

A National Initiative to Eliminate Hepatitis C in the United States

Rachael L. Fleurence, PhD, MSc

*Senior Advisor to Dr Francis Collins
National Institutes of Health*

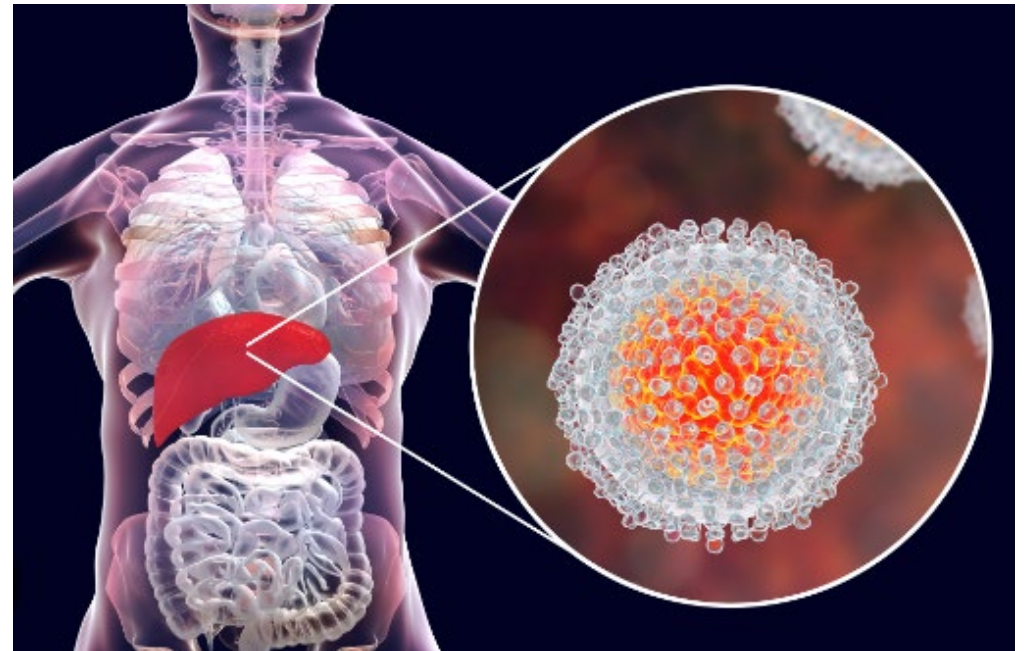
Joshua M. Sharfstein, MD

*Vice Dean for Public Health Practice and Community
Engagement*

Director, Bloomberg American Health Initiative

Professor of the Practice in Health Policy and Management

October 20, 2023





Outline

- Thank you for clinical trials on direct acting antiviral agents
- Description of Proposed National Hepatitis C Initiative
- Projection of Benefits
- Value of PCORnet
- Conclusion



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Thank
you!



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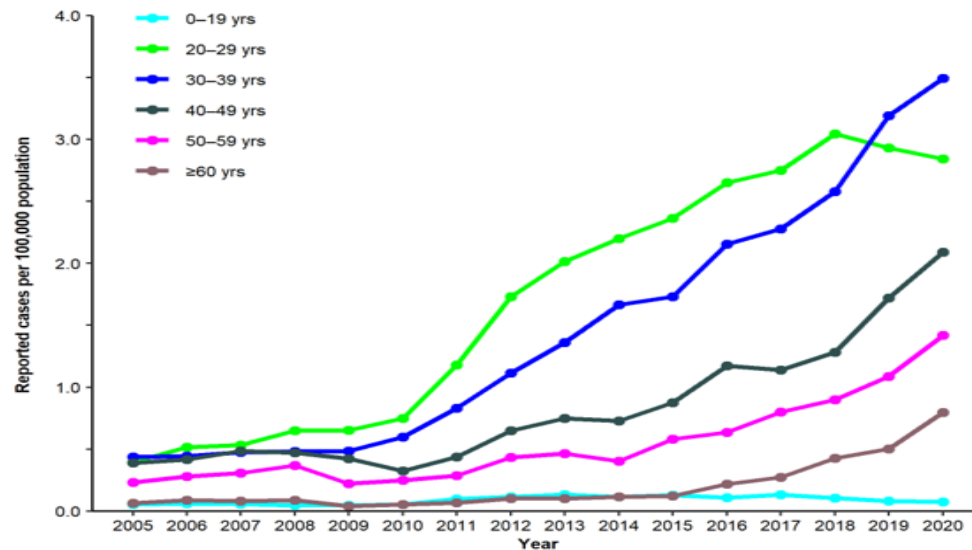
Hepatitis C is a Public Health Crisis in the United States

