Addressing Structural Barriers to HCV Treatment

This is a PDF version of the following document:
Module 4: Treatment of Hepatitis C Infection
Lesson 4: Addressing Structural Barriers to HCV Treatment

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Background

There are an estimated 2.2 million Americans with hepatitis C virus (HCV) infection, making HCV the most common blood-borne infectious disease in the United States.[1] Chronic HCV infection is associated with significant morbidity and mortality, driven largely by progression to liver cirrhosis, liver cancer, and death. Infection with HCV is often associated with substance use, mental health disorders, and poverty, all of which contribute to the stigma and discrimination associated with this infection. Since 2014, HCV has become one of the few chronic viral infections that can be cured through the use of safe, well-tolerated, oral direct-acting antiviral (DAA) medications. The currently recommended DAA therapy cures HCV infection in 95% or more of persons with chronic HCV.[2] The availability of DAA therapy has revolutionized the management of HCV and provides an opportunity not only to prevent the negative health consequences of HCV at the individual level but also to prevent new infections by reducing the reservoir of people infected with HCV who can, in turn, transmit HCV to others. This concept of treatment as preventions is supported by modeling data and recent real-world experience suggesting that treating a significant proportion of people with HCV can lead to reductions in both incident and prevalent infections over time.[3,4,5,6]

CDC 2030 HCV Elimination Goals

The Division of Viral Hepatitis at the Centers for Disease Control and Prevention (CDC) has issued a strategic plan for HCV elimination that outlined the following goals by 2030 when compared to a baseline in 2017 (Figure 1).[7]

- Decrease new HCV infections by 90% for 2030
- Reduce HCV-related death rate by 65% for 2030
- Reduce the rate of new HCV infections in persons who inject drugs by 90% for 2030
- Increase the proportion of persons with HCV viral clearance by more than 85% for 2030

These HCV elimination goals have proved challenging amid the ongoing opioid epidemic in the United States.[8,9,10] From 2015 to 2021, there was an overall 106% increase in the estimated number of new HCV infections, with relatively stable numbers from 2021 to 2023.[11,12,13] Multilevel barriers at the patient, provider, and system levels contribute to difficulties with access to HCV testing and treatment, substance use treatment, and harm reduction services required to achieve HCV elimination goals. This topic review will identify and discuss the major structural barriers to HCV treatment in the United States.

The Path to HCV Cure: HCV Care Continuum

Steps in HCV Care Continuum

The “care continuum” or the “cascade of care” is a public health framework that outlines the benchmarks a society needs to track in order to optimize care for its population and it was first introduced in the HIV arena.[14,15] The main steps in the HCV care cascade include testing to diagnose HCV infection, linkage to HCV care for those individuals who test positive, treatment of HCV with DAA medications, and measurement of HCV RNA level at 12 weeks after completion of treatment to evaluate whether the individual is cured of HCV (Figure 2). An undetectable HCV RNA 12 weeks after the end of treatment is considered a sustained virologic response (SVR 12) and is equivalent to an HCV cure.

HCV Care Continuum Prior to the DAA Era

Prior to the availability of oral DAAs, estimates of progress along the HCV care continuum suggested that approximately 50% of individuals chronically infected with HCV were aware of their HCV infection, 16% were prescribed HCV treatment, and 9% were cured (Figure 3).[16]

HCV Treatment Cascade in the DAA Era

A 2023 CDC study of longitudinal data from a large national commercial laboratory of testing conducted from 2013-2022 reported that among an estimated 1.7 million persons ever infected with HCV, 88% received viral testing, 69% of those tested had initial infection, but only 34% (356,807 of 1,042,082) of those with initial infection were classified as cured or cleared (Figure 4).[17] A modeling study projected that with the current gaps in the cascade, only marginal improvement would be expected by 2030, with 62% aware and 49% cured by 2030.[18] In a cross-sectional study of the National Health and Nutrition Examination Survey (NHANES), among individuals followed from 1999-2016, only 49.8 % of participants were aware of their HCV infection.[19]

HCV Testing: Access, Efficiency, and Reimbursement

Limited Testing and Awareness of Infection

Many persons with chronic HCV infection do not have symptoms and only present with symptoms decades after infection when the disease has advanced to liver cirrhosis or hepatocellular cancer. Diagnosis of HCV infection requires specific tests and is often carried out as a 2-step process. The first test is an HCV antibody immunoassay, a marker of prior HCV infection. A reactive antibody test must then be confirmed with HCV RNA testing to assess for viremia. Detection of HCV RNA is consistent with active infection and should be followed immediately with an evaluation for antiviral therapy. Historically, there has been confusion about this algorithm and limited infrastructure for HCV testing.[20]

