KEY CONSIDERATIONS FOR HCV ELIMINATION IN THE U.S.

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Disclosures

- Funding received from Gilead, AbbVie, Merck
- Funding received to UB for participation in trials sponsored by Intercept, Genfit, Eli Lilly, BMS,
- Extramural funding received from PCORI, NIH, FDA, and Fund for Public Health of NYC.

Overview

- Hepatitis C virus (HCV) background
- Barriers to HCV care
- Solutions
- Surveillance, Screening, and Linkage-to-Care
- State-level HCV elimination efforts
- HCV elimination requirements

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HEPATITIS C VIRUS

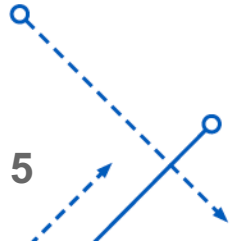
A brief background

Hepatitis C Virus (HCV)

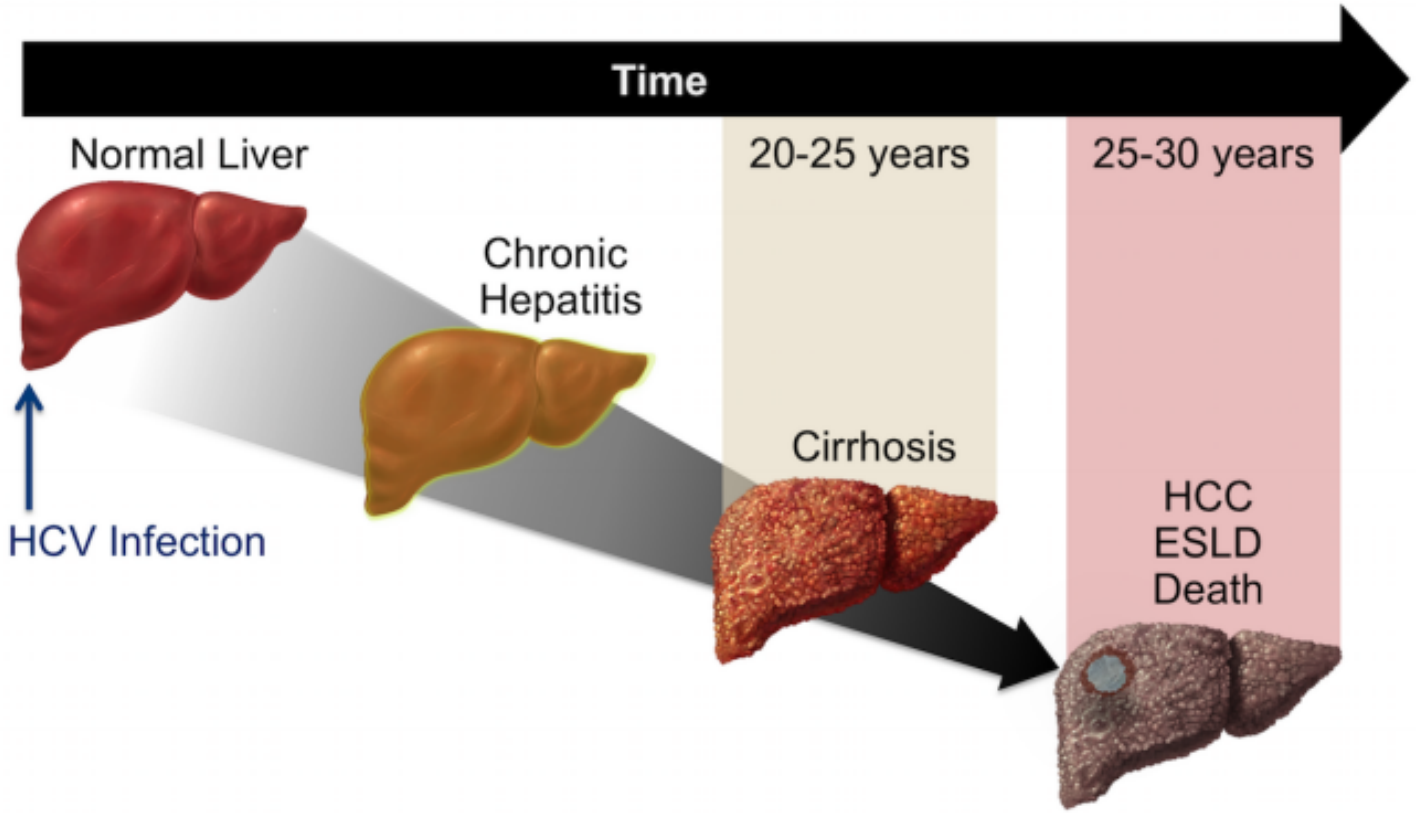
Virus that infects the liver
Spread through infected blood
Substance users & baby boomers
Untreated can lead to liver failure and liver cancer

Kills more Americans each year than HIV
+ 60 other infectious diseases combined

17,253 HCV-related deaths in 2017



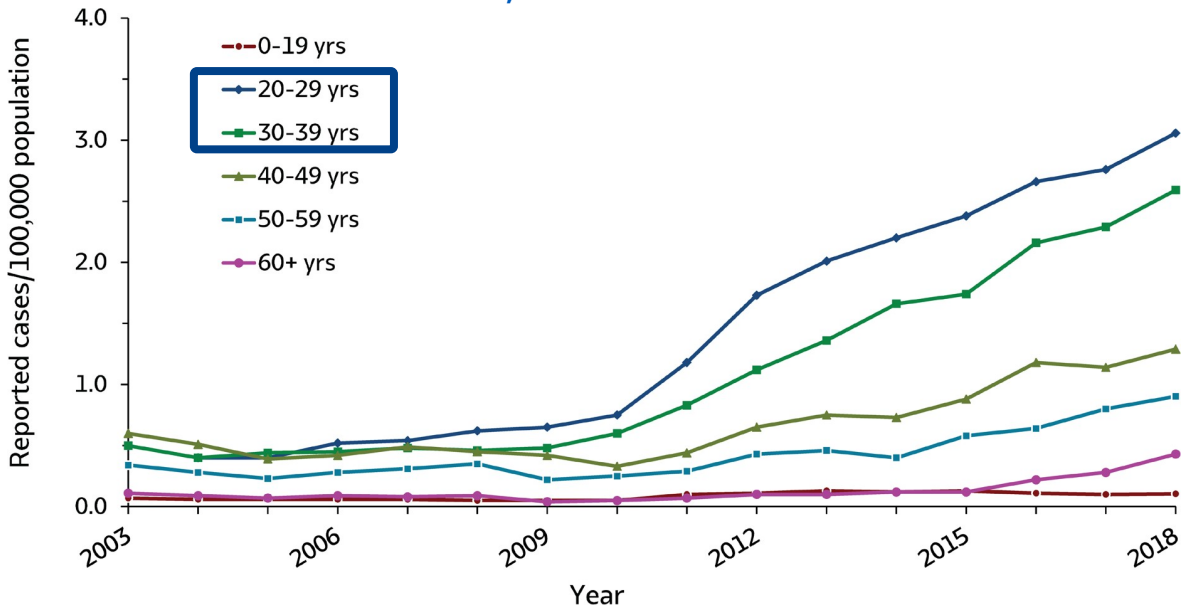
HCV progression is mostly asymptomatic over 20-30 years



Populations most at risk for HCV

- Historically – Baby Boomers
- Currently – Patients who inject drugs (PWIDs)

Rates of reported acute hepatitis C, by age group — United States, 2003–2018



Source: CDC, National Notifiable Diseases Surveillance System

Primarily younger PWIDs living in rural areas

HCV-Related Disparities Among African Americans

- **Disease prevalence among African Americans vs non-Hispanic White persons**
  - Twice as high as non-Hispanic whites
  - Less likely to spontaneously clear HCV infection
  - Higher risk of ESLD complications
  - Hepatocellular cancer rate 2x higher
  - Lower likelihood of getting on transplant list
- **Awareness of HCV infection and treatment among African Americans vs non-Hispanic White persons**
  - Less likely to be aware of HCV infection
  - Less likely to be referred and linked to specialty care
  - Less likely to receive HCV treatment
  - Less likely to be listed for transplant
  - Longer liver transplant wait lists

Armstrong. Ann Intern Med. 2006;144:705. Bradley. Hepatol Comm. 2020;4:355. Liu. Dig Dis Sci. 2014;59:1950. Mir. J Clin Gastroenterol. 2012;46:e62. Bailey. J Natl Med Assoc. 2013;105:108. Tohme. Am J Public Health. 2013; 103:112. Trooskin. World J Gastroenterol. 2007;13:1074. Rosenblatt. Hepatol. 2021;[Epub]. Wong. JAMA Netw Open. 2020;3:e1920294.

Highest HCV-Associated Death in Non-Hispanic AI/AN and Non-Hispanic Blacks

- CDC analysis of 2016-2017 Multiple Cause of Death (MCOD) and National Vital Statistics System data
- In 2017 there were 17,253 HCV-associated deaths among 325.7 million US residents and 2.8 million total deaths
- Age-adjusted HCV-associated death rate: 4.13/100,000 population (95% CI: 4.07-4.20)
- Racial disparity in HCV-associated deaths:
  - Ref: Non-Hispanic White 3.70 (3.63-3.78)
  - Highest: **Non-Hispanic AI/AN** 10.24 (9.04-11.44), **Non-Hispanic Black** 7.03 (6.79-7.28) and **Hispanic** (5.29 (5.09-5.51)
  - Lower: **Non-Hispanic API** 1.86 (1.67-2.05)