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

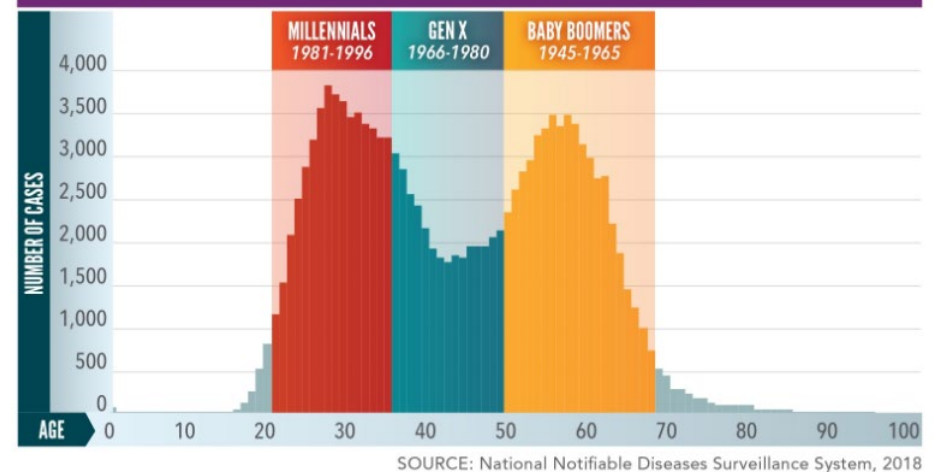


2020 data are provisional. Rates are per 100,000 population. Source: CDC, National Notifiable Diseases Surveillance System

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



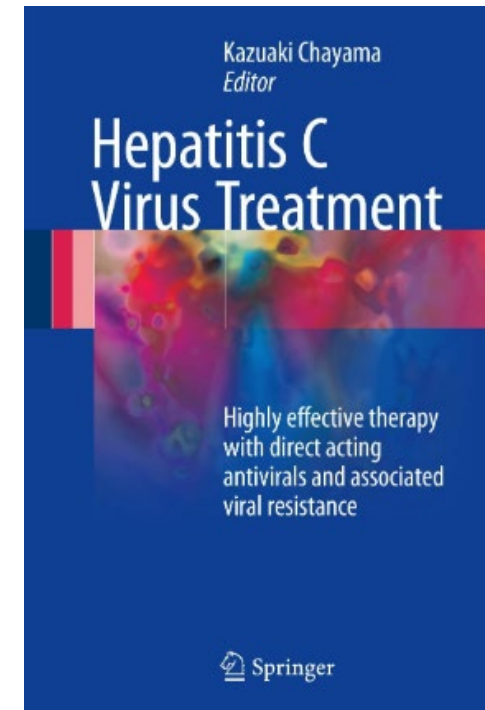
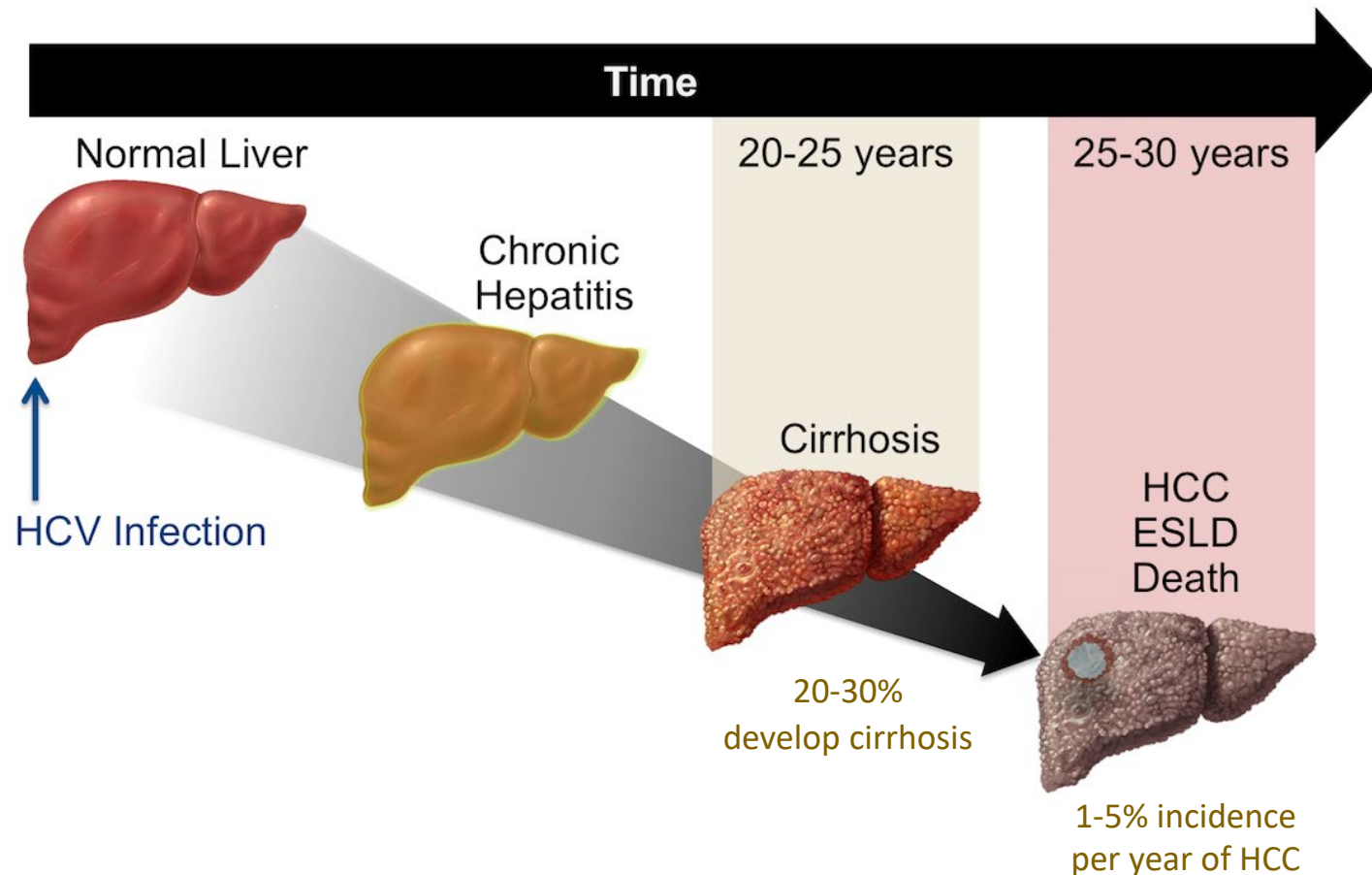
SOURCE: National Notifiable Diseases Surveillance System, 2018

