

Developing Pathways to Hepatitis C Elimination in the United States

July 20, 2022

11:00 am-2:00 pm ET

Discussion Guide

Summary

Hepatitis C is a bloodborne liver infection caused by the hepatitis C virus (HCV). Acute hepatitis C can be a short-term illness with spontaneous clearance. However, over half of acute cases become chronic infections. This can result in serious and costly long-term complications including cirrhosis and liver cancer.¹ The Centers for Disease Control and Prevention (CDC) report that hepatitis C is associated with 50% of the liver cancer incidence, whose rate of death is increasing faster than any other form of cancer.² Despite curative treatment options for hepatitis C, the hepatitis C incidence rate increased 71% from 2014 to 2018, with two-thirds of cases occurring among people most impacted by the opioid crisis.³ With cost effective and curative treatment options there is an opportunity to both contain and eliminate hepatitis C in the U.S.

To consider and advance the development of a national strategy for the containment and elimination of Hepatitis C in the United States, the Margolis Center for Health Policy is convening a roundtable for health care leaders to address the following topics:

- Given the impact on increasing death rates from liver cancer, what is the opportunity to harness the resources through the Cancer Moonshot goals to advance a national hepatitis C elimination strategy?
- What might be the key components of a national hepatitis C elimination strategy?
- What role would federal, state, and regional stakeholders play in implementing this strategy?

Background

Hepatitis C is a bloodborne liver infection caused by the hepatitis C virus (HCV). In the U.S., 2.4 million individuals are infected with the virus.⁴ While overall prevalence has trended downward with treatment in recent years, hepatitis C incidence has increased.⁵ Between 2014 and 2018, the number of estimated annual acute hepatitis C infections increased 71% (from 0.7 per 100,000 people to 1.2 per 100,000 people), with two thirds of cases occurring among people most impacted by the opioid crisis.⁶ Left untreated, hepatitis C results in serious and costly complications including hepatocellular carcinoma, cirrhosis, liver failure, and liver transplantation.⁷ Effective treatments are direct acting antiviral (DAA) therapies, which inhibit viral protein synthesis and prevent HCV replication. Multiple DAA treatment options have become available since 2013 that can cure hepatitis C in 90% or more of cases.⁸

Challenges in Eliminating Hepatitis C

Following the availability of DAA therapies, drug procurement in the face of large incident populations of HCV patients initially presented a clear barrier to broad access to curative treatment. Substantial unit prices for the curative DAA therapies, in the range of \$84,000 per patient for commercial payers, and similarly costly for Medicaid plans which impacted state budgets, led public and private payers to take steps to limit access to the therapies despite their curative value. Over time, with multiple competing DAA regimens available, rebates have increased and net prices have fallen substantially. As we describe below, many states, the Veteran's Health Administration (VHA), and some private purchasers have implemented

drug purchasing arrangements that achieve substantially broader availability with lower net prices per patient.

Even with easier access to DAA treatment, the care cascade, the pathway through which at risk individuals are screened and followed through virus clearance, is not straightforward for most patients. Hepatitis C requires a two-step diagnostic process, with an HCV antibody screening and PCR RNA confirmatory test. While HCV antibody rapid, point-of-care tests are available in addition to standard laboratory testing, RNA confirmatory tests are performed in the lab, and take several days to process. Following diagnosis, patients undergo initial disease evaluation by a trained provider to determine viral genotype and severity of liver damage. DAA therapy is prescribed after assessment and patient referrals to subspecialists are made based on the severity of complications. Patients return after their 8-24-week DAA regimen for a follow-up test to determine whether sustained virologic response (SVR) was achieved.

Despite the availability of curative and cost-effective treatments, the complex care cascade presents a great challenge to millions of Americans. Gaps exist at nearly every stage of the care pathway. At a surveillance level, many regions lack the data infrastructure for patient identification. Individuals do not know to seek treatment as acute hepatitis C is often asymptomatic, and there is insufficient health education around screening recommendations and transmission risk factors. Even when aware of HCV, patients may not know of testing and treatment opportunities or may have limited access to testing sites. If a patient receives a positive test, provider shortages, especially within rural areas, can make it difficult to reach a trained provider, preventing them from following through with clinical evaluation. In addition to remaining financial and prior authorization barriers to DAA treatment, stigma or discrimination by providers, and substance use disorders (SUD) or other comorbidities can make treatment uptake and adherence challenging.^{9,10}

Finally, reinfection in some at-risk populations remains a concern. While not the primary focus of this discussion guide, pairing a comprehensive strategy for screening and treatment with strategies related to diminishing the risk of acquiring or reacquiring HCV, for example, through innovative SUD risk reduction programs, is also an important consideration for elimination.

Addressing Barriers to Access

There are currently several federal, state, and regional programs currently aimed at eliminating hepatitis C in the U.S. According to Department of Health and Human Services (DHHS) monitoring, there are currently 8 federal or multi-state initiatives, as well as 22 state and regional programs targeting hepatitis C.¹¹ These programs have several overlapping features that have helped them engage the public and successfully test and treat members of hardy reached communities for HCV. These features include comprehensive surveillance efforts to track patient and community progress, educational and public awareness efforts that particularly target communities at risk, expanded screening sites, linkage to care between diagnosis and treatment, and provider training to allow non-specialist health care providers to offer hepatitis C care. These elements are key to not only identifying and recruiting patients to commence care, but also to provide them with the most navigable care pathway in which they are supported from screening to end of treatment, and are able to access local providers.

