



GHAPP

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Advanced Practice Providers

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Chronic hepatitis C: Access to treatment and elimination strategies

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Disclosures

Michelle Barnett, PA-C, DFAAPA

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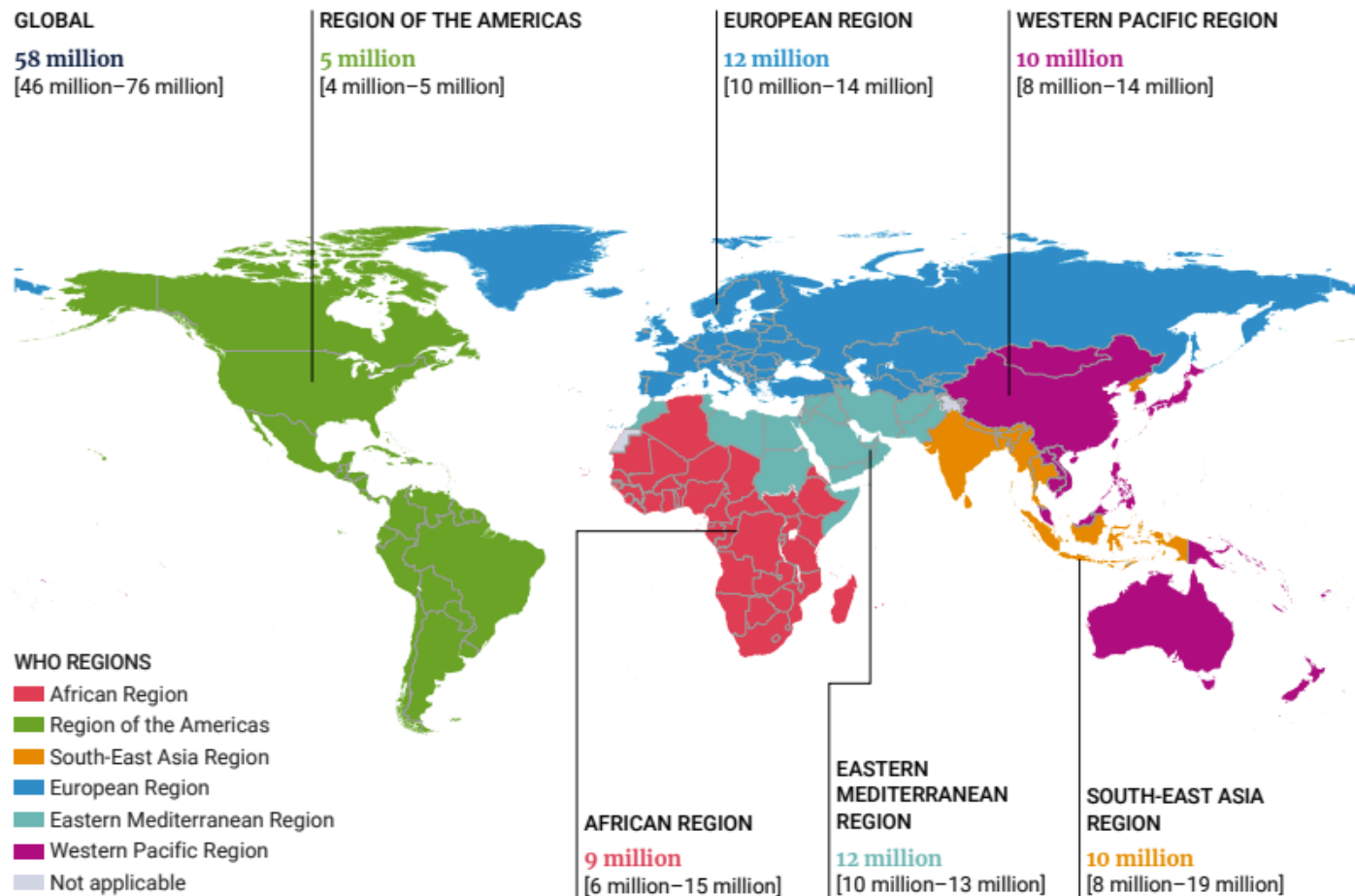
Allison Hobbs, APRN-C

Advisory Board: Gilead, Clinical Area – HCV

Objectives

- Updated HCV epidemiology (United States)
- Understand treatment availability
- Recognize World Health Organization Elimination Goals
- Delineate micro-elimination strategies
- Identify barriers to micro-elimination
- Understand the importance of harm reduction in micro-elimination

Global Prevalence of Chronic HCV Infection



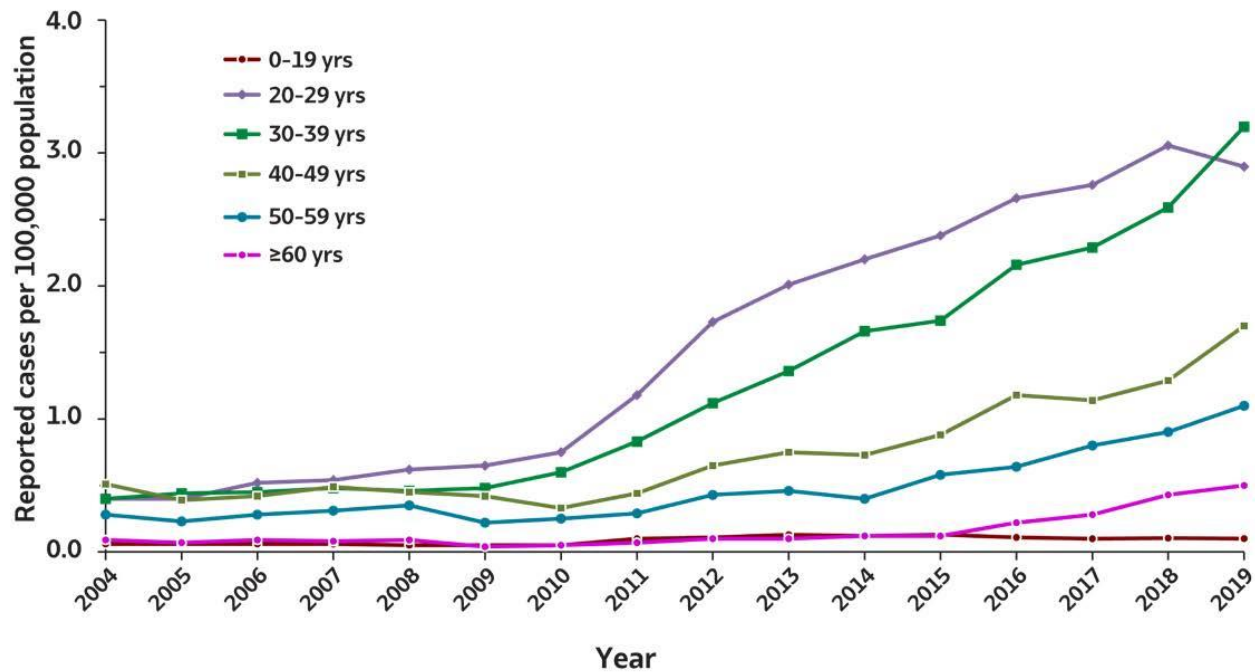
World Health Organization. Interim Guidance for Country Validation of Viral Hepatitis Elimination. Technical Report. June 2021.
<https://www.who.int/publications/i/item/9789240028395>



Acute Hep C Cases

2019 VIRAL HEPATITIS
SURVEILLANCE REPORT

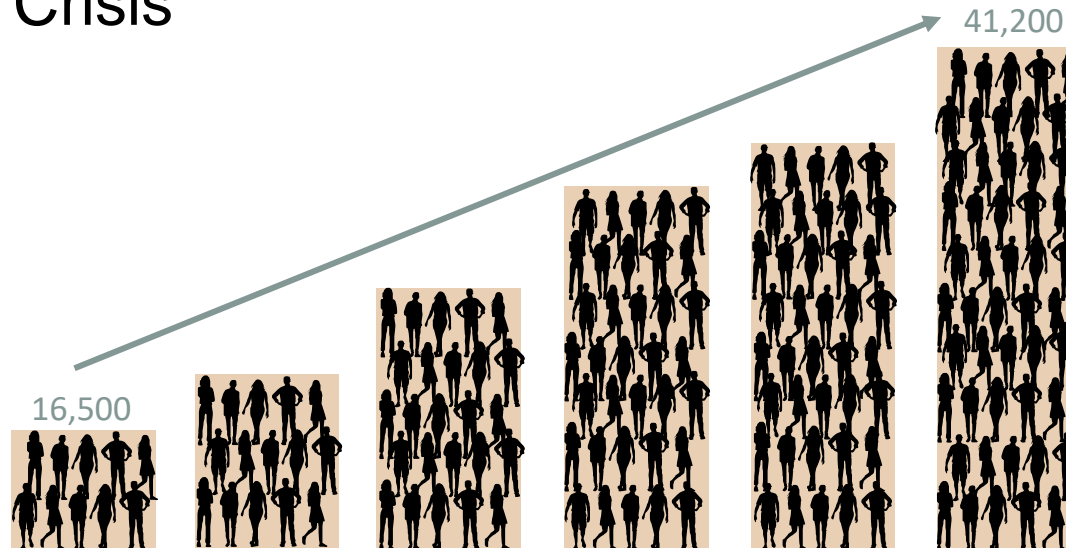
Figure 3.4. Rates of reported acute hepatitis C virus infection, by age group
— United States, 2004–2019



Acute Hep C Cases

Why are HCV cases on the rise?