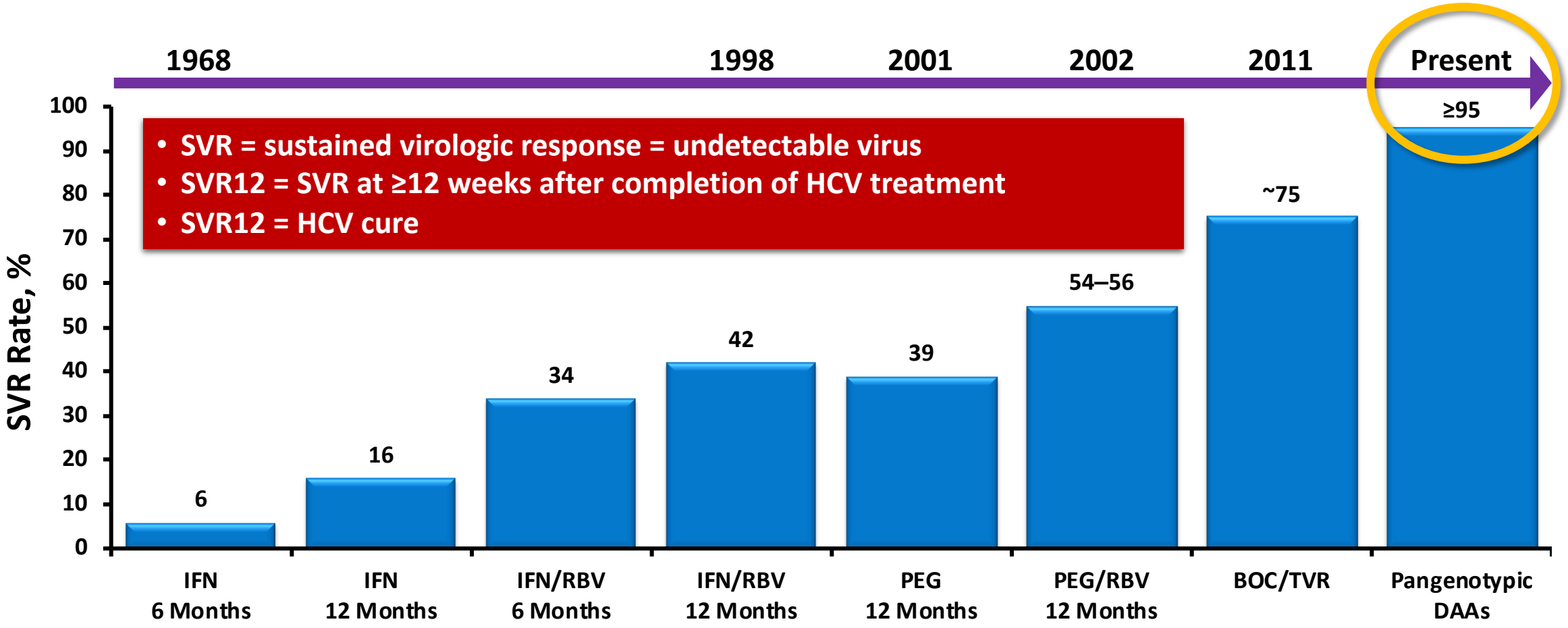
	United States	
Category	**Rate (95% CI)**	**%**
Overall	4.13 (4.07-4.20)	-
Sex		
Male	6.12 (6.01-6.23)	71.2
Female	2.32 (2.26-2.39)	29.8
Race/ethnicity		
Non-Hispanic White	3.70 (3.63-3.79)	63.0
Non-Hispanic Black	7.03 (6.79-3.79)	19.1
Hispanic	5.29 (5.09-5.51)	14.0
Non-Hispanic API	1.96 (1.67-2.05)	2.2
Non-Hispanic AIAN	10.24 (9.04-11.44)	1.7
Year of birth		
Before 1945	6.52 (6.21-6.83)	9.8
1945-1965	16.90 (16.62-17.19)	78.6
After 1965	.91 (.87-.95)	11.6

Ly. Clin Infect Dis. 2020;71:1149.

Slide credit: clinicaloptions.com

Evolving HCV Treatment

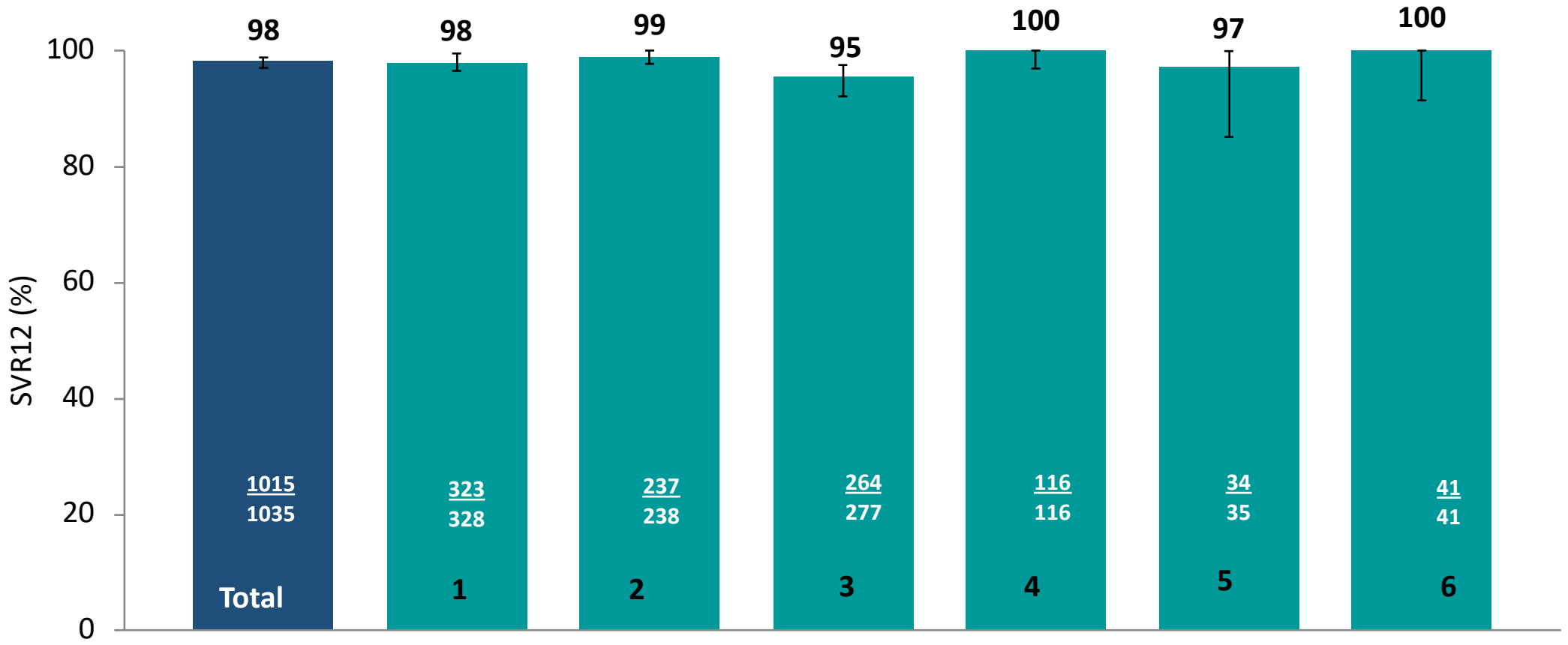
It's Come a Long Way



BOC, boceprevir; DAA, direct-acting antiviral (drug); IFN, interferon; PEG, pegylated interferon; RBV, ribavirin; SVR, sustained virologic response; TVR, telaprevir.
Adapted from Strader DB, Seeff LB. *Clin Liver Dis.* 2012;1(1):6-11.

Persons with HCV genotype 1, 2, 3, 4, 5, or 6 infection can be effectively treated with 1 tablet daily for 12 weeks

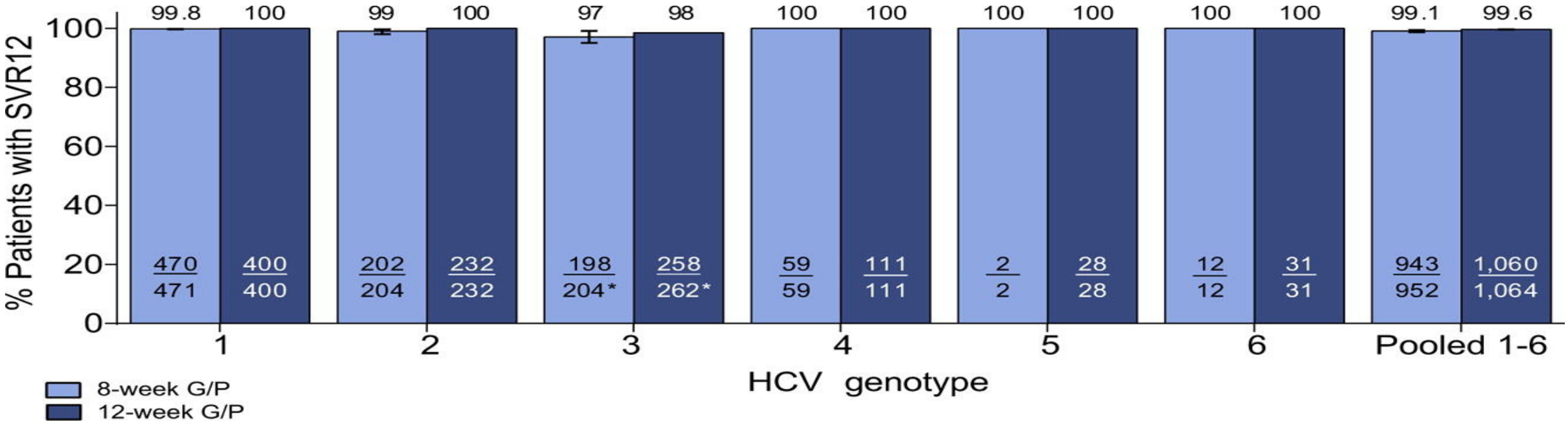
Sofosbuvir/Velpatasvir



Feld JJ et al. NEJM 2016; Foster G et al NEJM 2016

Persons with HCV genotype 1, 2, 3, 4, 5, or 6 infection can be effectively treated with 3 tablets daily for 8 weeks

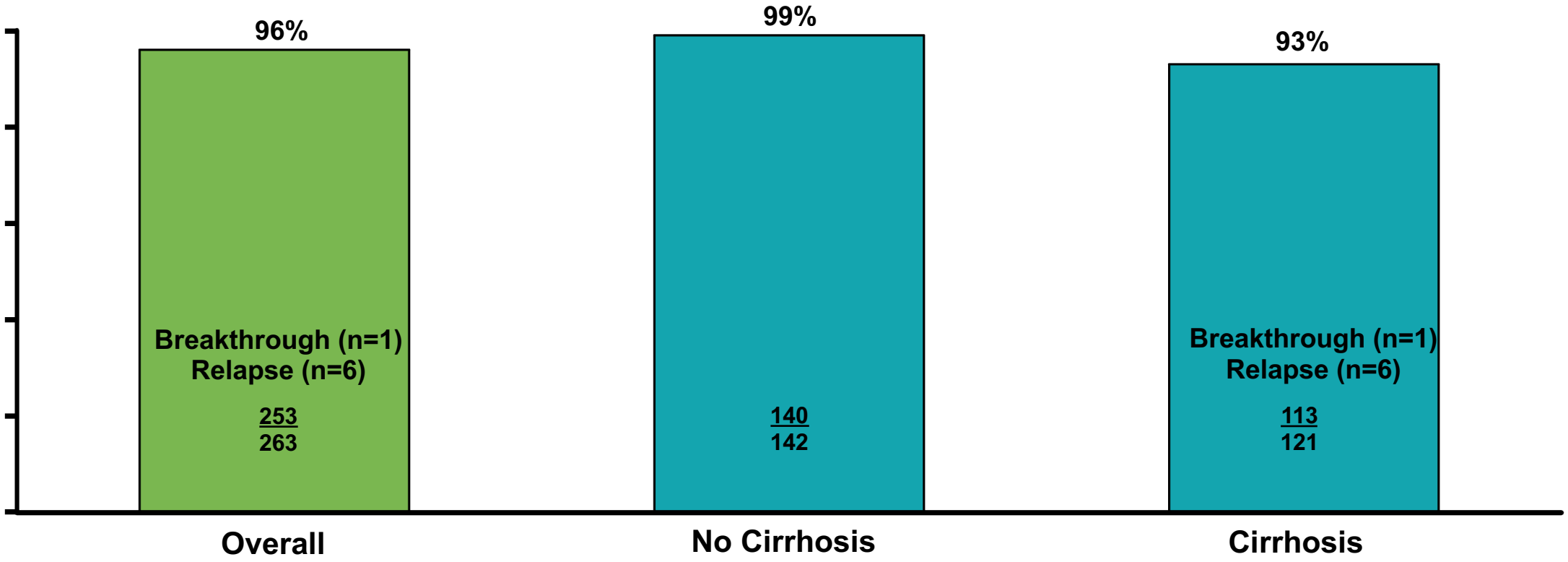
Glecaprevir/Pibrentasivir



Puoti M et al. Journal of Hepatology (2018); Brown RS et al. Journal of Hepatology (2019)

Overall Cure Rates in NS5A inhibitor – Experienced patients

Sofosbuvir/Velpatasvir/Voxilaprevir (Genotypes 1-6)



No placebo patients achieved an SVR12.
*P<0.001 for superiority versus pre-specified goal of 85% for sofosbuvir/velpatasvir/voxilaprevir.

