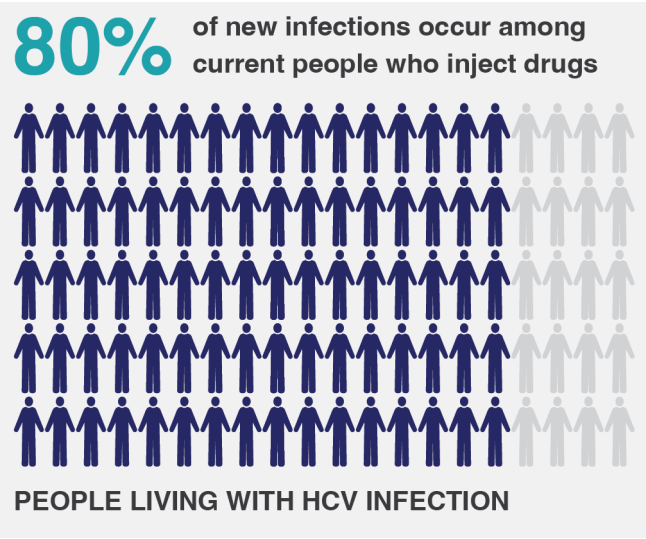
TAG
Treatment Action Group

NOW is the Time for Hepatitis C Virus Elimination

1. Brief Background

Hepatitis C virus (HCV) infection is a serious public health epidemic in the United States, with about 66,700 cases of acute HCV registered in 2020 alone.[1] Every year, 15,000 people die from hepatitis C-related liver disease, surpassing the death rate from HIV.[2] Of the 2.4 million people estimated to have chronic HCV,[3] 40 percent are not aware of their status, resulting in low treatment rates. HCV has been aptly called the silent epidemic because a person can have the virus for years — even decades — before they experience symptoms. In fact, most symptoms only appear when liver damage has occurred.[4] Chronic HCV can lead to liver damage, liver failure, cirrhosis, liver cancer, and even death, all of which can be prevented with the timely initiation of treatment with direct acting antivirals (DAAs), which effectively cure HCV within 8 to 12 weeks. Yet, several factors impede access to these DAAs.

Figure 1. HCV burden among people who inject drugs



Source: 1) Hajarizadeh B, et al. Nature Rev Gastroenterol Hepatol 2013.
2) Grebely J and Dore GJ Antiviral Research 2014. In Press.

2. Barriers to HCV Care

Complex Diagnostics Process

HCV diagnosis involves a multistep process. The first step is a simple HCV antibody test to determine whether an individual has been exposed. If the test is negative, it means the individual has not been exposed and no additional steps are required.

If the test is positive, it means the individual has been exposed to HCV and a confirmatory test needs to be performed to determine if there is HCV RNA in the blood. If the confirmatory test is negative (no HCV RNA detected), it means the individual was either exposed to HCV and the virus was spontaneously cleared or there was an error in the initial HCV antibody test. This means the individual is HCV-free and no additional steps are required.

