

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

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*National Institutes of Health*

NASTAD Annual Meeting, May 23 2023





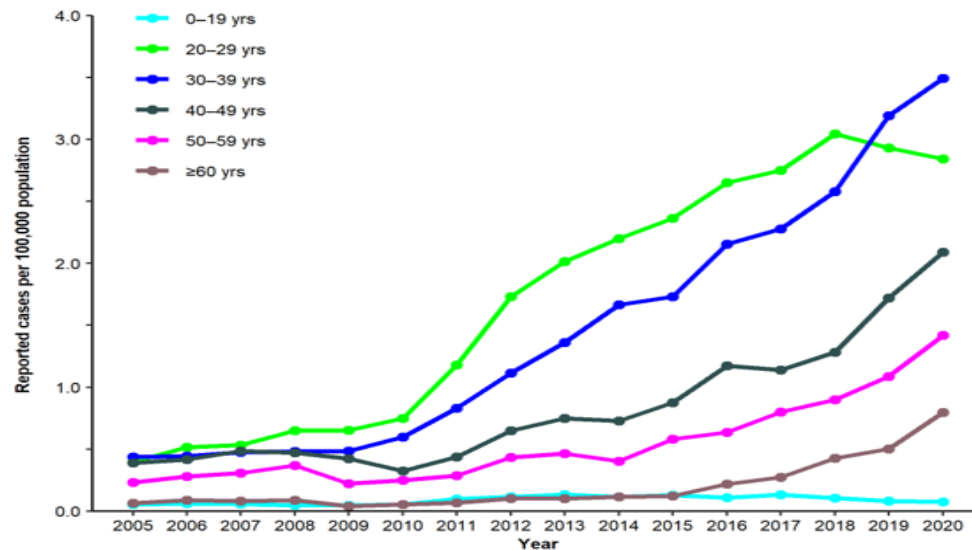
# Hepatitis C is a Public Health Crisis in the United States

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

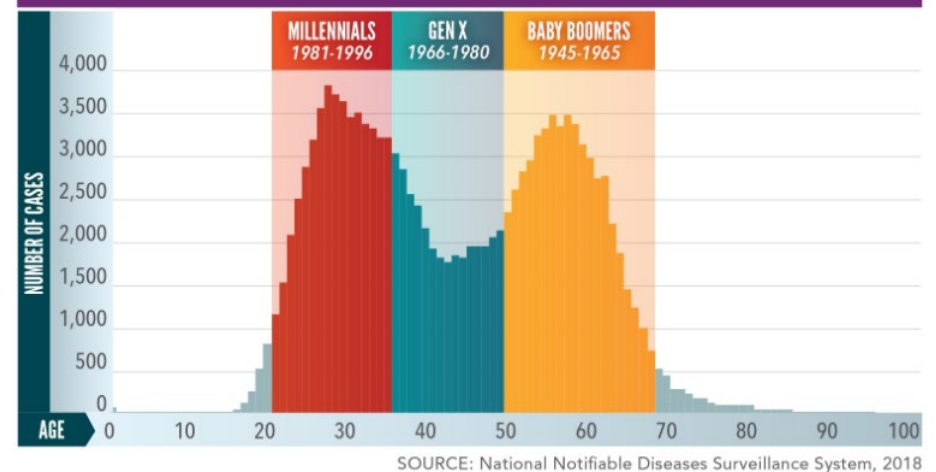


2020 data are provisional. Rates are per 100,000 population. Source: CDC, National Notifiable Diseases Surveillance System