While each of these programs are tailored to their region, these overlapping features suggest that there are core activities that can be the foundation of a strategic framework to eliminate hepatitis C. This strategic framework can be the basis to establish a national strategy that integrates essential components of a hepatitis C elimination program, but also allows policy makers to tailor the program to specific

population needs. A strategic framework for a national strategy to eliminate hepatitis C can include the following:

- 1) **DAA procurement models** that assure adequate availability of affordable DAAs, typically by negotiation between a manufacturer and payer/purchaser to acquire sufficient DAA supply for the relevant population at a relatively low average price per unit. This approach replaces a reimbursement model with high prices per unit and smaller expected patient uptake with an expectation. It may also potentially include a partnership with the manufacturer to reach the full population treated. For example, volume discounts with large rebates or (for some states) spending caps with nominal prices above the cap can help achieve this “population based” procurement approach. To succeed, the procurement model must be paired with a comprehensive and accountable care cascade strategy to assure through planning and tracking of key performance indicators that the relevant patient population is identified for treatment and reaches SVR.
- 2) **Surveillance** which includes networks to enable data sharing and infrastructure to support patient identification, planning, and progress tracking. This will be important to identify and address the spread of hepatitis C early on, particularly in areas with hardly-reached communities with high transmission.
- 3) **Awareness and linkage to screening** which includes public and provider specific education of hepatitis C and available testing and treatment options. Stakeholder-relationship building will facilitate educational efforts. This will be necessary to increase awareness of the risks associated with chronic, untreated hepatitis C and resources to test and treat.
- 4) **Screening infrastructure** to increase resources and opportunities across different health care settings to screen all patients. This will be crucial to increasing the number of people who learn about the HCV virus and seek care.
- 5) **Diagnosis, linkage to care, and disease assessment** which includes networks and resources to refer all diagnosed patients to an appropriately trained provider. This is necessary to ensure that patients who test positive receive high quality care and move towards treatment.

Purchaser Considerations

This strategic framework provides a general guide to core components of a hepatitis C elimination program. HCV affects diverse patient populations with distinctive clinical and socioeconomic features, and differences in the purchasers financing care. Some key patient populations include: Medicaid beneficiaries, Medicare beneficiaries, incarcerated populations, the uninsured, private health insurance recipients, American Indians and Alaska Natives (AIAN) who receive care through the Indian Health Service; and military veterans who may receive care through the VHA health system. People who inject drugs (PWID) are disproportionately represented in some of these coverage groups.

As there are differences in provider networks and prescription drug coverage across purchasers, so are different the barriers to care across patient populations. These may include different challenges to drug procurement as well as barriers to care delivery. Below we present the unique considerations for the major patient groups.

State Medicaid

Medicaid beneficiaries are among those most heavily impacted by hepatitis C. Approximately 3.02% of Medicaid beneficiaries 18 and older are infected with hepatitis C.¹² Large Medicaid populations mean that states face a considerable cost burden in hepatitis C elimination despite the decrease in the cost of DAAs in recent years. Coupled with budget cycles linked to legislative sessions and state spending constraints, it is difficult for states to accommodate large up-front spending increases on drugs that can improve health and prevent costly downstream complications. Medicaid programs may also face barriers in locating patients due to insufficient data infrastructure, and limited sharing capabilities between states agencies. Medicaid beneficiaries tend to have lower educational attainment and higher rates of psychiatric illness, comorbid chronic conditions, and substance use disorder than the privately insured.^{13,14} These factors may contribute to a lack of awareness of testing and treatment options, as well as stigma that prevents patients from seeking care. Many beneficiaries live in rural areas without Rural Health Clinics (RHC) or Federal Qualified Health Centers (FQHCs) to help provide hepatitis C screening.¹⁵ If a patient is screened, barriers to reaching care include finding local providers who accept Medicaid patients, transportation, long wait times for appointments, inconvenient office hours, and occupations that don't allow for flexible schedules.¹⁶ In addition, due to the high-cost burden of providing DAA therapies, many states have rationed treatment through prescribing restrictions. While some state restrictions have lessened, these restrictive policies remain prevalent and are the strictest among purchasers. Current restrictions include: prior authorization requirements; fibrosis restrictions; substance use restrictions prior to or during treatment; counseling on substance use; specialist prescriber requirements; restricted access to retreatment.¹⁷

There are approaches to address Medicaid-specific barriers related to drug procurement that could support a national strategy. Several states, including Louisiana, Washington, and Michigan, have piloted payment contracts with manufacturers to improve access to DAA therapies for Medicaid beneficiaries and the incarcerated. These population-focused procurement models establish annual caps for state expenditures on DAAs, linked to nominal net price per unit for additional courses through supplemental drug rebates. The Department of Corrections in these states also contract with 340B covered entities to provide clinical services to the incarcerated at a discounted price. These states lifted prescribing restrictions for Medicaid beneficiaries and the incarcerated to improve clinical access to DAAs. Other Medicaid programs could evaluate the feasibility of implementing expenditure-cap models that procure a large volume of DAAs while controlling spending, and remove the remaining prior authorization and prescribing restrictions that limit widespread access.

Beyond drug procurement, surveillance and screening remain a persistent barrier across most Medicaid programs. In order to identify patients before chronic infection, states could strengthen local and state-level surveillance. This may involve updating data requirements, diversifying data sources and integrating systems to promote data transfer across state agencies. Increasing awareness of HCV, and testing and treatment options may be achieved through targeted educational campaigns in different languages and at different comprehension levels. States can launch mixed-media marketing campaigns as well as utilize managed care organization (MCO) communication channels to reach beneficiaries. Since many individuals face barriers accessing screening facilities, increasing and diversifying testing locations through Medicaid SUD Waivers, and developing innovative models such as mobile clinics is crucial. Washington, for instance, leveraged state and federal funding to provide rapid HCV antibody screening in community settings. In the same vein, Medicaid beneficiaries will benefit from expanded specialty training for primary care providers as well as other authorized prescribers such as nurse practitioners and physician assistants.

