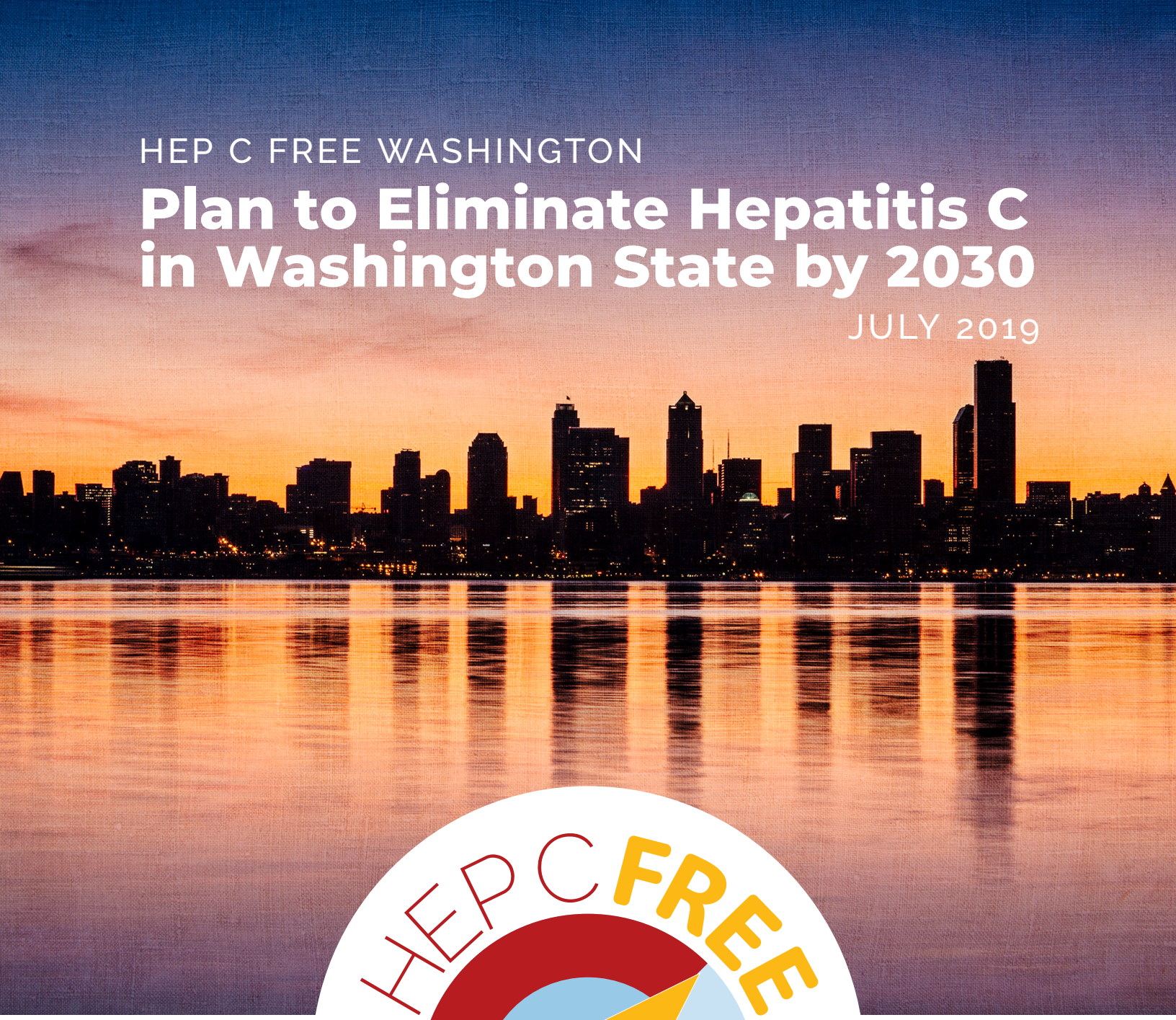

HEP C FREE WASHINGTON

Plan to Eliminate Hepatitis C in Washington State by 2030

JULY 2019

HEP C FREE

WASHINGTON 2030

WORLD HEPATITIS DAY | JULY 28

For more information

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Contents

Hepatitis C Free Washington (Hep C Free WA)

Who we are: A collective impact initiative seeking a multisector response to the public health threat of hepatitis C.

