

Advancing Hepatitis C Elimination:

Strategic Framework for a National Program

Executive Summary

Chronic hepatitis C infection continues to cause significant morbidity and mortality (especially in American Indian and Alaska Native (AI/AN) and Black non-Hispanic populations, as well as people born between 1945-1965) and is a leading cause of liver cancer and liver transplantation in the US, despite the availability of diagnostic tests and curative therapies.¹ Growing experience with mechanisms to increase access to “test to treat” initiatives as part of enhanced and community-based primary care models, community-based COVID-19 responses, and improving diagnostic technologies and digital supports makes this an opportune moment to prioritize containment and elimination of hepatitis C. A comprehensive national response facilitating a streamlined test to treat pathway that combines innovative drug procurement models and diagnostic development with integrated treatment, enhanced disease detection and monitoring, and provider education will substantially impact the number of patients treated and cured of hepatitis C. However, questions remain about implementation considerations for such activities on a national scale.

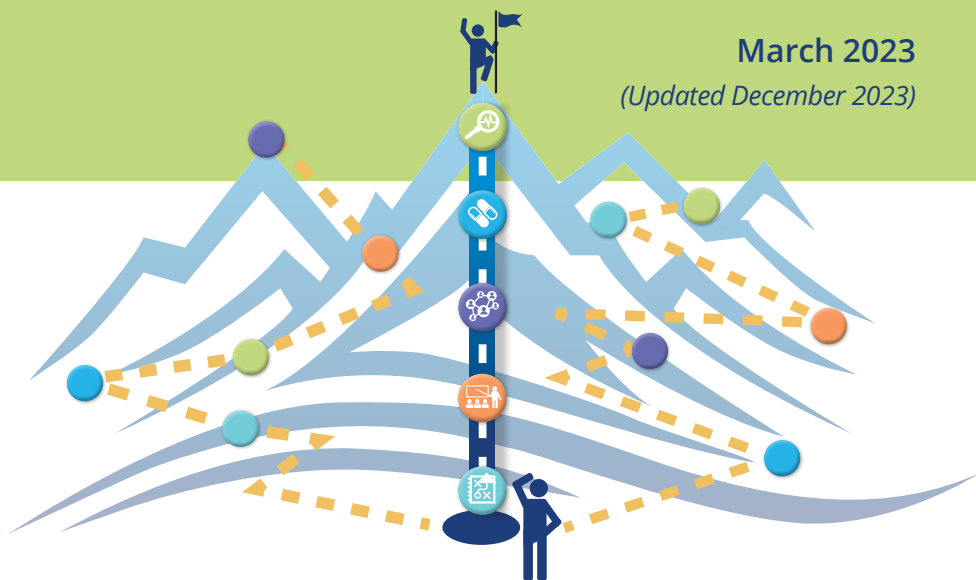
Building on prior convenings and growing experience with hepatitis C initiatives, the Duke-Margolis Institute for Health Policy has developed an evidence and context-based preliminary strategic framework that can provide a foundation for implementation of a national elimination strategy. The framework reflects learnings from federal, state, regional, and local public health entities and initiatives to overcome barriers to test and treat hepatitis C. The core components of the framework include:

1. Accelerated development, regulatory review, and Food and Drug Administration (FDA) approval of rapid point-of-care (POC) tests and expanded use of “reflex” testing to enable testing and treatment in a single visit.

2. Expanded disease detection and monitoring through collaborations between health care and public health.
3. Population-level procurement models for availability of diagnostics and direct acting antivirals (DAAs) at low unit costs.
4. Financial and technical support for investments and sustainability for primary care services and community-based organizations to deliver the full cascade of hepatitis C prevention and treatment.
5. Provider and public education about hepatitis C and accessibility of testing and treatment.

The purpose of this document is to describe key components of the preliminary framework and detail supportive information drawn from various activities, programs, plans, and goals identified by key stakeholders. This includes an assessment of key implementation considerations for patient populations that receive care supported by different major insurance programs and financing systems, with the goal that a national strategy can build on existing efforts in each program and be sustained within them in order to reduce the need for additional funding.

This document begins with an overview of the burden of disease of hepatitis C in the United States (US), followed by descriptions of preliminary strategic framework components, an analysis of regional and state-based programs designed to expand access to care and how such existing programs can inform a strategic framework for a national program, and concludes with context-based implementation considerations for a national program.