Department of Corrections

Hepatitis C prevalence ranges significantly across states and prison systems, but approximately 20.35% of incarcerated people have hepatitis C, making up nearly 30% of the total U.S. cases.^{18,19} Screening practices vary across prison systems and given the cost of treatment and limited health staff, states may not have the resources to implement universal testing. Prisons systems often lack capacity to provide education and counseling, and many patients remain unaware of their status. For patients who are screened, the dearth of providers remains a barrier to accessing medical care and DAA therapy. State and federal incarcerated individuals also have more difficulty than Medicaid patients accessing timely, appropriate care and hepatitis C drugs. Prisons have more leeway in determining treatment access due to lower standards for healthcare based on what classifies as “reasonably adequate” care. In most cases only patients in advanced stages of disease are eligible for DAA therapy.²⁰

Solutions for hepatitis C elimination among the incarcerated must target DAA procurement, screening, access to medical providers, and individual level barriers. The controlled nature of prisons means that universal surveillance and testing could be relatively easily implemented if sufficient state and federal funding becomes available. This has already occurred in states like Indiana, which conducted universal opt-out testing.²¹ State and federal funding may also be used to support care linkage and non-traditional care models. A model that can connect patients with providers and peer support groups where healthcare and educational capacity is limited can be effective. DAA procurement challenges that remain may require increasing the strategic use of 340B discounts in providing care or a federally-supported drug procurement program that promotes widespread DAA use. Departments of Corrections could also lift standard prescription requirements to provide care to all patients with hepatitis C. For example, Alaska and Louisiana lifted prescribing restrictions for the incarcerated and partnered with covered entities to receive 340B prescription drug discounts.

The Veteran's Health Administration

The VHA has a history of innovative population-focused hepatitis C treatment programs. As a result of these innovative efforts, the VHA has cured over 100,000 veterans since 2014.²² As of 2020, 170,000 veterans were in care and 20,000 were awaiting treatment. This makes up about 1% of the veteran population.

When DAA therapies were approved, the VHA, with congressional support, developed a network of hepatitis C Innovation Teams (HITs) to implement innovative treatment strategies.²³ These teams are small, agile, and field-based units trained in clinical systems redesign and innovation to improve care pathways. They include subject matter experts in hepatitis C, clinical pharmacy, system redesign, and informatics. HITs operate within each Veterans Integrated Service Network region, and receive VHA funding to focus on specific issues within their region. These teams rely on a national leadership team which guides HITs in addressing regional barriers and setting annual testing and treatment goals.

The HIT Collaborative has emerged with successful and innovative strategies to improve care delivery. Several HITs worked together to create a national clinical hepatitis C dashboard that allows providers to identify untreated patients.²⁴ This clinical dashboard included tools to document hepatitis C screening, evaluation and treatment, including an electronic medical record (EMR) trigger to evaluate diagnosed veterans who have deferred treatment. Other HITs were successful in engaging non-traditional providers to treat patients. These care settings included pharmacist-led clinics, group visits, and primary care treatment.²⁵

Despite all these innovations in care, eliminating hepatitis C in the veteran population still faces various barriers along the care pathway, which intersect with other features that place many veterans at higher risk. Veterans are more likely to experience mental health and substance use disorders than the general population, and make up a disproportionate number of the homeless adult population.^{26,27} These factors may cause difficulty in accessing screening and subsequent treatment options. While the VHA has expanded hepatitis C care to all veterans in recent years, until 2016 prescribing restrictions on degree of fibrosis, severity of underlying liver disease, and substance use, limited access to care.^{28,29} Continued congressional funding and support for the VHA HIT Collaborative is necessary to maintain high testing and treatment rate, and expand innovative care delivery models.

Private Health Insurance

The prevalence of hepatitis C is lower among the privately insured when compared to other purchaser segments and the wider population. Approximately 0.95% of people with private insurance have hepatitis C.³⁰ Despite the smaller portion of HCV infected patients with private insurance, private payers provide coverage for the majority of US adults and thus are a key part of an overall strategy to eliminate hepatitis C.

Individuals enrolled in private insurance may have limited awareness of the availability of HCV screening and treatment if they do not have a closely engaged primary care provider. In reaching care, privately insured patients may face wait times and provider network restrictions, particularly those who are of low socioeconomic status.³¹ Although patients still need prior authorization for DAA therapy and specialty care is required in some cases, payers have eased prescribing restrictions around fibrosis score and sobriety, increasing access for more patients. Through negotiated rebate agreements and discounts, payers have been able to reduce spending on DAA therapies, passing along savings to beneficiaries in the form of lower out-of-pocket costs of therapy.³² Despite these improvements, many commercially insured patients remain unaware of their HCV infection and go untreated; but with relatively low prevalence, the cost of identifying at-risk patients and implementing initiatives to assure that they are screened and treated may be higher on a per-case basis.

In order to adequately surveil the privately insured, private purchasers must fund data infrastructure, which may be linked to state collection efforts for further insight. Commercial plans may also implement a HIT-like strategy to assess screening and treatment in their population, and engage the hardly-reached among them. In order to increase awareness of HCV testing and treatment, it will be crucial to engage primary care providers in awareness efforts. Purchasers may consider incorporating physician incentives and expanding testing sites to other health care settings like pharmacies to increase use of testing and treatment services. Like other patient populations, the privately insured will benefit if more primary care providers are trained and/or supported in hepatitis C care. Private insurance purchasers also have the ability to further negotiate with manufacturers to lower DAA purchasing prices, linked to steps to increase expected volume of uptake, enabling them to broaden access to DAAs and lower cost-sharing for their patients.