Our vision: A world free from hepatitis C.

Our mission: Working together to eliminate hepatitis C in Washington State by the year 2030.

Our values:

- **Easy access for all.** Hep C Free WA believes all people at risk for and living with hepatitis C should have easy access to testing, care, and a cure for hepatitis C.
- **Uphold the dignity of each person.** Hep C Free WA believes we must reduce hepatitis C related stigma, recognize the worth of affected communities, and ensure whole-person care to eliminate hepatitis C and promote wellness.
- **Clear communication.** Hep C Free WA strives to educate all Washingtonians about hepatitis C, including how to prevent hepatitis C, where to get tested, and how to get cured.
- **Health equity.** Hep C Free WA works so that all communities impacted by hepatitis C receive what they need, including services that are culturally relevant and in language they understand, to prevent, diagnose, and cure hepatitis C and achieve the highest level of health and wellbeing.
- **Innovative solutions.** Hep C Free WA seeks new and creative ideas to address hepatitis C by centering the voices of those disproportionately impacted and pairing community wisdom and strengths with the best available data.

Executive Summary

The hepatitis C virus (HCV) is a public health crisis in Washington State. At the beginning of 2018, an estimated 59,100 Washingtonians were living with HCV. In September 2018, Governor Inslee issued **Directive of the Governor 18–13** (the Directive), "Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach." In response to the Directive, the Washington State Department of Health brought together a broad range of partners to develop the Hep C Free Washington initiative. With a shared mission of eliminating HCV in Washington State by the year 2030, the partners developed a set of recommended goals and actions to achieve the mission.

Hep C Free WA Goals

Overarching Coordination Goal

1. Ensure implementation of the Hep C Free WA recommendations in order to achieve HCV elimination by 2030.

Data and Strategic Information Goals

2. Identify data sources and strategies to strengthen the characterization of HCV disease burden within Washington State.
3. Obtain resources and build capacity for continuous data monitoring, evaluation, quality improvement, and reporting.
4. Identify and track data metrics using currently available data.
5. Determine metrics using data not yet available or accessible.

Community-Based Responses and Interventions Goals

6. Improve access to and use of preventive and health care services in non-clinical settings through expansion and co-location of services.
7. Improve access to and use of clinical care and supportive services by sufficiently scaling coverage and widening the scope of community-based navigation and case management programs.
8. Increase HCV awareness, resources, and education, and reduce stigma.

Clinical Strategies Goals

9. Improve access to and use of clinical care for marginalized populations at risk for or living with HCV through innovative service delivery models.
10. Build the capacity of the health care workforce to diagnose and treat HCV.
11. Improve diagnosis of HCV in primary care settings.
12. Improve HCV disease intervention services.
13. Improve access to HCV treatment and comprehensive health care.
14. Improve the ability of people taking HCV direct-acting antivirals to complete treatment.
15. Improve follow-up clinical care for people who have completed HCV treatment.

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Introduction

"Hepatitis" means inflammation of the liver. There are many causes of liver inflammation, including heavy alcohol use, toxins, some medications, and certain medical conditions. Hepatitis is often caused by a virus (known as "viral hepatitis"). A virus that primarily attacks the liver, causing inflammation, is called "hepatitis," followed by a letter (e.g., A, B, C, D).

The three most common forms of viral hepatitis in the United States are hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Although each can cause similar symptoms, they are spread in different ways and can affect the liver differently.