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



Hepatitis C 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

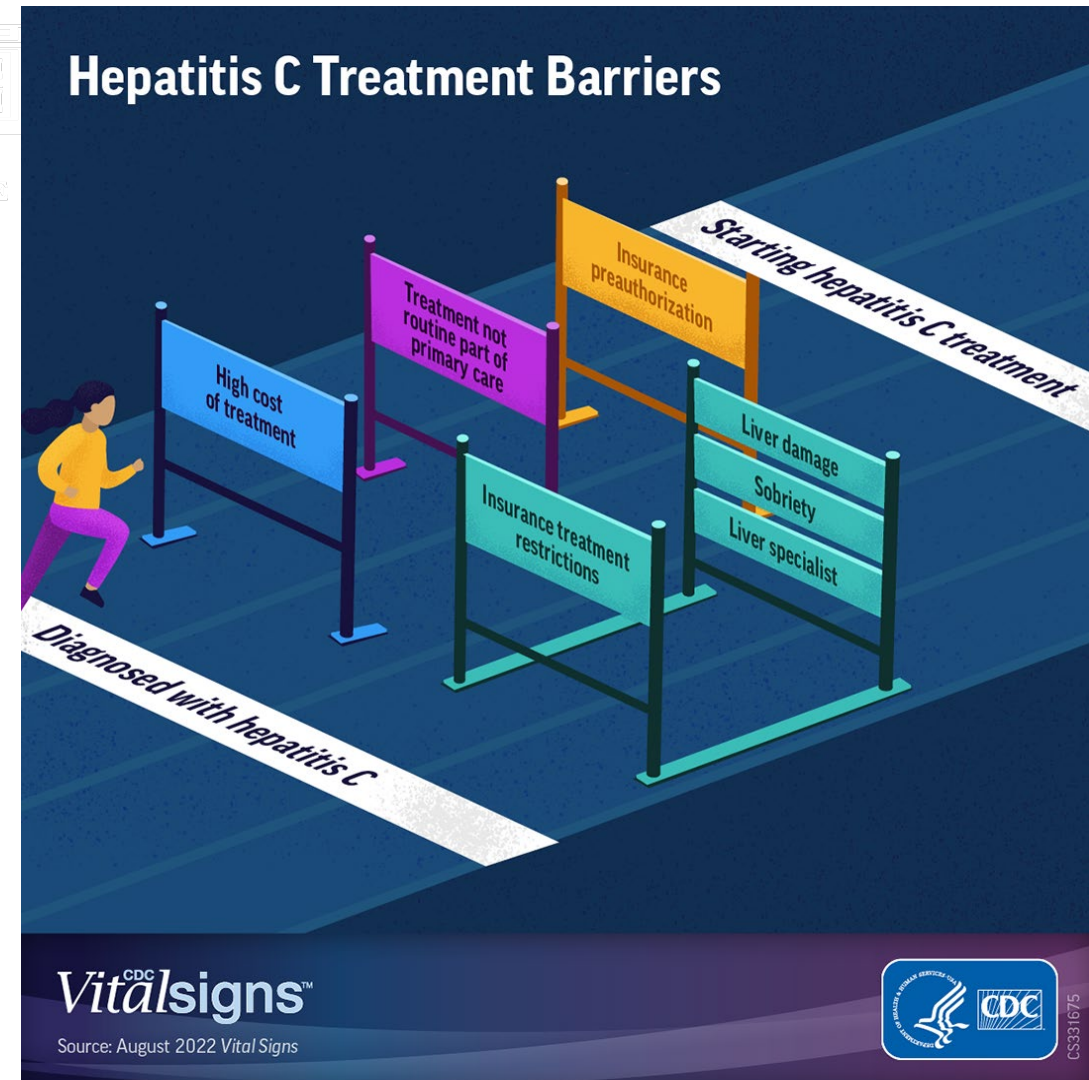


Hepatitis C is now curable! But the cure isn't reaching everyone

- Lack of **awareness** of condition in 40% of patients
- Lack of **point-of-care diagnostics**, 3 steps to treatment initiation and loss of contact
- **High cost** of treatment
- **Insurance prior-authorization requirements** (liver damage, sobriety, specialists)
- Treatment not routine part of **primary care**
- **Underserved and hard-to-reach populations:**
