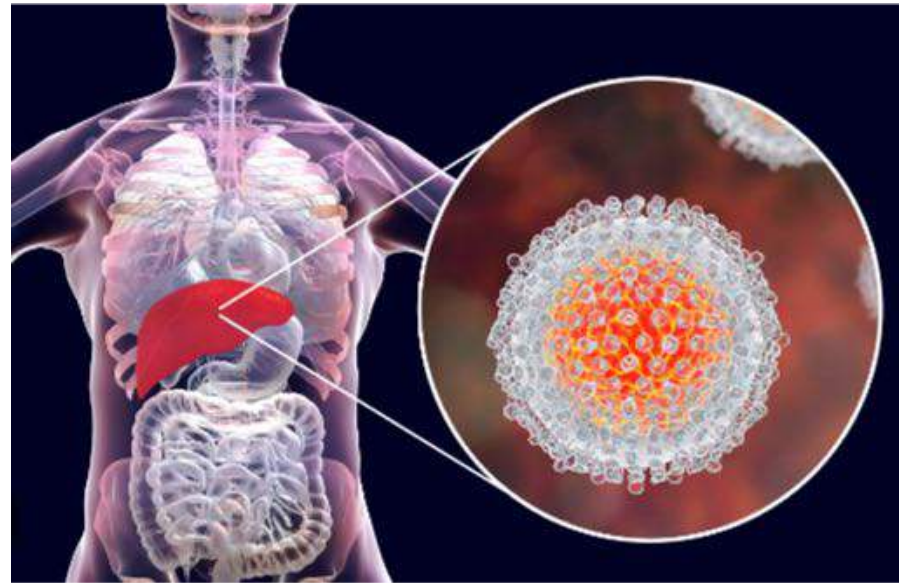


*A National Initiative
to Eliminate Hepatitis C in the
United States*



Briefing August 2023



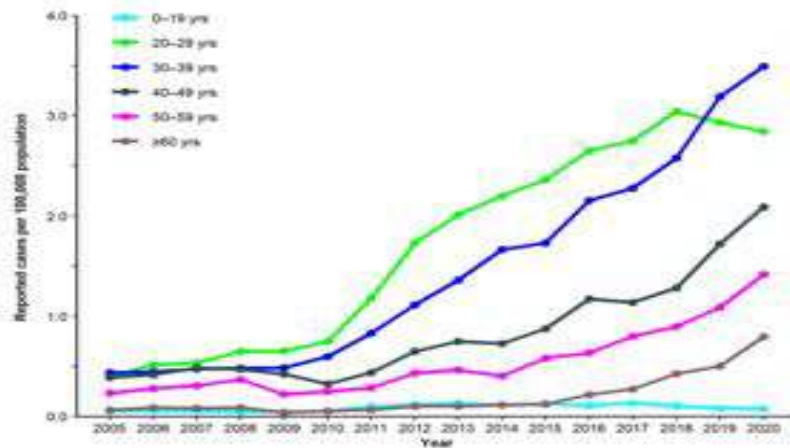
Hepatitis C is a Public Health Crisis in the United States

Slide credit: Division of Viral Hepatitis, CDC

Acute Infections

- Rate of reported acute hepatitis C cases **increased 400%** during 2010–2020
- Rates are highest among 20–39 year-olds

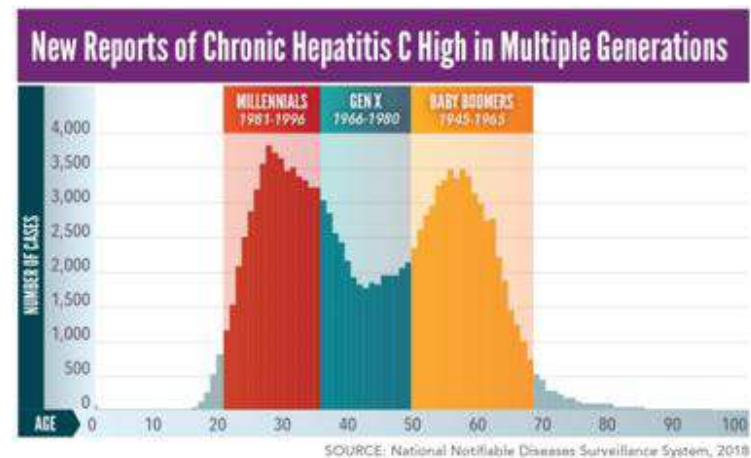
Rates of reported cases of acute hepatitis C virus infection, by age group – United States, 2005-2020