- Opioid Crisis



Burden of HCV in the US

- Hepatitis C virus (HCV) kills more Americans than the 60 other reportable infectious diseases, including HIV, combined
- Baby boomers (born between 1945 and 1965), especially African Americans, face high burdens of chronic HCV infection
- People who inject drugs face rapidly rising rates of acute HCV infection as a result of the growing opioid epidemic
- This is a pivotal moment in HCV treatment, because curative treatment regimens are now available
 - These treatments are significantly more effective, rapid, and tolerable than prior regimens
 - With curative treatment, eliminating HCV as a public health threat is a real possibility

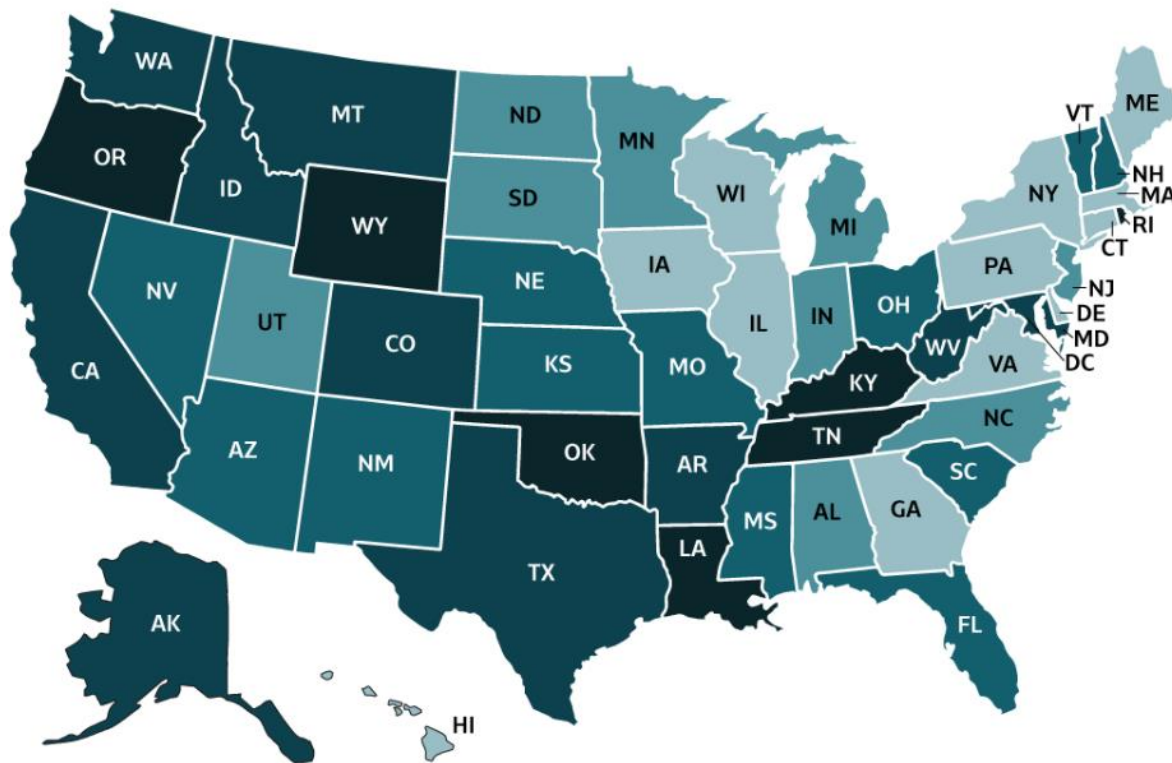
1. Centers for Disease Control and Prevention (CDC). Hepatitis C FAQ for Health Professionals. <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#section1>

2. CDC. Hepatitis C Kills More Americans than Any Other Infectious Disease. <http://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html>

3. National Academies of Sciences, Engineering, and Medicine. A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report.

<http://www.nationalacademies.org/hmd/Reports/2017/national-strategy-for-the-elimination-of-hepatitis-b-and-c.aspx>

Rate of HCV Death Varies by State



Cases/100,000 Population	States
0-2.49	CT, DE, GA, HI, IL, IA, ME, MA, NY, PA, VA, WI
>2.49-3.12	AL, IN, MI, MN, MO, NJ, NC, ND, SD, UT
>3.12-3.85	AZ, FL, KS, MS, NE, NV, NH, OH, SC, VT
>3.85-5.49	AK, AR, CA, CO, ID, MD, MT, TX, WA, WV
>5.49-11.00	DC, KY, LA, NM, OK, OR, RI, TN, WY

Benefits of Treatment & Cure

- Curative treatment **reduces**:
 - Risk of liver cancer by 75%
 - Risk of all-cause mortality by 50%
- Curative treatment **improves**:
 - Cost-effectiveness compared to past treatment regimens
 - Cost-effectiveness compared to long-term treatment of HCV-associated conditions
 - Patient quality of life
- Curative treatment **prevents** future transmission of HCV
 - Rates of reinfection among persons who inject drugs are relatively low, especially with behavioral support, and should not be a justification for withholding curative treatment

1. CDC. CDC Fact Sheet: Viral Hepatitis and Liver Cancer. <http://www.cdc.gov/nchhstp/newsroom/docs/factsheets/viral-hep-liver-cancer.pdf>

2. Saab, et al. Cost-effectiveness Analysis of Sofosbuvir Plus Peginterferon/ribavirin in the Treatment of Chronic Hepatitis C Virus Genotype 1 Infection. *Alimentary Pharmacology & Therapeutics*. 2014;40(6):657-675.

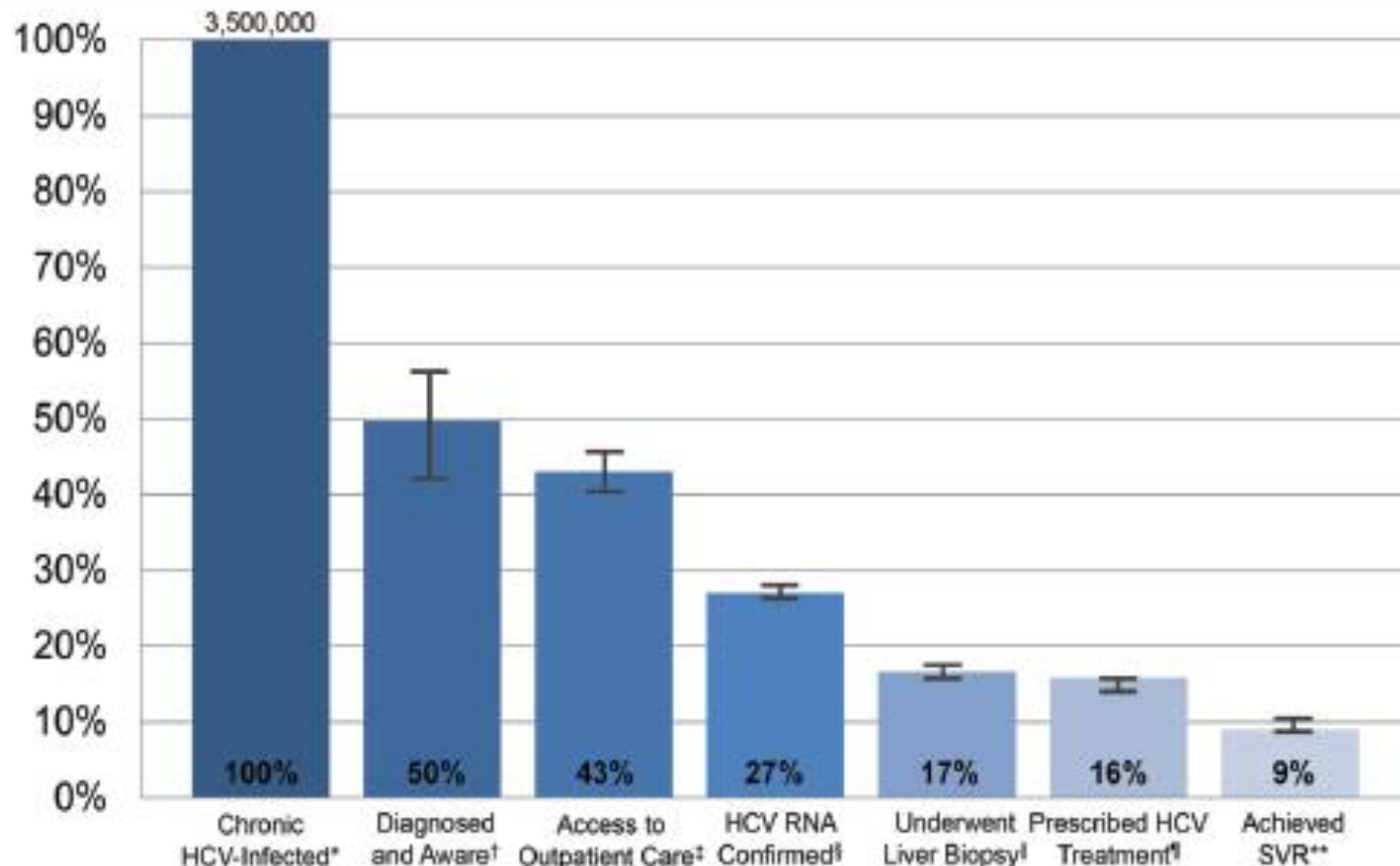
3. Alcorn, K. Reinfection after hepatitis C cure: Prevention may require long-term support for people who have injected drugs. 2015.

<http://www.aidsmap.com/Reinfection-after-hepatitis-C-cure-prevention-may-require-long-term-support-for-people-who-have-injected-drugs/page/2973522/>

AASLD/IDSA Guidance: Simplified Pretreatment Assessment

- **Within 6 mos prior to initiating treatment**
 - Complete blood count (CBC)
 - International normalized ratio (INR)
 - Hepatic function panel (liver function tests)
 - Estimated glomerular filtration rate (eGFR)
- **Anytime prior to starting antiviral therapy**
 - Quantitative HCV RNA (HCV viral load)
 - HCV genotype—only if a nonpangenotypic DAA will be prescribed
 - Other viral tests: HIV antigen/antibody test and HBsAg
 - Check for drug–drug interactions with DAA therapy

Treatment cascade for chronic HCV infection



* Chronic HCV-Infected; N=3,500,000.

† Calculated as estimated number chronic HCV-infected (3,500,000) x estimated percentage diagnosed and aware of their infection (49.8%); n=1,743,000.

‡ Calculated as estimated number diagnosed and aware (1,743,000) x estimated percentage with access to outpatient care (86.9%); n=1,514,667.

§ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage HCV RNA confirmed (62.9%); n=952,726.

|| Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage who underwent liver biopsy (38.4%); n=581,632.

¶ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage prescribed HCV treatment (36.7%); n=555,883.

** Calculated as estimated number prescribed HCV treatment (555,883) x estimated percentage who achieved SVR (58.8%); n=326,859.

Note: Only non-VA studies are included in the above HCV treatment cascade.