 - People who inject drugs
 - Justice-involved populations



Slide credit: Division of Viral Hepatitis, CDC



Hepatitis C Virus: Failure to Reach Most of Those Infected

ADULTS DIAGNOSED AND CURED* OF HEPATITIS C IN THE U.S., 2013-2022



*Cured is defined as viral clearance, which is an undetectable hepatitis C virus ribonucleic acid (HCV RNA) after a prior test result of detectable HCV RNA.

**Referred to as Other (client or self-pay) in the analysis

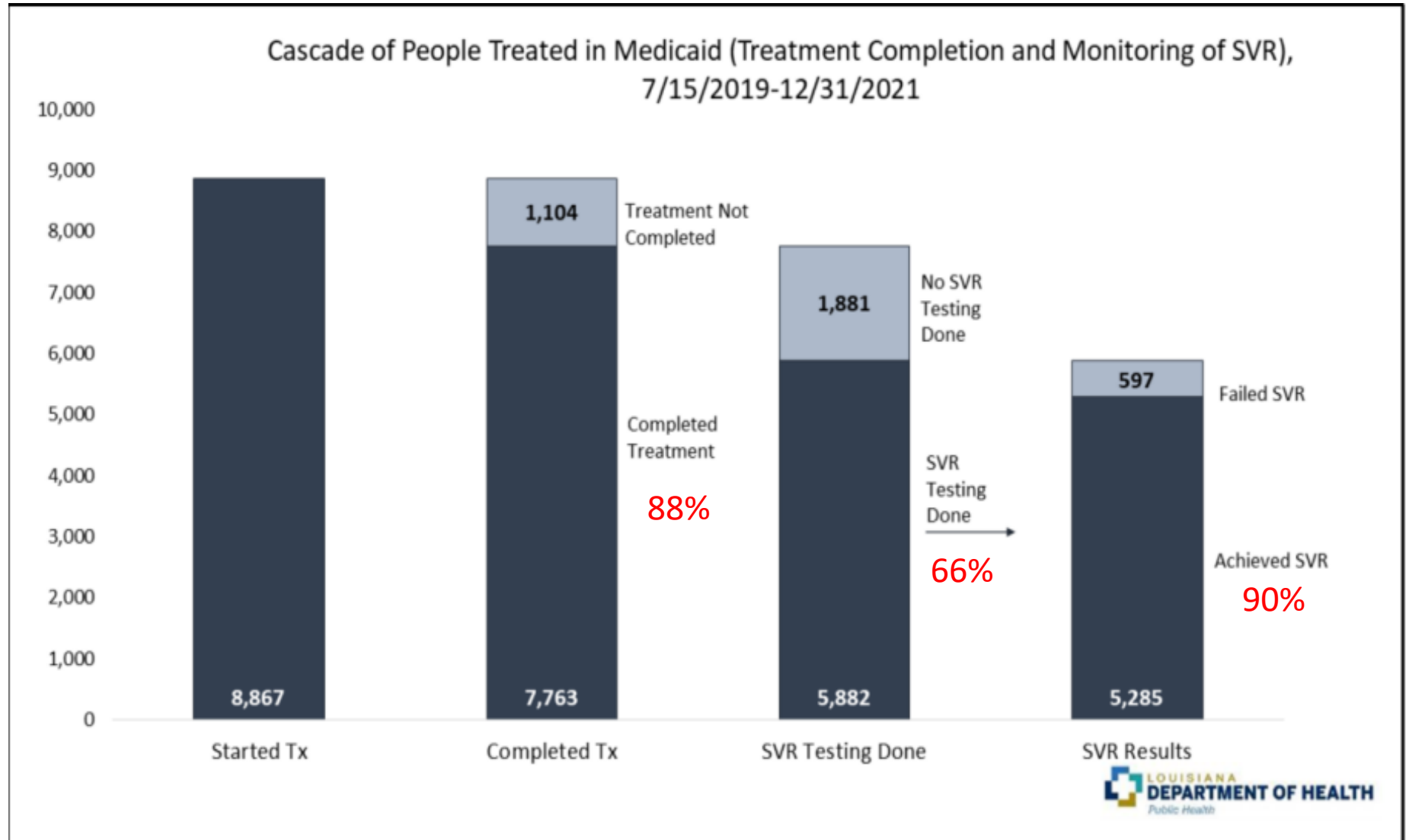
Source: Centers for Disease Control and Prevention