2020 data are provisional. Rates are per 100,000 population. Source: CDC, National Notifiable Diseases Surveillance System

Chronic Infections

- Estimated **2.4 - 3 million** (or possibly more) people living with hepatitis C
- About 40% of people with hepatitis C are unaware of their infection

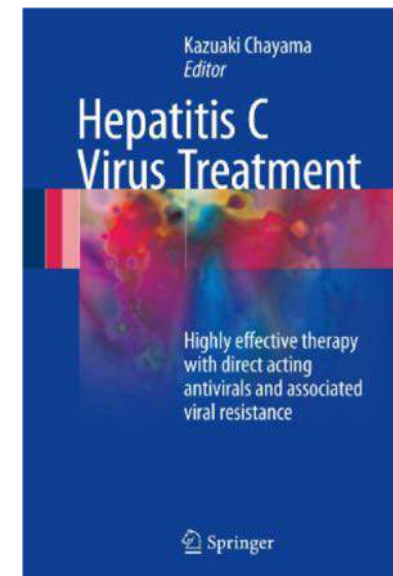
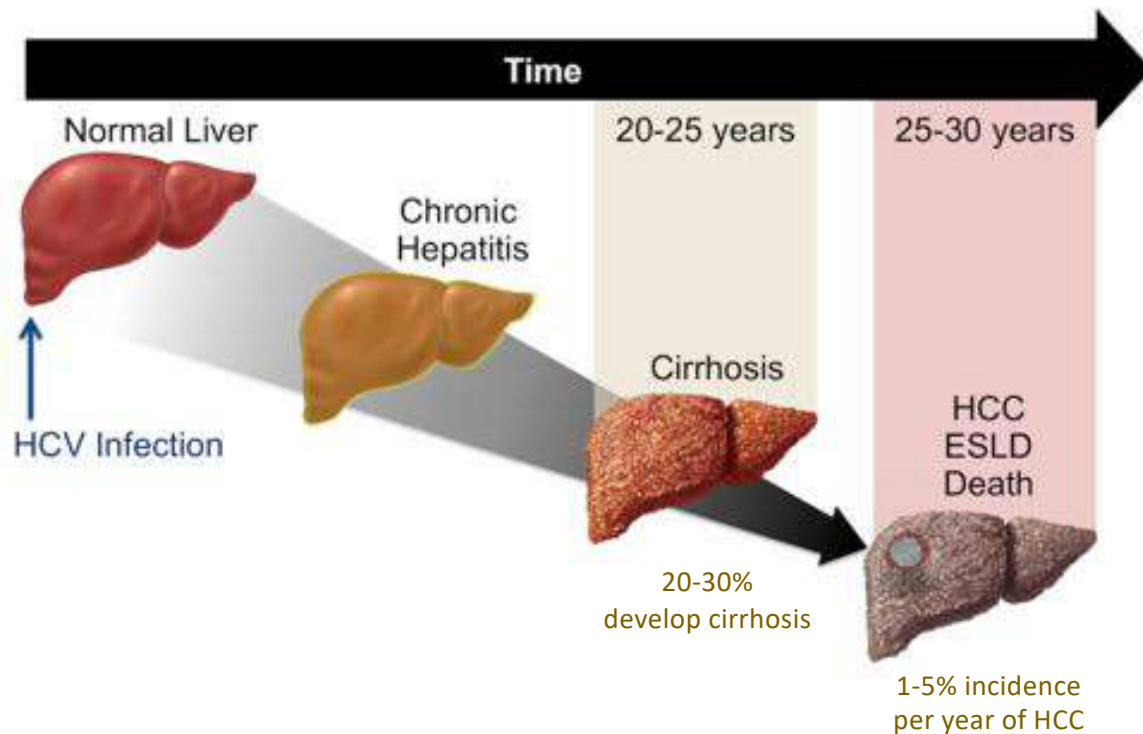


Sources: Hofmeister et al, Hepatology, 2018; Patel et al, CID, 2019; Ryerson et al, MMWR, 2020.



Hepatitis C Virus (HCV) Infection and Liver Disease

Untreated, chronic HCV infection leads to liver damage, liver cancer (HCC), and death



But now it's curable!

