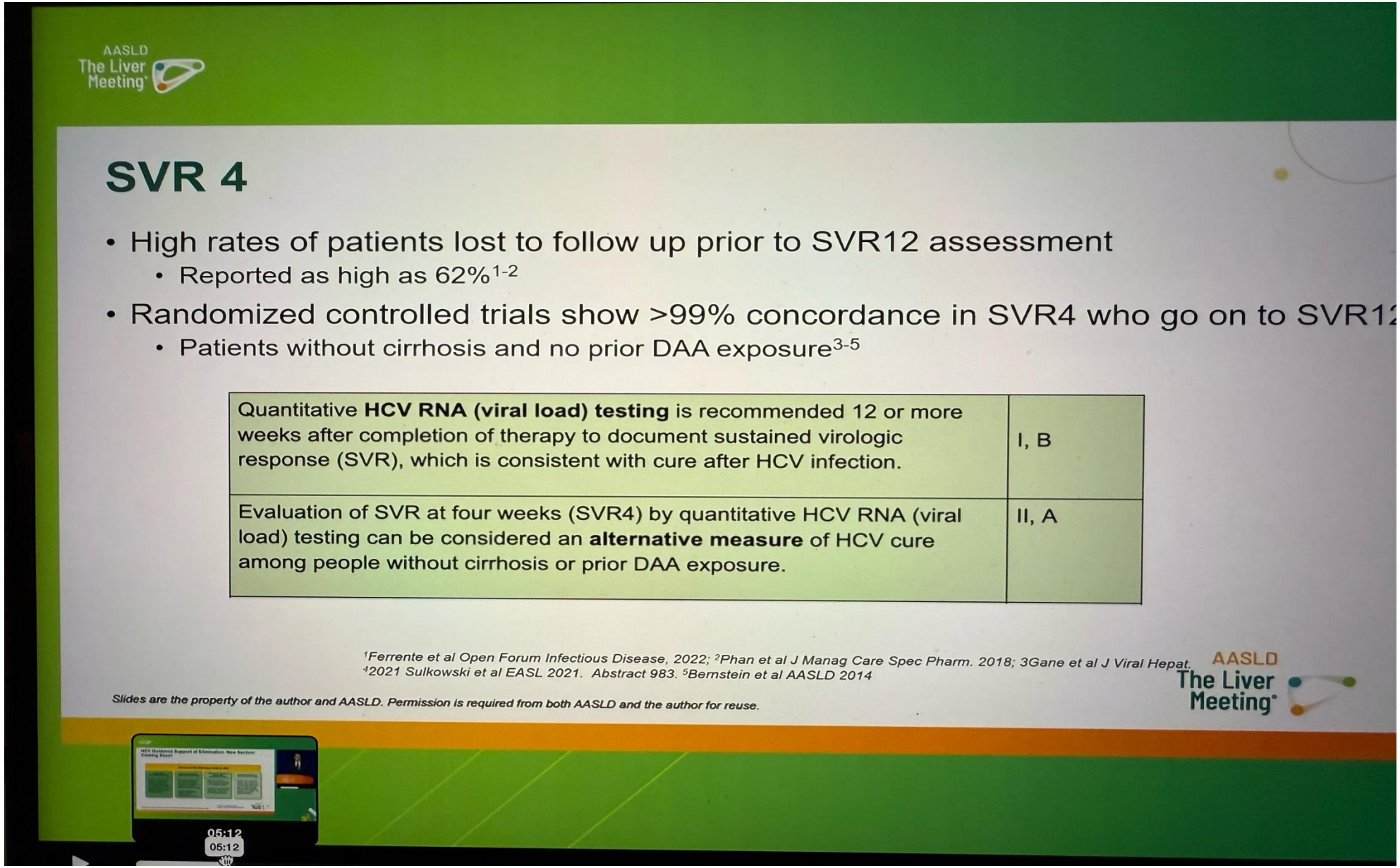
AASLD
The Liver Meeting
SVR 4
• High rates of patients lost to follow up prior to SVR12 assessment
• Reported as high as 62%[1-2]
• Randomized controlled trials show >99% concordance in SVR4 who go on to SVR1
• Patients without cirrhosis and no prior DAA exposure[3-5]
Quantitative HCV RNA (viral load) testing is recommended 12 or more weeks after completion of therapy to document sustained virologic response (SVR), which is consistent with cure after HCV infection.
I, B
Evaluation of SVR at four weeks (SVR4) by quantitative HCV RNA (viral load) testing can be considered an alternative measure of HCV cure among people without cirrhosis or prior DAA exposure.
II, A
[1]Ferrente et al Open Forum Infectious Disease, 2022; [2]Phan et al J Manag Care Spec Pharm. 2018; 3Gane et al J Viral Hepat.
[4]2021 Sulkowski et al EASL 2021. Abstract 983. [5]Bernstein et al AASLD 2014
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The Liver Meeting
05:12
05:12