## 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

### New Reports of Chronic Hepatitis C High in Multiple Generations



SOURCE: National Notifiable Diseases Surveillance System, 2018

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

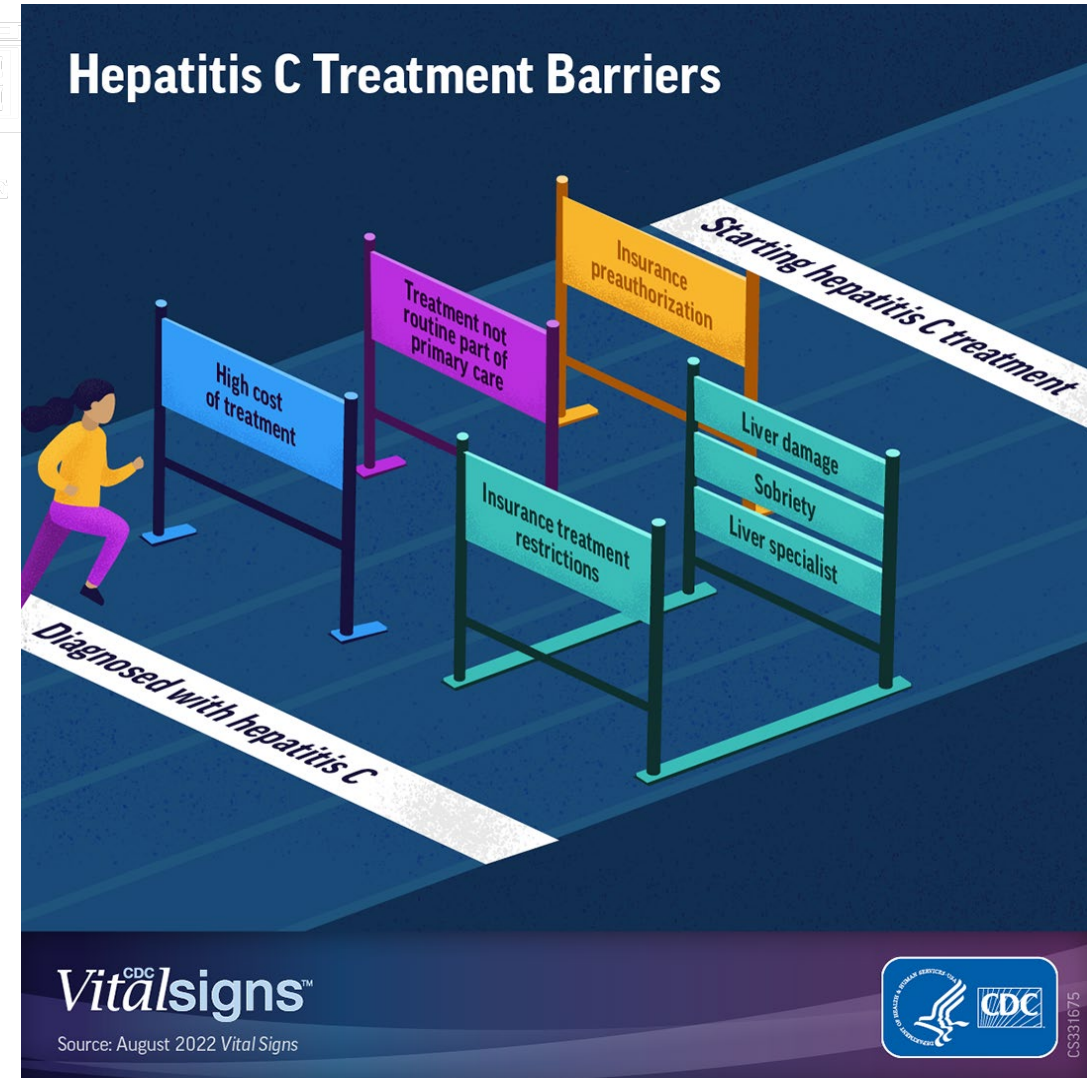


# Hepatitis C is now curable! But the cure isn't reaching everyone

- 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