Slide credit: Division of Viral Hepatitis, CDC

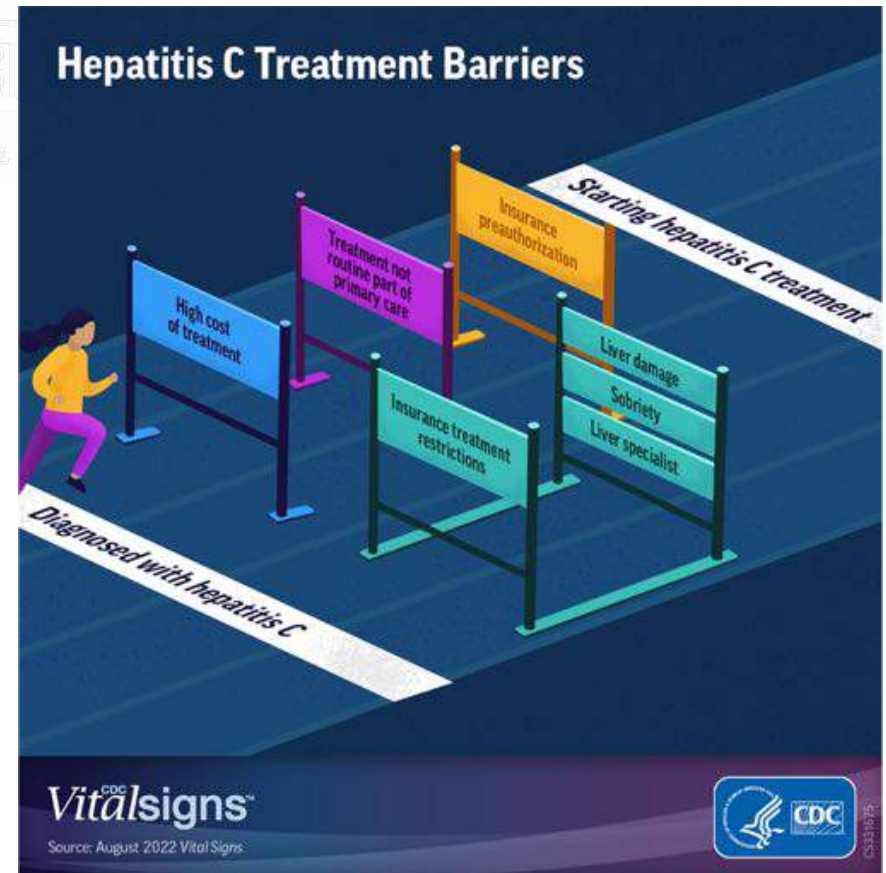
Source: www.hepatitis.uw.edu; HCC = hepatocellular carcinoma; ESLD = end-stage liver disease.