Introduction

Chronic hepatitis C, a bloodborne liver infection, is a leading cause of serious liver diseases including hepatocellular carcinoma. Despite the availability of multiple curative treatments since 2013, the incidence of hepatitis C virus (HCV) in the US increased by 71 percent between 2014 and 2018, with two-thirds of cases occurring among individuals impacted by the opioid crisis, with over 2 million estimated chronic cases.² Hepatitis C also contributes to significant health care spending; Medicaid data from 2012 showed health care costs were estimated to be between \$10,561 and \$46,263 annually per person depending on disease severity.³

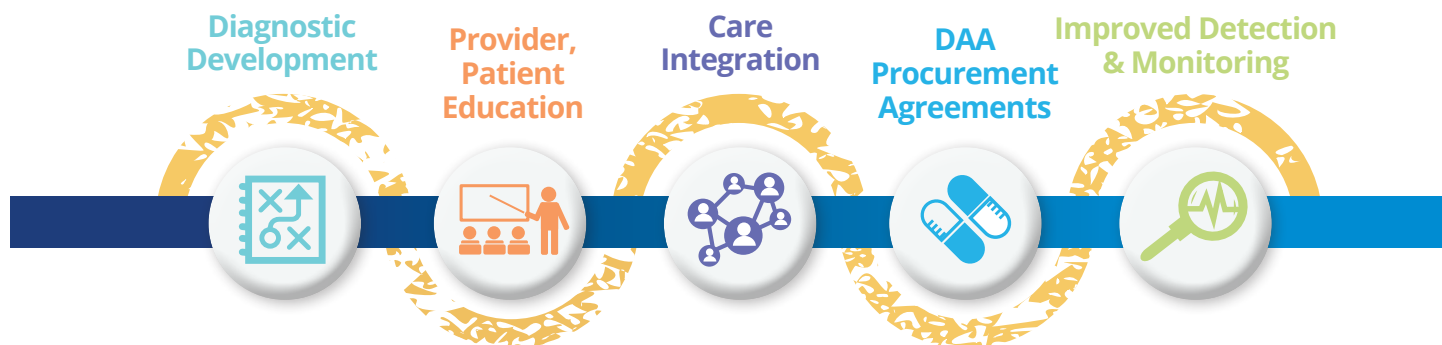
In the US, the care cascade to both diagnose and treat hepatitis C can be complex. Diagnosis of hepatitis C currently requires a two-step testing process: an HCV antibody screening followed by a polymerase chain reaction ribonucleic acid (RNA) confirmatory test. While rapid POC antibody tests are available, RNA confirmatory tests can currently only be conducted in a lab. Beyond a two-step diagnostic approach, barriers to care include inadequate disease detection and monitoring as well as failure to identify patients with chronic infection. Following diagnosis, patients undergo disease evaluation by a provider to determine the viral genotype and characterize the severity of liver damage. Typically, this requires a referral to a specialist provider, which is another point at which patients may be lost to follow up. Once DAA treatment is prescribed, patients may be referred to subspecialists for additional care based on the severity of disease. Following a treatment regimen ranging from eight to 24 weeks, an additional test will determine if patients achieve sustained virologic response (SVR).

The Viral Hepatitis National Strategic Plan describes milestones for national hepatitis C elimination, which have led to the creation of many hepatitis C elimination programs at the local, regional, state and national level targeting various impacted populations.⁴ Regional and state Medicaid hepatitis C treatment models illustrate the implementation pathways required for programs aiming to increase the number of patients treated and reaching SVR. While many of these programs are in their early stages, preliminary results indicate that there are marked improvements in treatment uptake following program implementation.^{5,6}

There are opportunities to expand access to hepatitis C care and treatment by combining both drug procurement models similar to those piloted in Louisiana, Washington, and Michigan with coordinated care delivery models similar to regional programs piloted in Seattle, Chicago, and Baltimore. These models show that innovative population-focused drug procurement models coupled with supports for improving access to test to treat care pathways in primary care programs and other community-based settings for patients without access to adequate primary care could result in a substantial increase in the number of patients treated and that reach SVR.^{7,8,9} For populations not easily reached through insurance-based drug procurement and test to treat programs, the unprecedented public health and health care response to COVID-19 included extending access to comprehensive test to treat approaches to uninsured and underserved populations.¹⁰ Even with these unprecedented efforts, however, test to treat programs still faced challenges reaching rural populations and populations without access to telehealth.^{11,12}

A national program could be designed to scale components from successful models of comprehensive hepatitis C screening, testing, and payment, particularly to improve access and uptake for populations served by Medicaid and Medicare, as well as other high-risk individuals who are uninsured or underserved by existing health care infrastructure. The proposed components of a national strategic framework – *diagnostic development, disease detection, drug procurement, awareness and education, and care integration*– address barriers to access identified in previous meetings and reflect lessons learned from successful local and regional programs for treating hepatitis C.