HCV Care Models for Elimination

Mix-and-Match Approach: Settings, Services, Providers

Settings

- Sexual health clinics
- NSP services
- Substance use clinics
- Primary healthcare/GPs
- Community health centers
- Prisons – State / Federal; Jail

Services

Screening

Confirmed viral load

Treatment

Follow-up

Providers

- Other specialists
- Primary care providers
- Addiction medicine providers
- Nurse Practitioners, Physician Assistants, Pharmacists
- Peer support workers
- Others (ie mental health providers)

Clinical Models to Improve Linkages to HCV/Addiction Care and Treatment Uptake

Conventional referral

- System is difficult to navigate for many
- Transportation
- Need a multidisciplinary approach
- Utilization of case managers
- Peer navigators

Telemedicine

- Useful to deliver services to any setting (prison, rural, substance abuse clinics)
- Provide specialty care where not otherwise available
- Supportive data in both addiction and HCV settings
- Slows cascade

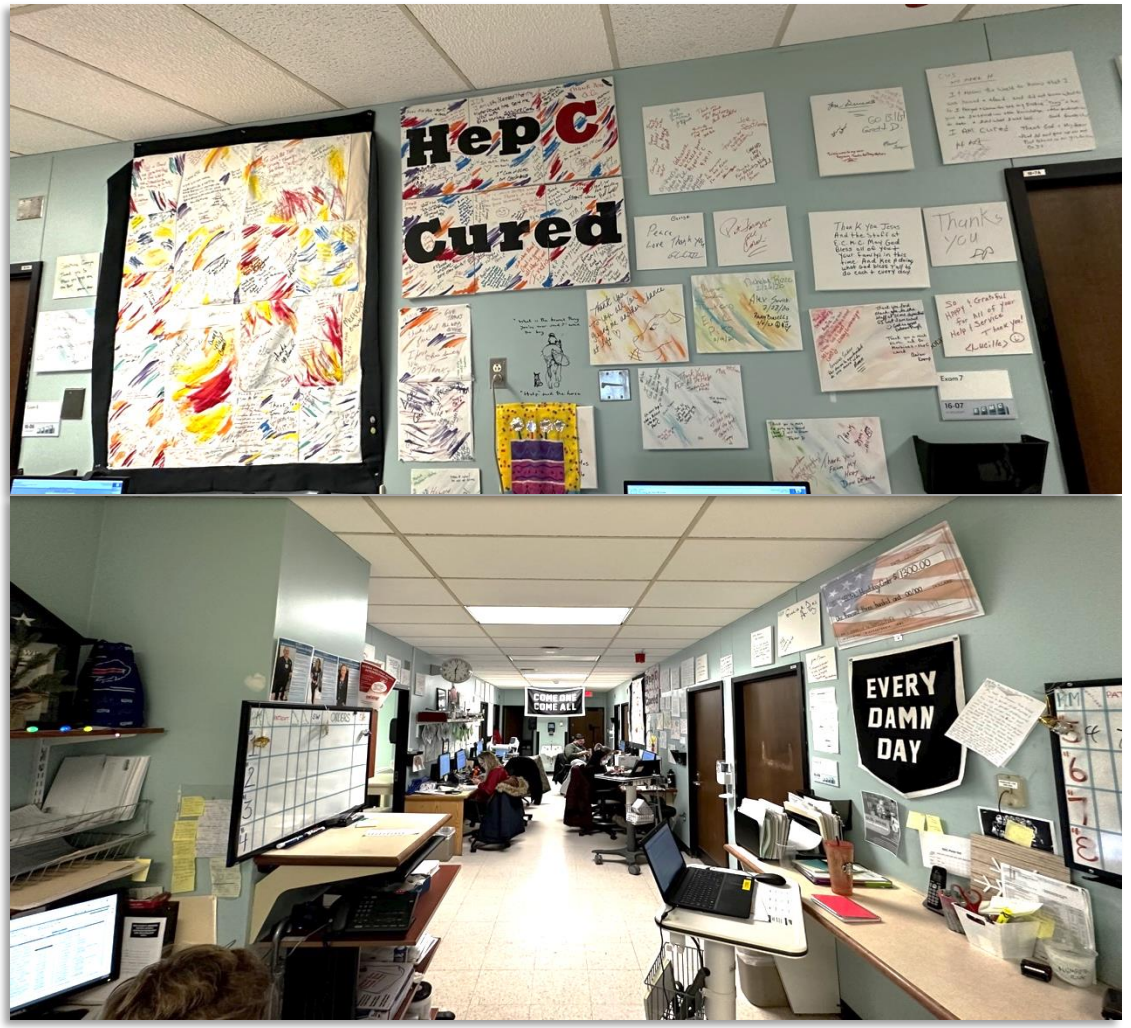