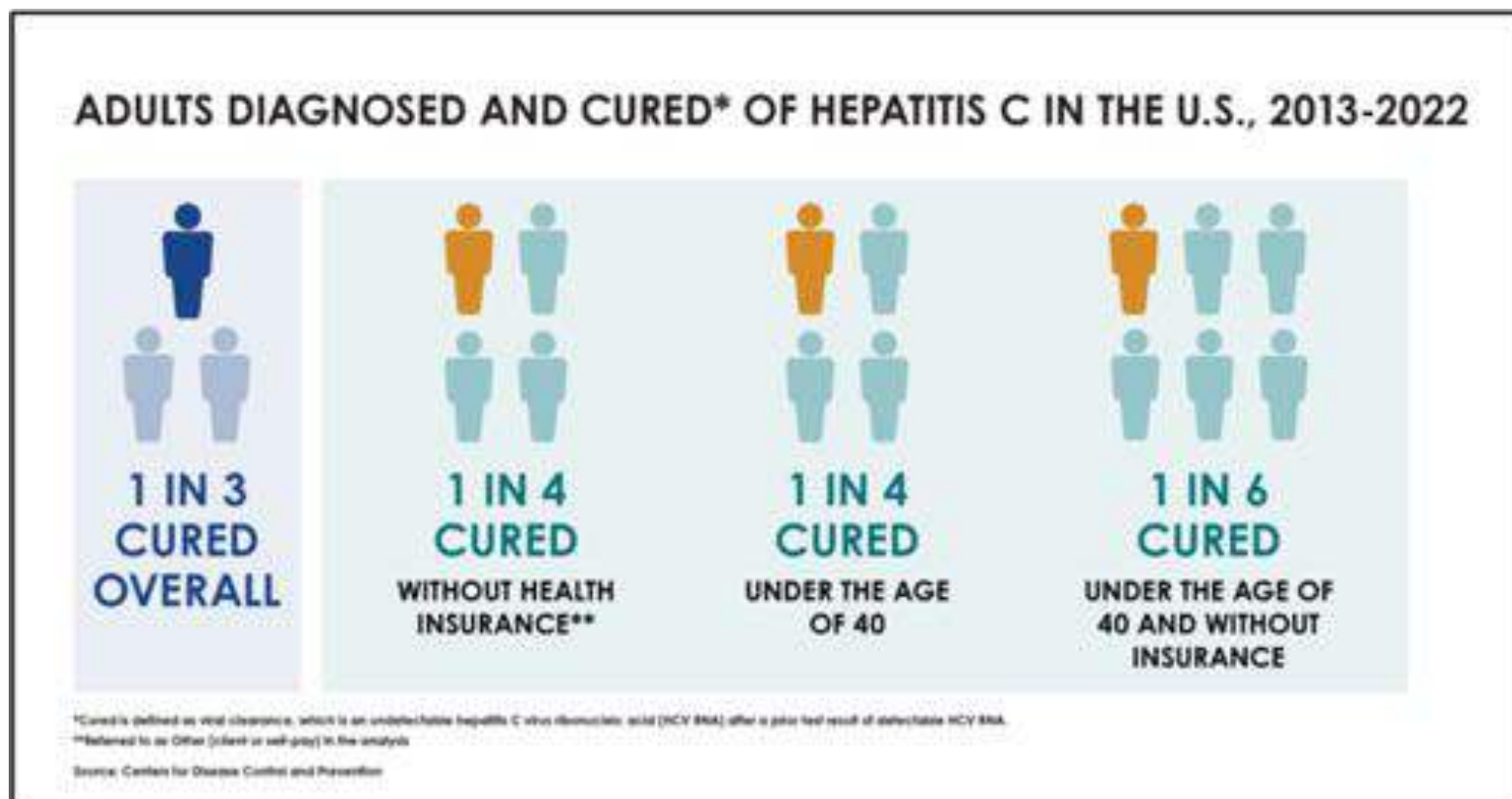
Hepatitis C is now curable! But the cure isn't reaching everyone

- **Lack of awareness** of condition (40% do not know they are infected)
- **Two step diagnosis**, lack of point-of-care diagnostics, loss of contact
- **High cost** of treatment (initially \$90K, still \$20K)
- Insurance treatment **restrictions** (liver damage, sobriety, pre-authorization requirements, specialist needed)
- Treatment not routine part of **primary care**
- **Underserved and hard-to-reach populations** including uninsured, people who inject drugs, justice-involved populations