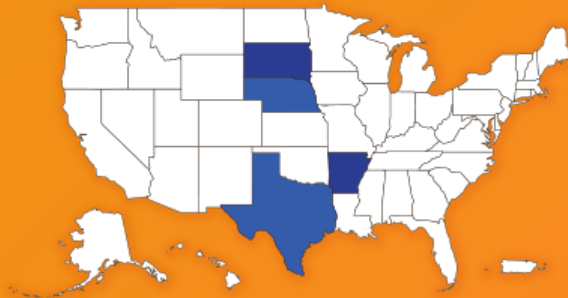
Access to Treatment: Restrictions 2021

Hepatitis C treatment restrictions have **lessened** over the last decade since the **introduction of direct-acting antivirals (DAAs)**. Fewer treatment restrictions allow for **increased access to Hepatitis C treatment** for patients in Medicaid programs.

Current Hepatitis C Treatment Restrictions for Medicaid, 2021

32 states

have eliminated or reduced fibrosis restrictions, 4 remain.



F0/No Restrictions

F1

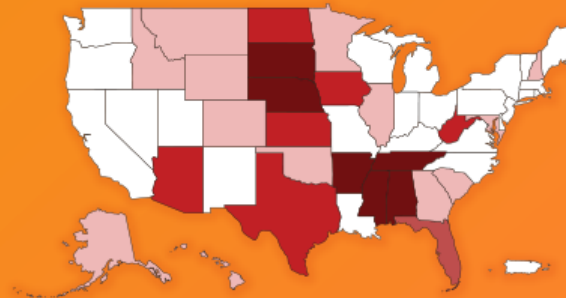
F2

F3

F4

21 states

have loosened sobriety restrictions, 28 remain.



No Restrictions

Screening and Counseling for Substance Use

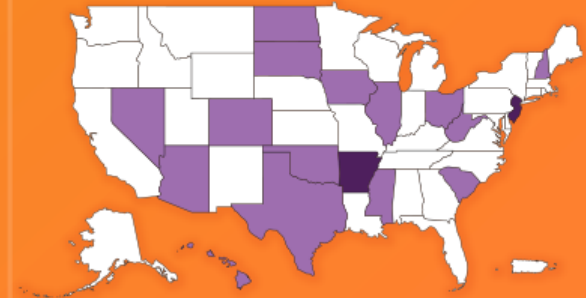
Abstain (1 mo.)

Abstain (3 mos.)

Abstain (6 mos.)

25 states

have scaled back prescriber restrictions, 18 remain.



No Restrictions

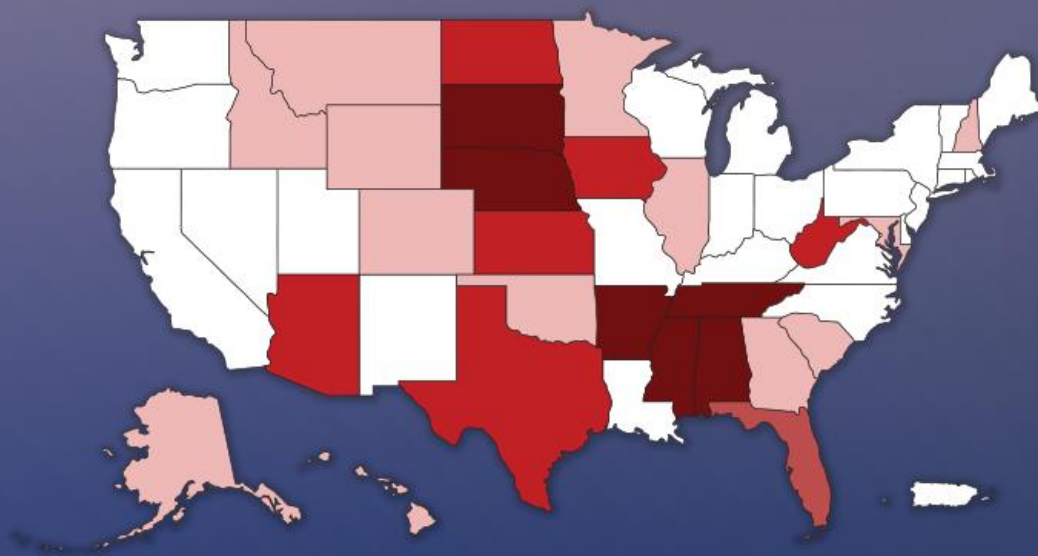
By or in Consultation with a Specialist

Specialist Must Prescribe

**Statuses are as of April 2021. *For purposes of analysis, District of Columbia and Puerto Rico are treated like states.*

Access to Treatment: Restrictions 2021

As of April 2021, **more than half** of U.S. states* have **sobriety restrictions** for Hepatitis C treatment.



Some sobriety restrictions **require individuals to abstain from using alcohol and/or drugs** for a specified timeframe prior to starting Hepatitis C treatment.

Sobriety Restrictions, 2021

No restrictions

Screening and Counseling for Substance Use

Abstain (1 mo.)

Abstain (3 mos.)

Abstain (6 mos.)

**For purposes of analysis, District of Columbia and Puerto Rico are treated like states.*

Access to Treatment: Restrictions 2021

As of April 2021, **48 states*** have **no fibrosis**
(liver scarring) **restrictions** for Hepatitis C treatment.

Nebraska, Texas, Arkansas, and South Dakota still have fibrosis restrictions.

Nebraska



Texas



Arkansas



South Dakota

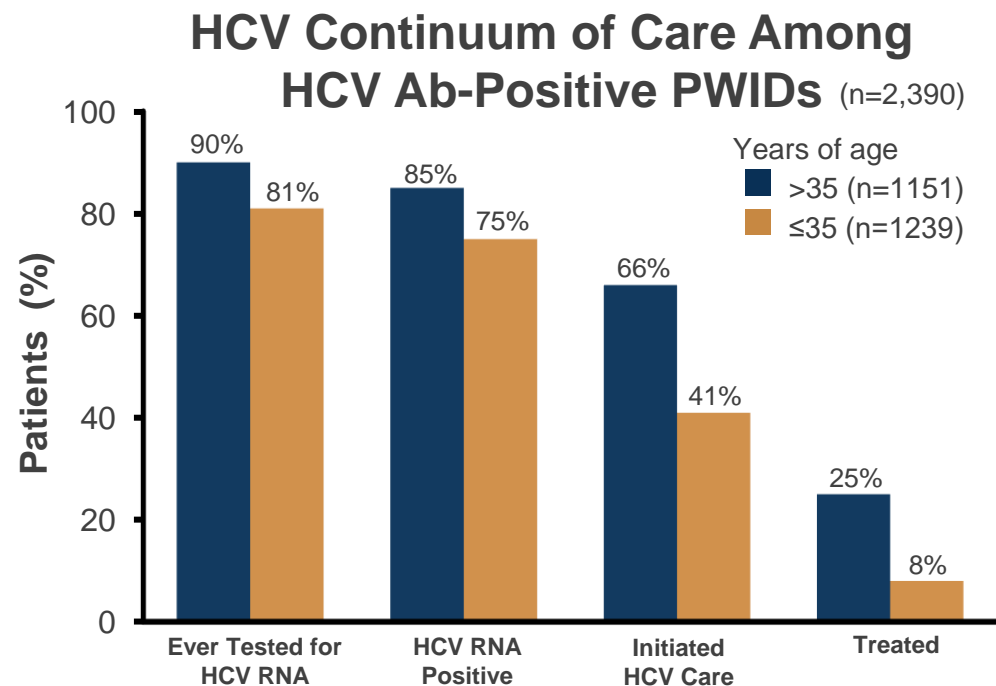


Fibrosis restrictions **require patients to wait** until Hepatitis C
damages their liver before receiving Hepatitis C treatment.

**For purposes of analysis, District of Columbia and Puerto Rico are treated like states.*

HCV Access to Treatment: HCV Continuum of Care Among PWID

- Random sample of newly reported HCV antibody positive persons (Philadelphia Center for Public Health n=29,820; 2013-2017)
- Measurable gaps exist in the HCV continuum of care for PWIDs, especially those ≤ 35 years of age
 - Only 29% and 10% of PWIDs >35 and ≤ 35 years of age, respectively, were treated
- Need for enhanced navigation to services



HCV Access to Treatment: State Programs

“Netflix Model”

- Louisiana
- Washington
 - Programs include testing and linkage-to-care services
 - Broad access to treatment

Telehealth/Telementorship Models

- Veterans Affairs
- Project ECHO (Extension for Communities Healthcare Outcomes)
- Kentucky Hepatitis Academic Mentorship Program (KHAMP) & US-HAMP