- **Hepatitis A** is usually a short-term (acute) infection that goes away on its own. It spreads through oral-fecal contact, such as through contaminated food or water. This can happen when a person with HAV does not adequately wash their hands and prepares or serves food. It can also spread during oral-anal sex contact ("rimming") with someone with HAV). There are vaccines to prevent HAV. There is no specific medical treatment for HAV.
- **Hepatitis B** can also begin as a short-term infection, but in some people the virus remains in the body and causes lifelong (chronic) infection. More than 90% of infants that are infected develop chronic HBV infection. In otherwise healthy adults, only 5-10% of those infected develop chronic HBV infection. For the other 90% of adults, the infection will go away on its own. Hepatitis B spreads through blood-to-blood contact (e.g., sharing of needles and syringes, sharing of medical equipment such as glucose monitoring devices) or when sexual fluid from someone living with HBV enters the body of someone without the virus (e.g., through condomless sex). A pregnant person living with HBV can transmit the virus to their child at birth. Many

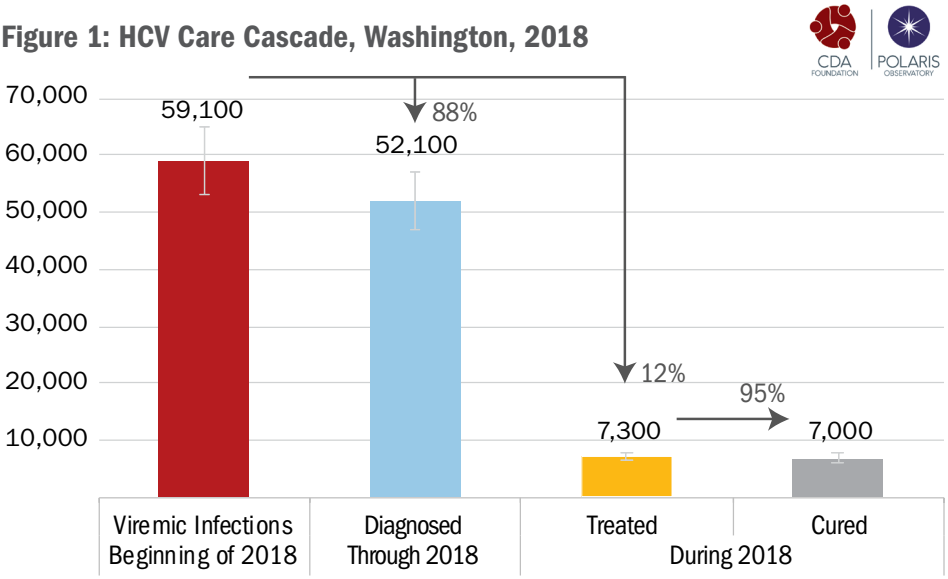
people will not have any noticeable symptoms for many years, but during this time the virus damages the liver. Like HAV, there are vaccines to prevent HBV. Most people diagnosed with chronic HBV infection need medical treatment for the rest of their lives. While not a cure, the medication helps reduce the risk of liver disease and prevents the spread of HBV to others.

- **Hepatitis C** can also begin as a short-term infection (occurring within the first six months after someone is exposed to the hepatitis C virus). It spreads through blood-to-blood contact. For about 75% of people, the virus stays in the body and becomes a chronic (lifelong) infection if left untreated. Many people will not have any noticeable symptoms for many years, but during this time the virus damages the liver. Unfortunately, there is no vaccine to prevent HCV. However, new all-oral medications called "direct acting antivirals" (DAAs) can cure the infection in almost all patients in as little as eight weeks with minimal or no side effects.

Every year HCV kills more people than over 60 other CDC-reportable infectious diseases combined, including HIV, HBV, and tuberculosis.

Hepatitis C is the most common bloodborne (spread by blood) infection in the United States. The United States Centers for Disease Control and Prevention (CDC) estimate that about 2.4 million people are living with HCV in this country, but the actual number could be much higher. In the United States, reported cases of acute (new) HCV infection increased 350% from 2010 through 2016 (from 850 to 2,967 reported cases), rising each year during this period. This increase reflects new infections associated with rising rates of injection-drug use, and, to a lesser extent, improved testing and case detection. Several investigations of newly acquired HCV infections found that most occurred among young persons (20-39 years old) who inject drugs. Most new cases of acute HCV are not identified or reported to public health because most adults and adolescents with HCV do not have symptoms. The CDC estimates 41,200 new HCV infections happened in 2016.[1] In the United States, HCV is a leading cause of liver cancer and one of the leading causes of liver damage resulting in the need for liver transplant. In addition, HCV has extrahepatic manifestations — in other words, HCV can cause conditions outside of the liver. For example, HCV is associated with hematologic, endocrine, neurologic, cardiovascular, and renal disease.[2] Every year HCV kills more people than over 60 other CDC-reportable infectious diseases combined, including HIV, HBV, and tuberculosis.