Colocalization

- One-stop shopping
- Multiple services offered in one location
- Minimizes loss to follow-up
- Streamlines care

“La Bodega”, Buffalo, NY: The Community One-Stop Clinic

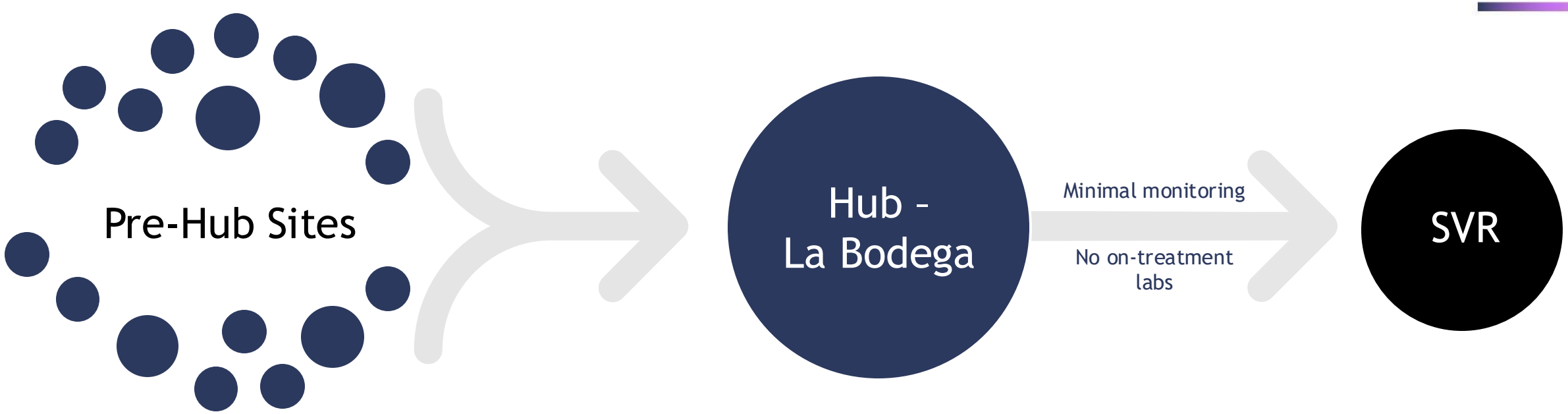
La Bodega

- Conventional Hepatology
- Conventional Addiction Medicine
- Combined Hep/Addiction



Slide courtesy of Anthony Martinez.

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



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

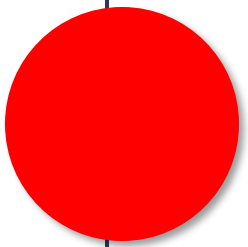
- Individualized screening protocol: POC Ab test; conventional Ab w/PCR reflex
- Single number and email for referral
- La Bodega staff schedules/ navigates system

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

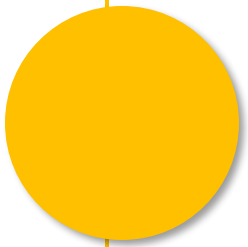
- Staff assists with refills based on triage system—red, yellow, green

Ab=antibody; MAT=medication-assisted treatment; OB=obstetrics; PCR=polymerase chain reaction; POC=point of care; SVR=sustained virologic response.