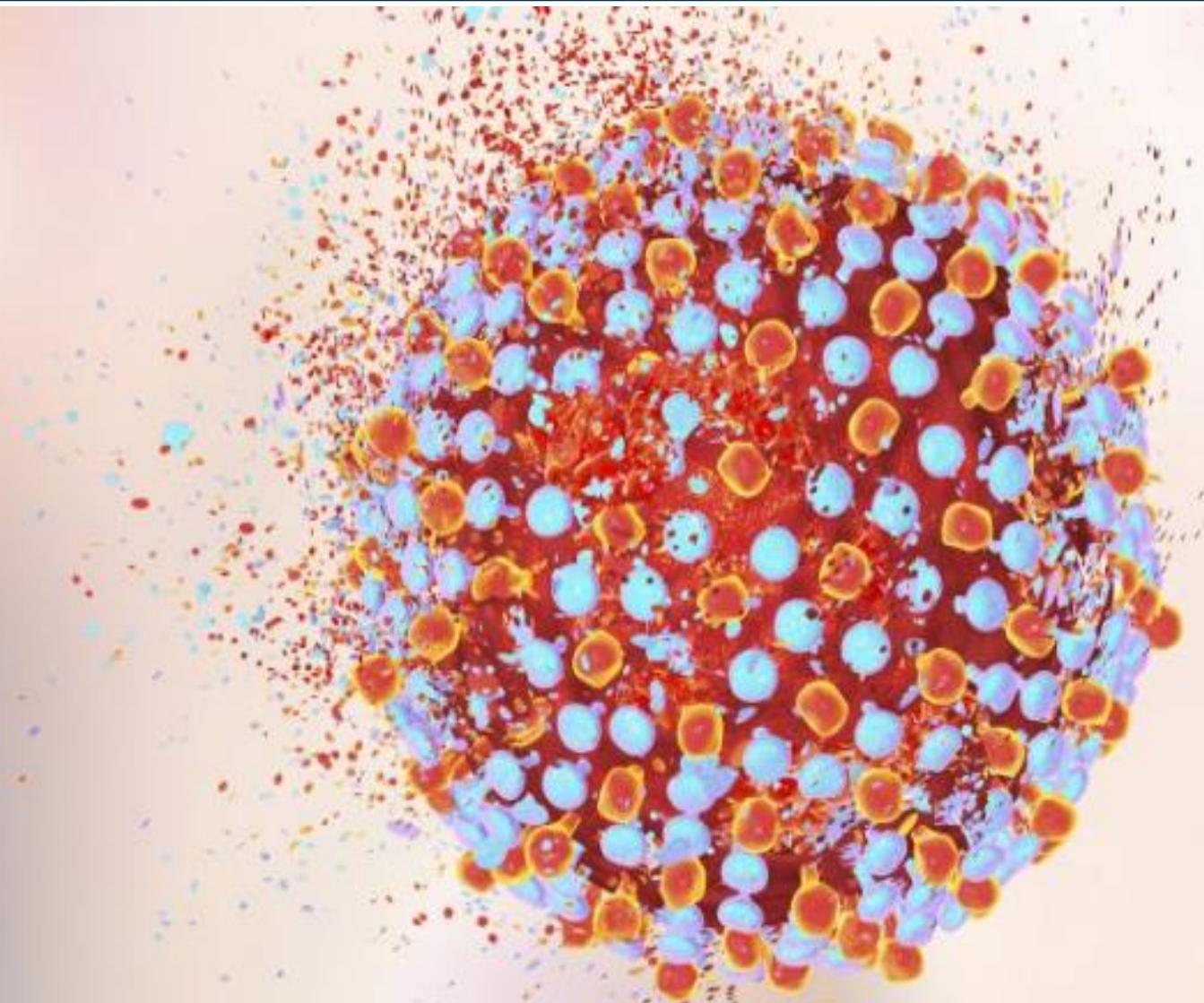
Project ECHO: Physician Peer Support for Expanding Access to HCV Treatment

- First developed by University of New Mexico in 2003 to build primary care capacity to treat HCV infections in rural, underserved populations
- Video conferences link interdisciplinary specialist teams with primary care providers for longitudinal co-management
- ECHO sessions include:
 - Brief didactic
 - Case presentations
 - Discussion with community of learners
- Physician survey data demonstrated significant increases in provider knowledge, self-efficacy, and professional satisfaction

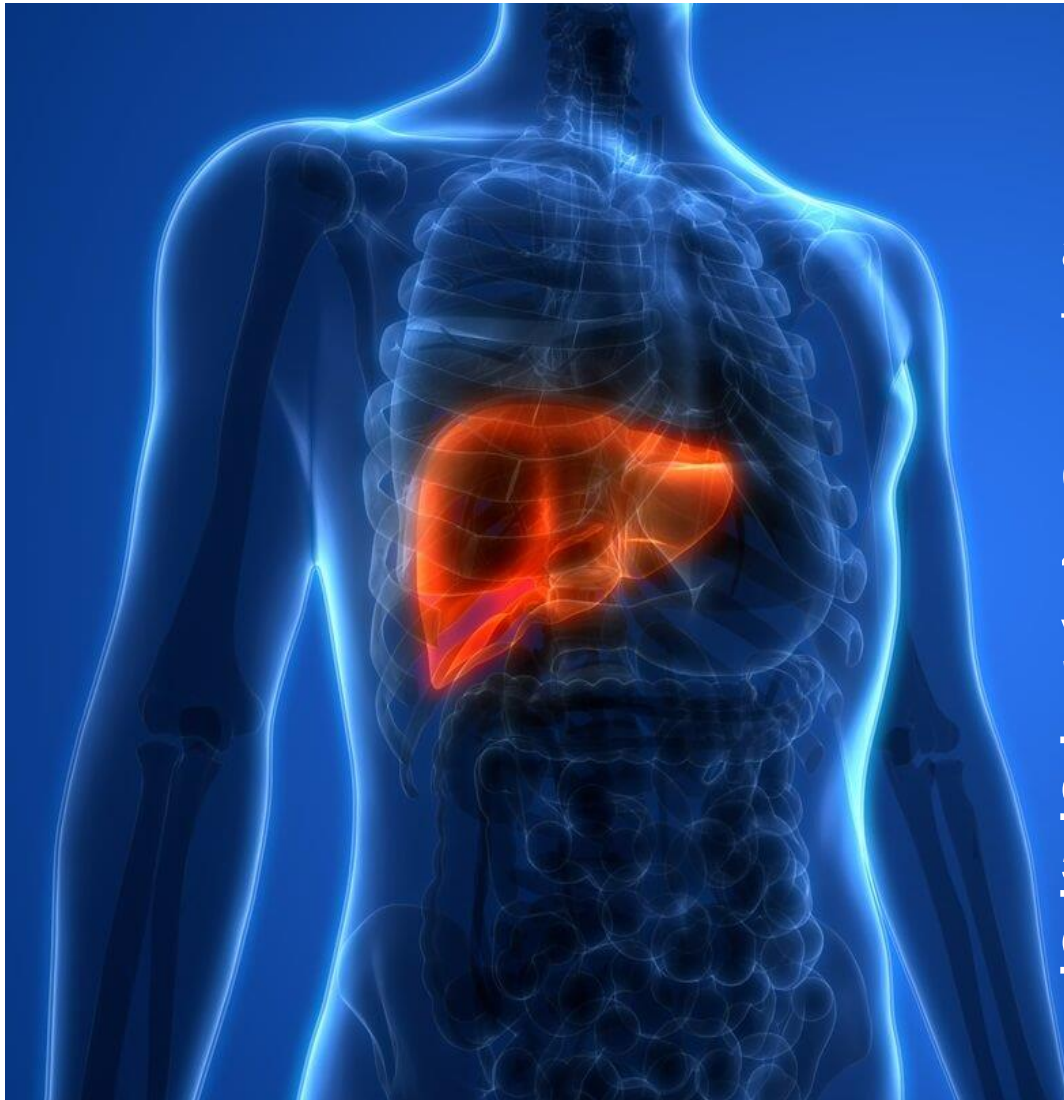


Slide credit: clinicaloptions.com

HCV Elimination Strategies



HCV Elimination: Why?



In the United States alone, studies suggest that a fourfold increase in treatment of hepatitis C (from about 100,000 to 400,000 patients per year) **could prevent more than 250,000 deaths and more than 500,000 cases of cirrhosis per year.**

HCV Elimination: World Health Organization



COMBATING HEPATITIS B AND C TO REACH ELIMINATION BY 2030

MAY 2016

ADVOCACY BRIEF

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HCV Elimination: World Health Organization

“A world where viral hepatitis transmission is stopped and everyone has access to safe, affordable and effective treatment and care”

WHO 2030 Targets

- 90% HCV Diagnosed
- 80% Treated
- 80% Reduction in new HCV infections
- 65% Reduced HCV-related mortality

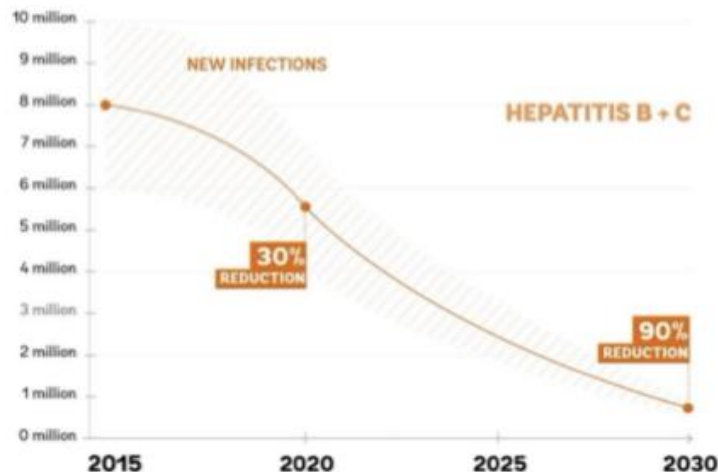
***“Elimination” =
90% reduction in
incidence by 2030***

**Important to remember→
Elimination does not equal Eradication**

HCV Elimination: World Health Organization

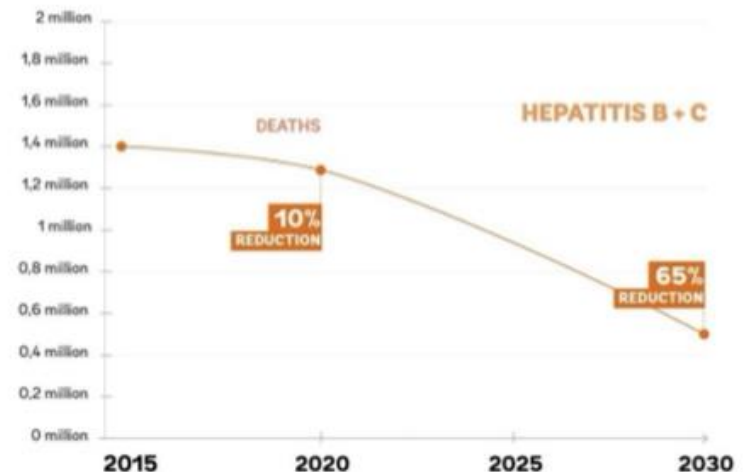
Impact targets for elimination

**90% reduction in new cases of
of chronic HBV and HCV infection**



**6-10 million infections (in 2015) to
900,000 infections (by 2030)**

**65% reduction in deaths from
chronic HBV and HCV**



**1.4 million deaths (in 2015) to under
500,000 deaths (by 2030)**

HCV Elimination: World Health Organization

Countries on Track for 2030 Goal:

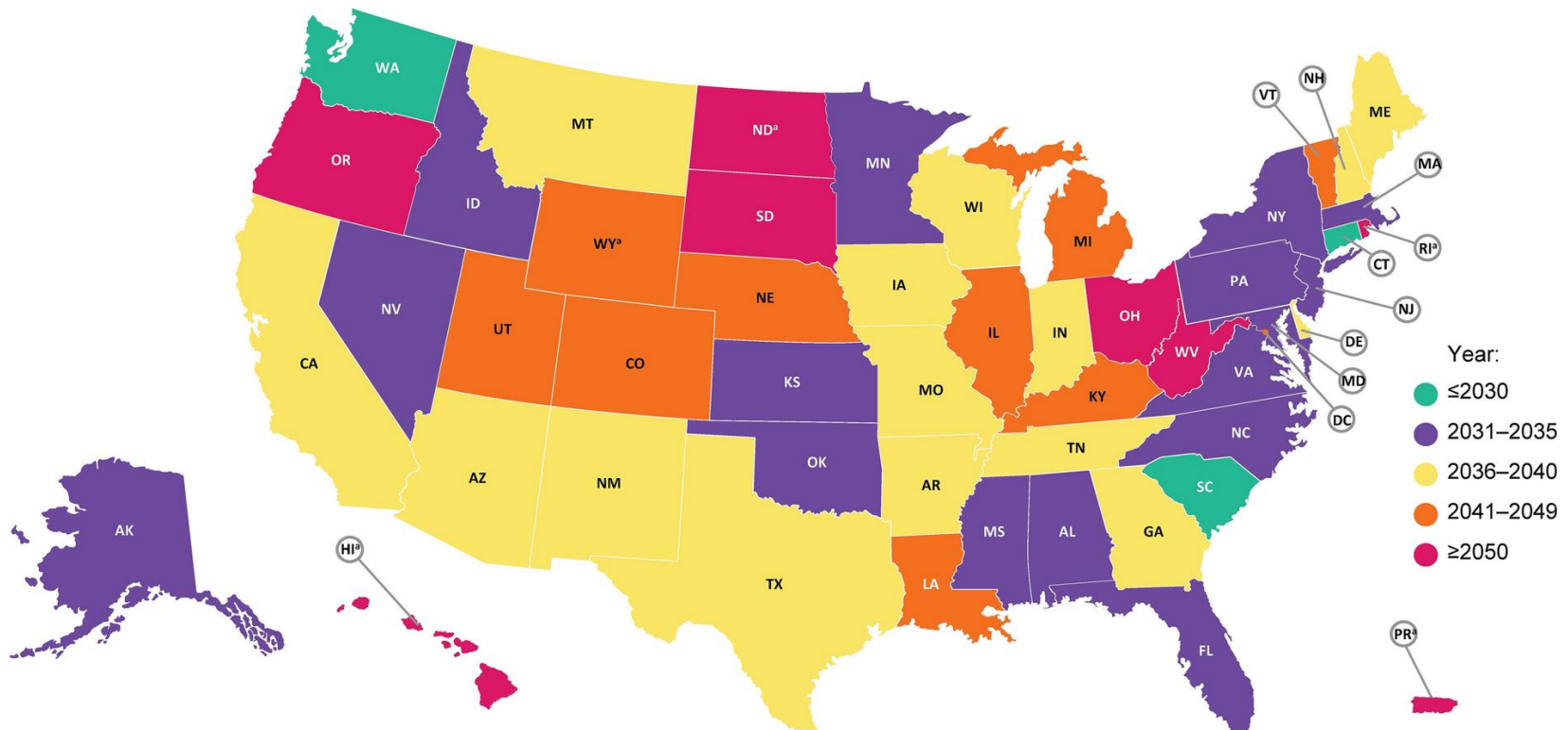
- Australia
- France
- Iceland
- Italy
- Japan
- South Korea
- Spain
- Switzerland
- United Kingdom
- Egypt
- Georgia
- Mongolia



*What about
the United
States???*

HCV Elimination: WHO

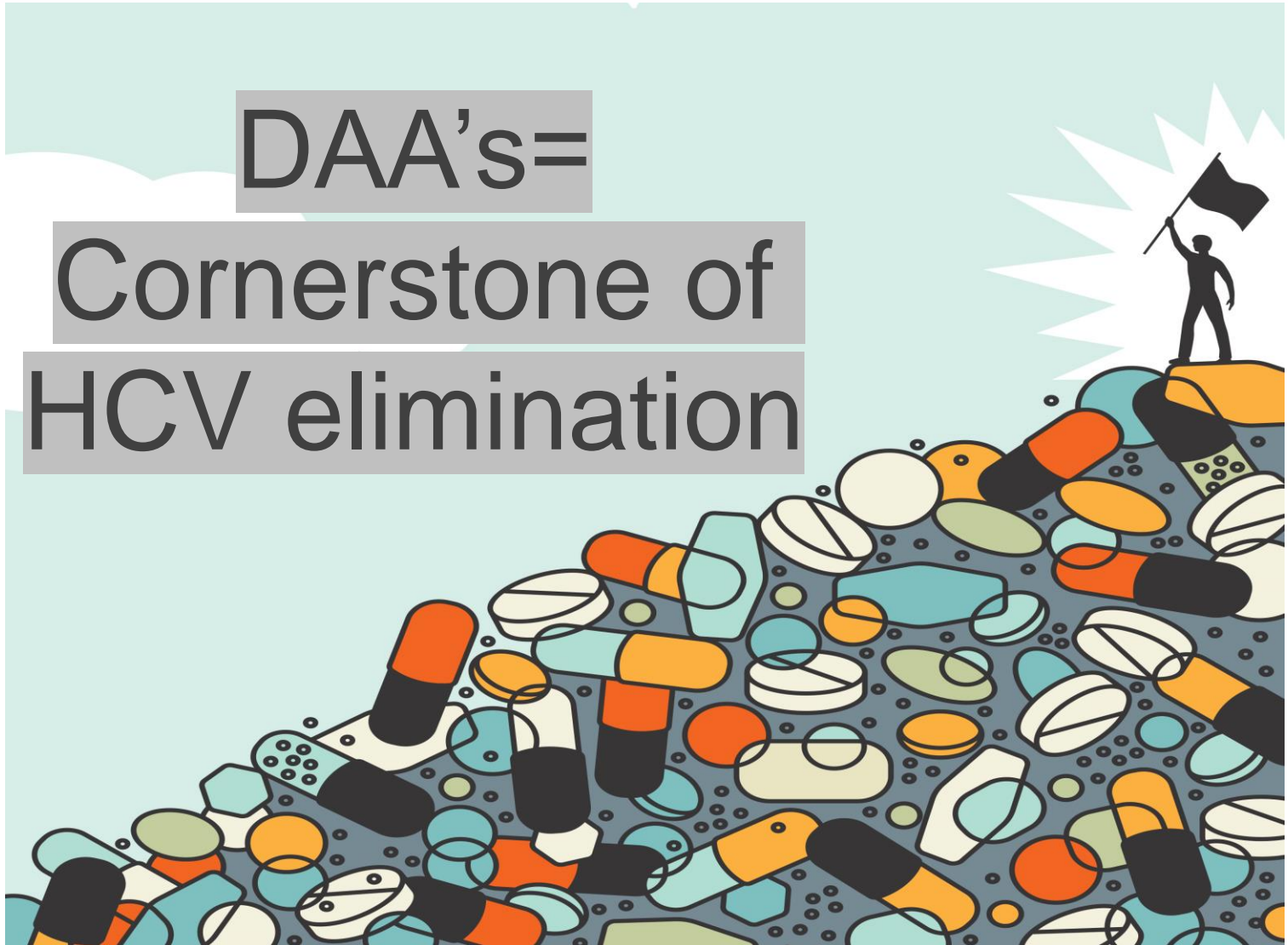
When will the United States achieve the WHO's elimination targets for hep C?



^aThe estimation may be less accurate owing to the small number of HCV patients in the area.
HCV, hepatitis C virus.

HCV Elimination: Direct-acting antivirals (DAAs)

DAA's=
Cornerstone of
HCV elimination



HCV Elimination: Direct-acting antivirals (DAAs)

We have the
muscle...
So how do
we flex???



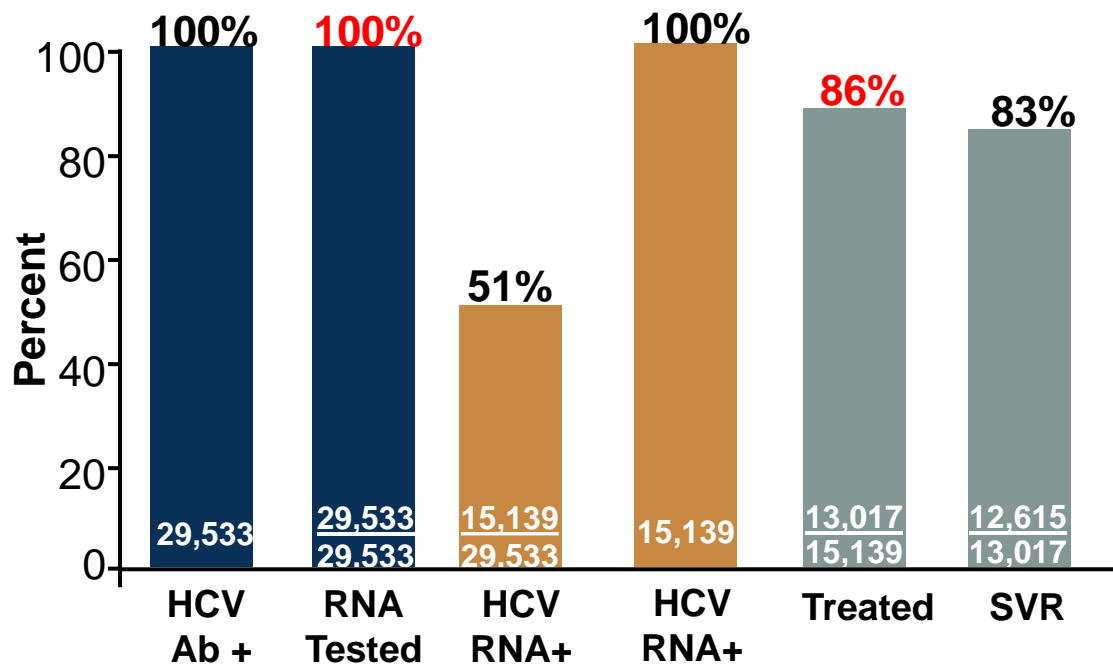
HCV Elimination: Micro-Elimination

- Reduces HCV incidence, prevalence, and mortality by tailoring health services to overcome barriers.
- Breaks down national elimination goals into smaller goals for individual population segments/groups
- Allows for treatment and prevention interventions to be delivered more quickly and efficiently