Slide credit: Division of Viral Hepatitis, CDC



Hepatitis C Virus: Failure to Reach Most of Those Infected

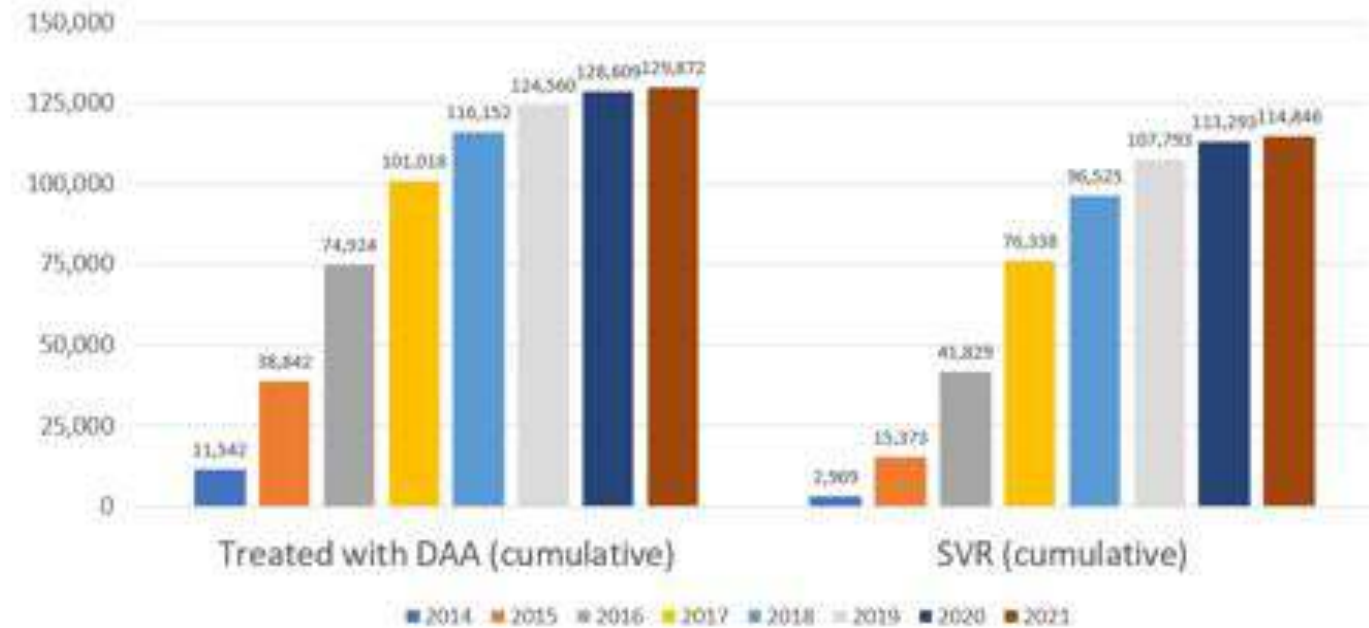




Veterans' Affairs Hepatitis C Elimination Program

Veterans' Administration, Hepatitis C elimination program (2014-2021)

Hepatitis C Treated (DAA) and SVR
VA 2014 – 2021 (March)



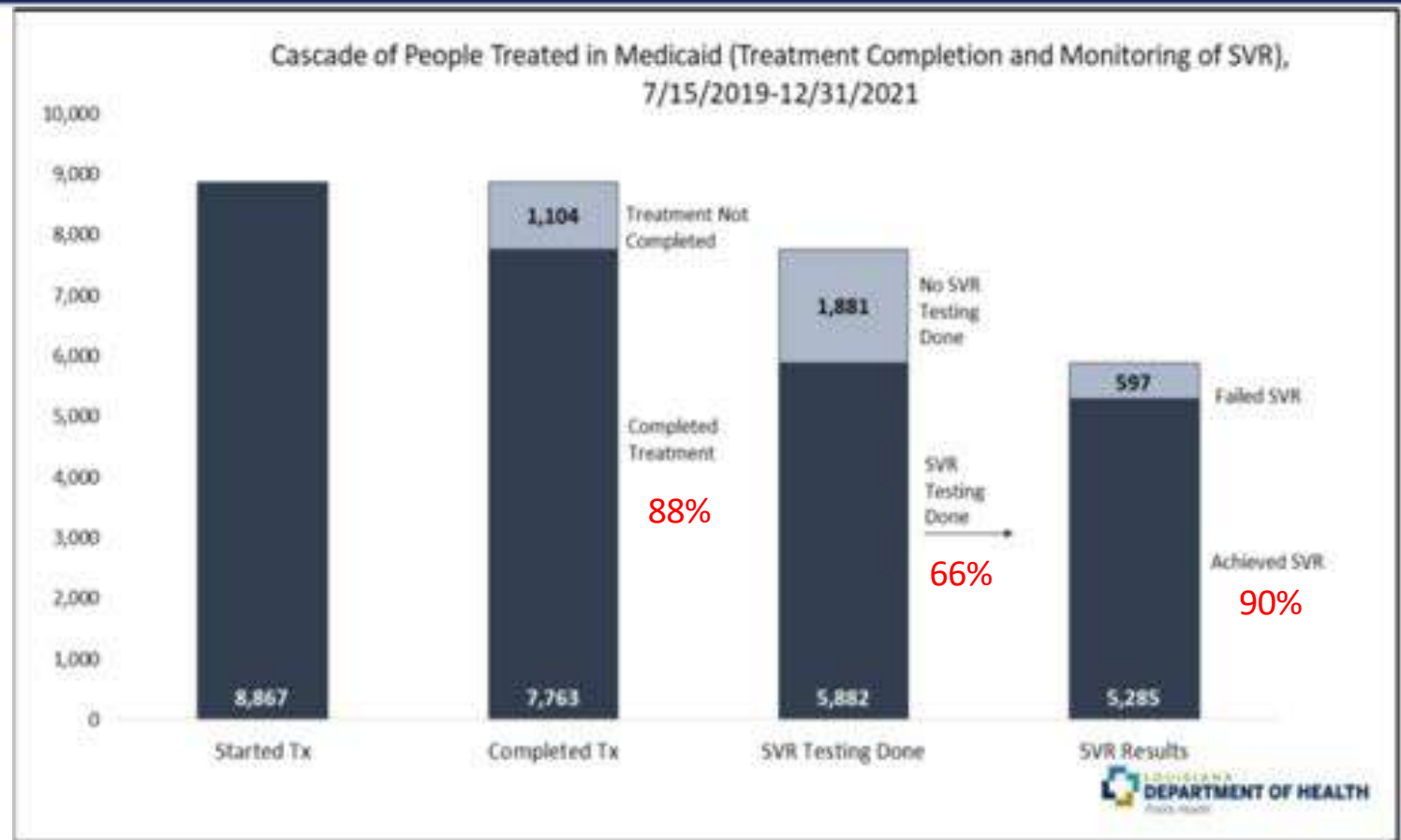
Acknowledgements: Veterans' Health Administration, Dr Tim Morgan, VA and Dr Pam Belperio, VA