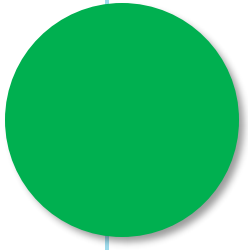
La Bodega Medication Triage System



- Full support required—meds delivered to clinic or held at clinic; frequent check-ins and reminders via phone, text, social media



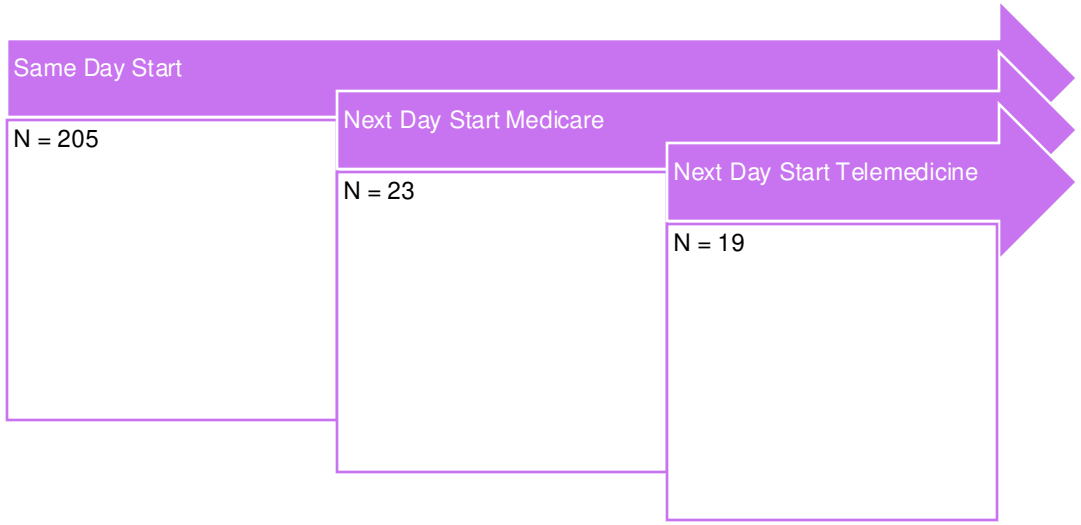
Intermediate support—meds delivered to the patient;
La Bodega staff tracks refills, deliveries; less frequent check-in

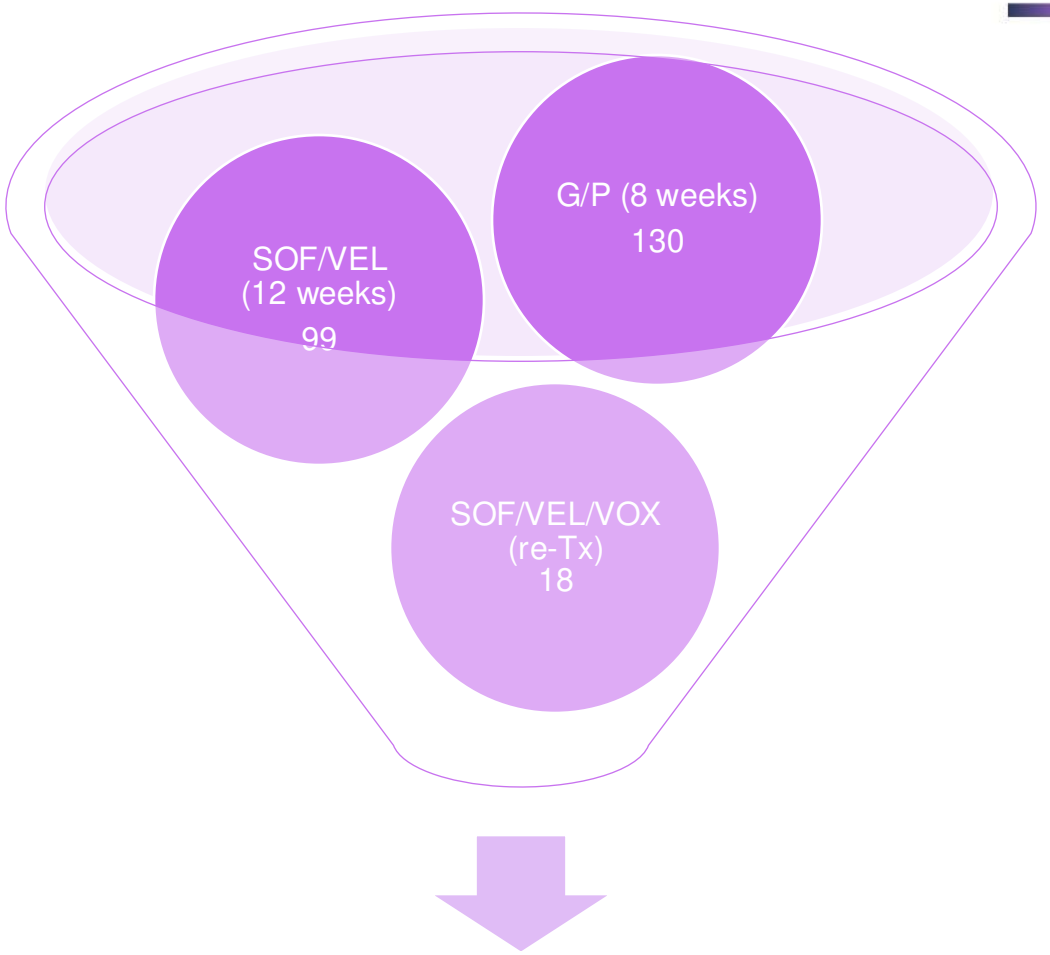


Minimal support required—script written,
see you in 5-6 months!