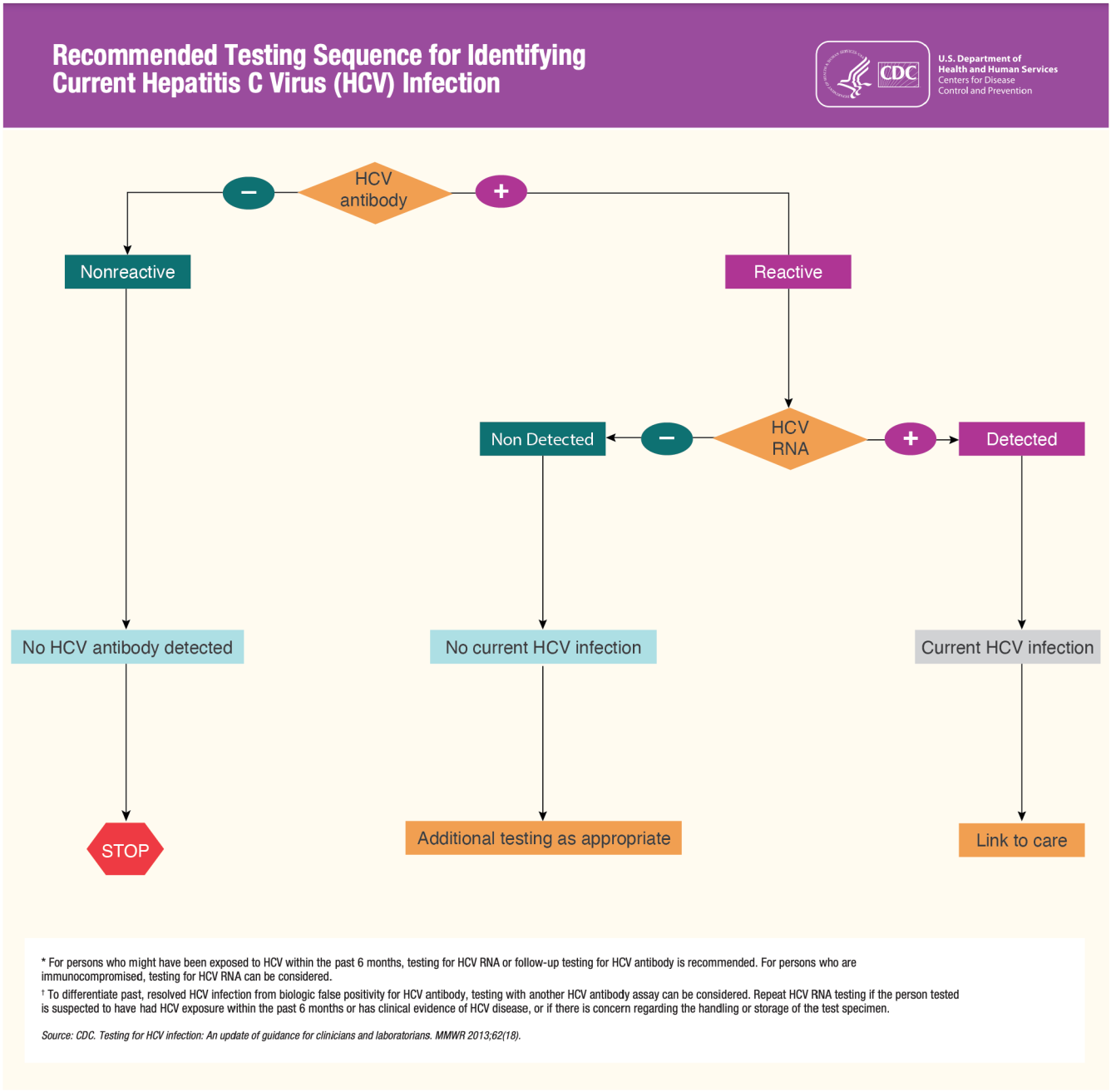
On the other hand, if confirmatory test is positive (if HCV RNA is detected), it means the individual has HCV and should be linked to care. Once the individual is linked to care, the provider will counsel and discuss next steps with the individual and recommend additional tests, including those for hepatitis B virus, HIV, and a liver test to determine if liver damage has occurred, all of which may or may not be done on site. This cumbersome process can take two to three weeks and requires multiple visits to a care provider and/or testing sites, posing a significant barrier for almost everyone. United States-based studies have shown that 28–93 percent of individuals with positive antibody tests do not receive follow-up RNA testing.[5] This gap is larger among younger people and those who currently inject drugs, particularly among those who have recently initiated injection drug use. In addition to people who inject drugs, other high-

burden populations like people experiencing housing instability, people who are incarcerated, and other people who have difficulty navigating traditional health care systems face significant difficulties following through with this complex process.

Treatment Cost

The full treatment course for HCV today costs about $24,000, which is inaccessible for many Americans, especially people who are uninsured or underinsured. For those who have HCV and other conditions, treatment may need to be provided by a specialist because it may require monitoring, involving additional costs.

Figure 2. Hepatitis C Virus diagnostics process



Source: https://www.cdc.gov/hepatitis/hcv/pdfs/hcv_flow.pdf.