Pilots show that this can work in the states

Louisiana,
Medicaid cohort,
2019-2021

SVR = sustained
virologic response

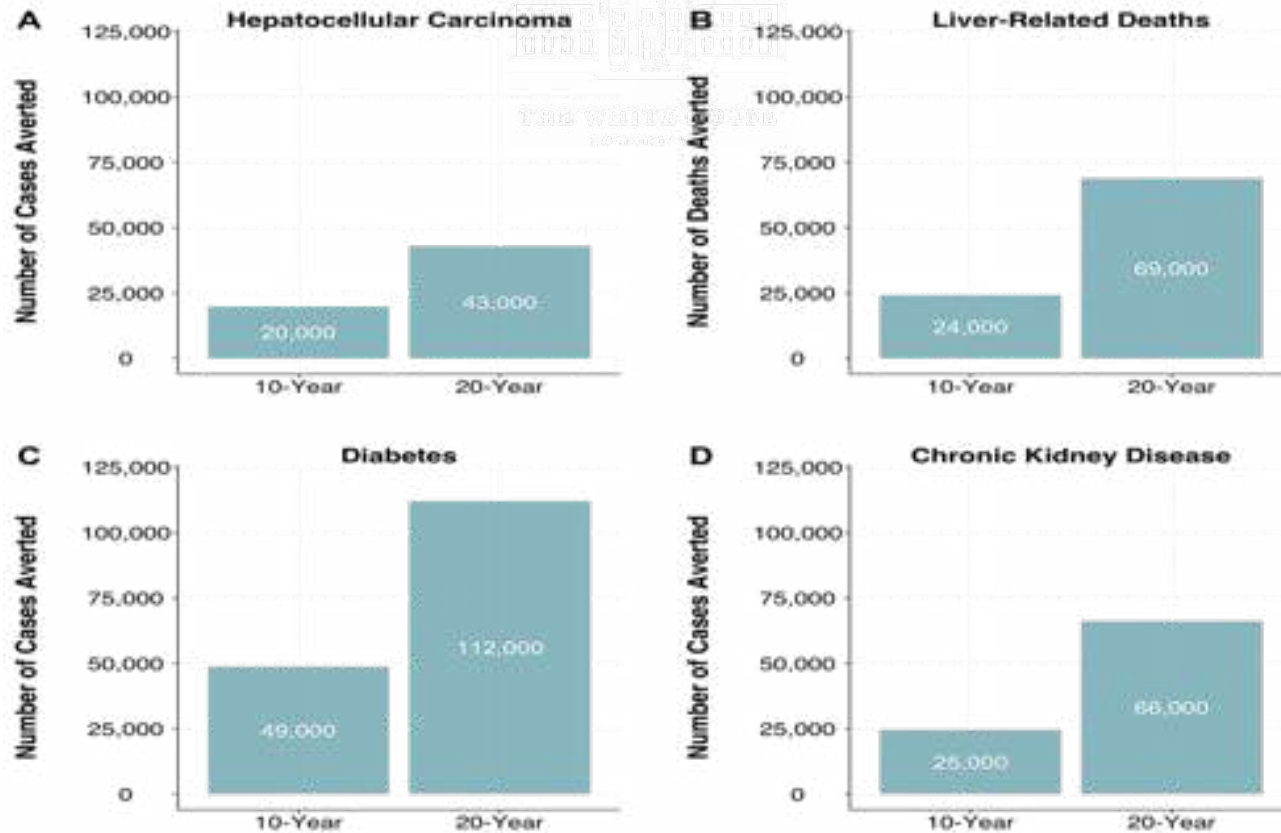


Acknowledgements: Louisiana Department of Health and Dr Risha Irvin, Johns Hopkins University