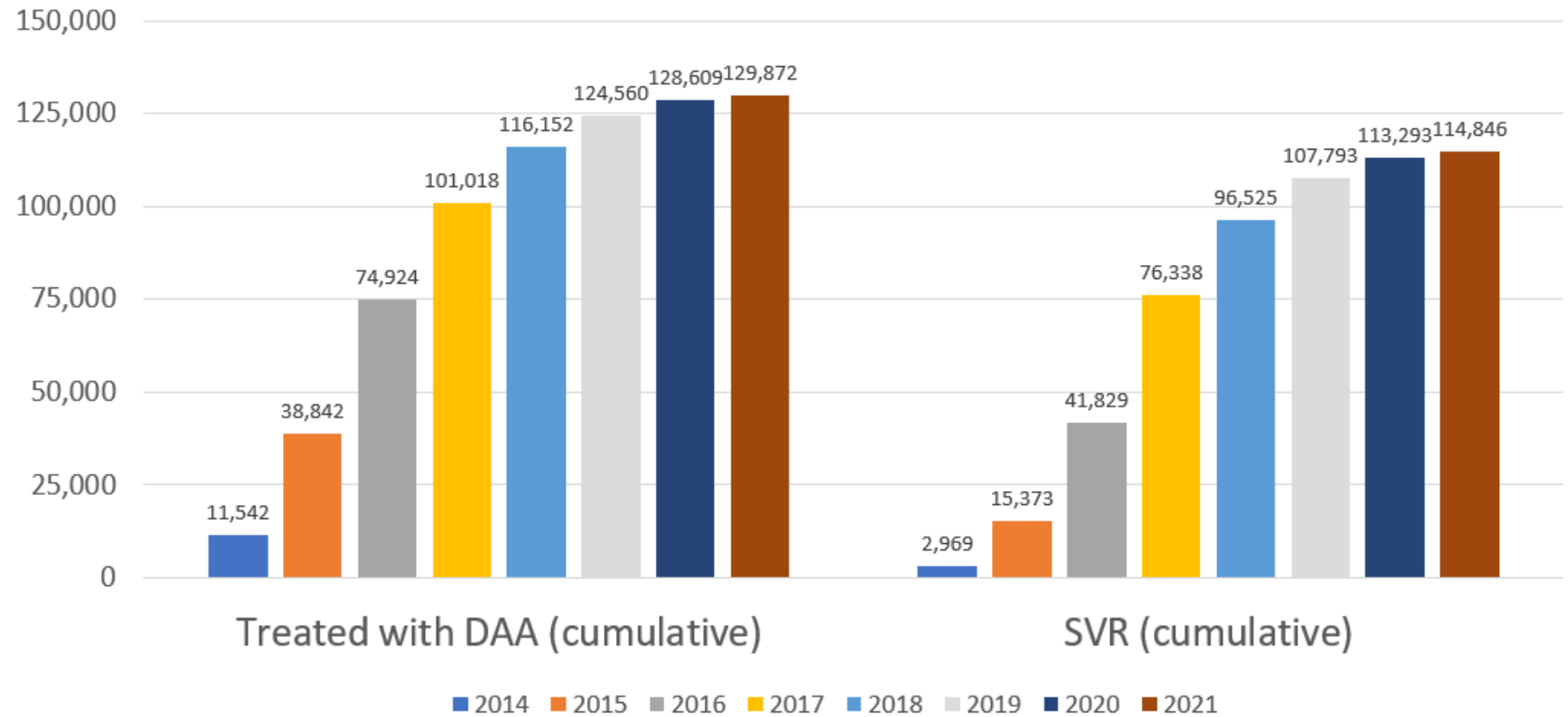




# Veterans' Affairs Hepatitis C Elimination Program

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

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



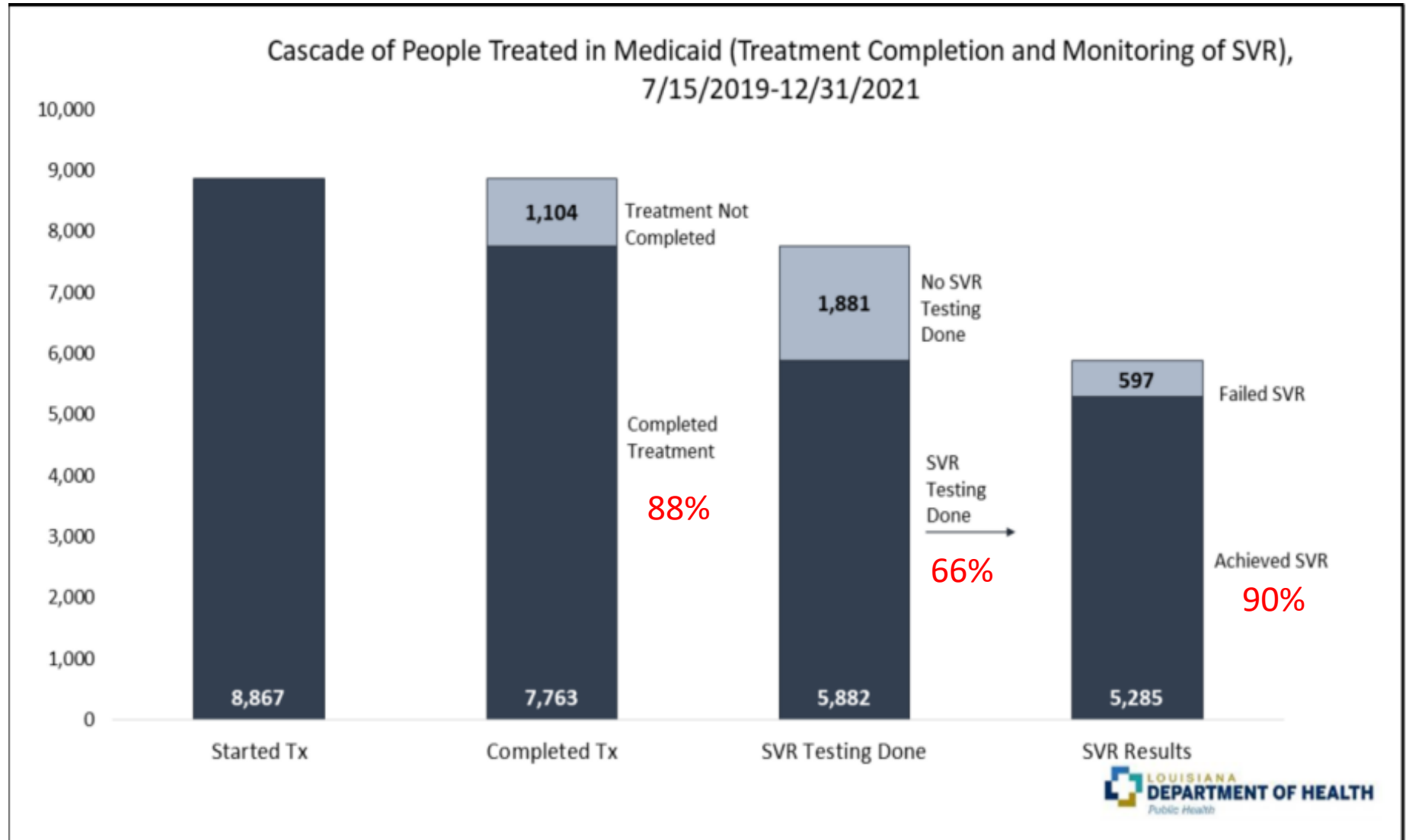
Acknowledgements: Veterans' Health Administration, Dr Tim Morgan, VA and Dr Pam Belperio, VA