Expanding Access to HCV Testing

It is critical that HCV testing is made available in a wide range of settings and provided in a non-stigmatizing manner. Based on 2020 recommendations from the Centers for Disease Control and Prevention (CDC), testing for HCV is currently recommended at least once in a lifetime for all adults 18 years of age or older and all pregnant women during each pregnancy; one-time HCV screening is also recommended, regardless of age, for persons with recognized conditions or exposures (Table 1).[21] Further, routine periodic HCV testing is recommended at least annually for populations with ongoing risk of incident HCV infection or reinfection, such as people who inject drugs and men with HIV who have sex with men[21]. These recommendations are also endorsed in the AASLD-IDSA HCV Guidance and by the U.S. Preventive Services Task Force (USPSTF).[22,23] To increase access to HCV testing, it should be provided in a broad range of settings, including primary care clinics, obstetric offices, emergency departments, public health clinics, substance use treatment programs, syringe service programs, jails and prisons, and other community-based settings. Multiple studies have demonstrated the feasibility of expanding settings to increase access to HCV testing.[24,25]

Improving HCV Testing Efficiency

Consideration will need to be given to the needs of the populations being tested in these settings to ensure awareness of infection and subsequent linkage to treatment for those who are found to have active HCV infection. Implementation strategies that simplify the traditional 2-step HCV testing algorithm are needed. For individuals being tested in settings where they routinely receive care, such as in a primary care setting, reflex antibody to HCV RNA testing (where the remaining serum from a person who tested positive for HCV antibody is then tested for HCV RNA) is preferred so that chronic HCV, if present, can be diagnosed with one blood draw.[21,22] In other settings, such as community-based and drop-in testing centers, emphasis may need to be placed on the use of point-of-care, rapid HCV testing that does not require phlebotomy. Strategies that utilize point-of-care testing can be particularly effective in reducing disparities in HCV status awareness, as identified in the National Viral Hepatitis Strategic Plan and endorsed in the National Viral Hepatitis C Elimination Initiative.[7,26] Point-of-care HCV RNA testing, available in the United States since 2024, has created new opportunities for test-and-treat models of care, with significant promise for advancing HCV micro-elimination efforts.[27]

Reimbursement for HCV Testing

Policy changes, such as the Affordable Care Act, have expanded access to insurance for a large proportion of the United States population and provided coverage for HCV testing without cost-sharing. Medicare and commercial payers have also fully integrated universal screening coverage. For all adults aged 18 and older, a once-per-lifetime HCV antibody screening is fully reimbursable with zero cost-sharing (no copay or deductible) when ordered in a primary care setting. To maximize the benefits of the expanded HCV testing recommendations and coverage for this testing, efforts are required to increase awareness and support for providers in implementing non-stigmatizing universal HCV testing. Other implementation strategies that could facilitate increased HCV testing include electronic medical record prompts and reminders.[28,29,30]

Improving Services for Linkage-to-Care

Linkage to care is a key step in the pathway to effective HCV treatment. Multiple studies have shown a major drop-off at this step in the HCV care continuum.[31] Thus, consideration will need to be given to the needs of persons undergoing HCV testing to ensure those with positive HCV RNA test results become aware of their infection and are subsequently linked to HCV care and treatment. Several care continua have shown a steep drop-off from awareness of HCV infection to attendance at an appointment for an initial HCV evaluation.[32,33]

Patient Navigation Services

One approach to increase linkage to care for HCV treatment evaluation is to provide patient navigation services. Lack of these services has been reported as a significant barrier to HCV treatment.[34] Patient navigators can play varied roles, including evaluating insurance needs and assisting with insurance applications; scheduling appointments; facilitating appropriate referrals; providing appointment reminders and linking to community transportation resources; and assisting with food security or substance use treatment. An urban safety-net health system that screened 21,018 people for HCV over a 2-year period between 2017 and 2019 identified 878 individuals with positive HCV RNA tests. Of 562 patients with chronic HCV who were eligible for navigation services, 50% (281 of 562) were successfully linked to imaging services.[35] Among those who completed imaging, 72% (203 of 281) attended their first HCV medical evaluation appointment.[35] Another study evaluated outcomes of a patient navigation program in which a team consisting of a nurse navigator, a pharmacist, and a pharmacy technician provided support completion forms for HCV drug access, appointment reminders, and rescheduling missed appointments.[36] This approach demonstrated a 3.7-fold increased likelihood of linkage to HCV care and a 3.2-fold increased likelihood of HCV treatment initiation at 6 months among the 584 patients diagnosed with HCV after program implementation compared to 796 patients diagnosed prior to program implementation.[36] These patient navigation services may be especially important for patients with limited financial resources and comorbid medical conditions, such as substance use and mental health disorders, or complex social circumstances, such as homelessness or previous incarceration.[37] These populations are also more likely to have HCV.[38] Using an embedded nurse navigator model at the University of Virginia infectious diseases HCV clinic, 76% (624 of 824) of persons referred for HCV care were successfully linked to care.[39]