Strategic Framework for a National Hepatitis C Elimination Program



Accelerating the **development, regulatory review, and FDA approval of rapid POC tests** and alternative one-step diagnostic approaches will be key for streamlining the care pathway by facilitating a single-visit, test to treat model and is needed to increase the likelihood that patients will both initiate and complete treatment in a variety of clinical settings. This includes treatment of patients in decentralized settings, where hardly-reached populations are more likely to receive their care. However, it may be some time before POC RNA tests are commercially available and widely accessible. Absent POC RNA diagnostics, the care cascade for any patient, regardless of payer coverage, will rely on the current two-step diagnostic process. The challenge in the two-step process is that patients may be lost to follow-up. One way to mitigate this challenge is the use of reflex testing to ensure each positive antibody test triggers use of a confirmatory RNA test.

Noting the importance of a more streamlined testing process, a new funding opportunity has emerged through the Independent Test Assessment Program (ITAP), established as part of the National Institutes of Health Rapid Acceleration of Diagnostics (RADx[®]) Tech program. This funding opportunity aims to facilitate expedited validation, authorization, and commercialization of POC hepatitis C RNA quantitative diagnostics.¹³ This program is likely to lead to clarification on FDA authorization requirements, including evidence thresholds for regulatory approval or clearance.

There are a number of factors that may impact the regulatory pathway and coverage landscape for novel POC hepatitis C diagnostics. For example, the sample collection mode used by diagnostics in development may have bearing on the regulatory pathway due to the impact on test sensitivity. Another consideration is whether developers will pursue marketing such products for CLIA-

waived settings initially or whether it will be desirable to seek review as a product intended for moderate complexity settings, which will have bearing on access across different population segments. As the POC hepatitis C RNA diagnostic presents a departure from the current two-step screening and diagnostic process, developers, as well as the FDA, will consider evolving regulatory requirements, which may have downstream effects on coverage and payment for the use of the products. It may be challenging to make the case for coverage of costly innovative one-step diagnostics when cheaper alternatives to screening and confirming hepatitis C infection exist. It will be important to identify all relevant coverage, payment, and cost-effectiveness considerations for diagnostic, screening, and POC tests as they become available. Different sites will likely make procurement decisions based on their capacity and resources available as well as established workflows.

Finally, while the ITAP program will spur development, it may not address manufacturing and scalability needs to broadly increase access. This also necessitates considerations for capacity building for onsite screening such as supply ongoing costs supplies, data analysis systems and maintenance, staff training, and certification.

Disease detection and monitoring will be important for identifying and addressing the spread of hepatitis C, particularly in areas with hardly-reached communities with high HCV transmission. Significant updates to as well as expansion of existing disease detection and monitoring infrastructure on the local and state level are needed to ensure all components of a national strategy are informed by timely, accurate data. Further, networks that enable data sharing and data aggregation into clinical dashboards to support patient identification, planning, and tracking progress will need to be established in order to support other components of a national elimination strategy.

Population-level DAA procurement models can ensure adequate availability of affordable DAAs for impacted populations. While the cost of DAAs have decreased over time as additional products have entered the market, many payers retain restrictive coverage policies by requiring prior authorization as well as prescriber and patient criteria. All patient populations across payer contexts would benefit from lifting prior authorization restrictions or other prescribing restrictions misaligned with clinical care guidelines such as fibrosis restrictions, substance use restrictions prior to or during treatment, counseling on substance use, specialist prescriber requirements, and restricted access to retreatment. Payment approaches through negotiated manufacturer and payer/purchaser agreements, coupled with expanded coverage policies will facilitate broader access to treatment. Linking these population-focused drug procurement models to clear, evidence-based strategies for increasing awareness and uptake of these drugs in effective test to treat pathways in primary care and other community-based settings could create new opportunities for partnerships between manufacturers, payers, and providers to create sustainable and effective health system capabilities to contain and eliminate hepatitis C.

Awareness and education about hepatitis C and availability of testing and therapeutics will be needed to overcome the existing knowledge gaps around impacted populations and treatment options. Such education will need to increase awareness of the risks associated with chronic, untreated hepatitis C and provide resources to test and treat. Outreach strategies to increase awareness about any new elimination program will be required, particularly if the program includes a change in existing policies. Peer-led initiatives may help mitigate stigma and encourage patients to seek treatment. Provider outreach and education may help address knowledge gaps around ability to treat and prescriber restrictions. Such education will need to include strategies of how to increase hepatitis C testing and treatment offerings among already heavily burdened providers.