Pilots show that this can work in the states

Louisiana,
Medicaid cohort,
2019-2021

SVR = sustained
virologic response



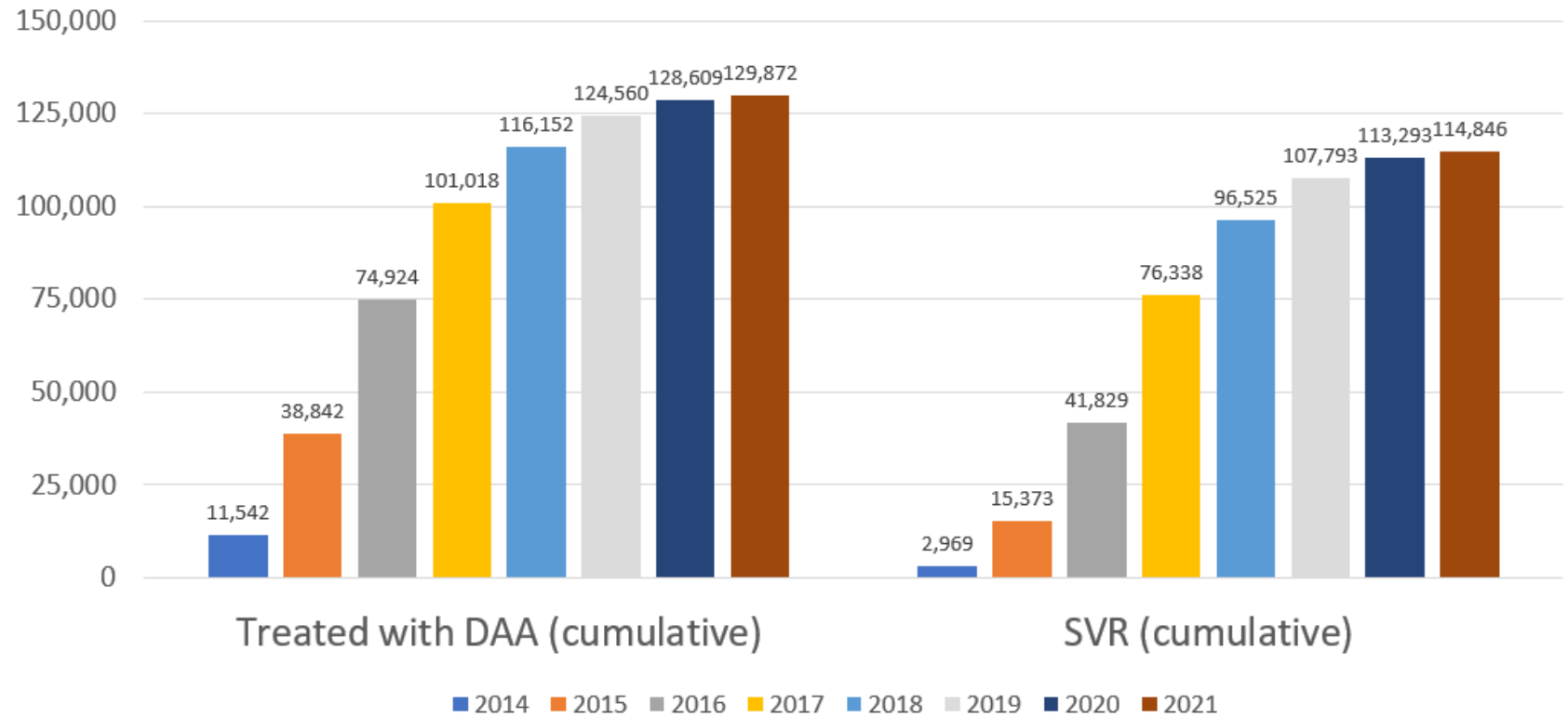
Acknowledgements: Louisiana Department of Health and Dr Risha Irvin, Johns Hopkins University