Bourlière M, et al. Hepatology. 2016;64(suppl S1):102A. Abstract 194.

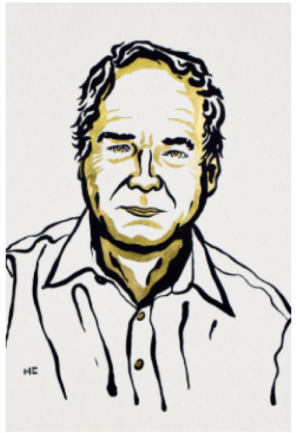
HCV Elimination – Why now?

- **Direct acting antivirals (DAAs)**
- **If done properly, HCV DAA's have:**
  - Near universal efficacy
  - Shortened duration of therapy
  - Minimal adverse events & impact on patient's quality of life
- **Can combine HCV treatment medications from different classes**
  - Multiple targets to increase efficacy
  - Decrease risk of viral resistance

The Nobel Prize in Physiology or Medicine 2020

awarded "for the discovery of Hepatitis C virus."

Ill. Niklas Elmehed. © Nobel Media.
Harvey J. Alter



Ill. Niklas Elmehed. © Nobel Media.
Michael Houghton

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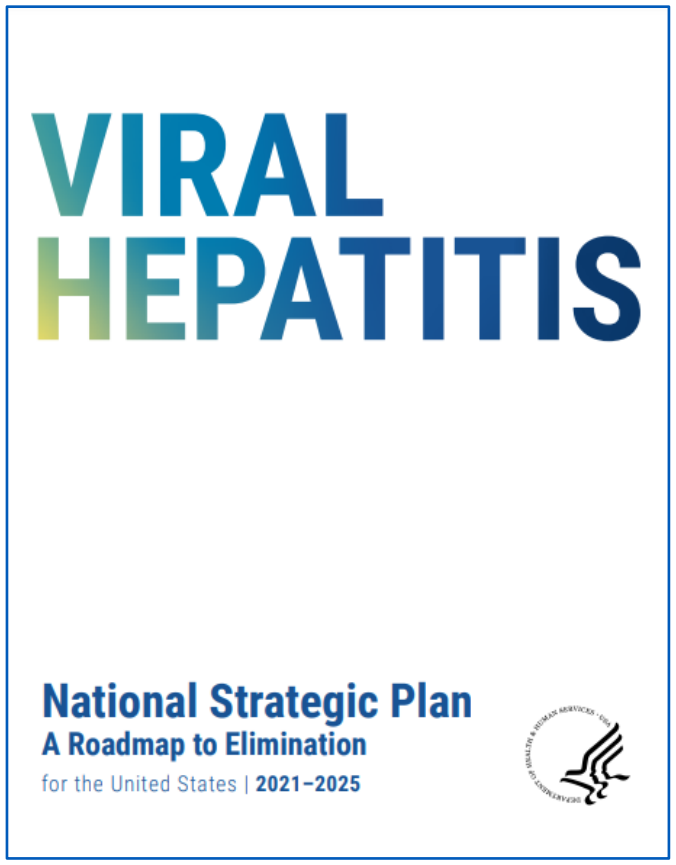
Charles M. Rice

HHS and WHO

- HCV elimination by 2030



Only Connecticut, South Carolina, and Washington are on track to meet 2030 HCV elimination target

Reference: Sulkowski M, Cheng WH, Marx S, Sanchez Gonzalez Y, Strezewski J, Reau N. Estimating the Year Each State in the United States Will Achieve the World Health Organization's Elimination Targets for Hepatitis C. Adv Ther. 2021 Jan;38(1):423-440. doi: 10.1007/s12325-020-01535-3. Epub 2020 Nov 3. PMID: 33145648; PMCID: PMC7609357.

HCV elimination requirements

- Remove policy barriers (e.g. prior authorizations)
- Improved provider education
- Patient advocacy, education, and outreach
- Innovative treatment models to engage traditionally underserved populations
- Coalition building of organizations most impacted by HCV (e.g. state health departments, department of corrections, Medicaid & third party payers)
- Subscription-based medication models

HCV Therapeutic Divide

HCV Treatment

- Near universal efficacy
- Minimal side effects
- Short treatment duration
- All-oral medication

HCV Disease State

- HCV infections continue to rise due to ongoing opioid epidemic
- Up to 50% unaware of HCV infection
- Shortage of treatment providers

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BARRIERS TO CARE

HCV Off-Site Referral Model

Methadone Programs

HCV providers are limited at OTPs

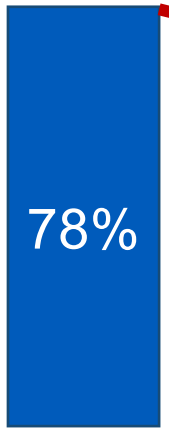
X

Barriers to Care

Liver Clinic

liver

Barriers to Off-Site Referral



78% of hepatitis C virus (HCV) infected patients at addiction centers are willing to get treated [1]

Variety of real-world barriers prevent HCV treatment access

- Stigma associated with substance use
- Lack of knowledge about HCV
- Competing priorities
- Limited or no insurance

~5%

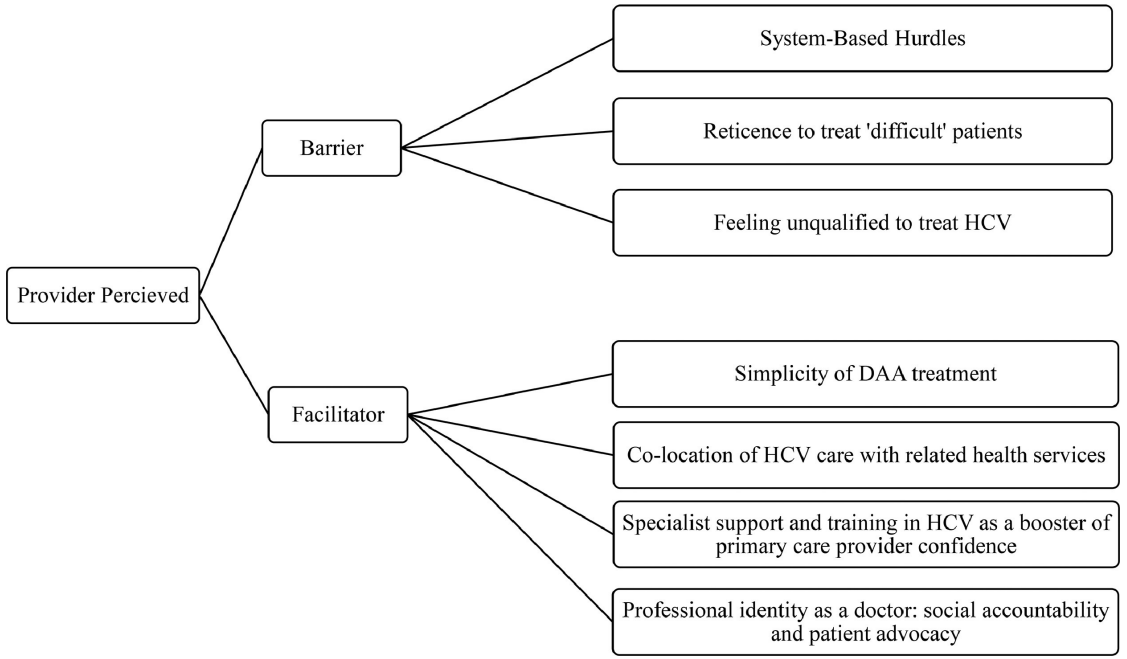
Only ~5% of HCV+ patients with addiction get treatment

[1]: Zeremski M, Dimova RB, Zavala R, et al. Hepatitis C virus-related knowledge and willingness to receive treatment among patients on methadone maintenance. *J Addict Med*. 2014;8(4):249-257. doi:10.1097/ADM.0000000000000041

Barriers among providers

- Concerns over re-infection
- Patient adherence
- Difficult to treat
- Provider shortage

Provider perceived barrier and facilitator to HCV treatment initiation



Reference: Amoako A, Ortiz-Paredes D, Engler K, Lebouché B, Klein MB. Patient and provider perceived barriers and facilitators to direct acting antiviral hepatitis C treatment among priority populations in high income countries: A knowledge synthesis. Int J Drug Policy. 2021 Apr 11:103247. doi: 10.1016/j.drugpo.2021.103247. Epub ahead of print. PMID: 33853727.