Finally, strengthening **care integration** will be crucial for increasing the number of people screened and treated by limiting barriers to care access that compound throughout the care cascade. Significant improvements are needed to support diagnosis, linkage to care, disease assessment and treatment. All patient populations will benefit from clinic-based interventions that support provider's ability to identify and treat high risk populations. Electronic health record (EHR)-based interventions may include automated prompts to alert providers when to screen patients for

hepatitis C linked to Centers for Medicare and Medicaid Services (CMS) supported electronic standards for tracking screening, treatment initiation, and completion.

It is important to note that the population affected by hepatitis C overlaps with populations with hepatitis B, human immunodeficiency virus (HIV), and substance use disorder (SUD). This population overlap presents both opportunities and challenges for streamlining the hepatitis C care cascade. Stakeholders may be able to leverage existing points of care and care programs to co-locate diagnosis and treatment for populations with multiple conditions. However, requirements to diagnose and treat multiple conditions at once can pose challenges such as increasing provider burden or risk of drop off points in the care pathway.

The incarcerated population is of particular focus as one of the populations with the highest prevalence of hepatitis C. Moreover, incarcerated populations also have a high likelihood of multiple conditions and cannot be reached through community-based approaches and traditional health care services. Increased care access will require innovative models for care delivery and harm reduction coupled with expanded coverage. This includes exploration of state mechanisms to receive additional authorities through CMS to expand coverage among the incarcerated prior to release and continuation of care post-release for hepatitis C services.

Population-Level Program Examples

Several programs to address hepatitis C have sought to demonstrate a reliable pathway for screening, testing, and treatment through innovative approaches for DAA access, improved disease detection and monitoring, provider training, patient identification, and care management.^{14, 15, 16, 17} These demonstration programs have been successful in increasing the number of patients treated with DAAs and could serve as guideposts for larger scale efforts towards elimination.

Demonstration programs that incorporate novel approaches to expand treatment access are the Medicaid population-based initiatives in Louisiana, Washington, and Michigan that leverage public-private partnerships to enhance DAA procurement and state-level efforts to identify, screen, and treat patients.^{18, 19, 20} These state models provide learnings about contract nuances for DAA procurement for large populations as states have been successful in navigating negotiations with manufacturers to secure large volumes of DAAs while reducing budgetary impacts and demonstrating willingness of manufacturers to engage in these types of contracts. Additionally, these programs demonstrated effective administrative measures for improving disease detection and monitoring, education, provider training and the treatment cascade. All three of these Medicaid population-based initiatives started within the last five years and have been complicated by the COVID-19 pandemic. As such, there is limited evidence on their overall effects. Preliminary data indicate that after the launch of the program in Louisiana, the number of patients initiating treatment jumped from 288 persons to 1,584 persons over one quarter in 2019. However, the number of patients starting treatment have gradually declined since this initial spike.²¹ While results may have been affected by historical access to DAAs, differing programmatic elements, and COVID-19 response, these programs demonstrate the importance of implementing a comprehensive approach that spans beyond DAA procurement as DAA procurement is necessary but not sufficient to eliminate hepatitis C in a given population.

The remaining examples below demonstrate that a comprehensive approach to streamlining the care cascade can create significant improvements in the number of patients identified, treated, and cured.

Programs in Seattle, Chicago, and Baltimore that focused primarily on treating hepatitis C in the baby boomer population in safety net health organizations and primary care clinics offer examples of successful implementation strategies necessary for reaching

impacted populations. Of note, these programs utilized a range of strategies including provider training, patient education, case management services, improved data collection, EHR prompts, and reflex testing, which resulted in improvements in screening and treatment rates.^{22, 23, 24} These care delivery-focused programs were successful in increasing the number of patients identified and treated for hepatitis C within a population traditionally hardly-reached by traditional health care systems, even in the absence of a DAA procurement component. These programs demonstrate the value of streamlining the care cascade and access to hepatitis C treatment in Federally Qualified Health Centers (FQHCs), community, and primary care clinics. Preliminary positive results indicate further streamlining the care cascade to a single visit may likely make a significant impact on rates of screening and treatment. However, in the absence of one-step POC diagnostics, these programs will be unable to implement a more ideal single visit, test to treat model of care.

Notable success has also been seen in programs for reaching patients within AI/AN populations. Of note, the Cherokee Nation (CN) Hepatitis C Elimination Program included a comprehensive range of elements in order to support improved patient identification and streamlining of care delivery among individuals living in a 14-county CN reservation in Oklahoma.²⁵ Program activities included universal screening, implementation of provider EHR prompts, implementation of an HCV registry, a public awareness campaign, provider training, case management, and delivery of harm reduction services linked to opioid use disorder treatment. Through this effort, HCV screening rates increased from 21 to 38 percent, and substantial improvements were made across the care cascade especially in hepatitis C linkage to care and curative therapies.