Peer Navigation

Peer navigation, the involvement of a person with a lived experience of HCV to support another in HCV linkage to care and treatment, is an approach to patient navigation that has been most studied in populations of people who use drugs.[40] Peer support has been associated with a higher rate of HCV linkage; in a trial that recruited participants from outreach services who had a substance use disorder and housing instability, 37% (23 of 63) people who were randomized to the peer support group had successful HCV linkage to care compared with only 18% (7 of 38) of those persons in the control group.[41]

Contingency Management

Another approach to linkage to care is contingency management, a type of behavioral therapy where positive behavior change is reinforced, incentivized, or rewarded. This strategy was shown to be effective in a small pilot study that examined contingency management as a strategy to improve HCV linkage to care rates among people who use drugs: participants were recruited through accessing a syringe service program in New York City and were enrolled in either a contingency management arm or an enhanced standard-of-care arm.[42] Participants in the contingency management arm received an expedited appointment, transportation assistance, a $25 incentive for up to 10 appointments, and $10 for each returned weekly medication blister pack; participants in the enhanced standard-of-care arm received only an expedited appointment and transportation assistance.[42] In this study, 74% (14 of 19) in the contingency management arm were successfully linked to HCV care compared with 6 of 20 (30%) in the enhanced standard of care arm,

demonstrating that contingency management can be an effective strategy for linkage to care.[42]

Integrated Care Models

One of the most effective strategies for improving linkage to care is to co-locate HCV testing and treatment within settings already accessed by people living with HCV (opioid treatment programs, primary care clinics, etc.), as detailed below in the section on expanding providers and settings beyond specialty care.

Limitations for Implementation of Services

Programmatic efforts and interventions outlined above are largely driven by time-constrained grant funding with limited opportunities for widespread implementation and sustainability. Efforts are needed to identify long-term funding sources to support the implementation and sustainability of these strategies for HCV treatment linkage.

Expanding Medical Provider Capacity

Treatment of persons with chronic HCV has traditionally been provided in gastroenterology and infectious diseases specialty settings. This is a major structural barrier to HCV treatment, since the limited number of specialists available to provide treatment can result in restricted access to treatment, long wait times for appointment scheduling, or, at times, lengthy travel to reach such settings, and, ultimately, attrition and loss of follow-up. The availability of pangenotypic oral DAAs that are highly effective, well tolerated, and safe has made the treatment of chronic HCV feasible for many primary care clinicians. The management of persons with chronic HCV by a specialist is now only required in select cases, such as for patients with decompensated cirrhosis or who have had liver transplantation. Streamlined HCV evaluation and simplified treatment algorithms for treatment-naïve persons with chronic HCV have been generated in the AASLD-IDSA HCV Guidance to promote HCV treatment by non-expert primary care clinicians.[43,44,45] Several studies have demonstrated the effectiveness of HCV treatment by primary care providers, substance use disorder treatment specialists, nurse practitioners, physician assistants, and pharmacists.[46,47] Nurse-led models of HCV treatment delivery have also proven effective.[48] A critical step to increase the number of HCV treatment locations is establishing training and support for various disciplines of medical providers in these settings. Several models and programs are available to increase medical provider's capacity and skills in providing HCV treatment.

- **Project ECHO**: The Extension for Community Healthcare Outcomes (ECHO) model was developed at the University of New Mexico Health Sciences Center as an innovative strategy to improve treatment access for underserved populations with complex medical problems, including HCV. In this model, providers co-manage their initial patient cohort via a confidential teleconferencing platform with input from experts and their community of peers.[49] Further, the ECHO program is structured such that in addition to providing direct consultation, subject-matter experts provide didactic training and facilitate collaborative learning for medical providers to gain competence and confidence in providing HCV treatment. This program has shown comparable HCV treatment outcomes (sustained virologic response rates) for patients treated at ECHO sites throughout New Mexico when compared with patients treated at the University of New Mexico viral hepatitis clinic.[49] A follow-up study that involved the New Mexico Veterans Affairs (VA) HCV ECHO program demonstrated that the 6,431 patients who had a primary care provider who attended at least one ECHO session had higher HCV treatment rates compared to the 32,322 VA primary care providers who did not participate in ECHO, but SVR rates were the same in the two groups.[50] Other adaptations of the ECHO model have similarly been shown to increase the number of medical providers trained to provide HCV treatment in non-specialist settings.[51,52]

- **Electronic and Remote Consultation**: Less intensive models, such as electronic/remote consultation services with a team-based approach to HCV treatment in primary care settings, have also been associated with increased rates of HCV treatment. For example, an initiative was implemented in a safety-net health system in California in which primary care providers were offered a 4-hour HCV treatment overview and ongoing support for providing HCV treatment through an electronic consultation system.[53] As a result, there was a 3-fold increase in HCV treatment in the post-implementation period compared to the pre-implementation period.[53] The National Clinician's Consultation Center, based at the University of California at San Francisco, provides clinician-to-clinician advice on HCV monoinfection and HCV-HIV coinfection management; this service provides the option to submit a clinical case online or to call for a phone consultation (844) 437-4636, available Monday-Friday 9 a.m. to 8 p.m. EST.