Treatment Cost

- Historically a challenge but prices have come down in recent years
- Discriminator State Medicaid Restriction Grades (via Stateofhepc.org)
  - Mississippi, South Dakota, and Arkansas are only two states with grade below a C

Reference: https://stateofhepc.org/report/#find-your-state

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OVERCOMING CHALLENGES TO HCV TREATMENT

Simultaneous treatment of HCV and OUD

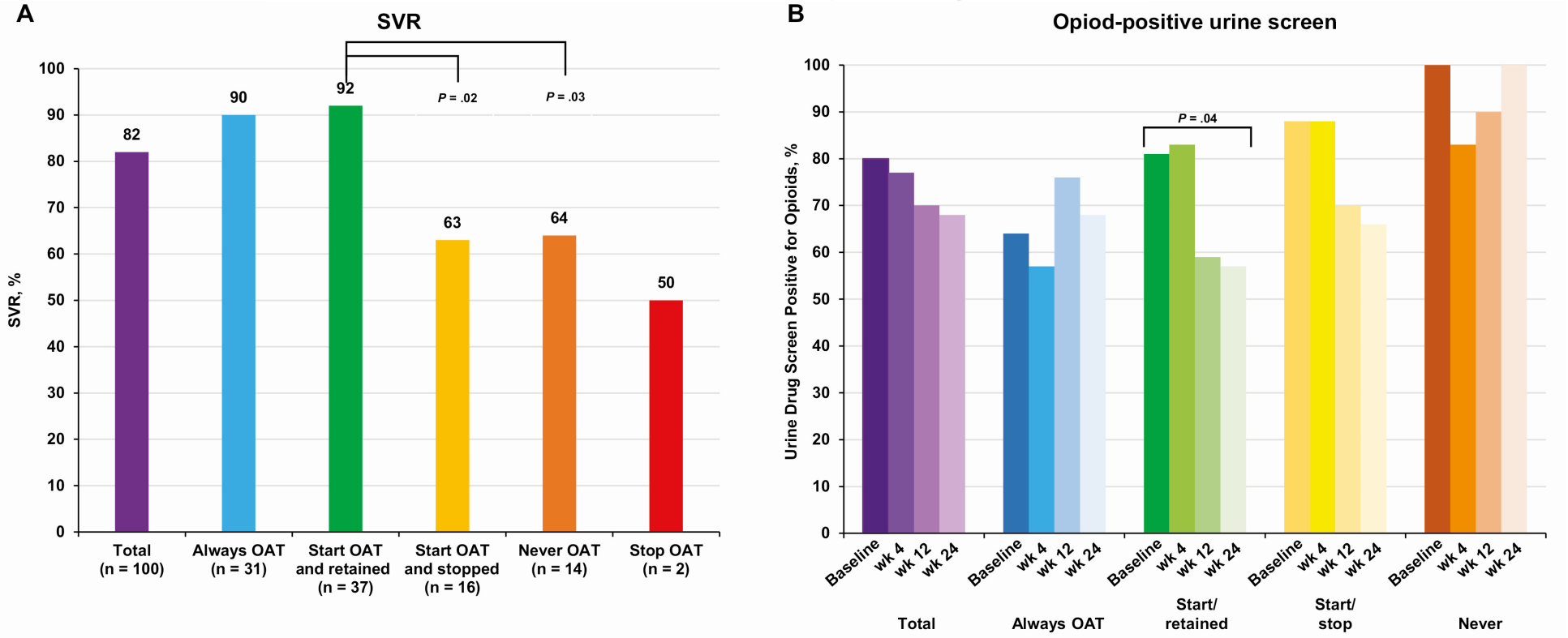
- Improves patient retention
- Improves patient adherence
- HCV treatment can be integrated in OUD care

…studies have consistently found insufficient testing and poor rates of treatment after HCV diagnosis among PWID. Bottlenecks often originate from state-level policies on Medicaid reimbursement and HCV surveillance efforts.

Ref: Blake A, Smith JE. Modeling Hepatitis C Elimination Among People Who Inject Drugs in New Hampshire. JAMA Netw Open. 2021 Aug 2;4(8):e2119092. doi: 10.1001/jamanetworkopen.2021.19092. PMID: 34342652; PMCID: PMC8335578.

Clinical Infectious Diseases
MAJOR ARTICLE

Concurrent Initiation of Hepatitis C and Opioid Use Disorder Treatment in People Who Inject Drugs



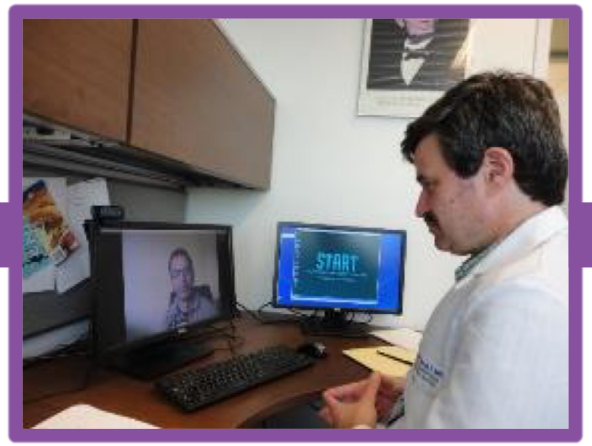
A. Patients receiving opioid treatment at week 24 were significantly more likely to achieve SVR

B. Significant decline in opioid-positive urine drug screens was seen in patients who started and were retained on opioid treatment

Reference: Rosenthal ES, Silk R, Mathur P, Gross C, Eyasu R, Nussdorf L, Hill K, Brokus C, D'Amore A, Sidique N, Bijole P, Jones M, Kier R, McCullough D, Sternberg D, Stafford K, Sun J, Masur H, Kottilil S, Kattakuzhy S. Concurrent Initiation of Hepatitis C and Opioid Use Disorder Treatment in People Who Inject Drugs. Clin Infect Dis. 2020 Oct 23;71(7):1715-1722. doi: 10.1093/cid/ciaa105. PMID: 32009165; PMCID: PMC7755091.

HCV Facilitated Telemedicine Model

Methadone Programs



Liver Clinic

Bring the HCV provider to a familiar and comfortable environment for patients

Integrated HCV Telemedicine Model

OTP patient screened for HCV

HCV +

Patient evaluations with provider via telemedicine

Patient and physician extender at OTP

HCV medication dispensed with patients existing methadone dose

Repeat until end of treatment

Pilot Study results

- 45 patients enrolled at one clinic
- Onsite medication dispensing increases HCV medication adherence

93% cured of HCV via Telemedicine

95% recommend over in-person referral

Clinical Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America | hivma hiv medicine association | OXFORD

Integrated, Co-located, Telemedicine-based Treatment Approaches for Hepatitis C Virus Management in Opioid Use Disorder Patients on Methadone

Andrew H. Talal,[1,2] Phyllis Andrews,[2] Anthony Mcleod,[2] Yang Chen,[3] Clewert Sylvester,[2] Marianthi Markatou,[3] and Lawrence S. Brown[2]

[1]Division of Gastroenterology, Hepatology, and Nutrition, Department of Medicine, University at Buffalo, State University of New York, [2]START Treatment and Recovery Centers, Brooklyn, and [3]Department of Biostatistics, University at Buffalo, State University of New York

Telemedicine and e-Health, VOL. 25, NO. 9 | Original Research

normal

Patient Reaction to Telemedicine for Clinical Management of Hepatitis C Virus Integrated into an Opioid Treatment Program

Andrew H. Talal, Anthony McLeod, Phyllis Andrews, Heidi Nieves-McGrath, Yang Chen, Andrew Reynolds, Clewert Sylvester, Suzanne S. Dickerson, Marianthi Markatou, and Lawrence S. Brown

Published Online: 6 Sep 2019 | https://doi.org/10.1089/tmj.2018.0161

Statewide HCV Elimination Network

- Patient-Centered Outcomes Research Institute (PCORI) funded a study to integrate HCV treatment into opioid treatment programs via telemedicine
- Project recruitment: March 2017-Feb 2020
  - >600 patients enrolled
- 12 sites across NYS, covering most metropolitan areas (6 upstate, 6 in NYC)
- Our integrated telemedicine model:
  - Removes time and place as obstacles from delivery of high-quality, cost-effective healthcare
  - Permits providers to treat patients statewide from the same location

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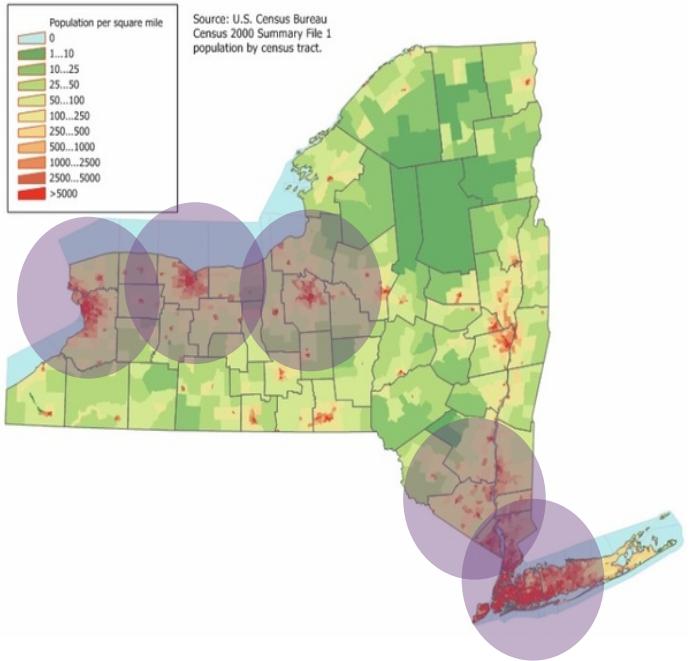
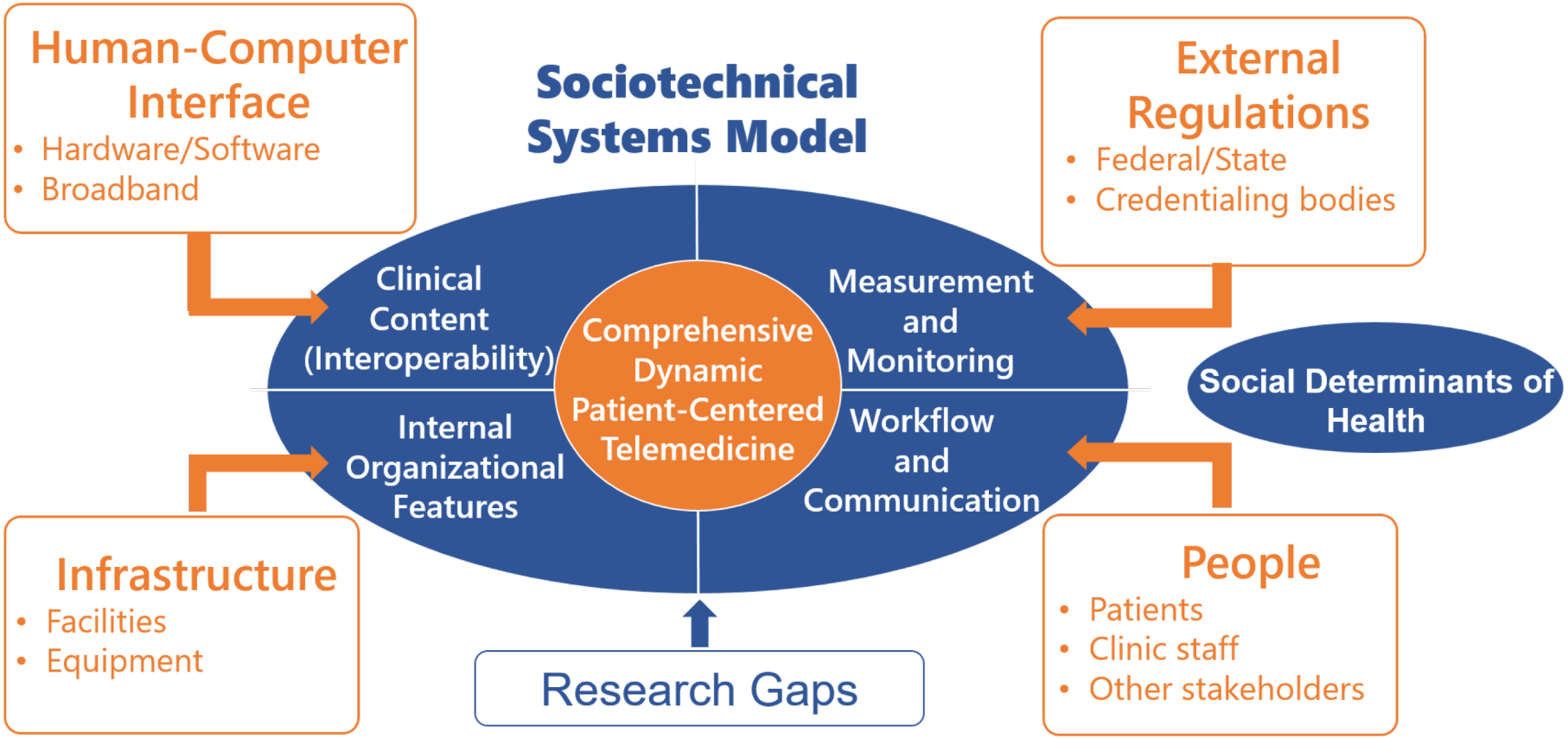
START
TREATMENT & RECOVERY CENTERS
The right way to treat people.