The didg^wálič Wellness Center in Washington on Swinomish Tribal lands demonstrated success in co-locating care with a single point of treatment and integrating ancillary services such as transportation and childcare to remove barriers to access.²⁶ This program began as a center to treat alcohol dependence then expanded to include opioid use disorder. The center continued to grow to meet the needs of the community and included services such as mental health care, primary health care, SUD treatment, medication assisted treatment, on-site social workers, and a hepatitis C treatment program. This program provides a replicable model for how to deliver tailored, culturally relevant care and social services to a historically hardly reached population.

The Veterans Health Administration (VHA) hepatitis C elimination program achieved significant success in identifying and treating the vast majority of impacted individuals served by the VHA.²⁷ The VHA is able to negotiate substantial discounts for drug prices to support large-scale DAA treatment for veterans under care of the VHA. In conjunction with drug procurement, the VHA established a national hepatitis C clinical dashboard and registry along with clinic-based interventions such as automated EHR prompts for providers. The VHA additionally established the Hepatitis C Innovation Team Collaborative, which included use of multi-disciplinary field-based care teams trained in clinical systems redesign and innovation to improve care pathways for hepatitis C.²⁸ Since 2014, the VHA has treated approximately 120,000 veterans. An estimated 20,000 veterans remain untreated.²⁹ This program is an example of combining a population-focused drug procurement component, improved disease detection and monitoring, and a targeted and coordinated care pathway.

Learnings from population treatment efforts for individuals at elevated risk of hepatitis C, but without access to adequate insurance, can also be leveraged. The Ryan White HIV/AIDS Program (RWHAP) is an example of a long-term national approach to treat HIV, especially among vulnerable and hard-to-reach populations. This program's experience, data, trusted relationships and care access points can serve as a model for hepatitis C elimination for an important segment of the hepatitis C-impacted population. The RWHAP is a comprehensive, multifaceted model that facilitates care at the local and regional level for patient populations historically underserved in traditional care settings. This program has been established for 30 years and has a robust network of clinics that have been successful in reaching and treating patients with HIV. In 2019, 568,000 people received services through RWHAP, and 88 percent of clients receiving RWHAP HIV medical care were virally suppressed (compared to national average of 66 percent).³⁰ The RWHAP program has also succeeded in decreasing disparities in viral suppression rates, which is a critical outcome for both reducing transmission of HIV and for reducing morbidity and mortality. Through its programming, between 2010-2014 RWHAP was able to reduce disparities in its clients between Black and white populations and between adolescents and young adults compared to older people, although there are still significant disparities across race, ethnicity, age, gender, and housing status.³¹

The COVID-19 test to treat programs for underserved populations can serve as a more recent example of a short-term national strategy for a test to treat pathway, combined with medical product procurement, disease detection and monitoring to identify high-risk areas, and patient outreach. The COVID-19 response demonstrated capacity to organize federal, state, and local entities on a range of services. Of relevance are rapid review, approval, and distribution of diagnostics and mobilization of the health care workforce to contain transmission through diagnosis, public education, coverage, and treatment. While a response on this scale and at this speed is not likely feasible for hepatitis C, the COVID-19 test to treat pathway, which was tailored to different population segments, can be replicated in a national approach to hepatitis C. There are a number of successes that can be directly applied to a test to treat model for hepatitis C, as well as opportunities to make improvements to this model to better address the needs of traditionally hard-to-reach populations.

Implementation Considerations by Population Segment

To limit the additional appropriations required for hepatitis C elimination and to encourage the development of sustainable capabilities for hepatitis C containment, building on existing coverage models and their efforts to strengthen population access to medications, beneficiary outreach, and primary care provider capabilities for testing and treatment can help support implementation of a national elimination strategy. Below are the considerations of how components of the strategic framework can be implemented across different patient populations, including patients without insurance or a usual source of care.

Medicaid

Disease Detection: States can develop or expand existing disease detection and monitoring infrastructure with financial support and guidance from the federal government. This will require updated technological infrastructure to support interagency data sharing and coordination as well as increased collection of case data from municipalities, which could facilitate a state-level hepatitis C registry. A state-level registry with integrated data sources can be used to create tools such as geospatial heat maps to identify outbreaks and clinical dashboards to track patients through the care cascade along with key performance indicators to help measure program progress. States can diversify data sources and access additional case data by collecting EHR data and through partnerships with private labs and specialty pharmacies. Increased measure reporting and standardized case definitions can support more comprehensive data analysis. For instance, Louisiana made updates to the state's public health reporting requirements to include both positive and negative tests to allow for better tracking of current infections as well as those who had been cured. CMS and the Office of the National Coordinator for Health Information Technology could support such efforts through development and implementation of national standards for electronic case reporting through level two or three clinical labs and test prescribers. Reporting could be deidentified and used to track regional progress and focus further reporting efforts.