HCV Elimination: Micro- Elimination

Successful Micro-Elimination in Egypt

From June 2016-18 → 12-80 yo in 63 villages in 7 governates of Egypt were tested and treated



Key Components

- Community mobilization
- Free testing (reflex RNA)
- Linkage to care
- Free treatment
- Education campaign
- Prevention

Ongoing immense screening program: 45 million people tested in 6 months

HCV Elimination: 3-Pronged Approach

CRITICAL TO ANY HCV ELIMINATION PROGRAM

- Harm Reduction
 - Syringe Exchange Programs
 - PWID account for 75% of new HCV cases
 - Helps reduce the transmission of HCV
- Addiction Care
 - Medication Assisted Therapy
 - Counseling Services
- HCV Treatment
 - Emphasis on PWID

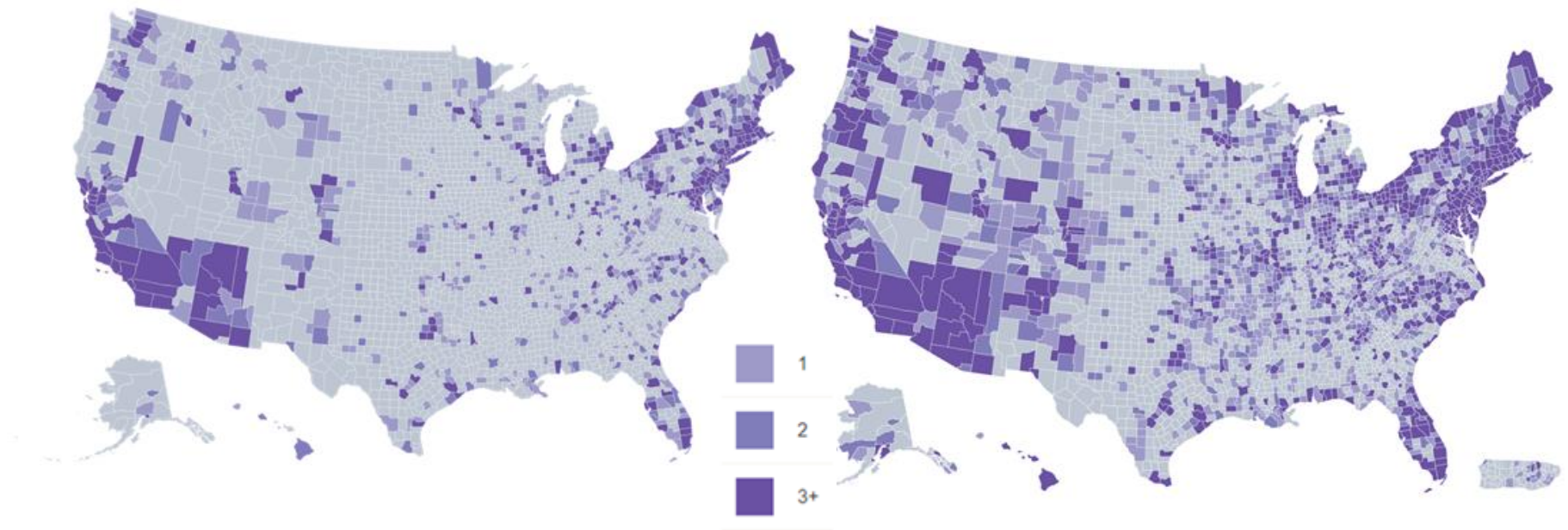


HCV Elimination: Harm Reduction

Medication Assisted Treatment

2009

2021



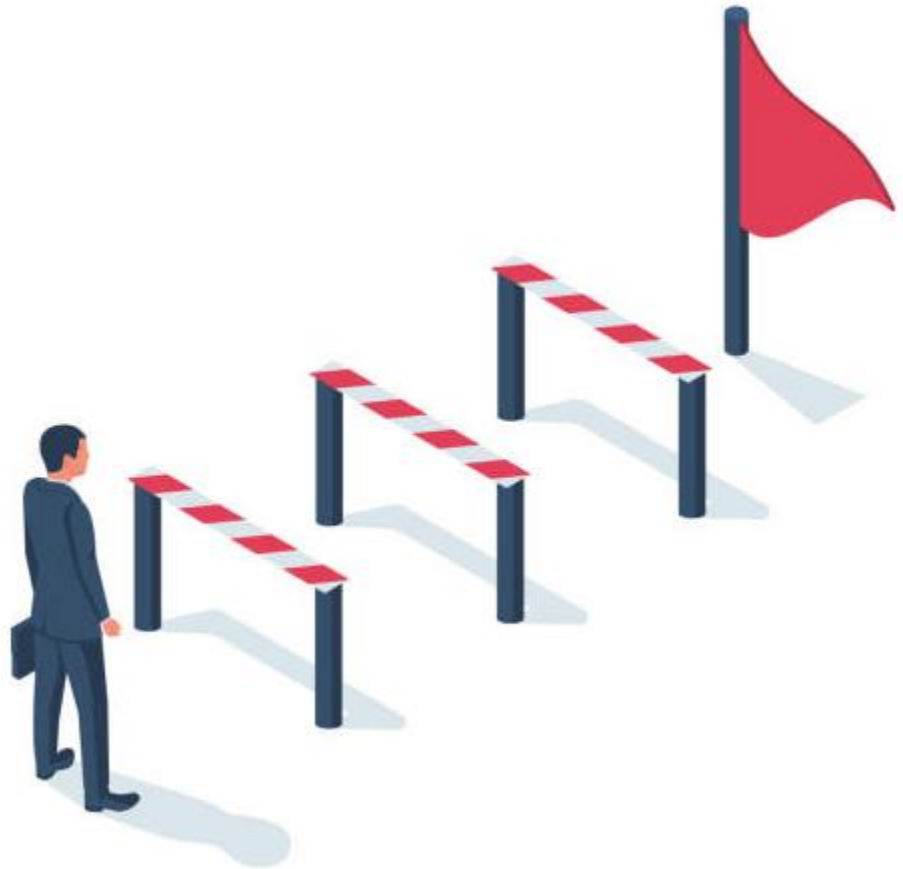
HCV Elimination: Barriers to Micro- Elimination

- “...especially critical for risk groups because the greatest obstacles to HCV control are the challenging social realities of those most affected by the disease.”
- Marginalized populations or sub-populations (i.e. PWID) are difficult to diagnose and link to care.
- Not a “one-size-fits-all” approach
- Data monitoring and improvement is CRITICAL!! Most countries don’t have accurate epidemiology data to assess potential populations for micro-elimination.

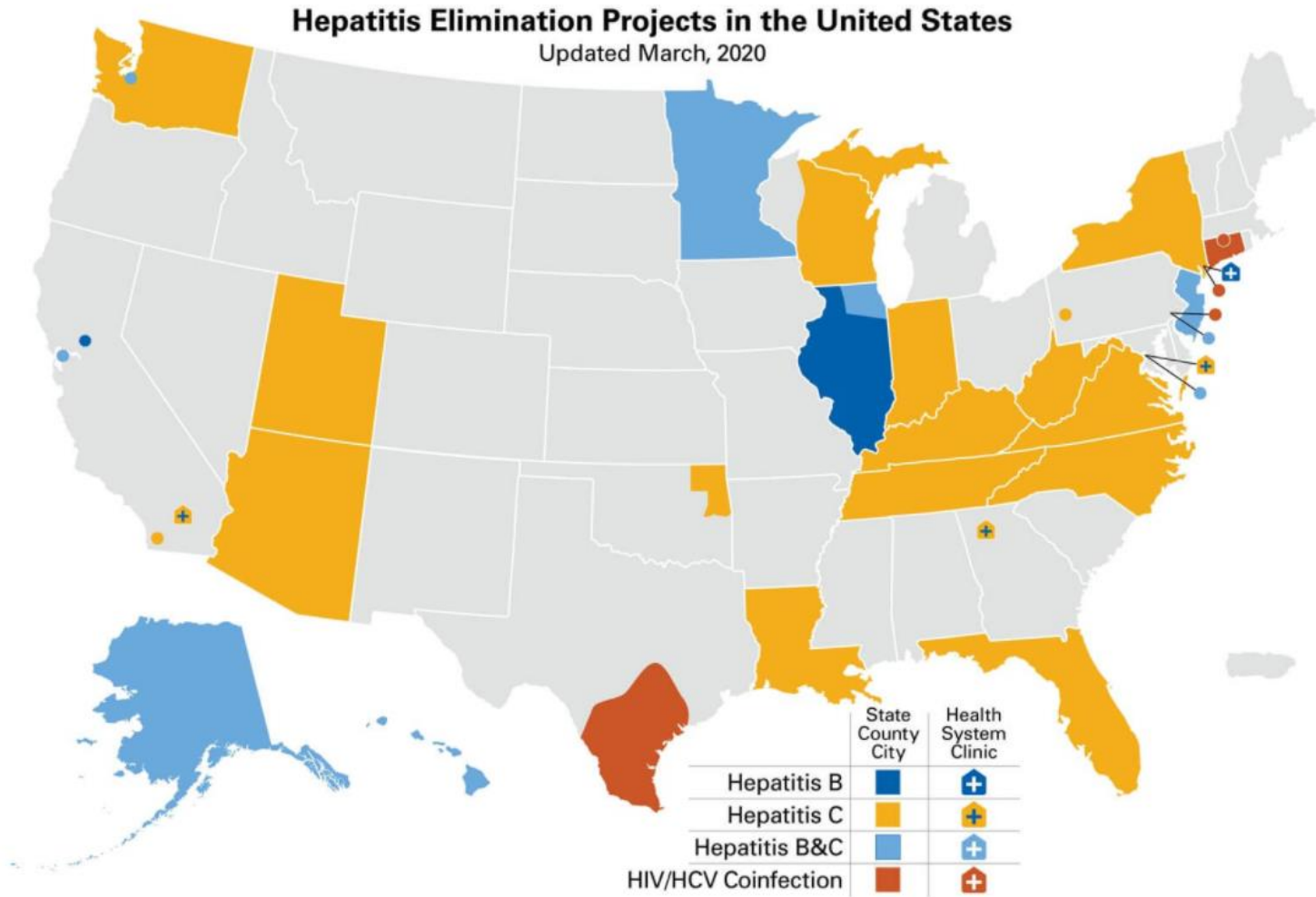
“The entire hepatitis elimination effort, micro- or otherwise, depends on improving the availability of reliable data to describe the epidemiology of HCV in a country.”