Mount Sinai Beth Israel



Patient-Centered Telemedicine Framework



Ref :Talal AH, Sofikitou EM, Jaanimägi U, Zeremski M, Tobin JN, Markatou M. A framework for patient-centered telemedicine: Application and lessons learned from vulnerable populations. J Biomed Inform. 2020 Dec;112:103622. doi: 10.1016/j.jbi.2020.103622. Epub 2020 Nov 10. PMID: 33186707.

Provider education and training

- Change provider misconceptions
  - Re-infection
  - Difficult to engage
  - Poor adherence
- Increase pool of available providers
  - Train PCPs
  - Advanced Practice Practitioners

In conclusion, despite the availability of effective all-oral DAA therapies, the rate of DAA prescribed treatment is much lower among patients with HCV SUD compared with patients with HCV without SUD

Results confirm prior studies that showed
that patients with SUD who are treated for HCV can achieve similar adherence and SVR rates to patients without SUD

Ref: Park H, Jiang X, Song HJ, Lo Re V 3rd, Childs-Kean LM, Lo-Ciganic WH, Cook RL, Nelson DR. The Impact of Direct-Acting Antiviral Therapy on End-Stage Liver Disease Among Individuals with Chronic Hepatitis C and Substance Use Disorders. Hepatology. 2021 Aug;74(2):566-581. doi: 10.1002/hep.31732. Epub 2021 Jul 1. PMID: 33544904; PMCID: PMC8339171.

System and Policy Changes

- Removal of prior authorizations
- No longer requiring liver damage or cirrhosis
- Promotion of public awareness about HCV screening
- Improvement of HCV surveillance by upgrading information technology infrastructure
- Expansion of HCV screening by partnering diverse healthcare organizations
- Implementation of harm reduction and prevention strategies via expansion of syringe service programs

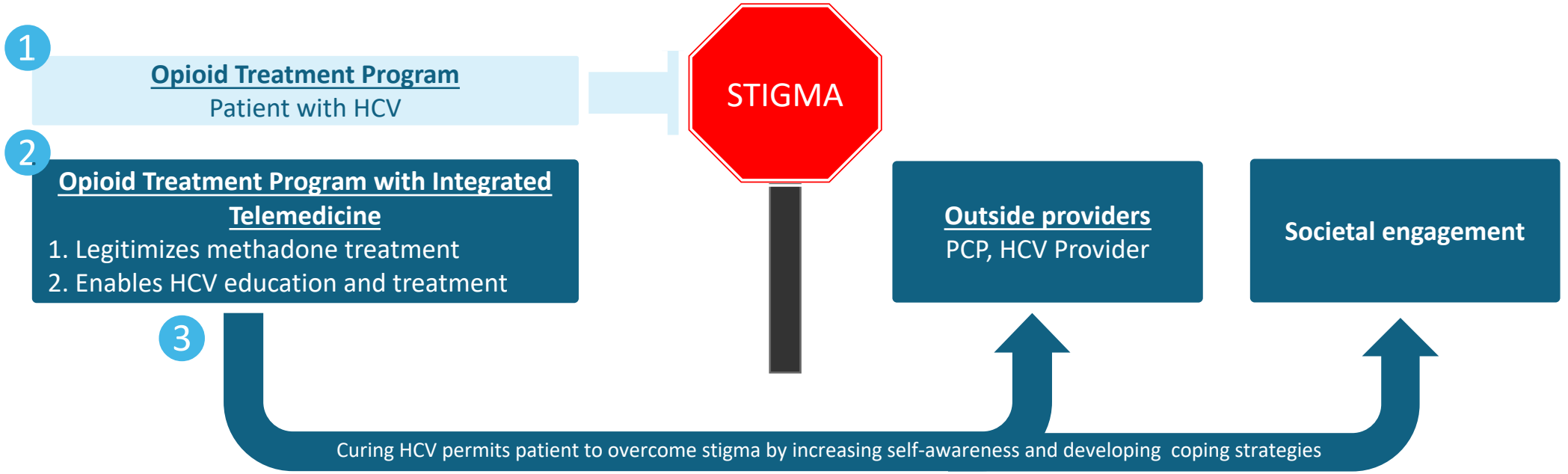
Change in public perception and stigma

- OUD as a medical condition, not a moral or social failure

- “I am in a methadone program” vs “I’m on methadone”
  - Being in a program means you have a doctor overseeing your treatment (medical supervision)

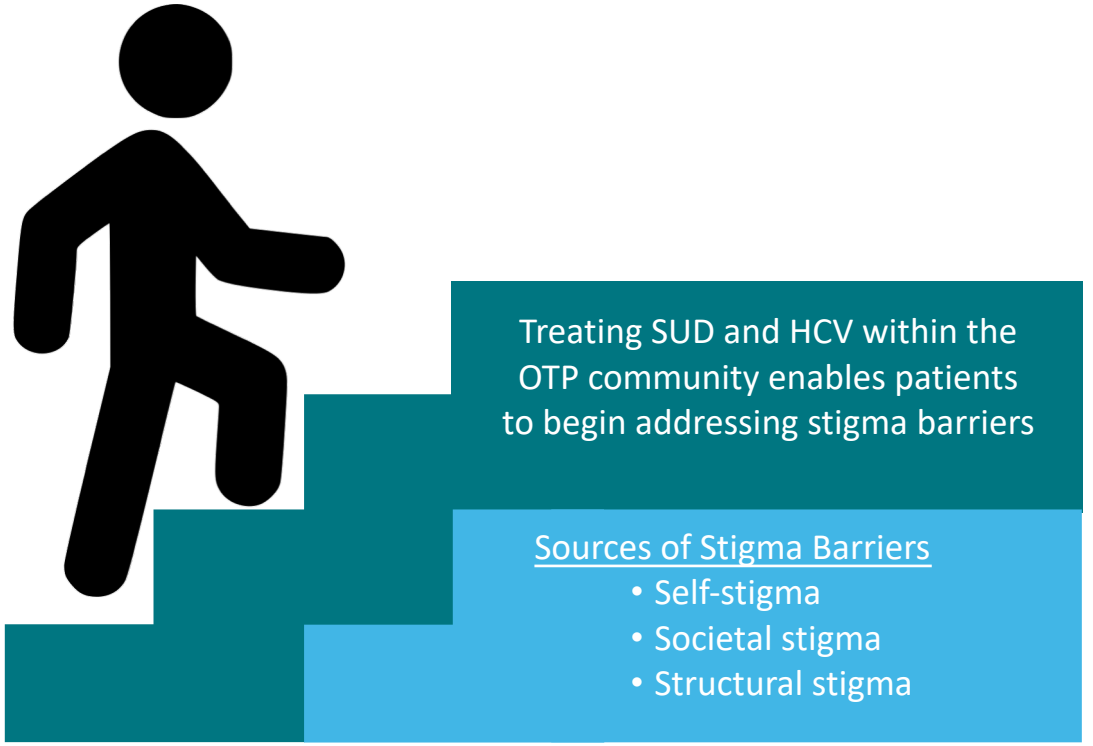
- Stigma can come from:
  - Self
  - Society
  - Structural

Stigma as a barrier to HCV care



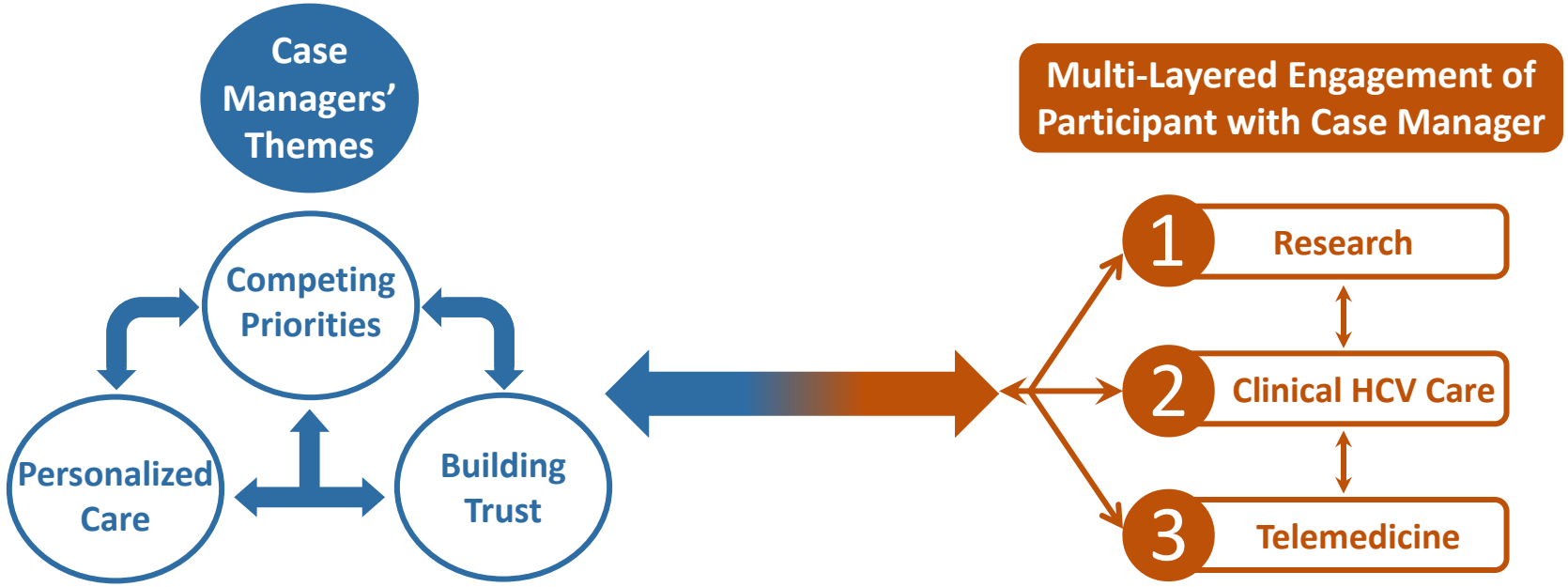
1. Patients in OTP rarely seek care outside the OTP due to stigma, competing priorities, and other barriers
2. Integrated telemedicine brings HCV care into OTP, a community that legitimizes methadone treatment and promotes HCV treatment
3. HCV treatment in OTP promotes patients overcoming HCV stigma and facilitates societal engagement