DAA Procurement: Population focused DAA procurement models can expand access to DAAs among Medicaid beneficiaries, as previously done in Louisiana, Washington and Michigan. Through this approach, states secure authority to engage in such arrangements through a State Plan Amendment (SPA) or other mechanisms. States and manufacturers develop agreements that establish an

annual cap for state expenditure linked to nominal net price per unit for additional courses through supplemental drug rebates. This approach benefits states, as they are able to procure a large enough volume of DAAs to treat the entire hepatitis C patient population while ensuring budget predictability and controlled DAA procurement expenditure. However, this approach requires integration with effective outreach and test to treat capabilities for Medicaid providers, as states will need to administer enough doses to surpass the agreed upon annual cap in order to benefit from the nominal price per unit. The national hepatitis C elimination program proposal includes a federal DAA procurement model for Medicaid beneficiaries as well as the uninsured, incarcerated, and those served by the Indian Health Service (IHS).

Awareness and Education: Federal funds could be allocated to support a national set of training and education resources that can be distributed based on existing best practices. States with Medicaid managed care organizations (MCOs) have means of reaching providers. As with provider training and outreach, patient education can be written in to performance improvement projects (PIPs) directing MCO Case Management teams to conduct patient outreach and education. Other strategies for public education include state-level multi-media educational campaigns with messaging informed by the Centers for Disease Control and Prevention (CDC) and other federal agencies.

Care Integration: Financial incentives, such as per-case "hepatitis C case management payments" linked to reporting on screening, treatment initiation, and completion rates, may be used in order to increase screening and treatment. These incentives can be implemented for relevant primary care providers in traditional fee-for-service Medicaid as well as MCOs. States have flexibility under managed care contracts to enhance provider reimbursement through plan rate increases for hepatitis C services or to direct plans to implement value-based payment arrangements or performance initiatives that link additional payments to performance metrics, and a growing number of states are implementing payment reforms for advanced primary care with accountability. States can include hepatitis C in quality improvement goals and require managed care plans to report on quality outcomes related to case management outreach, provider education, screening, and DAA treatment initiation through PIPs. This will not only incentivize providers to increase services but help create uniformity in tracking

and reporting among Medicaid managed care plans. Accordingly, these could also provide data on gaps where state public health initiatives can be used to improve outreach, screening, and treatment. Federal supports such as increased Federal Medical Assistance Percentage or SPA model templates can present opportunities for states to improve social support for patients facing significant barriers to care and to improve treatment compliance through new reimbursement pathways for nontraditional care and social services. For instance, Louisiana received authorities through SPA to reimburse case management and other services provided by community health workers as part of hepatitis C test to treat programs.

Medicare

Innovative Diagnostics: Medicare covers existing hepatitis C diagnostic tests and has coverage and payment frameworks for POC diagnostics that could be applied to new hepatitis C POC tests. Therefore, it will be important to understand the evidentiary needs for Medicare coverage based on the regulatory pathway developers consider pursuing for hepatitis C POC diagnostics. Test to treat case payment models could also be piloted, including in Medicare accountable care programs and Medicare Advantage.

DAA Procurement: Increased access to DAAs among Medicare beneficiaries will require lifting prior authorization and other access restrictions, such as step therapy and utilization management, and encouraging plans to cover authorized generics and to un-gate formulary access. The Center for Medicare and Medicaid Innovation has implemented payment models for insulin and other medications that aim to limit out-of-pocket costs. These models could be applied and combined with payment and care reform initiatives to support test to treat care pathways in primary care practices to help assure higher volume of sales in conjunction with lower per-patient drug costs. Alternatively, there could be a Tier 1 or 2 requirement for authorized generics to reduce cost sharing and Tier 3 requirement for branded DAAs, or plans could designate one DAA as “preferred” on the lowest tier or as part of a new “preferred” specialty tier. A requirement for mail order DAA prescription dispensing would also support patient access to treatment and pharmacy-based case management can support treatment compliance.