Restrictive Treatment Coverage Policies

In some states, Medicaid programs and insurance providers have restrictions that impede access to treatment. Some of these restrictions include:[6]

- Requiring **prior authorization** from insurer before treatment initiation;
- **Fibrosis restrictions** wherein an individual with HCV is intentionally allowed to develop advanced fibrosis (or get sicker) before they can be treated;
- **Sobriety restrictions** in the form of substance use restriction prior to or during treatment, including abstinence and mandatory substance use disorder treatment;
- **Prescriber restrictions** wherein only specialists can prescribe HCV treatment.

General Neglect of High-Burden Populations

HCV high-burden populations, including people who inject drugs, people who are incarcerated, men who have sex with men, and people who are unstably housed, constitute some of the most marginalized and stigmatized population groups in society, and their voices and concerns are often not taken into account in health programming and policy.

Other barriers to HCV care include: the fact that HCV treatment is not part of routine primary care, limited access to (and lack of trust in) the health care system by high-burden populations, limited awareness about HCV, little knowledge of new treatment options, fear of positive diagnosis, perceived low risk of infection, and stigma.

Figure 3. Barriers to Hepatitis C virus care

Source: https://www.cdc.gov/vitalsigns/hepc-treatment/index.html.

3. Why NOW is a Good Time for HCV Elimination

HCV is the only chronic infectious disease that can be cured with 8–12 weeks of treatment, yet HCV-related complications are a leading cause of liver transplants in the United States. The economic burden of chronic HCV is estimated to exceed $10 billion annually.[7]

The Viral Hepatitis National Strategic Plan: 2021–2025 commits to eliminating viral hepatitis by 2030 and highlights the urgent need to implement HCV point-of-care testing in communities at high risk of HCV. According to the national strategic plan, ensuring that people are tested, diagnosed, and initiated on treatment in one visit would significantly improve the HCV care cascade — and help prevent new transmissions.

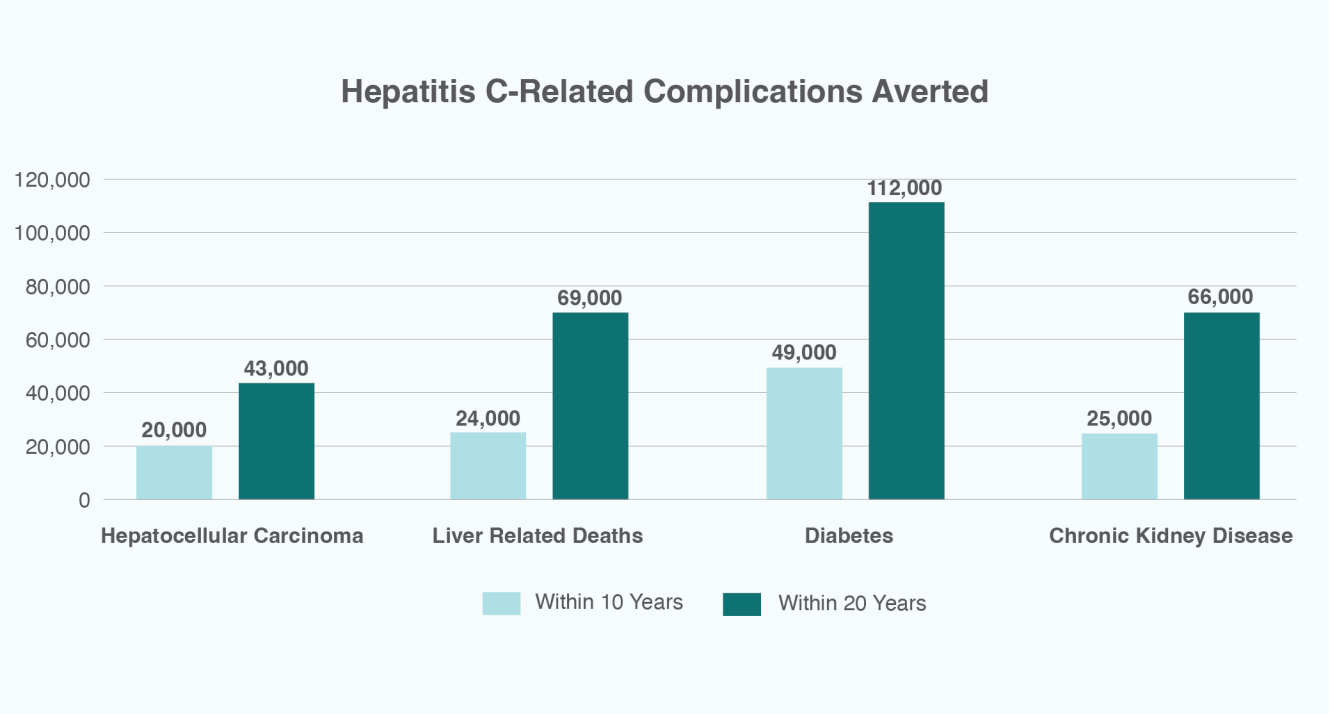
In addition, the White House Plan to Eliminate Hepatitis C released in early 2023 provides good momentum for reengaging communities and stakeholders to mobilize resources and ensure that everyone with or at high risk of HCV has access to diagnostic services, the cure and harm reduction services for prevention.