Medicare

The hepatitis C prevalence rate in the Medicare population is approximately 1.45%³³ In recent years, the incidence rate of hepatitis C has increased, a trend that may be attributable to the aging baby boomer population. However, the lack of a rigorous surveillance system may prevent Medicare from identifying patients who need treatment. Patients themselves may have limited awareness of testing recommendations for their age group, and fail to seek screening. They may also have limited access to screening, and even when they undergo screening and locate care, may face transportation or access

difficulties due to their age. As of 2015, all Medicare Part D plans covered at least one DAA. These drugs are often placed in the highest tier of the drug formulary, resulting in substantial out of pocket costs for patients that along with prior authorization and dispensing limits can complicate access. Awareness and costs thus remain significant barrier for many Medicare beneficiaries, especially those that do not qualify for subsidies.³⁴

Like other populations, Medicare beneficiaries may benefit from an expanded surveillance infrastructure that includes patient identification, linkage to care, and treatment information. But the structure of Medicare presents some challenges to implementing population-oriented strategies that integrate drug procurement and care models. In traditional Medicare, Part D plans provide standalone oral prescription drug coverage that is typically not integrated with medical coverage. Consequently, providing an integrated financial approach to improve access to testing opportunities and treatment, combined with an innovative drug purchasing model, requires special considerations. Similar to steps to encourage testing and follow-up for COVID-19, traditional Medicare may need to provide financial incentives for a test to treat model with point of care testing and initial consultation, or opt-out HCV screening during the Annual Wellness Visit for high-risk individuals and anyone not previously tested. Testing and treatment metrics could also be integrated into performance measures for traditional Medicare's alternative payment models for primary care, including the Medicare Shared Savings Program and Innovation Center pilots for primary and specialty care. Similarly, Medicare Advantage (now enrolling close to half of Medicare beneficiaries) could include performance measures and other quality improvement incentives. Medicare may also continue to examine prior authorization and distribution requirements. Finally, Medicare could undertake targeted educational activities to increase awareness among its at-risk beneficiaries.

Indian Health Service

The AIAN population has a hepatitis C prevalence rate of approximately 3.5%, although prevalence estimates vary greatly.³⁵ Like many other patient populations, AIAN patients face stigma in discussing their HCV status, and this may prevent them from learning more about the virus, and testing and treatment opportunities available. If patients do seek screening, they may face difficulty accessing testing services and subsequent treatment, as many IHS care sites are primary health clinics in rural or remote settings, making accessibility difficult if patients do not live near an IHS site of care.³⁶ There is also a shortage of primary care and specialty care providers in rural areas, which means that patients have not have access to an adequately trained provider once they access an IHS clinic.

Solutions for overcoming barriers for the AIAN population will have the greatest impact if they focus on improving surveillance, overcoming stigma, and scaling programs already in place that promote universal screening and linkage to care. In term of surveillance, increasing representation of this population in surveys and studies, such as the NHANES survey, will improve necessary data for resource allocation.³⁷ Infrastructure to support data collection and sharing between tribal programs and federal surveillance systems already gathering data can help capture a more comprehensive picture of infection and treatment and support the efficient use of resources.³⁸ Targeted education, especially in areas not served by IHS, will increase awareness around HCV, transmission risk factors and opportunities for linkage to care. Community health workers and case managers can be a way to reach patients and help overcome stigma and misconceptions associated with HCV, SUD services and treatment.

Mass testing is another promising approach for HCV elimination. The Cherokee Nation Health Services (CNHS) HCV elimination program implemented universal screening and made significant advances toward target measures. This approach can be replicated in other communities, particularly those with low

treatment uptake. Solutions for increasing treatment access include expansion of non-traditional care settings such as SSPs and virtual provider training programs such as the Project ECHO models. This model has already been utilized in elimination efforts targeting AI/AN, and has demonstrated success in improving access to care.³⁹ Waiving specialist requirements for prescribing will broaden the range of available prescribers and facilitate the use of pharmacist-led care models. Pharmacist-led models place the pharmacist as the head of the treatment team. Collaborative practice agreements authorize pharmacists to order laboratory tests, determine regimen and duration of therapy, manage side effects and provide follow-up care.⁴⁰

Uninsured

Among the uninsured, the hepatitis C prevalence rate is approximately 2.54%.⁴¹ Community based care delivery programs and safety net clinics provide services to the un or underinsured, but implementation occurs on a regional level, so funding and capacity may not support sustainable infrastructure, integrated systems or wide-reaching impact. Barriers to care for the uninsured population are numerous, and low socio-economic status is often the root cause. This population has low awareness of and uptake of hepatitis C treatment, and many may be unaware of the HCV, their personal status, its risk factors, or long-term impact. Patients may have difficulty navigating screening and treatment, or have a general mistrust of the medical system which can stem from language barriers and citizenship status.⁴² In addition, like Medicaid patients, uninsured patients in rural areas may not live close to RHCs and FQHCs with specialty care, or face transportation and scheduling barriers to attending appointments. Even if enrolled in treatment, the cost of DAA may be a major barrier to adhering to hepatitis C treatment, as many live below 200% of the FPL and are not eligible for public assistance.⁴³

Elimination of HCV in the uninsured population may begin with surveillance efforts among local safety net clinics to identify patients eligible for insurance coverage or other hepatitis C care support. More than a quarter of uninsured Americans are eligible for subsidies on the Marketplace, Medicaid or CHIP.⁴⁴ Targeted outreach and education by community-based organizations can reach them, link them to testing, and assist them in applying for insurance coverage. They will also benefit from some state level efforts to expand treatment access such as expanding hepatitis C testing opportunities in free and low-cost sharing sites and building a network of trusted Community Health Workers (CHWs) to aid patients in system navigation. Louisiana built such a network and looked to sustain it through innovative reimbursement models for care-coordination services. Additionally, expanding treatment to non-traditional care settings and strengthening safety net infrastructure through SUD Waivers, increased reimbursement to FQHCs, federal grants and Project ECHO-like models would increase access for the uninsured to free or low-cost care and DAA treatment.