# 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



# Other countries have embarked on national Hepatitis C elimination programs!



Public Health  
England

Protecting and improving the nation's health

## Hepatitis C in the UK 2020

Working to eliminate hepatitis C as a major public health threat

The NEW ENGLAND JOURNAL of MEDICINE

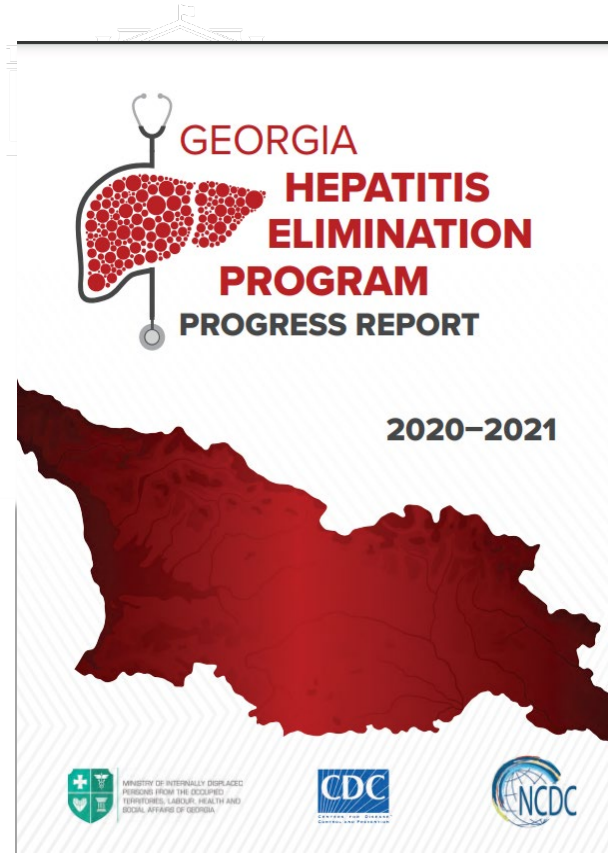
### SPECIAL REPORT

#### Screening and Treatment Program to Eliminate Hepatitis C in Egypt

Imam Waked, M.D., Gamal Esmat, M.D., Aisha Elsharkawy, M.D., Magdy El-Serafy, M.D., Wael Abdel-Razek, M.D., Reham Ghalab, M.Sc., Galal Elshishiney, M.Sc., Aysam Salah, B.Sc., Soad Abdel Megid, M.Sc., Khaled Kabil, M.Sc., Manal H. El-Sayed, M.D., Hany Dabbous, M.D., Yehia El Shazly, M.D., Mohamed Abo Sliman, M.Sc., Khalid Abou Hashem, M.Sc., Sayed Abdel Gawad, M.Sc., Nevine El Nahas, B.Sc., Ahmed El Sobky, M.Sc., Sahar El Sonbaty, M.Sc., Hamdy El Tabakh, M.Sc., Ehab Emad, M.Sc., Hany Gemeah, M.Sc., Amal Hashem, M.Sc., Mohamed Hassany, M.D., Naseif Hefnawy, M.Sc., Abdel N. Hemida, M.B., B.Ch., Ayman Khadary, M.B., B.Ch., Kamal Labib, M.B., B.Ch., Faisal Mahmoud, M.B., B.Ch., Said Mamoun, M.Sc., Tamer Marei, M.Sc., Saad Mekky, M.Sc., Alsayeda Meshref, M.Sc., Alaa Othman, M.Sc., Omnia Ragab, M.Sc., Elhag Ramadan, M.Sc., Ahmed Rehan, M.Sc., Tarek Saad, Ph.D., Ramy Saeed, M.Sc., Mohamed Sharshar, M.Sc., Hesham Shawky, M.Sc., Mohamed Shawky, M.Sc., Wael Shehata, B.Sc., Hanaa Soror, M.Sc., Mohsen Taha, M.Sc., Mahmoud Talha, M.Sc., Adel Tealaab, M.Sc., Mohamed Zein, M.D., Alaa Hashish, M.P.H., Ahmed Cordie, M.D., Yasser Omar, M.D., Ehab Kamal, M.D., Islam Ammar, M.D., Mohamed AbdAlla, M.D., Wafaa El Akel, M.D., Wahid Doss, M.D., and Hala Zaid, M.Sc.