Care Integration: A feasible short-term intervention targeting Medicare beneficiaries should focus on developing performance measures for Medicare Advantage plans and primary care providers to support

greater screening and treatment. For primary care providers in traditional Medicare, the Merit-Based Incentive Payment System (MIPS) is one mechanism to promote such initiatives. Currently, there are three hepatitis C-related MIPS measures that cover one-time screening for all patients, annual screening for patients who actively inject drugs, and screening for hepatocellular carcinoma.^{33, 34, 35} These measures can be updated to include new hepatitis C measures that promote care coordination as well as treatment adherence and completion. Further, hepatitis C test to treat measures can also be implemented in Medicare’s alternative payment models such as the Shared Savings Program. Analogous measures could be implemented for Medicare Advantage plans.

Uninsured

Disease Detection: Regional programs targeting vulnerable, hardly reached and uninsured populations can develop local registries through grant funding received for programming. The Hepatitis C Community Alliance to Test and Treat program developed a hepatitis C registry from a partnership between city and state health departments. The registry included data to track progression along the care pathway, such as the number of people screened, evaluated, treated, and cured. The registry brought together existing state-collected HCV disease detection and monitoring data, including laboratory data, provider reports, EHR data from clinical sites, and prescription information from two pharmacy chains.³⁶

DAA Procurement: States can support 340B covered entities to provide care for uninsured individuals and access to lower-cost drugs and can potentially extend these partnerships to community-based sites. DAA procurement and implementation strategies for the uninsured population will likely require additional Federal funds, even if 340B programs are leveraged. Expanding Medicaid, Medicare, and other programs targeting vulnerable populations may reach uninsured patients and limit additional costs.³⁷

Awareness and Education: Provider training in hepatitis C screening, diagnosis, and treatment through virtual health platforms such as Project ECHO is a strategy employed to overcome provider shortages and barriers to care access. Regional elimination programs, such as Sharing-The-Cure based in Baltimore, have used combined approaches such as Project ECHO models, learning modules, and online tutorials to increase provider confidence.³⁸ Project ECHO models can also be used for clinical capacity building

by training staff in supporting DAA access and other issues. Implementation of virtual learning platforms can be supported through expert partnerships and financial supports. Public education outreach on a local level can involve trusted community partners such as community health workers and community-based organizations to provide language specific and culturally relevant educational materials and directly connect individuals to screening opportunities.

Care Integration: Care management will support additional services that patients may require, including education, insurance enrollment, and wraparound services like transportation. Numerous regional pilot demonstrations provide best practices to support such efforts. Factors for success for expanding treatment in community settings have included: training primary care physicians to delivery care, technological support to facilitate patient identification and follow up through electronic medical record alerts, ECHO-like physician training, using care managers to guide patients through treatment, use of reflex testing, and decentralization of care to non-traditional care settings. Health Resources and Services Administration program expansions can support the development, expansion, and scaling of care management programs that include provider education, data infrastructure development, care management, capacity building at FQHCs and safety-net clinics, and use of mobile health clinics in regions with workforce shortages. It will be important to strengthen partnerships among community-based organizations to improve linkage to treatment and supportive social services among this population.

Incarcerated Settings

Disease Detection: Disease detection and monitoring improvements on the state level can include streamlined and frequent data sharing between state health departments and state Departments of Corrections (DOCs), along with measures to increase patient identification.

DAA Procurement: State DOCs can leverage the 340B program through state contracts with 340B covered entities to expand access to discounted DAAs for incarcerated individuals. States such as Alaska, Indiana, and New Hampshire established in-kind relationships with 340B covered entities also receiving Section 318 funding, an existing funding stream to treat sexually transmitted infections. Louisiana and Washington included parallel procurement contracts for their respective DOCs to increase access to DAAs among incarcerated populations.⁴⁰

Awareness and Education: Within correctional facilities, self-education modules for patient education are a means of increasing awareness and reducing transmission and reinfection. Project ECHO-like programs can facilitate peer-to-peer programs as well as education between providers and patients, and mobile sites providing clinical and pharmacy services can include educational outreach and resources. Self-learning models can be a solution where virtual communication platforms are not feasible and personnel is limited.

Care Integration: Universal screening in correctional facilities can prevent community spread. States, including Tennessee and Indiana, have implemented opt-out universal screening programs with reflex RNA testing in certain facilities.⁴¹ Programs for screening upon entry to correctional facilities necessitate that correctional facilities first conduct backlog screening of the existing population. The expansion of universal screening within correctional facilities has not been widely adopted due to persistent barriers to care access. In the face of severe provider shortages, DOCs can explore non-traditional care delivery models such as telehealth, pharmacist-led treatment models, and mobile clinics as well as concurrent treatment of hepatitis C, HIV, opioid use disorder, and mental illness. Several states have explored implementation of such models. For individuals transitioning out of correctional facilities, case-managers that help coordinate care or assist in Medicaid re-enrollment will help ensure the continuation of care.