Rapid Start Model April 2023- April 2024

- All regimens at parity
- No longer payer driver
- Patients able to choose regimen
- Meds on-site, rapid start / same-day / next day initiation
- N= 247





27 PATIENTS RECEIVED FULL SUPPLY OF MEDS AT THE INITIAL VISIT

Demographics

Age	<40 - 47% >40 - 53%	Genotypes	1a - 48% 1b - 9% 2b - 7% 3 - 21% 4 - 1% 6 - 1% Unknown - 13%
Gender	Male - 62% Female - 38%		
Fibrosis Stage	Non-Cirrhotic - 93% Cirrhosis - 7%		
Medically Assisted Therapy (MAT)	**58%** Buprenorphine - 71% Methadone - 27% Naltrexone - 2%	Concomitant Meds	None - 8% 1 - 10% 1-3 - 46% >3 - 36%
Active Substance Use	**Yes - 43%** Opiates - 51% Cocaine - 7% Methamphetamine - 3% Polysubstance - 25% Alcohol - 14%	Insurance	Medicaid - 83% Medicare - 12% Commercial - 5%

Regimen Preference

- 51% preferred a shorter duration of therapy, 30% preferred fewer pills, and 19% were prescribed based on medical necessity.
- Age <40 had a slight preference for a shorter duration of treatment (55% vs 45%; p=0.29)
- 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).
- Patients with a history of re-infection preferred a shorter duration of treatment (52.3% vs 44.44%, p<0.05)

Preference for shorter duration vs fewer pills		
MAT Use	On MAT: 59% (n=82) Not on MAT: 42% (n=45)	p<0.05*
Active substance use	Active use: 47% (n=66) No active use: 57% (n=61)	p=0.2
Treatment modality	Same day: 55% (n=109) Medicare: 37% (n=11) Telemedicine: 35% (n=7)	p=0.2

Adherence: Same Day vs. Medicare vs. Telemedicine

- **Overall full adherence rate 59%.**
- Rates of adherence (58% vs 67% vs 58%, p=0.4) were not significantly different among modalities
- Adherence was the greatest but not significant in those receiving fewer pills:
- 67% - fewer pills
- 59% - shorter duration
- 49% - medical necessity
- **Overall loss to follow-up rate 32%**
- A greater but not statistically significant percentage of patients undergoing same-day treatment were lost to follow-up vs. Medicare next -day starts (31% vs. 19%, p=0.18).
- **Those receiving telehealth had significant follow-up loss (68%, p<0.01).**

Results

- **Overall SVR = 97% mITT (124/128)**
  - Treatment failure n = 4
  - Deceased n = 4
  - Psychiatric Hospitalization n = 2
  - Relocated n = 2
  - Incarcerated n = 5
  - Declined f/u n = 2
  - Pending n = 104

- Rates of SVR between the rapid start and Medicare treatment were similar (98% vs 94%, p=0.32).
- **Tele-med achieved the lowest percentage of SVR (67%, p<0.01, per protocol).**
- Past history of reinfection was similar among all groups (11% vs. 6% vs. 16%, p=0.57).
- No cases of reinfection to date.

Results – Active Substance Use

- Active use within 3 months (N = 107)
- Patients with active substance use were more likely to receive MAT (79% vs 41%, p<0.001).
- Had lower medication adherence (50% vs 67%, p<0.01) vs non-substance users.
- More likely to be lost to follow-up (36% vs 30%, p=0.09).
- SVR rates between the two groups were not significantly different (94% vs 99%, p=0.15).