Chronic hepatitis C virus (HCV) infection is a major global health problem affecting 1% of the world population.<sup>1-2</sup> The Sustainable Development Goals that were adopted by the United Nations

ment available for all and to scale up treatment to millions, as described previously.<sup>10</sup> More than 2 million patients were treated by 2018 (representing 40% of the total HCV-infected popula-





## Economic benefits of a Hepatitis C elimination program – prior publications

Clinical Gastroenterology and Hepatology 2017;15:827–837

### SYSTEMATIC REVIEWS AND META-ANALYSES

Fasiha Kanwal, Section Editor

#### Direct-Acting Antiviral Agents for Patients With Hepatitis C Virus Genotype 1 Infection Are Cost-Saving

Jagpreet Chhatwal,<sup>\*,†,§</sup> Tianhua He,<sup>||</sup> Chin Hur,<sup>\*,†,§</sup> and Maria A. Lopez-Olivo<sup>¶</sup>

#### Cost-effectiveness of direct-acting antivirals for chronic hepatitis C virus in the United States from a payer perspective

David E Kaplan, MD, MSc, FACP, AGAF, FAASLD; Marina Serper, MD; Ankita Kaushik, PhD; Claire Durkin, MD; Angie Raad, MSc; Fadoua EL-Moustaid, PhD; Nathaniel Smith, PhD; Alon Yehoshua, PharmD, MS

MILLIMAN WHITE PAPER

#### Costs and Considerations for Elimination of Hepatitis C Virus in the United States

A scenario analysis of the costs and timeline associated with hepatitis C elimination

Ryan Cloninger, Senior Pharmacy Benefits Analytics Manager  
Kristin Niakan, MPH, Senior Pharmacy Benefits Analytics Manager  
Kali Schweitzer, PharmD, Senior Managed Care Pharmacist  
Susan Silseth, FSA, MAAA, Senior Consulting Actuary

Commissioned by: Gilead Sciences, Inc.

- **2017 Systematic Review** concludes DAAs both save lives and reduce costs.
- **2022 Veterans' Affairs Study** concludes significant reduction in advanced liver disease and \$7-\$9 Billion cost savings (\$69,000 per cured vet) over 50 years in the VA. Cost savings as early as 5 years after treatment begins
- **2023 Milliman Report identified** savings from \$28 Billion to \$46 Billion (depending on the increased rates of testing and treatment) over 10 years. Over 30 years, the savings were even greater between \$226 and \$257 billion.