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

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

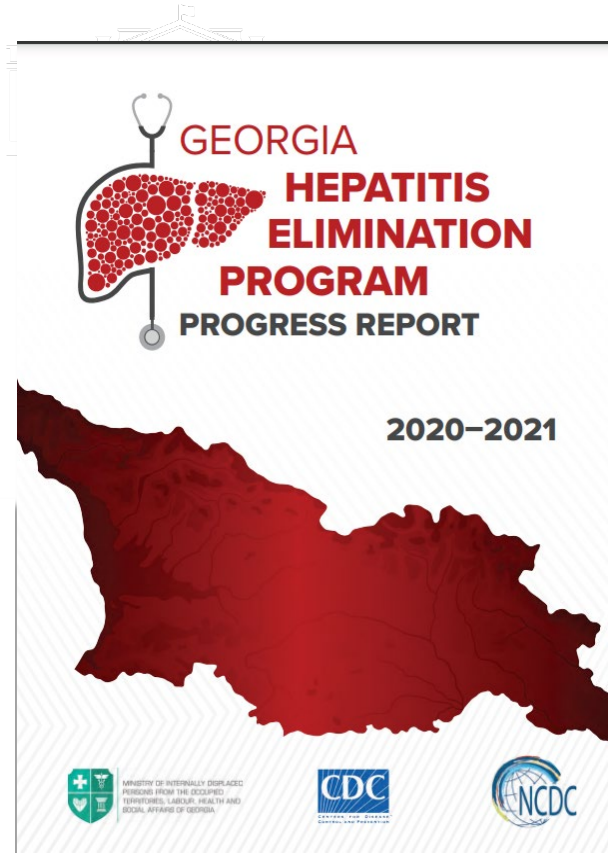
SPECIAL REPORT

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.¹⁻² 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.¹⁰ More than 2 million patients were treated by 2018 (representing 40% of the total HCV-infected popula-





A Proposed National Initiative on Hepatitis C



*“I would like, if it’s possible, to be as bold as possible and contemplate not just an effort that would improve the situation, but that would **eliminate hepatitis C in the United States**. That’s a scary word and obviously would require a huge investment to try to reach everybody.”*

-Francis Collins, March 8, 2023

*“NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby **proclaim May 19, 2023, as National Hepatitis Testing Day**. I encourage all Americans to join in activities that will **increase awareness about viral hepatitis and what we can do to prevent and treat it.**”*

-President Joe Biden, May 18, 2023

VIEWPOINT

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

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

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.¹ 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.⁴ 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%.⁵ 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

- 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-



Direct Acting Antivirals



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

3) Empower implementation efforts:

- Public awareness campaign
- 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





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

4) Possible clinical research components

- **Treatment during pregnancy**
- **Vaccine development**
- **Implementation model research**