Veterans Health Administration (VHA)

Disease Detection: A main component of the VHA hepatitis C elimination program was the creation of clinical dashboards to provide better care by giving providers easy access to up-to-date information on patient status and community disease burden and progress. The dashboards included tools to document screening, assessment, and treatment, and EHR based tracking of any patients who deferred treatment. Clinical dashboards were in conjunction with the development of the Clinical Case Registry, which captured clinical, laboratory, and pharmacy data on a local and national level for all veterans with hepatitis C under the care of the VHA. Both can be augmented as patient identification becomes more challenging among hardly reached veterans and serve as models for other programs.

DAA Procurement: The VHA is among the largest federal purchasers. Through the federal ceiling price program, VHA can receive drug prices lower than on the Federal Supply Schedule (FSS).

Awareness and Education: The Hepatitis C Innovation Teams (HITs) or small multidisciplinary expert teams were designed to be malleable to address the needs of the region of focus. HITs worked with a limited number of clinics and could use differing strategies to overcome provider hesitation or reluctance to provide hepatitis C treatment. The diverse teams of clinicians, social workers, peer support specialists, mental health, and substance use providers could work closely with patients and veteran community organizations and communication channels could be leveraged for outreach to help combat stigma and misinformation.

Care Integration: Further strategies for VHA can include rescreening guidance to continue to monitor for new cases. There are not significant insurance coverage changes within this population, and it can be a good population to pilot rescreening and provide lessons for other populations.

Indian Health Service (IHS)

The Public Health Service, which includes IHS, is also among the largest federal purchasers and, along with the VHA, can receive drug prices lower than on the FSS. There have been several successful hepatitis C elimination programs among AI/AN populations.^{42, 43, 44} Successful programs that co-locate care for SUD, mental health, and hepatitis C, can be replicated and adapted to provide culturally relevant care that meets the needs of different tribal nations. Staff and provider shortages among the rural IHS clinics will require non-traditional care delivery such as pharmacist-led treatment models and telehealth models to link patients to specialty care. Project ECHO has been an effective and commonly used tool in Indian nations to increase provider education and support in hepatitis C screening, evaluation, and treatment. State Departments of Health can be tapped to support multi-media campaigns that are language specific and culturally relevant for AI/AN populations, and community organizations and IHS clinics can conduct outreach to increase public awareness and reduce stigma.

The program in the Cherokee Nation also included home visits conducted by a public health nurse for individuals unreachable by telephone or mail to ensure treatment adherence, and case managers helped obtain direct-acting antivirals (DAAs) through insurance or patient-assistance programs. Not all AI/AN persons will receive care through IHS hospitals or health clinics and efforts to increase screening and treatment among Medicaid and uninsured populations will also reach some individuals within

AI/AN populations. This necessitates consideration of how to ensure culturally competent care delivery among AI/AN populations seeking care outside of IHS hospitals and clinics appropriate funding for resources and training in culturally competent care.

Resource Supports

The success of a national strategy will in part be determined by the cost associated with streamlining the care cascade for all the impacted populations. Cost assessments will be needed for each of the components to inform further strategies around both short and long-term funding. A number of organizations have provided cost assessments of various activities and evidence exists that can be leveraged to estimate programmatic costs for various activities and payers. Finally, there is a need to demonstrate cost effectiveness of POC diagnostics in reducing overall cost burden from untreated hepatitis C in comparison with the current two-step diagnostic process.

A number of the policies described could be achieved in the near term through existing administrative authorities. States have certain authorities through state plan amendments to expand coverage for hepatitis C services among some non-eligible populations and integrate hepatitis C screening opportunities in syringe service programs (SSPs) and SUD treatment centers. Existing federal funding can be used more efficiently by co-locating treatment for opioid use disorder, mental illness, HIV, and hepatitis C given the significant overlap in patient populations. Funding for HIV programs, SUD treatment programs, and SSPs could be leveraged by piloting models that incorporate testing and treatment for hepatitis C alongside these services. There is additional opportunity to develop IT infrastructure and support telehealth through leveraging CDC Public Health Infrastructure and Capacity funding to issue grants. Short term actions such as these can help inform funding needs as well as implementation of a national strategy.

Conclusion

The strategic framework for a national hepatitis C elimination strategy as detailed above has been informed by the successes and limitations of regional, state, and federal level programs for treating and eliminating hepatitis C as well as learnings from the COVID-19 test to treat model. However, there are additional considerations that may impact design and implementation of a coordinated national effort, including strategies to mitigate disparities in treatment access and identifying patients.

Further discussions with stakeholders will help identify additional operational considerations for the implementation approaches described.

Funding

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