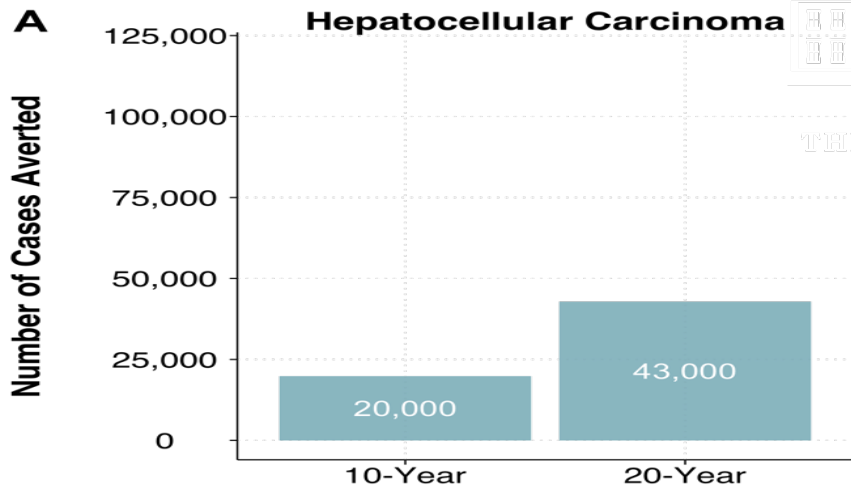


# Economic benefits of a Hepatitis C elimination program: new analysis

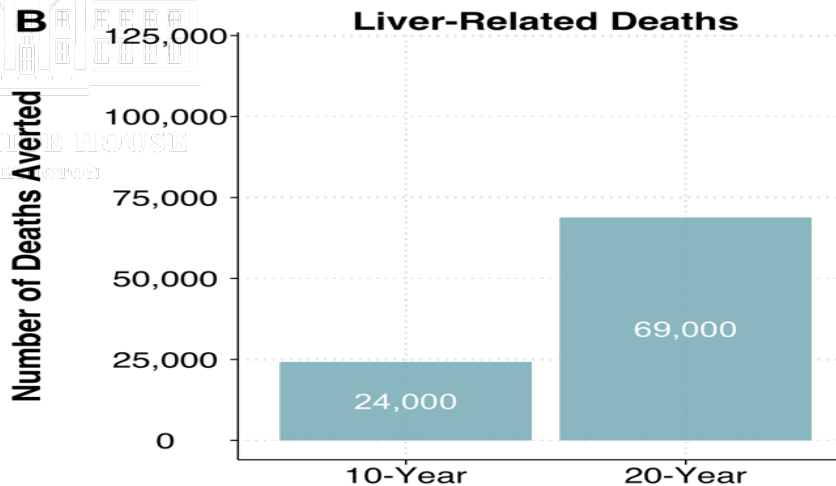
## Chhatwal et al. (2023) NBER Working Paper

### Hepatitis C-Related Complications Averted

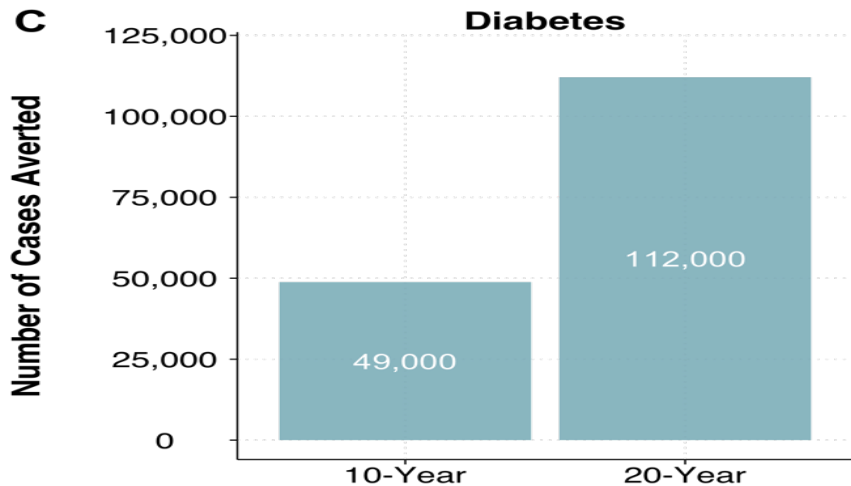
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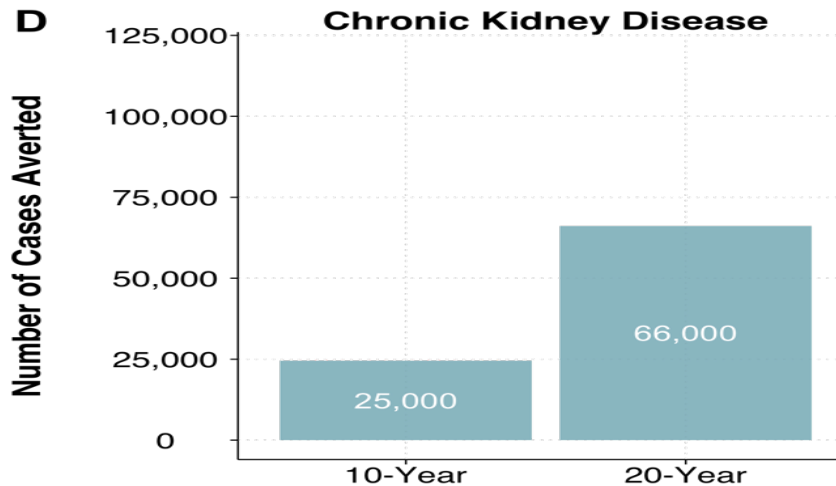
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**C**