Expanding Settings for HCV Clinical Care and Treatment

Other factors, such as mistrust of the health system, perceived and enacted stigma, and competing priorities, may negatively impact the willingness or ability of some individuals to link to HCV care in specialist settings.[54] Increasing access to HCV therapy for the broad range of populations who need HCV treatment requires that treatment services are made available in a wide range of settings where individuals feel safe and comfortable accessing care. These settings include primary care, substance use disorder treatment programs, opioid treatment programs, public health clinics, needle and syringe service programs, jails and prisons, and other community-based settings. Policies that incentivize health systems to screen for and treat HCV may help expand HCV testing and treatment across a broader range of settings, such as primary care, corrections, or substance use disorder care settings.

Expediting the Start of HCV Treatment

The growing availability of point-of-care HCV RNA testing has enabled same-day HCV diagnosis and treatment initiation. A systematic review and meta-analysis of 45 studies demonstrated that on-site point-of-care testing was associated with shorter median time from diagnosis to start of therapy (19 days vs. 67 days) and greater treatment uptake (77% vs. 53%) compared with standard testing.[55] Notably, the impact of point-of-care testing was greatest in those settings where testing and treatment were provided at the same site and on the same day. The rapid treatment strategy (compared with usual care) has also been shown in a randomized pilot trial to be effective in young persons who inject drugs with higher rates at each step of the care cascade: clinic attendance (100% vs. 45%), treatment initiation (93% vs. 27%), and treatment completion (93% vs. 9%).[56]

Insurance and Medicaid Restrictions to HCV Treatment

Prior Authorization for HCV Treatment Coverage

Although many state Medicaid programs have eliminated the need for prior authorization for DAAs, prior authorization is still a requirement in some jurisdictions, depending on the health insurance payer. This process requires medical care providers to complete and submit documentation to insurance companies or payers to get advance approval for medications to be covered by the payer. These processes vary by payer/insurance plan, require completing various forms, are generally time-consuming, and can delay HCV treatment. Some studies have reported that pre-authorization requirements significantly increase medical provider workload, and, in many cases, remain a significant obstacle to HCV care delivery.[57] Prior authorizations can also request additional information that should not impact coverage of HCV treatment, such as substance use status. This information is then used as justification to deny coverage of treatment. For medical providers and health care settings willing to take on HCV treatment, the additional workload and time required for prior authorization requests may serve as a deterrent to providing HCV treatment. Overall, prior authorizations can hinder the delivery of HCV treatment.[57]

Restricted Access to HCV Treatment Medications

Oral DAAs are significantly less expensive now than when they were initially approved in 2014. Many payers, however, continue to restrict access to treatment due to cost. In particular, restrictions based on fibrosis stage and sobriety continue to pose a significant barrier to accessing HCV treatment.[58,59,60] The AASLD-IDSA HCV Guidance recommends HCV treatment for all persons with acute or chronic HCV infection, regardless of disease severity, except in those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy.[43]

Restrictions Based on Substance Use

Sobriety restrictions, which require patients to be abstinent of alcohol or other drug use for varying time durations prior to payer approval of HCV treatment, are also a major barrier to HCV treatment. Multiple studies have demonstrated high HCV cure rates regardless of ongoing substance use.[61,62] In addition, modeling and real-world data have demonstrated that increasing HCV treatment uptake in persons who inject drugs is needed to significantly reduce the reservoir of HCV-viremic individuals who can subsequently transmit HCV to others.[4,5,63] In addition, these restrictions create further barriers for people who use drugs and send the message that this group is not deserving of HCV treatment. The AASLD-IDSA HCV Guidance recommends against any mandatory pretreatment screening for alcohol or drug use.[43] In addition, the AASLD-IDSA HCV Guidance states that HCV treatment should not be restricted among persons with alcohol or injection drug use by requiring sobriety or abstinence, noting these types of prerequisites create a major barrier to HCV treatment, thereby potentially excluding populations that would likely derive clinical and prevention benefits from therapy.[43]

Large-Scale Discounted Purchasing of Medication

Instead of restricting access to HCV treatment, state Medicaid programs and other jurisdictions could explore innovative models such as the “Netflix” subscription payment model adopted by the states of Louisiana and Washington, in which a lump sum was agreed upon and paid to a pharmaceutical company in exchange for an unlimited number of treatment courses to treat all Medicaid beneficiaries and individuals in correctional facilities in the state over a 5-year period.[64,65] With a standard model that does not include lump-sum payments, pharmaceutical companies will make the greatest profit by increasing the price per treatment, which inherently restricts access to medications. The lump-sum payment strategy allows pharmaceutical companies to increase their profit and guarantee revenue without limiting access to medications. Other strategies may also be worth exploring, such as the Australian national DAA model, which provides unrestricted, universal access to oral DAA treatment with an annual cap on HCV treatment expenditures.