The plan proposes to:

- Develop a point-of-care HCV RNA single-visit test that can diagnose and initiate people on treatment within one hour. This will involve the use of a fingerstick test developed by Cepheid — which is already approved and being used in Australia and Europe. Based on the plan, the expediated Food and Drug Administration (FDA) approval process for diagnostic devices utilized to speedily approve COVID-19 point-of-care (POC) tests (through an FDA/National Institutes of Health [NIH] collaboration) could be used to quickly approve this test;
- Adopt a "Netflix" model for DAA purchase — as was implemented in Louisiana — on a national scale. Under this Netflix-model approach, the federal government will negotiate with DAA manufacturers and agree on a fixed lump sum of money in exchange for access to DAAs for Medicaid, people who are uninsured, people who are incarcerated, people on opioid treatment programs, and native Americans; and
- Empower health care delivery by allowing more providers to treat HCV, expanding the use of telehealth, increasing the number of community health workers, and reenergizing HCV vaccine research using the promising mRNA technology.

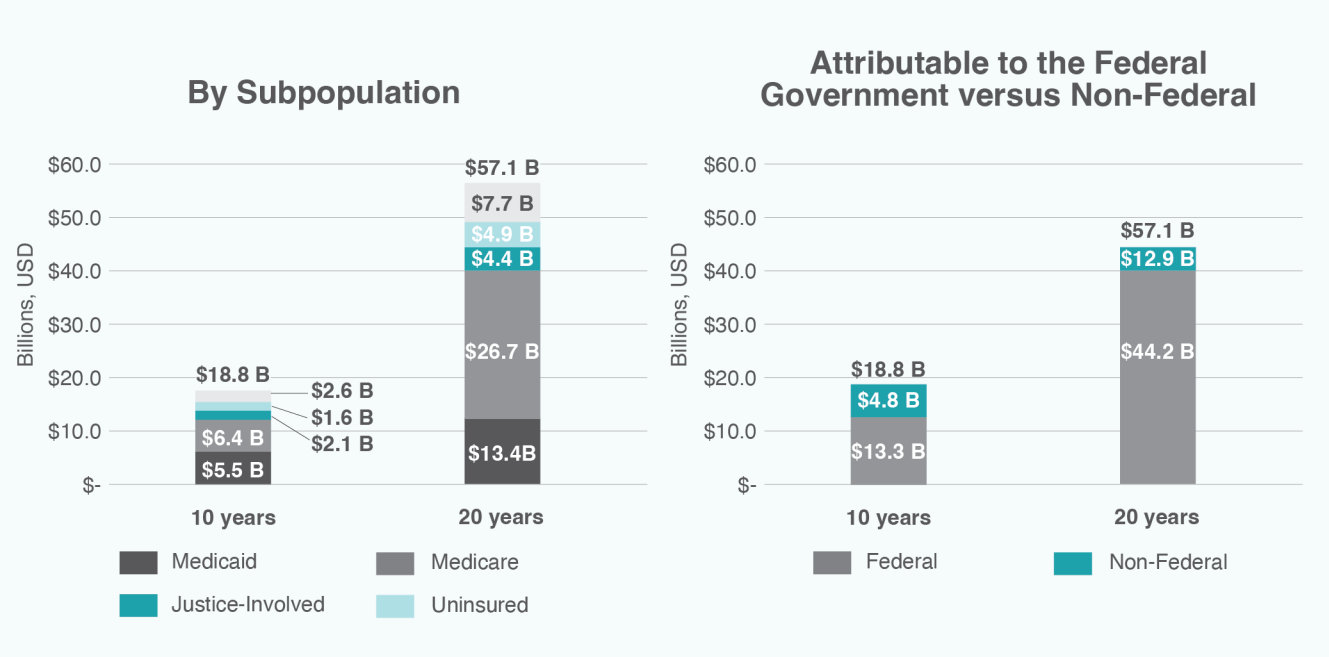
Implementing the above measures will improve health and quality of life, save lives, and prevent new transmission and unnecessary suffering from HCV, resulting in major economic savings and sparing the health care system from preventable hospitalizations, liver transplants, and costs associated with end stage liver disease and liver cancer.