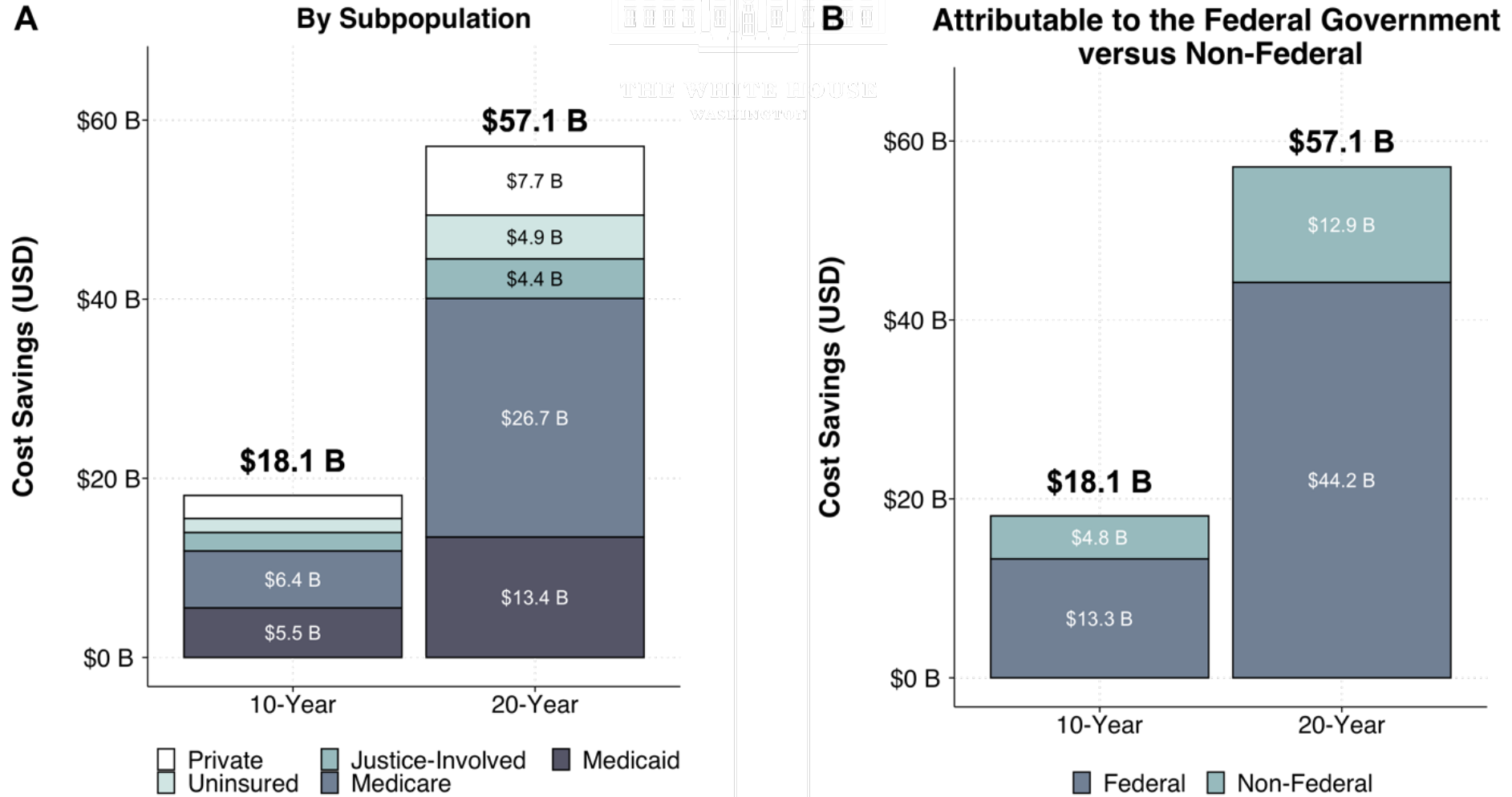
**D**





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

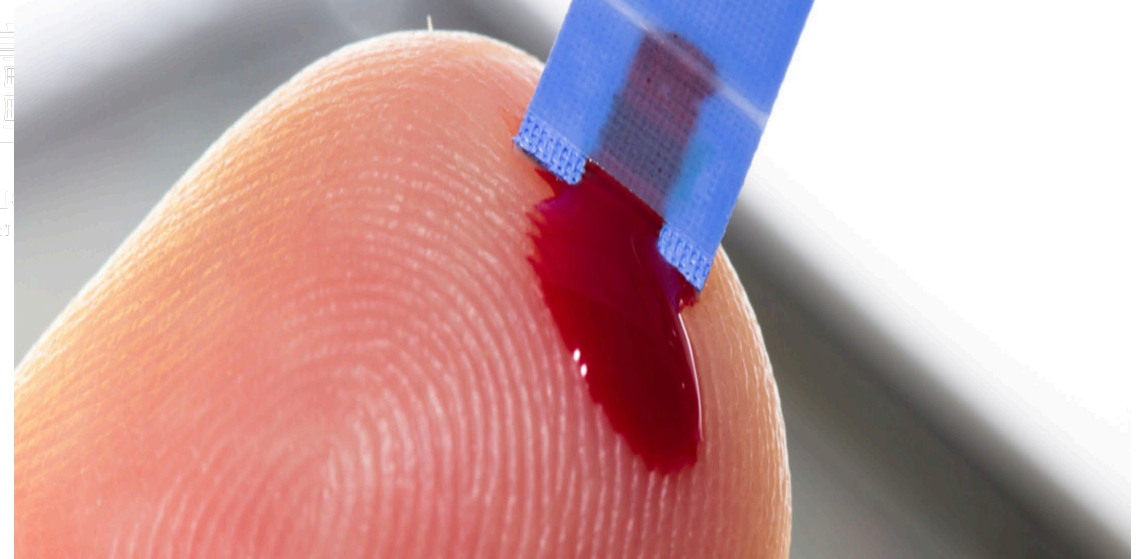
**Cumulative Cost Savings**



# Components of the President's National Initiative on Hepatitis C

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

- RNA POC tests are currently available in Europe and Australia, but not yet in the United-States.
- Plan: leverage the RADx ITAP program, with NIH, FDA and CMS, 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) is a point-of-care hepatitis C virus test that can detect active infection from a finger-stick sample of blood.

## 2) Providing broad access to curative hepatitis C medications



### a) National subscription model

- Federal government negotiates a fixed sum for drug access with participating manufacturers, following the model of Louisiana's so-called "Netflix Model" – but for the entire United States
- Already paid-for drugs are made readily 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

- Additional co-pay assistance is provided to Medicare beneficiaries for whom current costs are a barrier.

### c) Commercial insurance

- Private insurers will be strongly encouraged to increase coverage for hepatitis C testing and treatment, and to limit out-of-pocket costs.



## *Components of the President's National Initiative on Hepatitis C (cont.)*

**3) Empower implementation efforts:** To reach, test and treat all affected individuals, the initiative proposes to support the:

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



# Components of the President's National Initiative on Hepatitis C (cont.)

President's proposal is to seek Congressional approval for mandatory (non-discretionary) funding of this five-year initiative



- 1) Doesn't compete with other discretionary priorities
- 2) If can be approved, is funded for the entire period, not just year by year
- 3) Is not linked to annual Congressional budget process, could even be approved before October 1, 2023

**BUT – will need a favorable CBO score, compelling legislative language, and lots of bipartisan co-sponsors in both Houses.**

## VIEWPOINT

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

Rachael L. Fleurence, MSc, PhD  
Executive Office of the President, The White House, Washington, DC.

Francis S. Collins, MD, PhD  
Executive Office of the President, The White House, Washington, DC.

+ Multimedia  
+ Related article

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 9 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.<sup>1</sup> More than 15 000 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 even likely 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