Resources for Medication Access

- **State of Medicaid Access**: The National Viral Hepatitis Roundtable and Harvard Center for Health Law and Policy Innovation provide an online, state-by-state assessment of DAA access through Medicaid programs (see Hepatitis C: State of Medicaid Access).[66]
- **Patient Advocate Foundation:** The Patient Advocate Foundation's Total Assist is a nonprofit organization that provides assistance, including case management services, to persons living with chronic diseases, including HCV.
- **Patient Assistance Programs**: The HealthWell Foundation has a patient assistance program that includes assistance with hepatitis C medication costs.

Summary Points

- There is a real opportunity to achieve HCV elimination by reducing the HCV viral burden on a population-based level through large-scale treatment as prevention with DAAs. There are, however, several structural barriers and gaps in the HCV care cascade that pose challenges to this goal.
- Identifying persons with HCV through widespread screening has been hampered by limited access to testing and an inefficient testing algorithm that still relies on a blood draw and laboratory-based assessment of HCV RNA to confirm chronic infection. Point-of-care RNA testing can facilitate diagnosis and linkage.
- Linkage to care is another area in need of improvement in the care cascade. Strategies such as navigation services or contingency management have proven successful but are resource-intensive to sustain.
- To expand HCV treatment, more medical providers and health care settings beyond specialists and hospital-based settings must integrate HCV care into other routine care services. Non-traditional care settings and nonspecialist providers have been shown to deliver HCV treatment with comparable success rates.
- Insurance-mandated prerequisites and prior authorization remain important barriers to expansive HCV care. Exclusions based on disease severity or substance use have delayed treatment or restricted access to treatment for key populations, despite recommendations against such exclusions and emphasizing the importance of treating all individuals with chronic or acute HCV infection.

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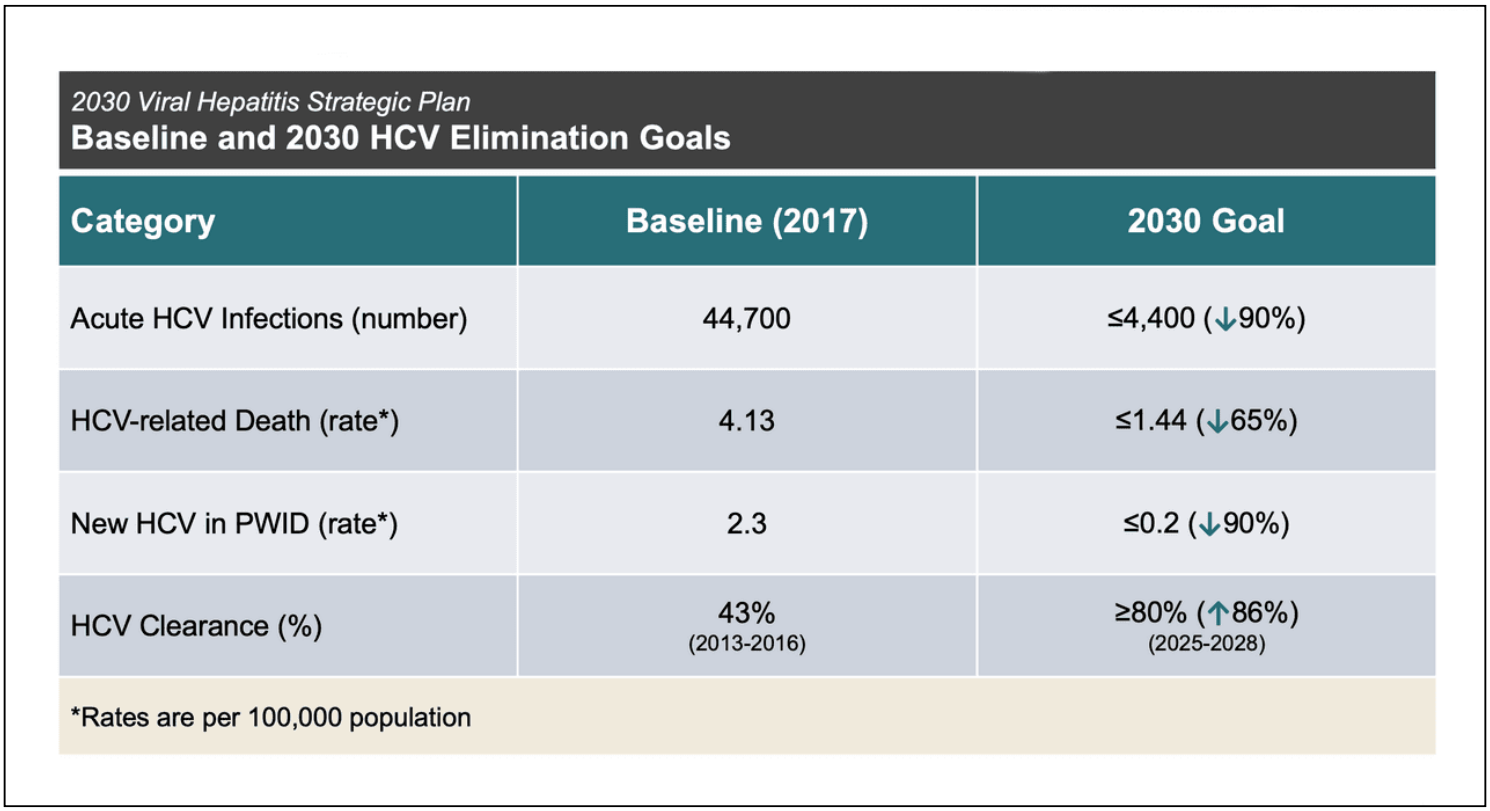
Figures