Comparison between active substance users and non-users			
	Active users (n=107)	Non-active users (n=140)	Significance
SVR	94%	99%	p=1.5
MAT	79%	41%	p<0.001***
Adherence	50%	67%	p<0.01**
Follow-up loss	36%	30%	p=0.09

Results – Other Subgroups

- HIV / HCV co-infection: n = 5 (4 SVR, 1 pending)
- Hepatocellular Carcinoma: n = 1 (SVR)
- Full medication supply (Sof/Vel): n = 27 (13 SVR, 12 pending, 1 failure, 1 deceased)
- 3rd Trimester Pregnancy (Sof/Vel): n= 7 (4 SVR, 1 pending, 2 LTFU)

➢ All with active substance use

➢ All on MAT (5 buprenorphine, 2 methadone)

➢ No cases of vertical transmission to date

Results – Telemedicine

- All telemedicine was done in acute detoxification settings
- N = 19
- Initial appointment linkage = 100%
- Treatment initiation = 100%
- SVR n = 2 (67%), Tx failure n = 1
- LTFU = 68%
- Confirmed that all patients received the full course of medications.

La Bodega Buffalo

- **A hybrid model of outreach, referral, colocalization, and telemedicine,**
- **implemented statewide and nationally**

Key success factors of the model:
Meets the patients AND the providers where they are

Facilitating linkage

- Low threshold—no wait time
- Flexible and forgiving schedule
- Eases burden on referring provider
- "Show up and we will see you"

Transportation

- Arranged immediately if needed
- Public transportation vouchers provided
- Telemed, if needed
- Medicaid cabs
- "We go get you"

System navigation

- Appointments and follow-ups made for patients within days
- No formal referral process of labs needed from providers
- "Call this number"

Handpicked, dedicated team

- Multidisciplinary team
- Case manager, counselor, social worker, nurses, physician assistant, and secretaries
- No titles/hierarchy

Mix-and-match approach

- Multiple micro-models in place within a global structure, based on local resource availability
- "One size does not fit all"

La Bodega Harm Reduction Measures

Safe injection toolkit

- Sharps container
- Clean syringes x 10
- Sterile coolers x 3
- Clean water source
- Sterile tie downs
- Band-aids
- Alcohol prep pad
- Safe filter material

Harm reduction kit

- Case fentanyl test strips x 100
- Case worker/Never Use Alone contact info
- FTS x 3 and instructions
- Safe injection toolkit
- Case NARCAN Nasal Spray 4 mg x 12
- Sterile tie-downs x 5
- Alcohol prep pad
- Condoms/lip balm/sanitizer
- Discreet hold-all bag

- Uninterrupted MAT/MOUD/OAT
- Ongoing harm reduction education
- Overall retention in care = 90%

FTS=fentanyl test strip; MOUD=medication for opioid use disorder.

La Bodega Outreach, Education, and Advocacy

HCV mini-residency for addiction medicine providers

La Bodega rotation part of GME curriculum for GI, ID, addiction medicine fellows; IM and FM residents; med students

Implementation of screening (and treatment in collaboration with FM) for all children of HCV-positive moms

Implementation of universal screening in the foster care system

Local, state, and federal advocacy efforts

FM=family medicine; GI=gastrointestinal; ID=infectious diseases; IM=internal medicine.