tion goals. 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.<sup>4</sup> 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 (\$90 000 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 90%.<sup>5</sup> 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.



# Stakeholder Outreach

## Patient Advocacy Organizations:

American Liver Foundation  
Caring Ambassadors  
Coalition for Global Hepatitis Elimination  
DePauw University  
Hepatitis Appropriations Committee  
Hepatitis B Foundation  
Hepatitis C Mentor & Support Group, Inc.  
HIV and Hepatitis Policy Institute  
National Alliance of State and Territorial AIDS Directors (NASTAD)  
National Association of Community Health Centers  
National Harm Reduction Coalition  
National Viral Hepatitis Roundtable (NVHR)  
Philadelphia FIGHT Community Health Centers  
The AIDS Institute

Treatment Action Group

## Other Patient Advocacy Organizations

Access Support Network  
Digestive Disease National Coalition  
ekiM For Change  
End Hepatitis C  
Global Liver Institute  
Liver Coalition of San Diego  
National A Treatment Advocacy Program  
National Black Leadership Commission on Health  
NC Survivors Union  
Yakima Valley Farm Workers

## Professional Societies:

American Academy of Family Physicians (AAFP)

American Association for the Study of Liver Diseases (AASLD)

American Association of Medical Colleges (AAMC)

American Medical Association (AMA)

Infectious Diseases Society of America (IDSA)

Association of Schools and Programs in Public Health (ASPPH)

## State and Local Organizations:

Association of State and Territorial Officials (ASTHO)

National Academy for State Health Policy (NASHP)

National Association of Medicaid Directors (NAMD)



# Call to Action!

- A coalition led by the American Association for the Study of Liver Diseases (AASLD), the Association of Schools and Programs for Public Health (ASPPH), the National Viral Hepatitis Roundtable (NVHR) and the National Alliance of State & Territorial AIDS Directors (NASTAD) has formed to coordinate and activate the outreach of advocates and stakeholders to Congress.
- A sign-on letter has attracted more than 126 signatures (!) and has been sent to Congressional leadership.
- We hope we can count on your support for the national elimination program.
- **The time is now!**



To know what has to be done, then do it,  
comprises the whole philosophy of practical life.

-- *Sir William Osler*