Overcoming stigma through whole-patient care



Facilitated Telemedicine Promotes Confidence & Trust in Virtual Healthcare Delivery

Trust in Opioid Treatment Program



Ref : Talal AH, Jaanimägi U, Davis K, Bailey J, Bauer BM, Dharia A, George S, McLeod A, Morton K, Nugent A, Zeremski M, Dinani A, Des Jarlais DC, Perumalswami PV, Tobin JN, Dickerson SS. Facilitating engagement of persons with opioid use disorder in treatment for hepatitis C virus infection via telemedicine: Stories of onsite case managers. J Subst Abuse Treat. 2021 Aug;127:108421. doi: 10.1016/j.jsat.2021.108421. Epub 2021 Apr 21. PMID: 34134875.

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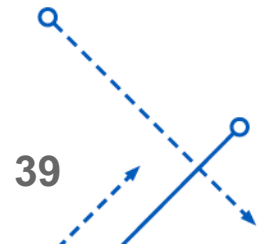
IMPROVING SURVEILLANCE, SCREENING, AND LINKAGE TO CARE

Screening vs. Surveillance

- Screening
  - At the level of the individual
  - Detection and diagnosis of asymptomatic conditions
- Surveillance
  - At the level of population
  - To detect and eliminate the underlying causes
- Relevance to HCV
  - Automated screening of high-risk populations
  - Surveillance to assess and confirm elimination efforts from a defined area

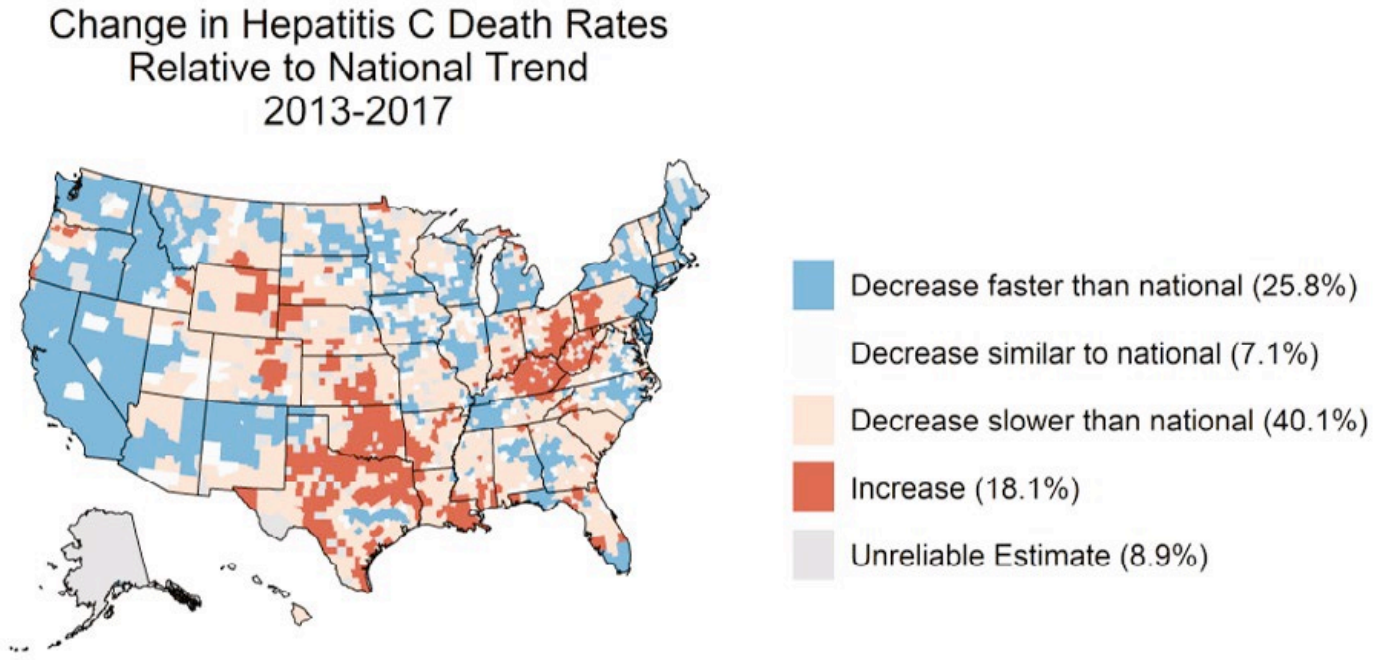
Surveillance

- HCV surveillance is critical to prevention and control strategies and ability to identify areas of high rates of infection
- Monitoring changes in acute disease incidence can be used to assess the effectiveness of prevention programs
- Current surveillance efforts are weak or unreliable due to:
  - Low screening and testing rates
  - Stigma
  - Asymptomatic nature of acute HCV
  - Most health departments unable to follow up on HCV+ reports



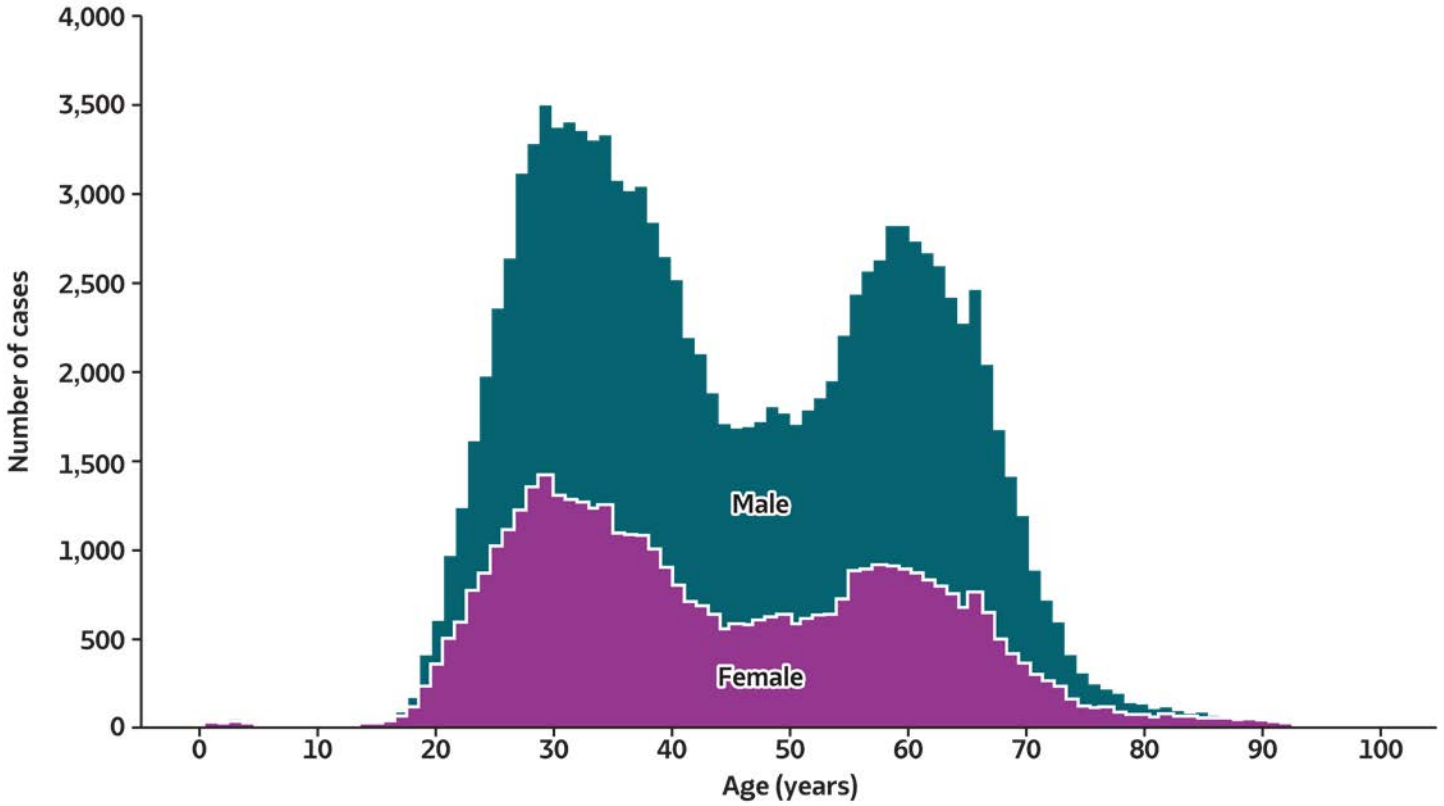
Changing Demographics

- Widespread shift in HCV mortality trends since 2013
  - Heterogeneity in HCV mortality at the county level
- Counties in the highest rate of HCV death among persons <40 are concentrated in areas with high rates of OUD and injection drug use



Ref: Hall EW, Schillie S, Vaughan AS, Jones J, Bradley H, Lopman B, Rosenberg ES, Sullivan PS. County-Level Variation in Hepatitis C Virus Mortality and Trends in the United States, 2005-2017. Hepatology. 2021 Aug;74(2):582-590. doi: 10.1002/hep.31756. Epub 2021 Jul 20. PMID: 33609308.