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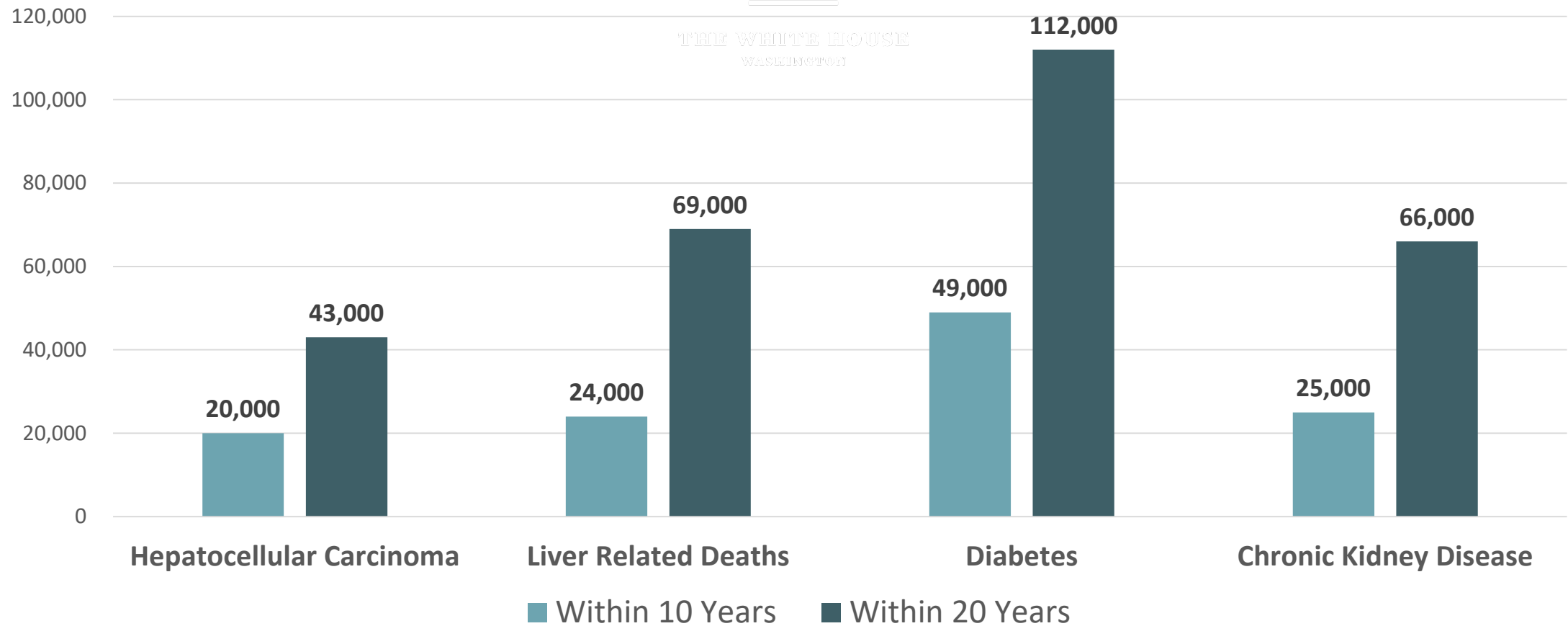
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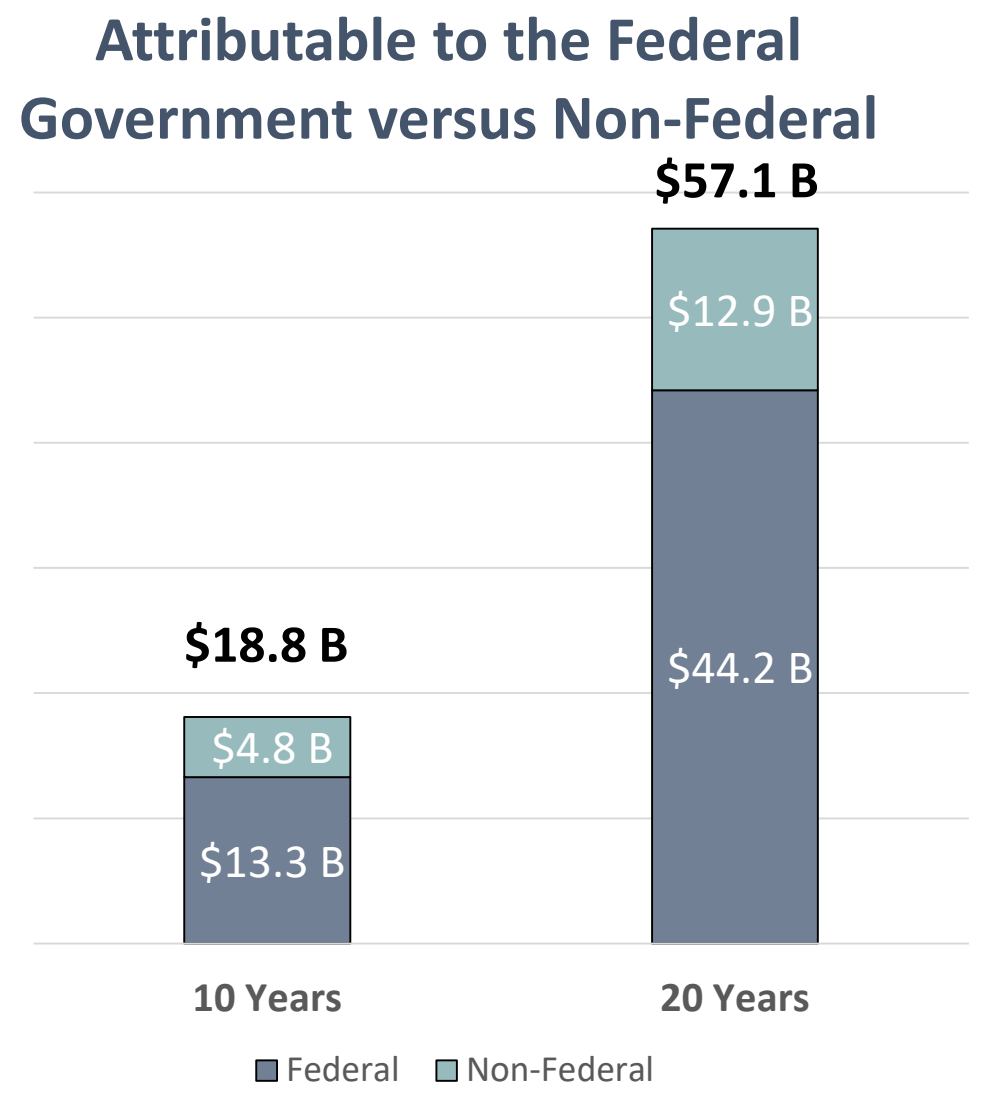
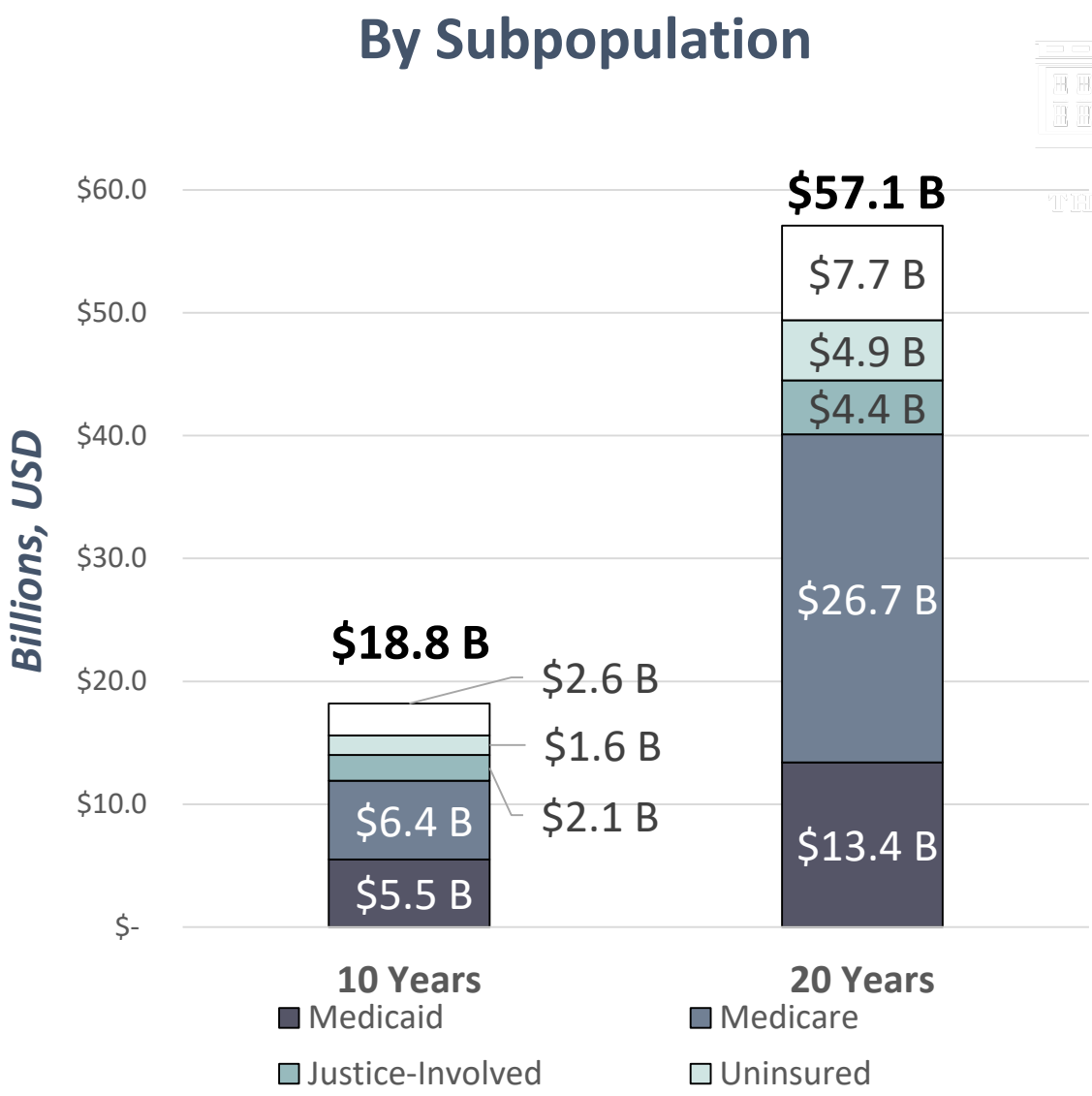
Economic benefits of a Hepatitis C elimination program: new analysis

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





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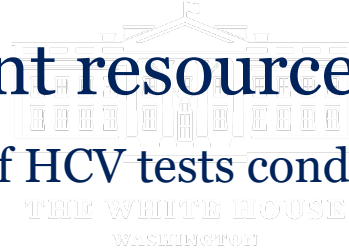
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Important role for PCORnet !

PCORnet has been an important resource:

- Executed a query to identify the volume of HCV tests conducted by participating health systems.
- The query also identified the number of co-infections with Hepatitis B virus.
- A manuscript is under development.
- Is engaging a select number of sites to support the ITAP clinical study for de novo clearance of a qualitative POC HCV test-to-treat platform
- Discussions are currently underway with 13 partner sites





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Takeaways for the clinical trial community

- 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.

- The current trends of Hepatitis C epidemiology in the United-States show that a cure is not sufficient to guarantee disease elimination

We appreciate your support for efforts to eliminate this terrible disease and look forward to your questions.