Figure 1 CDC Division of Viral Hepatitis 2030 Strategic Plan for Hepatitis C

Abbreviations: HCV = hepatitis C virus; PWID = persons who inject drugs

Source: Centers for Disease Control and Prevention (CDC). Division of Viral Hepatitis 2030 Strategic Plan, CDC. July 2026.



2030 Viral Hepatitis Strategic Plan
Baseline and 2030 HCV Elimination Goals

Category	Baseline (2017)	2030 Goal
Acute HCV Infections (number)	44,700	≤4,400 (↓90%)
HCV-related Death (rate*)	4.13	≤1.44 (↓65%)
New HCV in PWID (rate*)	2.3	≤0.2 (↓90%)
HCV Clearance (%)	43% (2013-2016)	≥80% (↑86%) (2025-2028)

*Rates are per 100,000 population

Figure 2 HCV Care Continuum

Abbreviations: DAA = direct-acting antiviral
This figure shows the five major stages of the HCV care continuum (colored circles), and the specific actions involved (arrows) to move individuals along the continuum.

Illustration: David H. Spach, MD

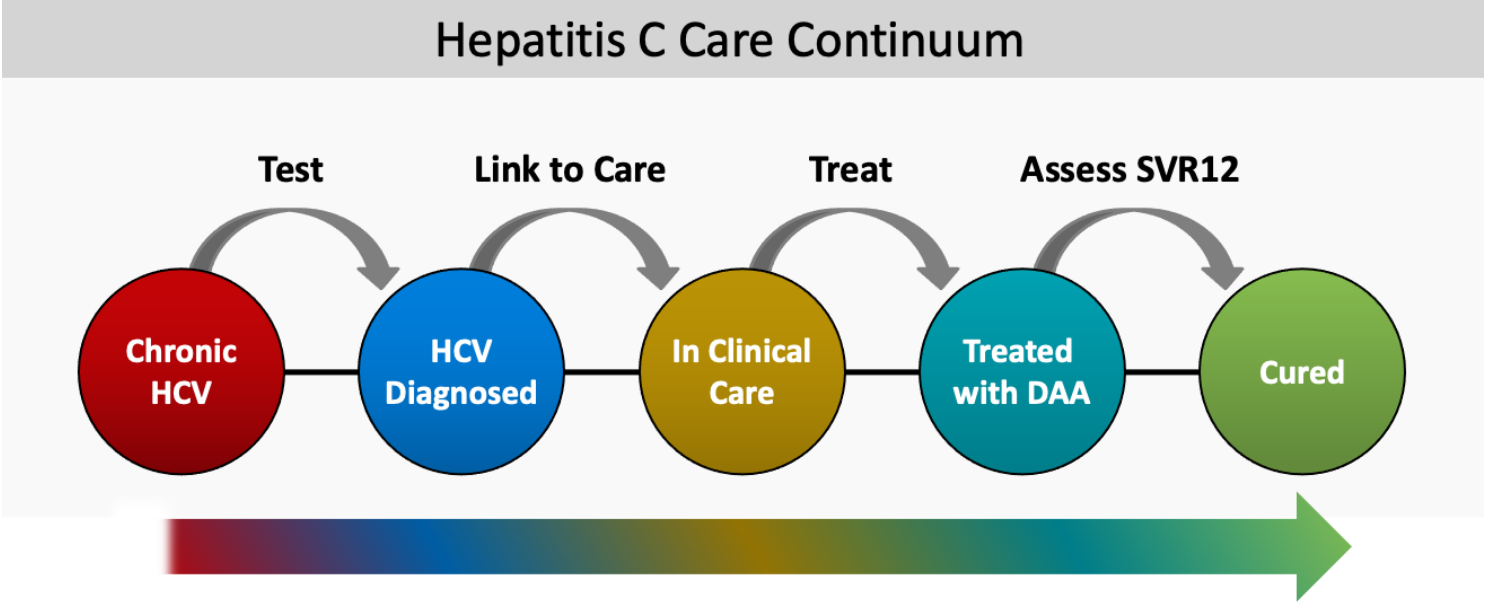


Figure 3 Treatment Cascade for People with HCV in the United States in the Pre-DAA Era

This treatment cascade is modeled based on studies from 2003-2013 (prior to the widespread use of direct-acting antiviral [DAA] medications).

Source: Yehia BR, Schranz AJ, Umscheid CA, Lo Re V 3rd. The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and meta-analysis. PLoS One. 2014;9:e101554.

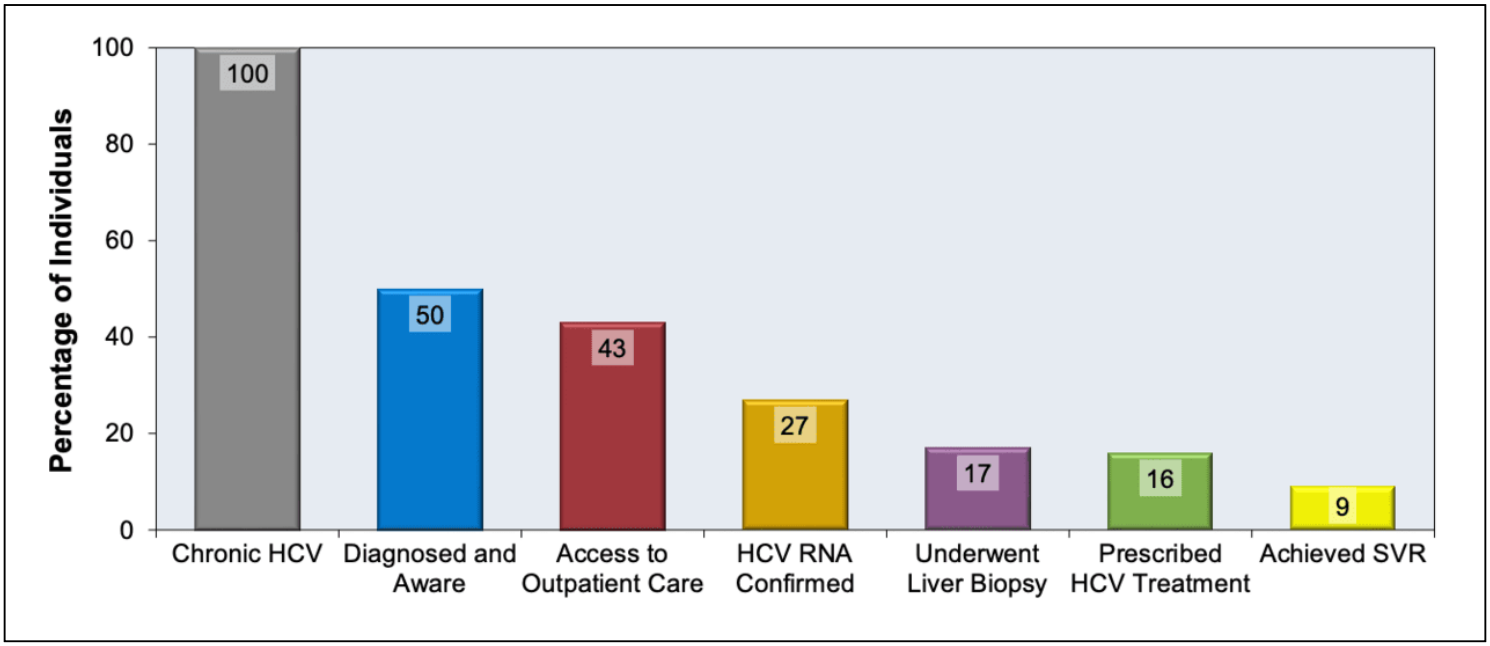


Figure 4 Treatment Cascade for People with Chronic HCV in the United States, 2023

Source: Wester C, Osinubi A, Kaufman HW, et al. Hepatitis C Virus Clearance Cascade - United States, 2013-2022. MMWR Morb Mortal Wkly Rep. 2023;72:716-20.