Figure 1: HCV Care Cascade, Washington, 2018



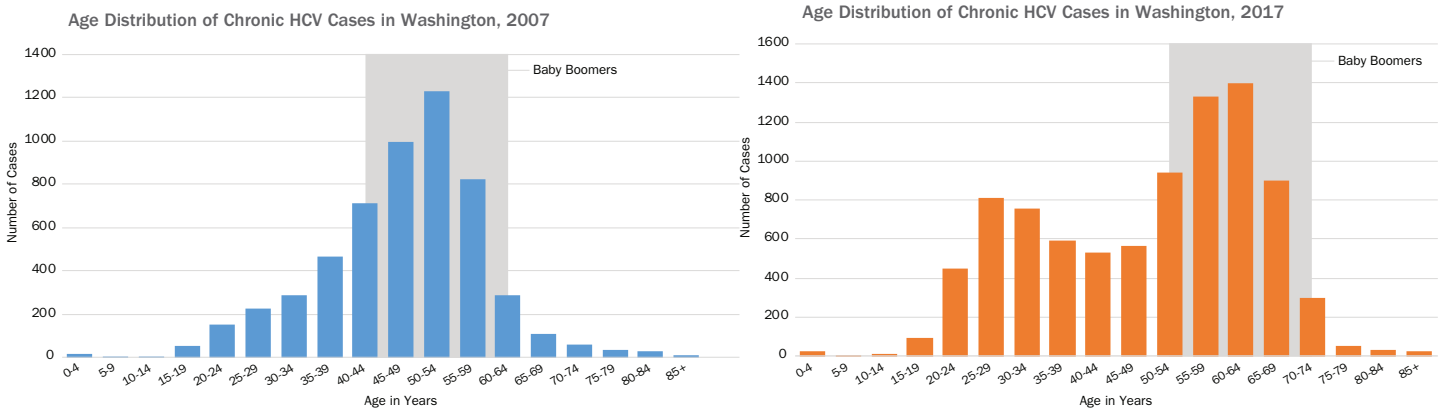
Source: Center for Disease Analysis Foundation report, 2019 (Appendix A)

In 2018, there were 188 reports of acute HCV infection in Washington, the most since 1995.

The HCV "treatment cascade," sometimes called the "care cascade," outlines the sequence of steps or continuum of services critical for addressing the testing, linkage to care, and treatment needs of people living with HCV.[3] **Figure 1** uses projections developed by the Center for Disease Analysis Foundation based on the best available data in Washington (**Appendix A**). It shows that while a high proportion of people living with HCV (labeled as "viremic infections) know their HCV status (labeled as "diagnosed"), few of them were actually connected to care and received HCV treatment in 2018. In Washington State, at the beginning of 2018, 79%, or 46,500, of the estimated 59,100 people (using a 95% uncertainty interval, 32,500-71,500 people is the possible range) living with chronic HCV were diagnosed. Of the total number of people living with HCV, 12% (7,300) were treated. Of the 7,300 treated, 95% (7,000) were cured. In 2018, it was estimated that about 2,950 Washingtonians were newly infected with HCV (39.9 per 100,000).

In Washington State, HCV poses a significant public health threat. On average, at least 582 people die from HCV-associated causes each year. From 2001 to 2010, an average of 24 cases of acute HCV infection were reported each year. Similar to national trends, since 2011, the number of acute cases in the state has risen dramatically. This reflects a rise in injection drug use associated with increased opioid and methamphetamine use, as well as improved detection of acute infection by health care providers. In 2018, there were 118 reports of acute HCV infection in Washington, the most since 1995. The number of chronic HCV cases reported to public health agencies has also increased. From 2001 to 2010, there were an average of 5,322 newly reported chronic HCV cases yearly. In 2016, there were 8,118 and, in 2017, there were 8,839 new reports. At this time, the data for 2018 are not finalized, but the number of chronic case reports is expected to be higher than previous years. Increases of chronic case reports are due to the rise in people injecting drugs, and improved testing — including universal one-time testing of Baby Boomers (people born from 1945 through 1965) and risk-based HCV testing — as recommended by the CDC.[4]

Figure 2: Age Shift among Chronic HCV Cases in Washington State, 2007 and 2017



Source: Washington State Department of Health, Hepatitis Surveillance Records

From 2007 to 2017 the state had a noticeable shift in the age distribution of newly reported chronic cases. This indicates two epidemics of chronic HCV — one among Baby Boomers and one among younger persons who were likely infected by sharing drug injection equipment.