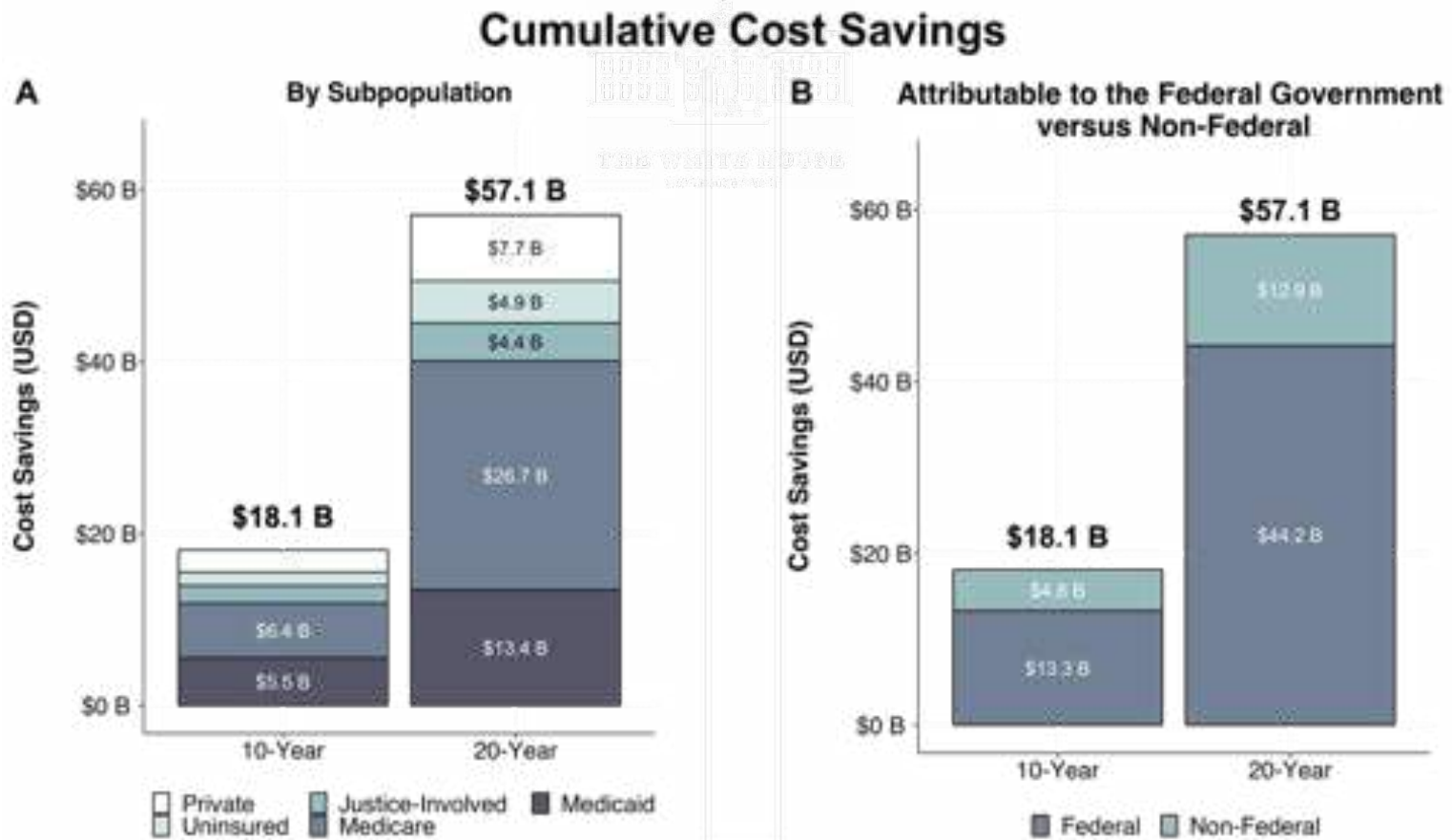
Economic benefits of a Hepatitis C elimination program: new analysis
Chhatwal et al. (2023) NBER Working Paper

Hepatitis C-Related Complications Averted



Economic benefits of a Hepatitis C elimination program: new analysis

Chhatwal et al. (2023) – NBER Working Paper





A Proposed National Initiative on Hepatitis C

VIEWPOINT

A National Hepatitis C Elimination Program in the United States: A Historic Opportunity