Figure 3.8. Number of newly reported* chronic hepatitis C virus infection cases†, by sex and age — United States, 2019



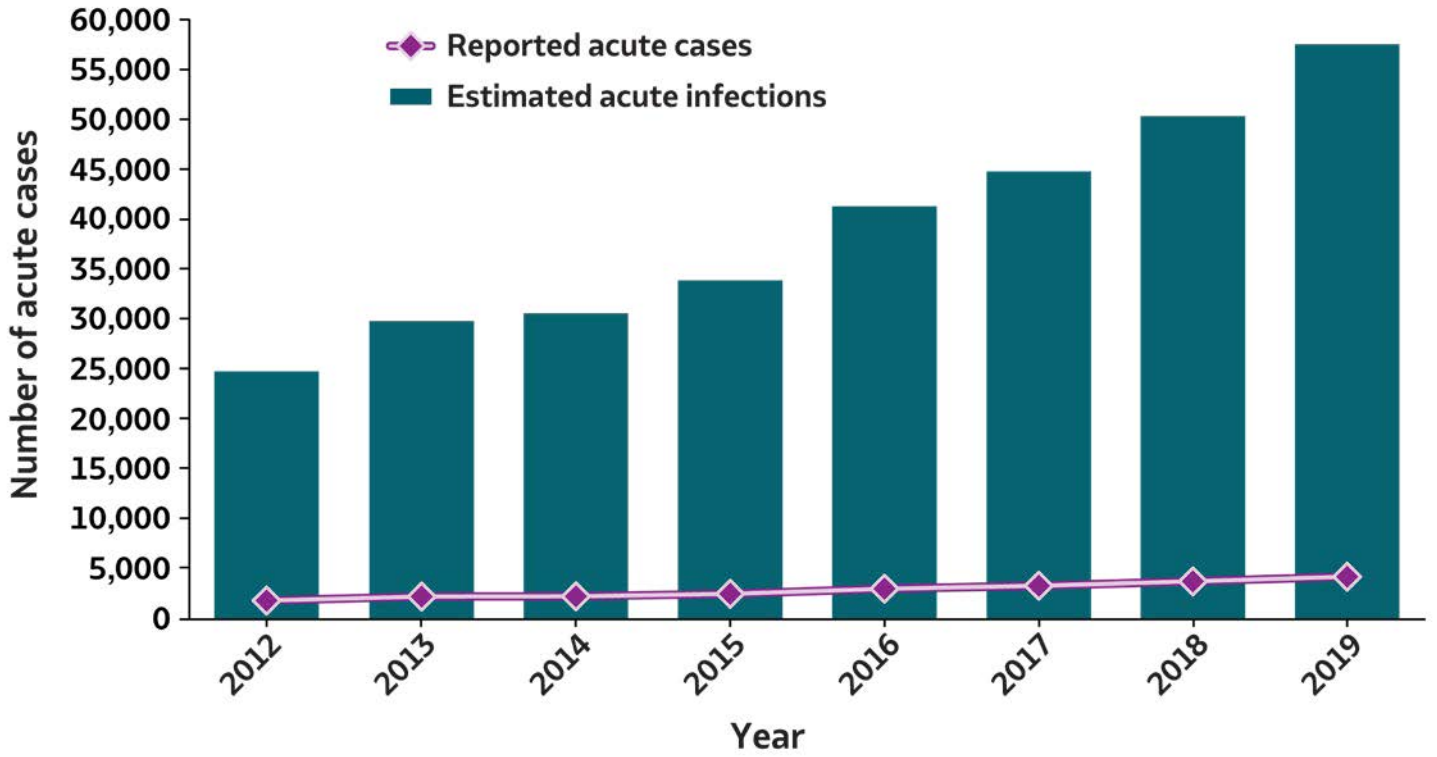
Source: CDC, National Notifiable Diseases Surveillance System.

* During 2019, cases of chronic hepatitis C were either not reportable by law, statute, or regulation; not reported; or otherwise unavailable to CDC from Arizona, Arkansas, California, Delaware, District of Columbia, Hawaii, Indiana, Kentucky, Mississippi, Nevada, North Carolina, Rhode Island, and Texas.

†Only confirmed, newly reported, chronic hepatitis C cases are included. For the complete case definition, see https://ndc.services.cdc.gov/conditions/hepatitis-c-chronic/.

Surveillance Needs

Figure 3.1. Number of reported acute hepatitis C virus infection cases and estimated infections* — United States,2012–2019



Source: CDC, National Notifiable Diseases Surveillance System..

Seroprevalence of HCV in Selected Countries With Significant Emigration*

Country	Predominant Genotype (%)	Prevalence, %	Total Cases (Thousands)
Afghanistan	3 (62.0)	0.5	181
Algeria	1 (87.6)	1.0	388
Brazil	1 (66.4)	0.9	1787
China	1 (58.0)	0.7	9795
Egypt	4 (90.0)	6.3	5625
Estonia	1 (72.7)	1.4	18
Gabon	4 (92)	7.0	124
India	3 (64.1)	0.5	6245

Country	Predominant Genotype (%)	Prevalence, %	Total Cases (Thousands)
Iraq	4 (52.9)	0.2	85
South Korea	1 (48.4)	0.5	231
Libya	Data conflicting	0.7	42
Pakistan	3 (79.0)	3.8	7172
Romania	1 (98.0)	2.5	547
Slovakia	1 (89.9)	0.6	33
Syria	4 (59.0)	3.0	554
Thailand	3 (47.8)	0.7	463

***Russia and Russian immigrants as well!**

Adapted from Polaris Observatory HCV Collaborators. Lancet Gastro Hep. 2017;2:161.

Slide credit: clinicaloptions.com

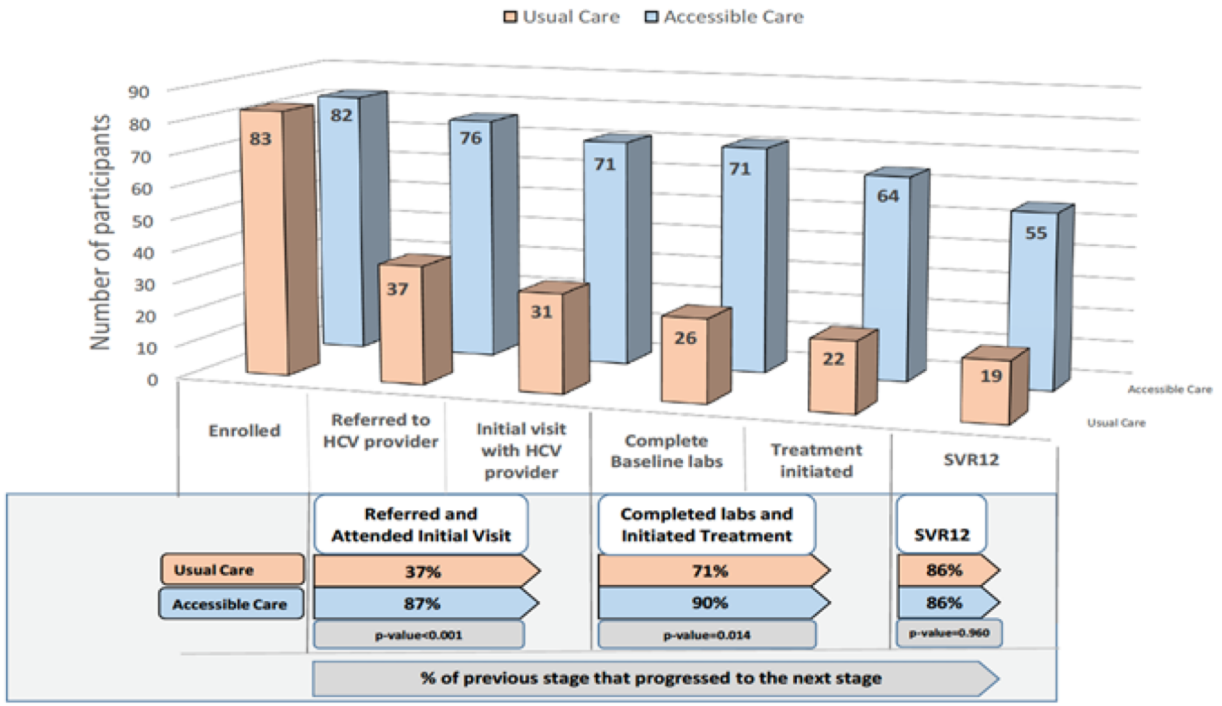
Screening and Linkage-to-care

- HCV screening needs to occur at least annually in locations with high-risk patient populations
  - Opioid treatment programs
  - Syringe service programs
  - Emergency department
- Dried blood spot as alternative to blood draw
  - For patients who are difficult blood draws
- Development of point-of-care diagnostics
  - HCV antibody and RNA
- Innovative screening locations
  - Community screening in neighborhoods
  - Mobile screening with ability to travel to high-risk areas.
  - Linkage with other types of services for social determinants of health

Treatment Locations

- Bring treatment to location where patients feel comfortable
- HCV treatment can be integrated into OTPs
- HCV treatment can also be offered at SSPs
- Mobile telemedicine

Hepatitis C virus (HCV) infection treatment cascade comparing the Accessible Care arm with Usual Care.



Eckhardt BJ[1]; Aponte-Melendez Y[2]; Fong C[2]; Kapadia SN[3]; Davis, L[2]; Smith M[3]; Marks KM[3], Mateu-Gelabert P[2]
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STATE-LEVEL HCV ELIMINATION ACTIVITIES

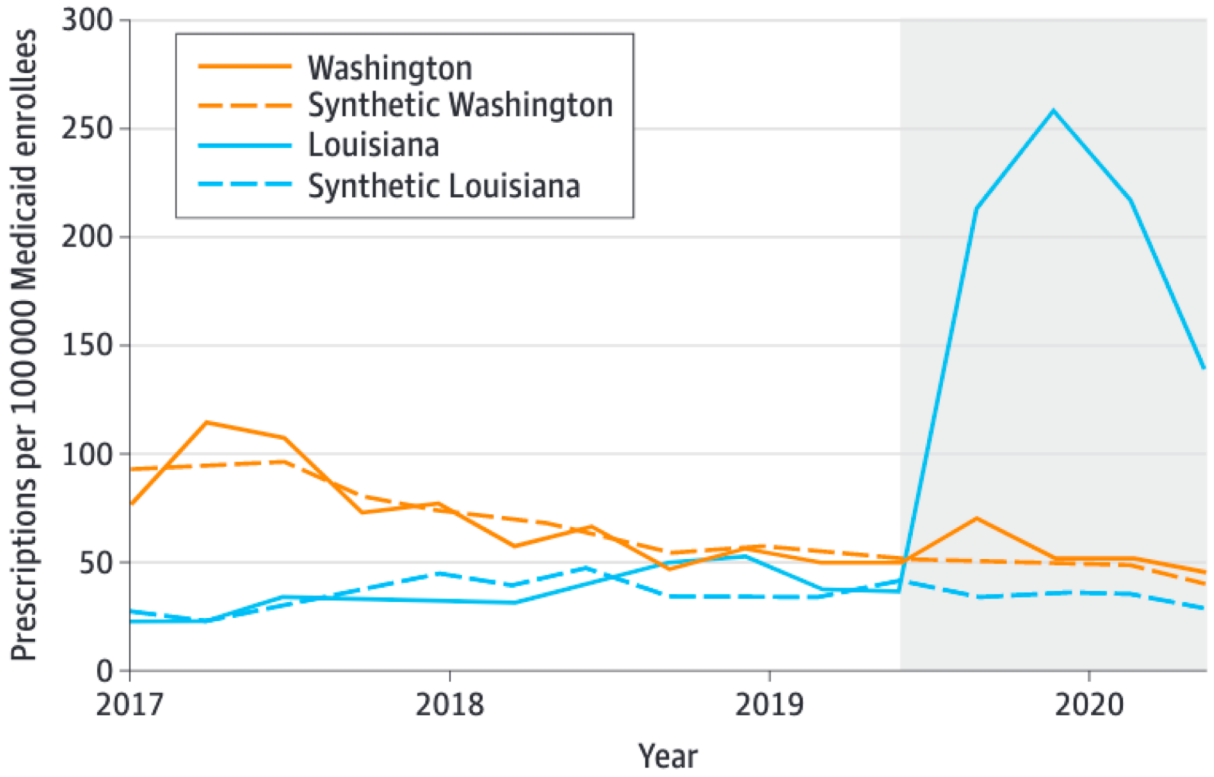
Louisiana

- 2018, $35 million USD spent on HCV treatment covered <3% of state Medicaid or prisoners with HCV
- Subscription-based model focused on Medicaid and incarcerated patients
  - Louisiana ranked #1 in 2019 for number of incarcerated individuals
  - Partnered with its DOC to implement a five-year plan to screen as many incarcerated individuals as possible.
  - As of June 2021, 8934 inmates were screened for HCV at six of eight Louisiana DOC facilities. Among them, 11% to 15% were HCV-infected and 1060 persons initiated HCV treatment.
- Removed liver damage and sobriety restrictions