Figure 5. Potential for lives saved and disease averted



Source: New analysis from Chhatwal et al. (2023) NBER Working Paper.

Figure 6. Economic benefits of a Hepatitis C Elimination program



Source: New analysis from Chhatwal et al. (2023) NBER Working Paper.

4. Recommendations and Way Forward

- Congress needs to develop and pass legislation codifying the New White House Plan to Eliminate Hepatitis C and provide the funding needed to implement the plan;
- The government needs to continue to fully fund the national hepatitis C elimination program;
- The government needs to fund hepatitis programs through the NIH and the Centers for Disease Control (CDC) Division of Viral Hepatitis;
- The FDA, the NIH, and diagnostic devices manufacturers need to work with advocates, researchers, and other stakeholders to develop and implement a rapid process for FDA approval of POC diagnostics;
- While the process for FDA approval is ongoing, diagnostic devices manufacturers need to work with health advocates on a pricing strategy that ensures widespread availability and access for people at high risk for HCV, and provide assistance programs for those who are uninsured and underinsured;
- State and local HCV elimination initiatives need to include strategies that will assist in actively finding and testing people at high risk for HCV and making POC tests available in the United State as soon as possible;
- States that receive opioid settlement funds should consider allocating some of those resources to actively finding and expanding access to rapid POC testing for high-burden populations and linking them to care.

Advocacy Opportunities

- Join the community coalition to advocate for federal legislation that would implement and fund the White House HCV Elimination Plan developed by the American Association for the Study of Liver Diseases (AASLD). For more information, contact Erika Miller, emiller@dc-crd.com.
- The worththecure website's collaboration tools provide interactive and customizable design templates and tools to support advocacy for access to HCV treatments.
- Join the National Viral Hepatitis Diagnostics Working Group to advocate for accessible, affordable, effective, and rapid viral hepatitis diagnostics that meet communities where they are by developing and implementing strategies and activities to achieve these advocacy goals. For more information, contact Adrienne Simmons, adrienne@nvhr.org.

References

1 https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-c.htm.
2 https://liverfoundation.org/liver-diseases/viral-hepatitis/hepatitis-c/#:~:text=Each%20year%2C%20more%20than%2017%2C000,aptly%20called%20the%20silent%20epidemic
3 https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm.
4 https://liverfoundation.org/liver-diseases/viral-hepatitis/hepatitis-c/.
5 Kapadia SN, Jordan AE, Eckhardt BJ, Perlman DC. The urgent need to implement point-of-care RNA testing for hepatitis C virus to support elimination. Clinical Infectious Diseases. 2023 Aug 27; ciad503, doi: 10.1093/cid/ciad503.
6 https://stateofhepc.org/.
7 Stepanova M, Younossi ZM. Economic burden of hepatitis C infection. Clinics in Liver Disease, 2017;21(3): 579-94. doi: 10.1016/j.cld.2017.03.012.