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One of the most dramatic scientific achievements of the last few decades has been the development of direct-acting antivirals (DAAs) that can cure hepatitis C in more than 95% of people infected. But 8 years after the first such treatment was approved in the United States, the simple 8- to 12-week oral cure is not reaching a significant fraction of the more than 2.4 million US residents chronically infected with hepatitis C.¹ More than 75 000 US residents die of hepatitis C every year unnecessarily. In its fiscal year 2024 budget proposal, the Biden-Harris administration has put forward a bold 5-year program to put the nation on course to eliminate hepatitis C in the United States.

The consequences of untreated hepatitis C can be severe: cirrhosis, liver failure, hepatocellular cancer, and death. Curative treatment stops transmission, prevents liver cancer and liver failure, and saves lives. It is overlikely to be cost-saving, by avoiding expensive medical treatments for liver failure and liver cancer. So why is this not a public health success story? One major reason is that many people with hepatitis C have poor access to health care and experience other chronic health and social

stressors. Only about one-third of people diagnosed with hepatitis C who have private insurance, Medicare, or Medicaid get treated, and the proportion is probably even lower for those without insurance.² This is in part due to current restrictions, such as requirements for patient sobriety, requirements to document evidence of liver fibrosis, and the restriction of access to treatment only to those seen by specialists, that have been put in place by public and private insurers in reaction to the high cost of DAAs (\$50 000 per patient initially, still around \$20 000). Low rates of treatment may also reflect the complexity of traversing the full cascade of care in our health care delivery system.

Addressing this missed opportunity can save both lives and money. A national effort can build on lessons from programs launched by jurisdictions such as the states of Louisiana and Washington, the Cherokee Nation, the Veterans Health Administration, and the Federal Bureau of Prisons. For example, the Veterans Health Administration has treated more than 92 000 veterans with hepatitis C virus since 2014, with cure rates exceeding 95%.³ A key lesson from these initiatives is that success requires both managing the cost of the medications and developing a comprehensive public health effort to identify persons with hepatitis C and link them to care.

To bring these efforts to a national scale, the Biden-Harris administration is calling on Congress to embrace its proposed 5-year program to eliminate hepatitis C in the United States. This program was developed through extensive con-

It is rare to have the opportunity, using a simple and safe oral medication, to eliminate a lethal disease. But that is the situation facing the United States with hepatitis C.

JAMA Published online March 9, 2023

Components of the National Initiative on Hepatitis C

1) Point-Of-Care (POC) diagnostic tests

- RNA POC tests not currently available in the United-States.
- Tests available outside of the US, including **fingerstick** sample collection
- Plan: leverage the **RADx ITAP program** to accelerate clearance and achieve reimbursement in the US.
- Enable hepatitis C **single-visit “test and treat” programs** to enhance cascade of care



Xpert HCV Viral Load test (manufactured by Cepheid, in use in Europe and Australia) is a point-of-care hepatitis C virus test that can detect active infection from a finger-stick sample of blood.

Components of the National Initiative on Hepatitis C

2) Providing broad access to curative hepatitis C medications

a) National subscription model

- **Fixed sum** for drug access negotiated by the US Government
- Follows Louisiana's "Netflix Model" – but for the **entire United States**
- Drugs to be made available to Medicaid beneficiaries, justice-involved populations, individuals in opioid treatment programs, the uninsured, and American Indians and Alaskan Natives.

b) Medicare Co-Pay Assistance

c) Commercial insurance



Direct Acting Antivirals



Components of the National Initiative on Hepatitis C (cont.)

3) Empower implementation efforts:

- Expansion of **screening strategies and settings**, especially for high-risk populations;
- Expansion of the **number of providers** using innovative telehealth methods such as the ECHO program;
- Expansion of the **number of community health workers** who can link people to care;
- Re-energizing of **vaccine research** and support for **preventive services**.





The Bottom Line....An Initiative to Eliminate Hepatitis C in the U.S.

Unless we take action, our system will be spending tens of billions of dollars for Hep C **care** over the coming decades – for people who are already infected.

How about instead we spend a few billion dollars now for Hep C **cure**?

It's the compassionate thing to do – we can prevent untold suffering and save tens of thousands of lives.

It's the economically wise thing to do – it's actually long term deficit reduction.

saveMoney
saveLife