HCV Elimination: Other Barriers

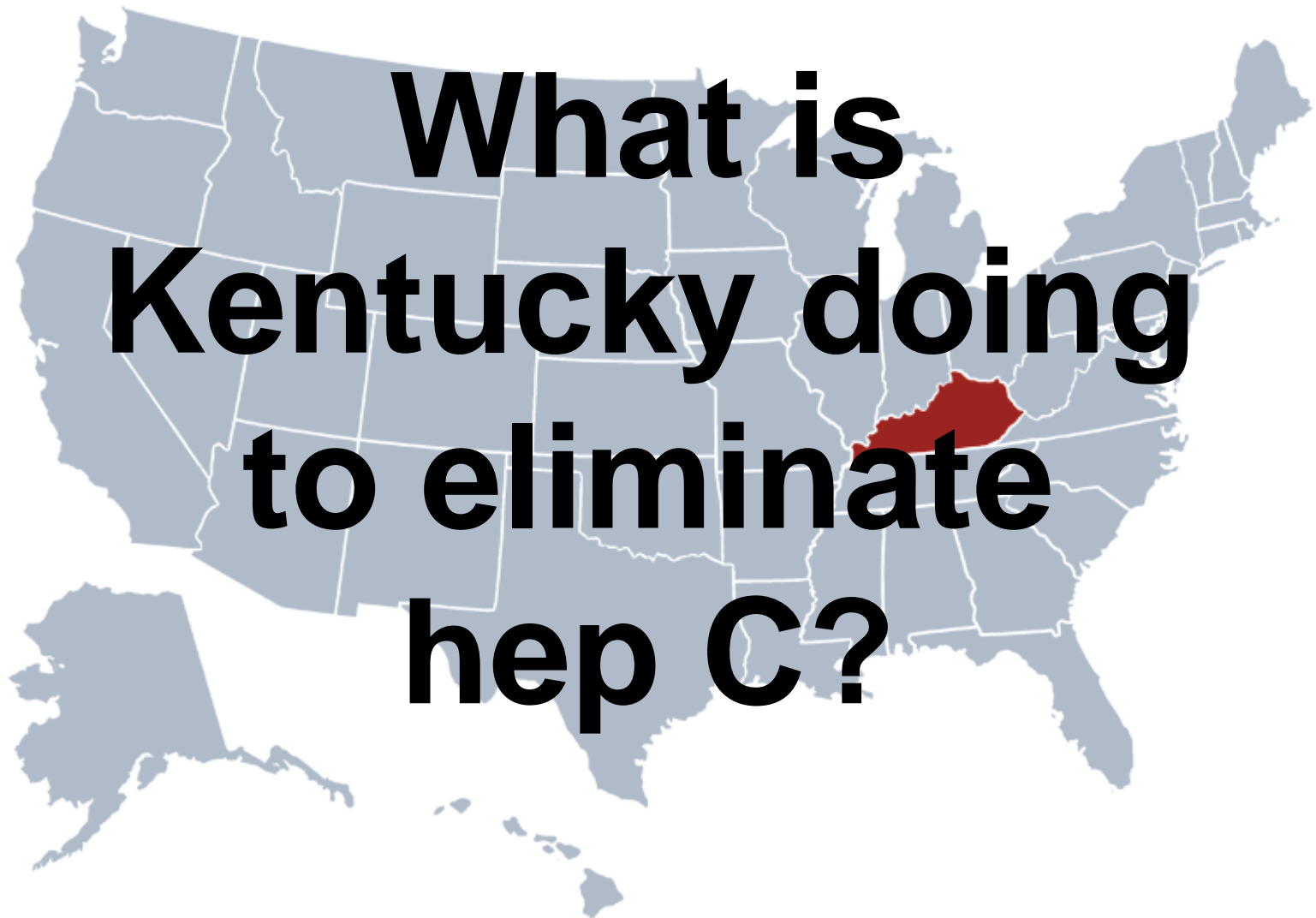
- Lack of awareness of HCV status
- Access to screening
- Stigma and discrimination
- Lack of SEP
- National elimination plan in the US does not exist
- Missed opportunities



HCV Elimination: States with plans



HCV Elimination: State Specific



**What is
Kentucky doing
to eliminate
hep C?**

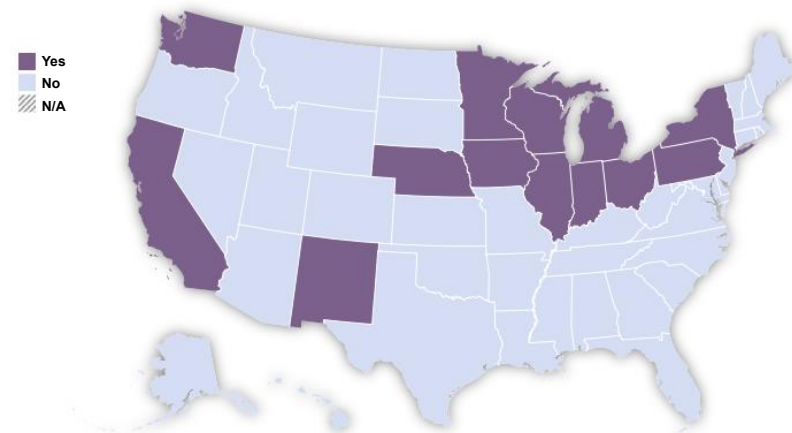
HCV Elimination Opportunities: Incarcerated Population

Hep C Antibody Prevalence



Hep C Screening at Intake

that is: Routine; Universal (Opt-out or Mandatory); since 2017

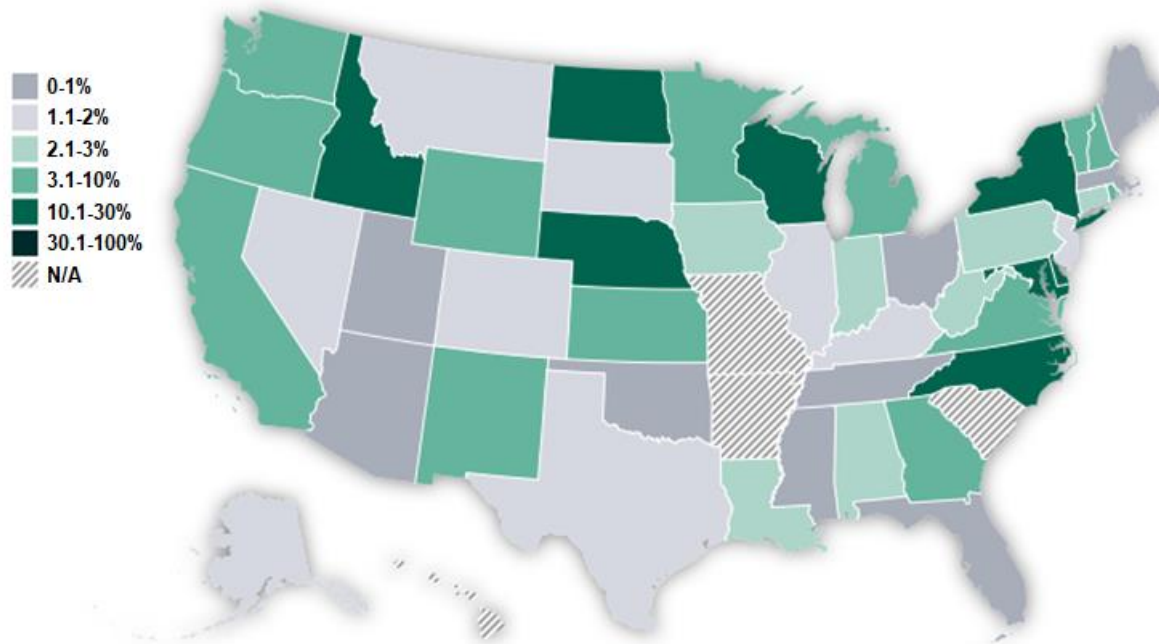


Kentucky

The state has a HCV prevalence in its prison population of **15.5%**. Data were last updated in **2017-2018**. Data source: STK.

HCV Elimination Opportunities: Incarcerated Population

Hep C Treatment



BOP Guidelines on HCV infection as of September 2018

Kentucky

% treated per year: **1.27%**
(of those infected)

% persons with viremia: **11.63%**

This state treated at least **34** people out of an estimated **2676** treatment candidates (1.27%) in FY2017.

Data source: Siraphob Thanthong-Knight

HCV Elimination Opportunities: Incarcerated Population

Appeals Court Upholds Rationing of Hepatitis C Treatment

The Kentucky Department of Corrections can deny a life-saving but expensive hepatitis C medication to inmates.

By [Associated Press](#) | July 10, 2021, at 11:18 a.m.



CINCINNATI (AP) — The [Kentucky](#) Department of Corrections can deny a life-saving but expensive hepatitis C medication to inmates, a federal appeals court ruled in a split decision. The dissenting judge in last week's 2-1 ruling at the 6th U.S. Circuit Court of Appeals said the majority's opinion will condemn hundreds of prisoners to long-term organ damage and suffering, The Courier-Journal reported.

Hepatitis C is the leading cause of liver transplantation and serious liver disease, including cirrhosis and liver cancer, and Kentucky has the highest infection rate in the United States. Newer treatments can cure nearly 100% of patients but cost \$13,000 to \$32,000. Because they cost so much, the Kentucky Department of Corrections has restricted use of the treatment to inmates with advanced liver scarring, or fibrosis.



HCV Elimination Opportunities: Pregnant Women



HEPATITIS C INFECTED PREGNANT WOMEN: FACTORS ASSOCIATED WITH LINKAGE-TO-CARE AFTER DELIVERY

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¹University of Louisville, Louisville, KY; ²University of South Florida, Tampa, FL

INTRODUCTION

Hepatitis C virus (HCV) infections have been increasing in women of childbearing age, especially in Appalachian United States¹. HCV can be transmitted from mother-to-baby during pregnancy².