There are promising models that may be augmented to increase state and federal ability to treat the uninsured. This includes the Ending the HIV Epidemic in the U.S. Initiative, which monitors HIV transmission in communities, and engages local stakeholders including health care providers, HIV advocates, and community leaders to tailor interventions to community needs and mitigate rapid transmission patterns.⁴⁵ This initiative also includes educational targeting to populations placed at risk, and collaboration with local health care settings to increase innovative testing techniques including self-tests, testing via mobile sites, and other nontraditional settings. Upon diagnosis, local partners are also engaged to provide treatment. This type of model is suitable to the uninsured population, who require community stakeholder engagement to facilitate their access to and adherence to care.

People who Inject Drugs

People with SUD are represented across purchaser groups, particularly within the uninsured, incarcerated, Medicaid beneficiaries, and veteran populations. In 2018, there were approximately 3.7 million PWID, of which approximately 40% had hepatitis C.^{46,47} Injection drug use is often co-occurring with mental health disorders, which presents challenges in Hepatitis C prevention, identification and treatment adherence.⁴⁸ PWID may be unaware of their status, or of testing and treatment opportunities. Even with awareness of testing and treatment site, they may be hesitant to seek care due to stigma or other barriers, and face difficulty adhering to or paying for treatment.

Payer-specific strategies and demographic targeted outreach campaigns, such as those based on region, race or ethnicity, incarceration status, mental health, income, homelessness, etc., will intersect with strategies benefiting PWID. SUD disproportionately affects those in lower socio-economic classes and programs that expand community-based clinics and leverage CHW will be especially effective. Strategies specific to this population include harm reduction campaigns educating PWID on hepatitis C transmission and safe practices, as well as connecting individuals to opiate replacement therapy and medication assisted treatment (MAT) programs. Improving care access will entail expanding testing and treatment to Emergency Departments, substance use treatment centers, methadone clinics and syringe service programs (SSPs), increasing the presence of SSPs throughout the state and providing federal funding for integrating wraparound services. These avenues to care will facilitate safe practices, and mitigate barriers to care related to stigma.

Building Upon Existing Cross-Cutting Solutions to Augment Access to Cures

In addition to leveraging successful programmatic components of ongoing hepatitis C elimination efforts, a national strategic framework can build upon other successful state- and federal-level programs addressing other pressing public health issues. They also provide insights into engaging in large-scale treatment procurement and care delivery by population, which will be useful to a national strategy design.

Project ECHO

Project ECHO aims to build the capacity of local health care systems and increase access to providers in hard-to-reach communities by training and tele-mentoring primary care providers in hepatitis C treatment.⁴⁹ This model has been expanded beyond hepatitis C, to health care problems including diabetes, bone health, rheumatology, and perinatal health. Project ECHO has been a component of many regional and state initiatives aimed at eliminating hepatitis C. Through this program hundreds of primary care providers have been educated and trained at identifying and treating hepatitis C as well as other health care needs.

Federally Qualified Health Clinics

Federally qualified health clinics (FQHC) have undertaken initiatives to identify, and track uninsured individuals and Medicaid and Medicare beneficiaries who need to begin HCV care. For example, the Public Health Management Corporation implemented universal, one-time HCV testing and linkage to care in its five FQHC.⁵⁰ These clinics each had unique patient populations including people experiencing homelessness, a predominately Hispanic population, and residents of nearby public housing facilities. Care started with HCV screening that utilized reflex testing technology to automatically test antibody-positive results for confirmatory HCV RNA. After linkage to a care provider, the clinics maintained a care continuum through retrospective chart review, incorporating specialty consultation notes, and reports from the on-site Linkage to Care Coordinator and HCV Treatment Coordinator.⁵¹

COVID Test to Treat

The federal US COVID Test-to-Treat Initiative provides insights into a federally-funded and administered procurement and care model which may be applicable to addressing gaps in hepatitis C care. The initiative is part of a broad federal strategy to efficiently connect eligible and high-risk individuals to COVID-19 treatment.⁵² Test-to-Treat combines large-scale, population-focused procurement of tests and treatments with a one-stop healthcare setting where patients can receive a rapid COVID-19 test, counseling and assessment from a healthcare provider, and a prescription for a COVID-19 oral antiviral if eligible.⁵³ Sites of care include pharmacies, community health centers, HRSA-supported federally qualified health centers, long-term care facilities, and veteran's affairs clinics.⁵⁴ Forty percent of these sites are in communities with high social vulnerability, and all sites are asked to collect demographic data on individuals receiving prescriptions in order to assess gaps in access to care sites. The hepatitis C care delivery pathway has many of the same access barriers as COVID-19 care, which may allow stakeholders to glean lessons from the Test-to-Treat Initiative and apply them to a potential hepatitis C model. Both care delivery pathways face: low awareness of and uptake of testing and treatment capacities; remaining questions surrounding payment and reimbursement structures for delivering care; and limited access to testing centers and treatment facilities for populations placed at risk.

The Ryan White HIV/AIDS Program

In addition to the Test to Treat Initiative, several other federal condition-based procurement and care models may provide insights into designing a federal hepatitis C care delivery model. The Ryan White HIV/AIDS Program, administered by the Health Resources & Services Administration (HRSA) provides medical care, medication, and essential support services to uninsured or under-insured people living with HIV/AIDS.⁵⁵ The program does not specifically procure medical services, but instead provides grants to cities, states, counties, and community-based groups for different health and social services. The Program is split into five parts with different beneficiaries and eligibility requirements. Through this structure, it is able to fund a wide range of care and support services, provide educational services to providers and patients, and develop innovative care models.⁵⁶ A similar approach may be suitable for reaching certain populations with HCV, which has a shorter treatment regimen, but similarly complex care pathway. However, the frequently asymptomatic nature of HCV poses an additional awareness and education barrier.