HCV Therapy in Pregnancy

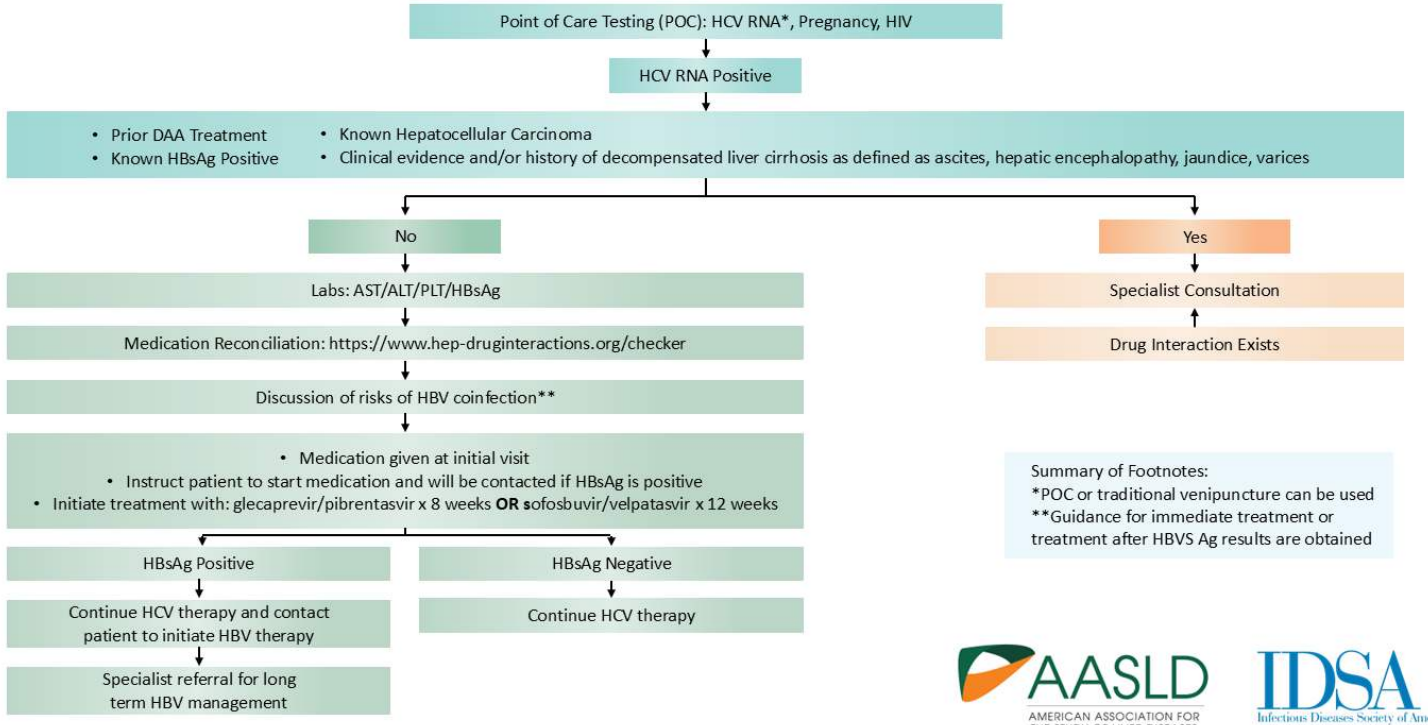
Current guidelines

Recommendation for Universal Hepatitis C Screening in Pregnancy	
RECOMMENDED	RATING
As part of prenatal care, all pregnant women should be tested for HCV infection with each pregnancy, ideally at the initial visit.	I, B

Recommendations Regarding Breastfeeding and Postpartum Care for HCV-Infected Women	
RECOMMENDED	RATING
Breastfeeding is not contraindicated in women with HCV infection, except when the mother has cracked, damaged, or bleeding nipples, or in the context of HIV coinfection.	I, B
Women with HCV infection should have their HCV RNA reevaluated after delivery to assess for spontaneous clearance.	I, B

Recommendation Regarding HCV Treatment and Pregnancy	
RECOMMENDED	RATING
For women of reproductive age with known HCV infection, antiviral therapy is recommended **before** considering pregnancy, whenever practical and feasible, to reduce the risk of HCV transmission to future offspring.	I, B

NEW HCV TEST AND TREAT ALGORITHM PRESENTED AT AASLD CONFERENCE



AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

IDSA
Infectious Diseases Society of America

Safety, Tolerability, and Outcomes of SofosbuviR/ Velpatasvir in Treatment of Chronic Hepatitis C Virus during Pregnancy: Interim results from the STORC study

Catherine Chappell, MD, MSc

Disclosures: I receive research funding from Gilead Sciences and Merck through my institution. I have served as a consultant for Gilead Sciences.

MAGEE-WOMENS RESEARCH INSTITUTE

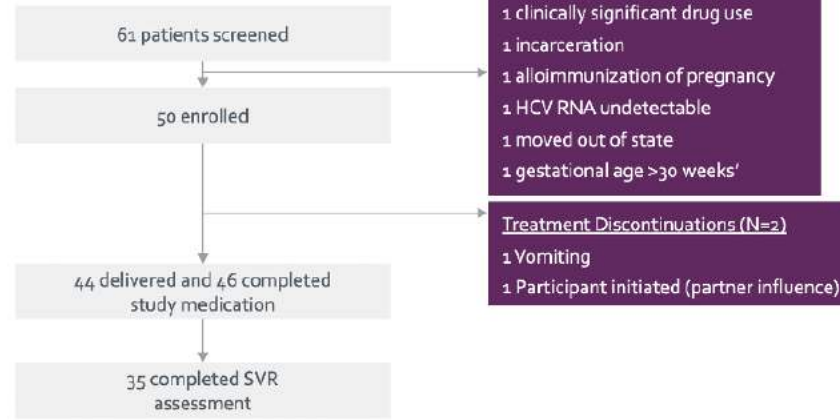
Safety, Tolerability, and Outcomes of Velpatasvir/SofosbuviR in Treatment of Chronic Hepatitis C Virus during Pregnancy (STORC)