- Kentucky was the first state to mandate HCV screening in pregnant women³

With increasing identification of HCV infected pregnant women, the University of Louisville (UofL) sought to develop a registry to enable a nurse-led linkage-to-care navigation program for both mothers and infants. Linkage-to-care is attending a first appointment with:

- Primary care provider
- Hepatitis care provider
- Mental health provider
- Addiction care provider

The specific aims of this study were to

- 1) to describe demographic factors such as age, ethnicity, substance use status, hepatitis C exposure or infection status, and insurance status for antepartum women;
- 2) and to determine if these factors correlate with the likelihood of linking-to-care.

METHODS

Secondary data analysis of the de-identified registry utilized univariate and bivariate statistics using SPSS version 25. Chi square and stratified chi square analysis was used to determine what relationships among variables were present. Data were collected January 2018-April 2019. The study was IRB approved as non-human subjects research.

RESULTS

97 HCV antibody positive women delivered during the study period:

- **89 (91.8%) had HCV RNA detected**

Demographics for HCV Infected Mothers:

- 88% (n=78) were white, 12 % were black (n=11)
- 77.3% (n=75) were not married
- 80.4% (n=78) had Medicaid insurance
- 25.8% (n=25) women reported using methamphetamine; 19.8% (n=19) reported using heroin during pregnancy

History of Drug Injection



■ Ever Injected Drugs ■ Never Injected Drugs

Smoking Status



■ Smoker ■ Non-smoker

Substance Use During Pregnancy



■ Illicit Drug Use ■ No Illicit Drug Use

- **81.4% (79) of the women linked to care.**
- Women newly diagnosed with HCV infection (p=0.012) and/or not receiving prenatal care (p<0.001) were significantly less likely to link-to-care.
- There was no difference in linkage-to-care rate with respect to substance of abuse, current IDU, age, insurance status, marital status, educational attainment, or other factor.

CONCLUSION

- **HCV infected postpartum women successfully link-to-care despite history of/ ongoing substance use, and regardless of substance(s) used.**
- Receiving no prenatal care and/or learning of HCV infection at the time of delivery is associated with reduced linkage-to-care
- New strategies for linking women without prenatal care and those newly diagnosed with HCV infection are needed.
- HCV infection in pregnant women in Kentucky is highly associated with any history of injection drug use.

REFERENCES

1. Zibbell, J.E., Asher, A.K., Patel, R.C., Kupronis, B., Iqbal, K., Ward, J.W., & Holtzman, D. (2018). Increases in acute hepatitis C virus infection related to a growing opioid epidemic and associated injection drug use, United States, 2004 to 2014. *American Journal of Public Health*, 108(2), 175-181. doi: 10.2105/AJPH.2017.304132
2. Mavilia, M.G., & Wu, G.Y. (2017). Mechanisms and prevention of vertical transmission in chronic viral hepatitis. *Journal of Clinical and Translational Hepatology*, 5(2)2, 119-129. doi: 10.14218/JCTH.2016.00067
3. KRS § 214.160

ACKNOWLEDGEMENTS

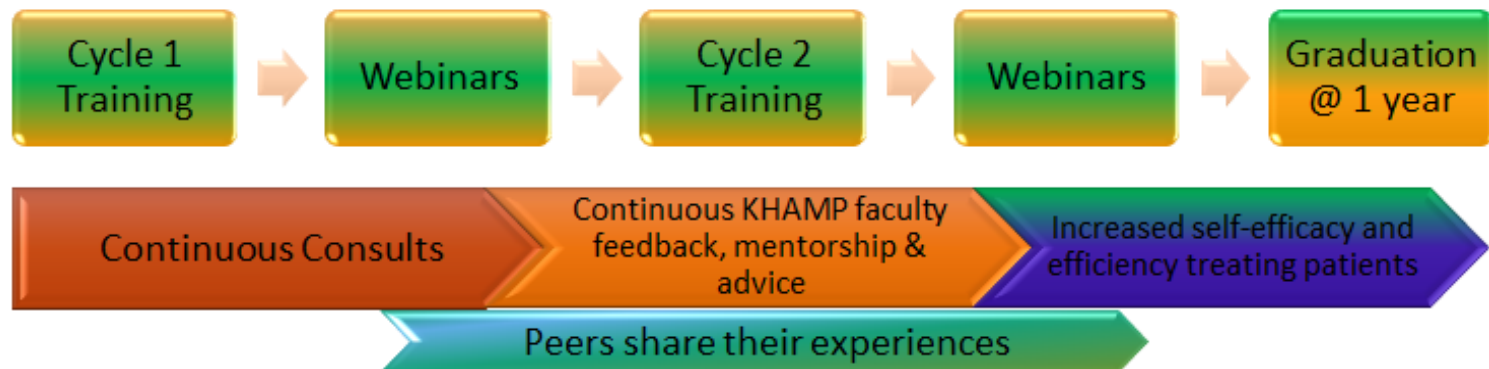
This work would not have been possible without a Gilead Frontlines of Communities in the United States (FOCUS) grant. The FOCUS grant helped us develop the registry and care navigation process from which the primary data source was created.

HCV Elimination Opportunities: Rural Areas



Kentucky Hepatitis Academic Mentorship Program

- Free, peer-based hepatitis C treatment training program for healthcare providers
- Mentorship and advice from hepatitis C treatment experts
- Allows increased access to care in high-risk, low-resource areas of Kentucky



HCV Elimination Opportunities: Hospitalized Population

UofL Health Inpatient Hep C Consultation Program

- Consultation service for inpatients with diagnosis of HCV (acute vs. chronic)
- Order placed in EMR by nurse or provider
- Hep C APRN will consult patient while hospitalized
- Provide education on HCV, harm reduction, treatment and cure
- Establish rapport
- **Linkage to care**



HCV Elimination Opportunities: Emergency Department

HEPATITIS C EXPOSURE AND OUTCOMES IN YOUNG ADULTS SEEN IN THE EMERGENCY DEPARTMENT

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Introduction

Kentucky is a national leader new cases of hepatitis C virus (HCV) infection. The University of Louisville Hospital Emergency Department (ED) implemented a program to increase HCV testing and diagnosis among young adults and linking those with infections to care.

The **specific aims** are

- 1) To estimate the prevalence of HCV Ab and HCV RNA in patients who are aged 18-45 years seen at the ED.
- 2) To describe demographic factors such as age, ethnicity, substance use status, and insurance status among HCV RNA positive patients in this age group.
- 3) To determine if these factors correlate with the likelihood of linking-to-care.

Methods

The hospital electronic medical record (EMR), Cerner, was modified to task a nurse-administered questionnaire as part of the ED triage process for adults aged 18-45. Patients had to be alert and oriented to complete the questionnaire.

Questionnaire:

- 1) Have you ever been told you have hepatitis C?
- 2) Have you ever had any tattoos or body piercings that were placed outside of a licensed business or by an unlicensed professional?
- 3) Have you ever been exposed to someone else's blood through your work or recreational activities?
- 4) Have you ever been told you liver enzymes (or liver tests were elevated)?
- 5) Have you ever, even just once or a very long time ago, injected or snorted drugs?
- 6) Have you lived with someone who has been diagnosed with HCV?

The EMR generated an order for HCV Ab for patients meeting the following criteria:

- 1) Completed ED triage questionnaire with at least one positive indicator
- 2) Did not opt-out
- 3) Had blood drawn as part of their care
- 4) Did not have a result for HCV Ab in the EMR from the past 90 days

Patients with HCV Ab were educated by a navigator on the meaning of the results.

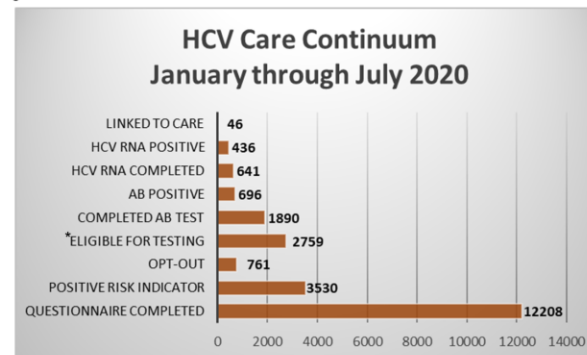
Those with HCV RNA were navigated to care through mental or addiction care services, primary care, or through an HCV treatment specialist.

Following IRB approval, a secondary data analysis on a de-identified database was completed. The database was queried for year of birth, race, ethnicity, gender, insurance status, presence of HCV antibody, HCV RNA status, tobacco use, alcohol use, substance use, incarceration status, linkage-to-care status and the type of organization linked to. Descriptive statistics were explored and chi square tests were performed to examine relationships among the variables.

Results

From 1/2020 through 7/2020, 3530 patients responding to the questionnaire indicated at least one positive indicator. 1890 unique individuals completed testing. 638 people were HCV Ab positive, representing a **36.8% HCV exposure rate** among those tested. HCV RNA was detected in 436 people, representing an **HCV infection prevalence of 23% among those tested**. 12.4% prevalence among those with a positive risk indicator, and an overall prevalence of 3.6%. The median age for HCV RNA positive patients was 34 years (IQR 29-39 years). 207 (71.6%) were male. There were no significant associations between gender, insurance status, substance use (including tobacco and alcohol), and incarceration status on HCV Ab or RNA prevalence; however, Black or African American patients were less likely to link-to-care ($p=0.046$), and those with any type of Medicaid insurance were more likely to link to care ($p=0.007$) during the study period.

Figure 1



*Patients were eligible for testing if they reported at least one risk indicator, did not opt out, had blood drawn as part of the visit, and had not had HCV Ab or PCR testing in the previous 90 days.

CONCLUSIONS

- The ED is an important place to detect HCV Ab and RNA in young adults.
- The rate of HCV exposure among young adults seen in this ED is high.
- Reflexing HCV Ab to HCV RNA is a best practice in the HCV care continuum.
- Research exploring factors associated with low rates of Black or African American patients linking to care is needed.
- A substantial time lag exists from the time of HCV diagnosis to linkage-to-care. Further work exploring timelines and factors associated with linkage are needed.

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Disclosures

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HCV Elimination: Can it happen?

“The simple reality is that progress toward the elimination of HCV will not occur at the same pace in all locations and all populations simultaneously. The strategic implementation of micro-elimination campaigns, the public tracking of their progress and the sharing of lessons learned from these efforts can generate the momentum needed for the entire world to achieve the WHO hepatitis C elimination targets by 2030.”



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Acknowledgments

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Discussion & Questions