Next Steps

This Discussion Guide has presented potential elements of a strategic framework for a national hepatitis C elimination program, and reviewed some of the experience relevant to HCV elimination across a range of population segments and purchasers. Key elements of this framework include working out a suitable drug procurement strategy, and supporting robust clinical pathways for identifying and treating patients. This national strategy could build on considerable existing activities aiming to reduce the burden of HCV while leveraging existing programs for populations most at risk will also help limit additional resource needs. The strategy will also require a data infrastructure that could include developing best practices for clinical dashboards to translate overall goals into access to drugs, effective screening, and linkage to care, along with key performance indicators to help measure progress. Clinical opportunities for provider education and training, greater flexibility in prescribing practices and virtual platforms will connect more patients with the care they require. Lastly, there are many programs in place that have demonstrated notable successes in engaging the patient populations with the greatest proportions of hepatitis C prevalence, namely, the uninsured, the incarcerated, and Medicaid beneficiaries, as well as highlighted the practical barriers that must be addressed for a successful program. Leveraging existing programs with

community ties and trusted community workers to engage and expand awareness for at-risk and hardy reached populations is critical to advance HCV elimination.

This multi-stakeholder meeting will center on the key elements and implementation considerations for a national HCV elimination strategy. Key questions for this meeting include:

- What are the key elements of a strategic framework for a national elimination strategy that can address the key barriers to each step in the care cascade for hepatitis C? How should the framework described here be modified or augmented?
- What are the most promising approaches to address barriers to care for each of the major population segments for hepatitis C?
- Is there an opportunity to develop a standard dashboard of key metrics to motivate and track progress for national hepatitis C elimination?
- What steps might the federal government take to support national elimination efforts? What roles should state and public health agencies take?
- What are the direct and indirect cost considerations to fund and resource a national elimination effort? Which stakeholders can support funding such an effort? What are the most feasible and efficient ways to build on existing efforts and resources?
- What other critical steps need to be addressed to implement an effective national hepatitis C elimination strategy?

¹ Jules Levin. Disease burden in patients with chronic hepatitis C virus (HCV) infection in a United States (US) private health insurance claims database analysis from 2003 to 2010 [Internet]. Conference Reports for NATAP. 2011 [cited 2022 Jul 12]. Available from: https://www.natap.org/2011/AASLD/AASLD_48.html

² Viral Hepatitis and Liver Cancer [Internet]. Centers for Disease Control and Prevention; Available from: <https://www.cdc.gov/nchstp/newsroom/docs/factsheets/viral-hep-liver-cancer.pdf>

³ Viral Hepatitis National Strategic Plan [Internet]. Department of Health and Human Services; Available from: <https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf>

⁴ Office of Infectious Disease and HIV/AIDS. Viral Hepatitis in the United States: Data and Trends [Internet]. HHS.gov. 2016 [cited 2022 Jul 16]. Available from: <https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html>

⁵ Spach D, Maria Corcoran. HCV Epidemiology in the United States [Internet]. Hepatitis C Online. 2021 [cited 2022 Jul 12]. Available from: <https://www.hepatitisc.uw.edu/go/screening-diagnosis/epidemiology-us/core-concept/all#hcv-incidence-united-states>

⁶ Viral Hepatitis National Strategic Plan [Internet]. Department of Health and Human Services; Available from: <https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf>

⁷ Jules Levin. Disease burden in patients with chronic hepatitis C virus (HCV) infection in a United States (US) private health insurance claims database analysis from 2003 to 2010 [Internet]. Conference Reports for NATAP. 2011 [cited 2022 Jul 12]. Available from: https://www.natap.org/2011/AASLD/AASLD_48.htm

⁸ Jung J, Feldman R, Kalidindi Y, Riley T. Association of Direct-Acting Antiviral Therapy for Hepatitis C With After-Treatment Costs Among Medicare Beneficiaries. JAMA Network Open. 2020;3(6):e208081

⁹ Jonas MC, Rodriguez CV, Redd J, Sloane DA, Winston BJ, Loftus BC. Streamlining Screening to Treatment: The Hepatitis C Cascade of Care at Kaiser Permanente Mid-Atlantic States. Clin Infect Dis. 2016;62(10):1290–6.

¹⁰ Lu CY, Ross-Degnan D, Zhang F, LeCates R, Lupton C, Sherman M, et al. Cost burden of hepatitis C virus treatment in commercially insured patients. Am J Manag Care. 2019 Dec 1;25(12):e379–87.