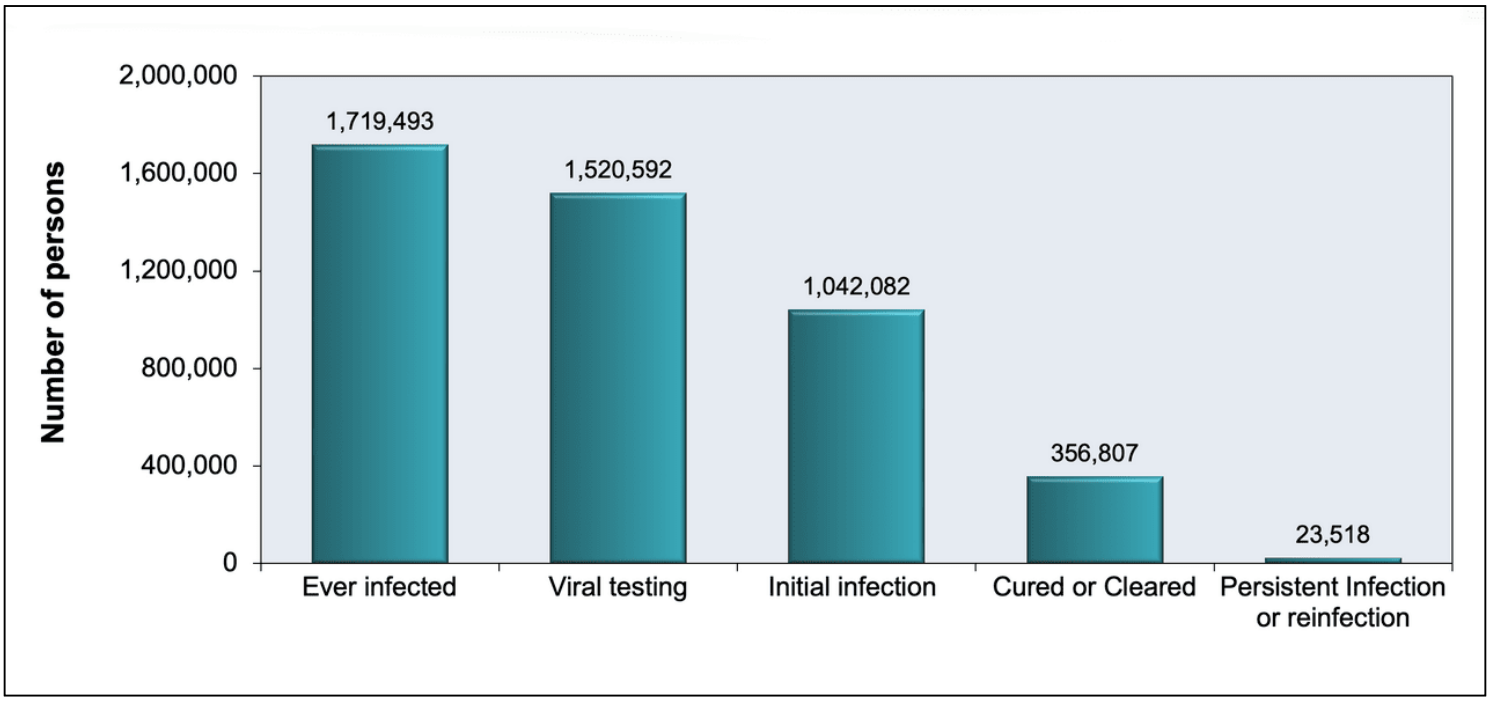


Table 1. CDC Recommendations for Hepatitis C Screening Among Adults — United States, 2020

Persons Recommended for Screening
Universal hepatitis C screening: • Hepatitis C screening at least once in a lifetime for all adults aged ≥18 years, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is <0.1% • Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is <0.1%
One-time hepatitis C testing regardless of age or setting prevalence among persons with recognized risk factors or exposures: • Persons with HIV • Persons who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago • Persons with selected medical conditions, including persons who ever received maintenance hemodialysis and persons with persistently abnormal alanine aminotransferase (ALT) levels • Prior recipients of transfusions or organ transplants, including persons who received clotting factor concentrates produced before 1987, persons who received a transfusion of blood or blood components before July 1992, persons who received an organ transplant before July 1992, and persons who were notified that they received blood from a donor who later tested positive for HCV infection • Health care, emergency medical, and public safety personnel after needlesticks, sharps, or mucosal exposures to HCV-positive blood • Children born to mothers with HCV infection
Routine periodic testing for persons with ongoing risk factors, while risk factors persist: • Persons who currently inject drugs and share needles, syringes, or other drug preparation equipment • Persons with selected medical conditions, including persons who ever received maintenance hemodialysis
Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks

Source:

- Schillie S, Wester C, Osborne M, Wesolowski L, Ryerson AB. CDC Recommendations for Hepatitis C Screening Among Adults - United States, 2020. MMWR Recomm Rep. 2020;69:1-17. [PubMed Abstract]