Washington State

- Subscription-based model focused on Medicaid and PWIDs
- No significant changes in HCV prescriptions
- Reasons for limited impact:
  - Had already removed liver damage and sobriety requirements
  - #8 on Commonwealth Fund 2020 Scorecard on State Health Systems Performance
  - Took a broad approach without focusing on specific, high-risk populations
  - COVID-19 pandemic

Figure 1. Trends in Hepatitis C Virus Prescription Fills in Treated States and Synthetic Controls



Reference: Auty SG, Shafer PR, Griffith KN. Medicaid Subscription-Based Payment Models and Implications for Access to Hepatitis C Medications. *JAMA Health Forum.* 2021;2(8):e212291. doi:10.1001/jamahealthforum.2021.2291

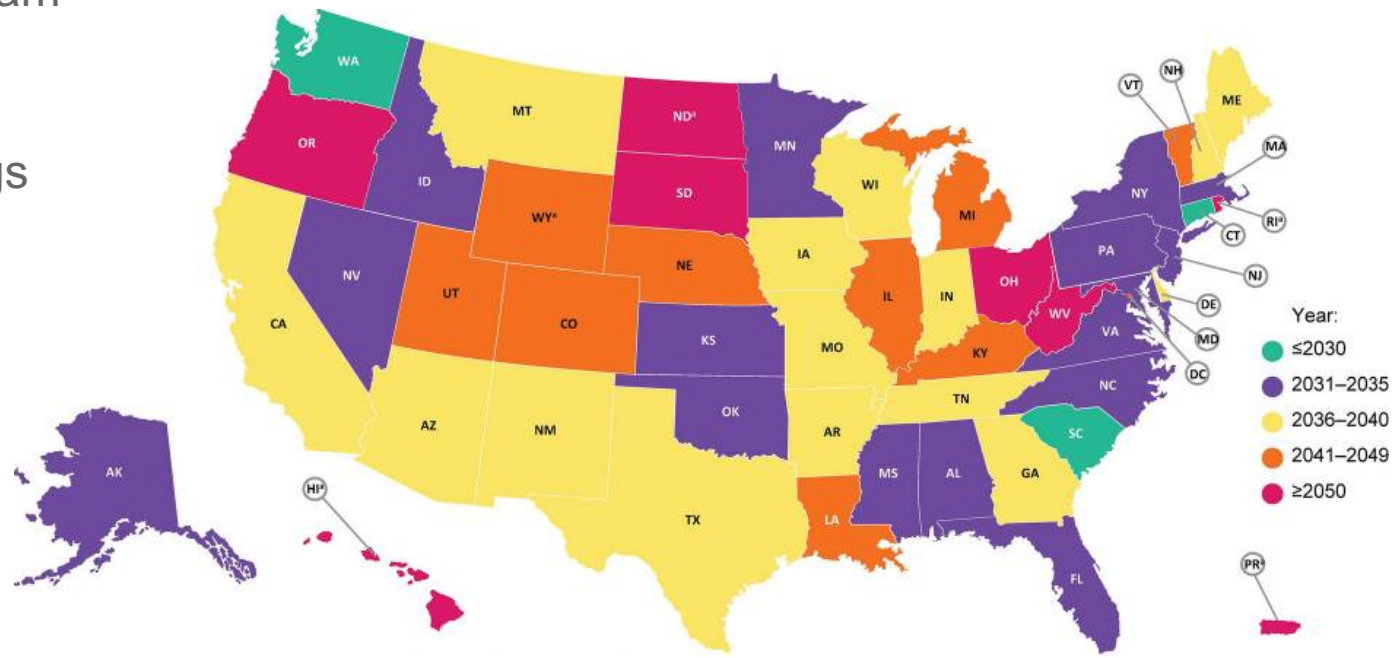
Michigan

- Promote universal HCV testing for all adults
- Mavyret available to all Medicaid and Healthy Michigan Plan beneficiaries
- Removal of prior authorization
- Development of HCV trainings for clinicians
- Establish clinical consulting line for peer-to-peer clinical advice

Other state activities

- States in planning stages of an elimination program
  - Hawaii, Pennsylvania, Michigan, New York
- States who have conducted stakeholder meetings in past three years
  - Alaska, Arizona, Florida, Minnesota, Utah, Virginia
- States who list elimination projects but have no publicly available plan
  - Indiana, Kentucky, North Carolina, New Jersey, Tennessee, West Virginia, Wisconsin

Year of achieving HCV elimination by state



Sulkowski M, Cheng WH, Marx S, Sanchez Gonzalez Y, Strezewski J, Reau N. Estimating the Year Each State in the United States Will Achieve the World Health Organization's Elimination Targets for Hepatitis C. *Adv Ther*. 2021;38(1):423-440. doi:10.1007/s12325-020-01535-3

Themes from State elimination plans

I. Promotion of public awareness about HCV screening via outreach campaigns, focus groups and community involvement
   - To formulate best practices for patient engagement, communication strategies, and service delivery

II. Improvement of HCV surveillance by upgrading information technology infrastructure, automating reporting and review, and developing an HCV task force to manage the volume of cases.

III. Expansion of HCV screening by partnering with primary care providers, Medicaid, OTPs, syringe services programs (SSPs), and departments of corrections (DOC) to standardize routine screening at priority sites.

IV. Implementation of harm reduction and prevention strategies via expansion of SSPs and OTPs, including continuity of care for opioid use disorder among those discharged from DOC facilities

State Hepatitis C Elimination Projects Provide a Roadmap for National Elimination. *American Journal of Public Health.* Submitted October 2021. Collaborative projections Louisiana Department of Health, Washington State Healthcare Authority, University at Buffalo, Weill-Cornell, University of Alabama, Birmingham

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INTERNATIONAL HCV ELIMINATION EFFORTS

Egypt

PRACTICE CHANGING

March 27, 2020

Egypt Implements Successful Nationwide Program to Eliminate Hepatitis C

Mary E. Wilson, MD reviewing Waked I et al. N Engl J Med 2020 Mar 19

- 2018 Egypt Ministry of Health HCV elimination project
- Screened 80% of residents (50 million) in 7 months
- 92% of those HCV+ started treatment
- $130.00 USD – Final cost to identify and cure HCV

Australia

- One of the first countries to use subscription drug pricing model
- Plan included:
  - Added DAAs to national reimbursement list
  - Remove treatment restrictions
  - Permitted general practitioners to prescribe
- Reduced patient cost from $77,219 USD to $31.89 USD
- 2016-2019 – 82,280 Australians initiated DAA treatment
  - 2015 – 11.1% treatment uptake among HCV+ patients
  - 2019 – 64.2% treatment uptake among HCV+ patients
  - 93% overall cure rate

On track to achieve 80% HCV treatment coverage and 90% incidence reduction by 2030

Ref: Innovative Payment Models: An Analysis of the Promise and Practice of Novel Hepatitis C Medication Procurement Strategies in the U.S. O-Neill Institute for National and Global Health Law. Georgetown Law. Hepatitis Policy Project. July 2021

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HCV ELIMINATION REQUIREMENTS

Public-Private Partnerships

HCV ELIMINATION CANNOT OCCUR UNLESS EXISTING CASES ARE IDENTIFIED, TREATED, AND CURED

- Payer coalitions
  - Collective power of agencies who are already paying for HCV treatment
- Subscription-based treatment models
  - Need to include support for outreach, education, and screening

Subscription-based payment model implementation in Louisiana was associated with an increase 534.5% Washington did not experience a significant change in prescription fills

Reference: Auty SG, Shafer PR, Griffith KN. Medicaid Subscription-Based Payment Models and Implications for Access to Hepatitis C Medications. *JAMA Health Forum.* 2021;2(8):e212291. doi:10.1001/jamahealthforum.2021.2291

Education and Outreach

- Increased public awareness
  - Stigma remains a major barrier for patients and providers
- Provider education
- Patient education
- Targeting locations with high concentration of at-risk patients:
  - Supervised injection facilities
  - Detoxification centers
  - Emergency departments
  - Homeless shelters

Surveillance and Screening efforts

- Surveillance to identify regions in need
- Automated screening of high-risk populations
- On-site HCV services integrated into clinics with high-risk patients
- Harm reduction and syringe service programs
- System for responding to surveillance data to identify regions with a mismatch between HCV disease burden and HCV screening and treatment activities.
- Screening in high-risk venues identifies considerable numbers of HCV-infected individuals and such strategic efforts are critical in resource-limited jurisdictions

In addition to reducing the risk of infection, harm-reduction programs can promote regular testing, facilitate linkage to care, and provide access to active PWID who are not often reached in traditional settings.

Ref: Blake A, Smith JE. Modeling Hepatitis C Elimination Among People Who Inject Drugs in New Hampshire. JAMA Netw Open. 2021 Aug 2;4(8):e2119092. doi: 10.1001/jamanetworkopen.2021.19092. PMID: 34342652; PMCID: PMC8335578.

Change in Social Perspective

- Emphasize whole-patient care
  - De-silo substance abuse treatment from co-morbid conditions such as HCV and HIV
  - Pair OUC and HCV care
  - Utilize peer advocates who have lived, shared experiences

Nationwide HCV elimination is possible

- Policy
  - DAA's make it medically possible yet policies, stigma, and education remain barriers
  - Subscription-based models can greatly expand treatment access
- Education
  - Patients, community, and provider with content appropriately targeted.
- Stigma
  - Need to drive national recognition of addiction as a disease state, not moral or personal failure
- Data
  - Innovative tools and technology, such as telemedicine, can help to bridge healthcare gaps
  - Support for screening and surveillance is continuously needed to identify areas in need

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