- ¹¹ Office of Infectious Disease and HIV/AIDS. Mapping Hepatitis Elimination in Action [Internet]. Department of Health and Human Services. 2019 [cited 2022 Jul 17]. Available from: <https://www.hhs.gov/hepatitis/mapping-hepatitis-elimination-in-action/index.html>
- ¹² Bush H, Paik J, Golabi P, de Avila L, Escheik C, Younossi ZM. Impact of hepatitis C virus and insurance coverage on mortality. *Am J Manag Care*. 2019 Feb;25(2):61–7.
- ¹³ Access in Brief: Adults' Experiences in Accessing Medical Care [Internet]. Medicaid and CHIP Payment and Access Commission; 2021 Nov. Available from: <https://www.macpac.gov/wp-content/uploads/2012/06/Access-in-Brief-Adults-Experiences-in-Accessing-Medical-Care.pdf>
- ¹⁴ Barriers to treatment of chronic hepatitis C with direct acting antivirals in an urban clinic - ScienceDirect [Internet]. [cited 2022 Jul 12]. Available from: <https://www.sciencedirect.com/science/article/pii/S1665268119300067?via%3Dihub>
- ¹⁵ Medicaid and Rural Health [Internet]. Medicaid and CHIP Payment and Access Commission; 2021 Apr. Available from: <https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf>
- ¹⁶ Allen EM, Call KT, Beebe TJ, McAlpine DD, Johnson PJ. Barriers to Care and Healthcare Utilization among the Publicly Insured. *Med Care*. 2017 Mar;55(3):207–14.
- ¹⁷ Suzanne Davies, Greenwald R, Julia Harvey. Hepatitis C: State of Medicaid Access [Internet]. Nation Viral Hepatitis Roundtable; 2022 Jun. Available from: https://stateofhepc.org/wp-content/uploads/2022/06/State-of-Hep-C-Report_2022-1.pdf
- ¹⁸ HCV Testing and Treatment in Correctional Settings [Internet]. American Association for the Study of Liver Diseases. 2019. Available from: <https://www.hcvguidelines.org/unique-populations/correctional>
- ¹⁹ Varan AK, Mercer DW, Stein MS, Spaulding AC. Hepatitis C Seroprevalence among Prison Inmates since 2001: Still High but Declining. *Public Health Reports*. 2014;129(2):187-195. doi:10.1177/003335491412900213
- ²⁰ Kil Huh, Alex Boucher, Frances McGaffey, Matt McKillop, Maria Schiff. Pharmaceuticals in State Prisons [Internet]. The Pew Charitable Trusts; 2017 Dec. Available from: <https://www.pewtrusts.org/-/media/assets/2017/12/pharmaceuticals-in-state-prisons.pdf>
- ²¹ State Activities to Combat Hepatitis C: Hepatitis C Medicaid Affinity Final Report. Office of Infectious Disease and HIV/AIDS Policy. October 2021
- ²² VA research on Hepatitis C [Internet]. VA Office of Research and Development. [cited 2022 Jul 16]. Available from: <https://www.research.va.gov/topics/hep-c.cfm>
- ²³ VA Expands Hepatitis C Drug Treatment [Internet]. Office of Public and Intergovernmental Affairs. [cited 2022 Jul 16]. Available from: <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=2762>
- ²⁴ Gonzalez R, Park A, Yakovchenko V, Rogal S, Chartier M, Morgan TR, Ross D. HCV Elimination in the US Department of Veterans Affairs. *Clin Liver Dis (Hoboken)*. 2021 Aug 18;18(1):1-6. doi: 10.1002/cl.1150. PMID: 34484696; PMCID: PMC8405054.
- ²⁵ Gonzalez R, Park A, Yakovchenko V, Rogal S, Chartier M, Morgan TR, Ross D. HCV Elimination in the US Department of Veterans Affairs. *Clin Liver Dis (Hoboken)*. 2021 Aug 18;18(1):1-6. doi: 10.1002/cl.1150. PMID: 34484696; PMCID: PMC8405054.
- ²⁶ National Institute on Drug Abuse. Substance Use and Military Life Drug Facts [Internet]. National Institute on Drug Abuse. 2019 [cited 2022 Jul 16]. Available from: <https://nida.nih.gov/publications/drugfacts/substance-use-military-life>
- ²⁷ Veteran Homelessness [Internet]. National Coalition for Homeless Veterans. [cited 2022 Jul 16]. Available from: <https://nchv.org/veteran-homelessness/>
- ²⁸ Fleming BS, Ifeachor AP, Andres AM, Reese LJ, Davis EE, Liangpunsakul S, White CA, Ruoff CM. Improving Veteran Access to Treatment for Hepatitis C Virus Infection: Addressing social issues and treatment barriers significantly increases access to HCV care, and many veterans successfully start therapy with the help of additional support staff. *Fed Pract*. 2017 Jun;34(Suppl 4):S24-S28. PMID: 28867928; PMCID: PMC5576442.
- ²⁹ Thomas G. Lynch. Evaluation and Treatment of Veterans with Hepatitis C (HCV) and Co-occurring Substance Use or mental Health Concerns [Internet]. Available from: <https://www.hepatitis.va.gov/pdf/memo-HCV-and-mental-health.pdf>
- ³⁰ Bush H, Paik J, Golabi P, de Avila L, Escheik C, Younossi ZM. Impact of hepatitis C virus and insurance coverage on mortality. *Am J Manag Care*. 2019 Feb;25(2):61–7.
- ³¹ Insurance Barriers Contribute to Health Disparities Among Commercially Insured Americans. Pharmaceutical Research and Manufacturers of America; 2022 Mar. Available from: <https://phrma.org/>