Primary Objectives	To evaluate the sustained virologic response 12 weeks after completion of SOF/VEL treatment (SVR12) in women treated during pregnancy.
	To evaluate impact of antenatal treatment with SOF/VEL on the gestational age at delivery for women who received SOF/VEL for HCV treatment during pregnancy.
Secondary Objectives	To evaluate the maternal and neonatal safety of HCV treatment during pregnancy with SOF/VEL
	To determine the rate of HCV perinatal transmission among women treated with SOF/VEL during pregnancy according to HIV co-infection status

Eligibility Criteria

Inclusion	Exclusion
• Age 18-45 years	• Previous DAA treatment without documentation of SVR
• HCV Ab+ / HCV RNA detectable	• Contraindicated medications
• Chronic HCV or no evidence of acute HCV	• History of cirrhosis
• 20-30 weeks of gestation (confirmed)	• Confirmed chromosomal anomaly
• Anatomy ultrasound without major anomalies	• Clinically significant non-therapeutic drug use (determined by site PI)
• Negative HBsAg	• Significantly abnormal labs at screening
• If HIV+, must be virally suppressed	• If HIV+, CD_4 <200 cells/mm3 in last 6 months
• If taking antacids, willing to modify for SOF/VEL treatment	• Enrolled in other study of investigational drug

Study Flow as of October 28, 2024



HEPATITIS C MANAGEMENT OF WOMEN IN THE THIRD TRIMESTER OF PREGNANCY IN LA BODEGA

Anthony Martinez, MD, AAHIVS, FAASLD[1]; Scott Springer, PA[2]; Ali A. Aijaz, DO[1]; Nariman Hossein-Javaheri, DO, MS[1]; Tricia Formato, PharmD[2]; Michelle Clark, CPhT[2]

1. University at Buffalo, Jacobs School of Medicine and Biosciences, USA
2. Erie County Medical Center, USA

RESULTS

- Fourteen women were evaluated in the third trimester.
- Two treated with ledipasvir/sofosbuvir achieved SVR.
- Eleven women began sofosbuvir/velpatisvir; Eight achieved SVR, three were lost to follow-up after initiating therapy.
- Among these eleven women, seven began therapy the same day using a test-and-treat approach; one received a full 84 day supply of medication; four achieved SVR, and two were lost to follow up.
- One individual, pregnant with twins, was seen and evaluated but lost to follow-up before initiating therapy.
- Four women started buprenorphine with HCV treatment while actively using narcotics.
- No cases of vertical transmission have been reported, and all women self-reported complete adherence.
- The overall SVR rate is 100% among those with available data.

Dispensed Item	Genotype	Fibrosis	Fibrosis Assessment	SVR	Days Supply	MAT	MAT Form	Active Use	CON Meds	Adherence
Epclusa®	3	F0-3	APRI/Fib-4/FTest	Yes	28	Yes	MTD	Yes, opioids	>3	Yes
Epclusa	3	F0-3	Fibroscan	Yes	28	Yes	BUP	No	0	Yes
Epclusa®	1a	F0-3	APRI/Fib-4/FTest	TBD	28	Yes	BUP	No	>3	Yes
Epclusa®	2b	F0-3	APRI/Fib-4/FTest	Yes	28	Yes	BUP	Yes, opioids	1-3	Yes
Epclusa®	3	F0-3	APRI/Fib-4/FTest	Yes	28	Yes	BUP	Yes, opioids	1-3	Yes
Epclusa	1a	F0-3	APRI/Fib-4/FTest	TBD	28	Yes	BUP	No	0	Variable
Harvoni	1a	F0-3	APRI/Fib-4/FTest	Yes	28	No	N/A	No	0	Yes
N/A	1a	F0-3	APRI/Fib-4/FTest	N/A	N/A	Yes	MTD	No	0	N/A
Epclusa®	3	F0-3	APRI/Fib-4/FTest	TBD	84	Yes	BUP	Yes, polysubstance	1-3	Yes
Epclusa	1a	F0-3	APRI/Fib-4/FTest	Yes	28	Yes	BUP	Yes, opioids	1-3	Yes
Epclusa®	1a	F0-3	APRI/Fib-4/FTest	TBD	28	Yes	BUP	Yes, polysubstance	0	Yes
Epclusa®	3	F0-3	APRI/Fib-4/FTest	TBD	28	Yes	MTD	No	1-3	Variable
Harvoni	1a	F0-3	APRI/Fib-4/FTest	Yes	28	Yes	BUP	No	0	Yes
Epclusa	1a	F0-3	APRI/Fib-4/FTest	Yes	28	Yes	BUP	No	0	Yes

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