- /media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/PhRMA_Equity_InsuranceBarriers.pdf#:~:text=However%2C%20extensive%20research%20demonstrates%20that%20historically%20underserved%20populations,facilitate%20access%20to%20medications%20is%20that%20socioeconomically%20disadvantaged%20patients
- ³² PBMs Reducing Drug Prices [Internet]. Nalashaa Healthcare Solutions; 2018. Available from: <https://nalashaahealth.com/Content/Whitepapers/pharmacy-benefit-managers.pdf#:~:text=PBMs%20are%20able%20to%20lower%20drug%20spending%20by,to%20reduce%20premiums%20and%20out-of-pocket%20costs%20for%20patients.>
- ³³ Bush H, Paik J, Golabi P, de Avila L, Escheik C, Younossi ZM. Impact of hepatitis C virus and insurance coverage on mortality. *Am J Manag Care*. 2019 Feb;25(2):61–7.
- ³⁴ Jung J (Kyoung-rae), Feldman R, Cheong C, Du P, Leslie D. Coverage for Hepatitis C Drugs in Medicare Part D. *Am J Manag Care*. 2016 May;22(6 Spec No):SP220–6.
- ³⁵ Mera J, Gahn D, Lyon L, et al.. The Road to Hepatitis C Elimination in Cherokee Nation Health Services In: Presented at the International Symposium on Hepatitis Care in Substance Users. Jersey City, NJ; September 15, 2017. [Google Scholar]
- ³⁶ Leston J, Finkbonner J. The Need to Expand Access to Hepatitis C Virus Drugs in the Indian Health Service. *JAMA*. 2016;316(8):817–818. doi:10.1001/jama.2016.7186
- ³⁷ Bruce V, Eldredge J, Leyva Y, Mera J, English K, Page K. Hepatitis C Virus Infection in Indigenous Populations in the United States and Canada. *Epidemiol Rev*. 2019 Jan 31;41(1):158-167. doi: 10.1093/epirev/mxz015. PMID: 31781749; PMCID: PMC7305812.
- ³⁸ Hepatitis C Elimination Strategy for AI/AN Communities [Internet]. Indian Country Echo; Available from: <https://cdn.indiancountryecho.org/wp-content/uploads/2021/07/HCV-Elimination-Strategy-for-AIAN-Communities.pdf>
- ³⁹ Cherokee Nation Health Services HCV Elimination Program [Internet]. Coalition for Global Hepatitis Elimination. [cited 2022 Jul 18]. Available from: <https://www.globalhep.org/programs/ Cherokee-nation-health-services-hcv-elimination-program>
- ⁴⁰ Geiger R, Steinert J, McElwee G, Carver J, Montanez R, Niewoehner J, Clark C, Reilley B. A Regional Analysis of Hepatitis C Virus Collaborative Care With Pharmacists in Indian Health Service Facilities. *J Prim Care Community Health*. 2018 Jan-Dec;9:2150132718807520. doi: 10.1177/2150132718807520.
- ⁴¹ Bush H, Paik J, Golabi P, de Avila L, Escheik C, Younossi ZM. Impact of hepatitis C virus and insurance coverage on mortality. *Am J Manag Care*. 2019 Feb;25(2):61–7.
- ⁴² Tolbert J, Nov 06, 2020. Key Facts about the Uninsured Population [Internet]. KFF. 2020 [cited 2022 Jul 16]. Available from: <https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/>
- ⁴³ Access in Brief: Adults’ Experiences in Accessing Medical Care [Internet]. Medicaid and CHIP Payment and Access Commission; 2021 Nov. Available from: <https://www.macpac.gov/wp-content/uploads/2012/06/Access-in-Brief-Adults-Experiences-in-Accessing-Medical-Care.pdf>
- ⁴⁴ Kendal Ortega, Robin Rudowitz. A Closer Look at the Remaining Uninsured Population Eligible for Medicaid and CHIP [Internet]. Kaiser Family Foundation. 2021 [cited 2022 Jul 16]. Available from: <https://www.kff.org/uninsured/issue-brief/a-closer-look-at-the-remaining-uninsured-population-eligible-for-medicaid-and-chip/>
- ⁴⁵ Ending the HIV Epidemic in the U.S. (EHE) [Internet]. Centers for Disease Control and Prevention. 2022 [cited 2022 Jul 16]. Available from: <https://www.cdc.gov/endhiv/index.html>
- ⁴⁶ Bradley H, Hall E, Asher A, Furukawa N, Jones CM, Shealey J, Buchacz K, Handanagic S, Crepaz N, Rosenberg ES. Estimated number of people who inject drugs in the United States. *Clin Infect Dis*. 2022 Jul 6:ciac543. doi: 10.1093/cid/ciac543. Epub ahead of print. PMID: 35791261.
- ⁴⁷ Grebely J, Larney S, Peacock A, Colledge S, Leung J, Hickman M, Vickerman P, Blach S, Cunningham EB, Dumchev K, Lynskey M, Stone J, Trickey A, Razavi H, Mattick RP, Farrell M, Dore GJ, Degenhardt L. Global, regional, and country-level estimates of hepatitis C infection among people who have recently injected drugs. *Addiction*. 2019 Jan;114(1):150-166. doi: 10.1111/add.14393. Epub 2018 Aug 28. PMID: 30035835; PMCID: PMC6657799.
- ⁴⁸ Substance Use and Co-Occurring Mental Disorders [Internet]. National Institute of Mental Health. [cited 2022 Jul 16]. Available from: <https://www.nimh.nih.gov/health/topics/substance-use-and-mental-health>
- ⁴⁹ Viral Hepatitis ECHO Programs [Internet]. [cited 2022 Jul 16]. Available from: <https://hsc.unm.edu/echo/partner-portal/programs/new-mexico/hcv-community/>

⁵⁰ Coyle C, Moorman AC, Bartholomew T, Klein G, Kwakwa H, Mehta SH, et al. The Hepatitis C Virus Care Continuum: Linkage to Hepatitis C Virus Care and Treatment Among Patients at an Urban Health Network, Philadelphia, PA. *Hepatology*. 2019;70(2):476–86.

⁵¹ Coyle C, Moorman AC, Bartholomew T, Klein G, Kwakwa H, Mehta SH, et al. The Hepatitis C Virus Care Continuum: Linkage to Hepatitis C Virus Care and Treatment Among Patients at an Urban Health Network, Philadelphia, PA. *Hepatology*. 2019;70(2):476–86.

⁵² Fact Sheet: COVID-19 Test to Treat [Internet]. Office of the Assistant Secretary for Preparedness & Response; 2022 Mar. Available from: <https://aspr.hhs.gov/TestToTreat/Documents/Fact-Sheet.pdf>

⁵³ Fact Sheet: COVID-19 Test to Treat [Internet]. Office of the Assistant Secretary for Preparedness & Response; 2022 Mar. Available from: <https://aspr.hhs.gov/TestToTreat/Documents/Fact-Sheet.pdf>

⁵⁴ Brian Canter, Matt D'Ambrosio, Katie Greene, Morgan Romine, Mark McClellan. COVID-19 Test to Treat Pathways: Policy Options for Achieving National Implementation [Internet]. Duke Margolis Center for Health Policy; Available from: <https://healthpolicy.duke.edu/sites/default/files/2022-05/Margolis%20Test%20to%20Treat%20Pathways.pdf>

⁵⁵ Ryan White HIV/AIDS Program Grantees [Internet]. Health Resources & Services Administration. [cited 2022 Jul 16]. Available from: <https://www.hrsa.gov/opa/eligibility-and-registration/ryan-white>

⁵⁶ Ryan White HIV/AIDS Program Parts & Initiatives [Internet]. Health Resources & Services Administration. [cited 2022 Jul 16]. Available from: <https://ryanwhite.hrsa.gov/about/parts-and-initiatives>