From 2007 to 2017 the state had a noticeable shift in the age distribution of newly reported chronic cases. This indicates two epidemics of chronic HCV — one among Baby Boomers (indicated by the gray shaded areas in **Figure 2**), and one among younger persons (people under the age of 40 in 2017) who were likely infected by sharing drug injection equipment. In 2007, 68.6% of chronic cases were among Baby Boomers and 21.9% were among people under 40. In 2017, 52.2% of chronic cases were among Baby Boomers and 31.0% were among people under 40 (see **Figure 2**). People who were infected with HCV decades ago are at high risk of cirrhosis and liver cancer. People who inject drugs, including those who are living with HCV, are also at high risk of other health problems including overdose, skin and soft-tissue infections, HIV infection, and fulminant (severe and sudden) hepatitis caused by HAV or HBV co-infection.

Priority Populations for Hepatitis C in Washington State

Identifying priority populations who are impacted by HCV more than others helps focus public health and treatment efforts toward those most affected and address health disparities. In addition to Baby Boomers and people who inject drugs, other priority populations include people who have experienced incarceration, people living with HIV, African Americans, and Native Americans.

People in jails or prisons

While about 1% of the population of the United States is living with HCV, the rates among people in correctional institutions (i.e., jails and prisons) are much higher. Recent estimates of the rate of chronic HCV infections in U.S. prisons is 17.4%[5] to 23.1%.[6] Correctional populations represent about one third of total HCV cases in the United States.[7] Populations most affected by incarceration, such as people who inject drugs, are more likely to be at risk for or living with HCV. About 11–15% of people incarcerated at any one time in Washington State Department of Corrections facilities are living with chronic HCV.[8]

People living with HIV

In the United States, about 1 in 5 people living with HIV have evidence of past or present HCV infection. As both HIV and HCV can be transmitted through direct blood-to-blood contact (e.g., sharing equipment for drug injection), having both HCV and HIV infection (co-infection) is common among people who inject drugs. An estimated 62-80% of people who inject drugs who are living with HIV are also living with HCV.[9 10 11] Sexual transmission of HCV is generally rare, but possible. An increasing number of studies show that sexual transmission of HCV is an important mode of HCV acquisition among men who have sex with men who are living with HIV.[12 13 14 15] Activities that may increase vulnerability to HCV include condomless anal sex, sharing of unsterilized sex toys, and non-injection drug use (e.g., smoking or snorting stimulants like methamphetamine, or inhaling "poppers").[16] Hepatitis C can accelerate liver disease in people living with HIV.[17 18 19 20 21] Of people newly diagnosed with HIV in Washington in the year 2018, 10% had acute or chronic HCV infection. Of all people living with HIV in Washington at the end of 2018, 9% had chronic HCV infection.[22] Recent studies have shown that acute HCV may be impacting men who have sex with men who are not living with HIV. Vigilance may be needed to address the prevention needs of this population.[23 24]

Nationally, American Indian/Alaska Natives have the highest rates of acute HCV and a rate of death related to HCV that is 2.7 times higher than non-Hispanic whites.

African Americans are about 11% of the U.S. population, but they represent 25% of people living with chronic HCV.

African Americans and Native Americans

Although nearly 75% of race/ethnicity data is not provided on HCV case reports submitted to the Washington State Department of Health, other sources of national and state data show there are significant HCV-related disparities among African Americans and Native Americans.

African Americans are about 11% of the U.S. population, but they represent 25% of people living with chronic HCV.[25] This disparity is particularly evident among African Americans ages sixty and older, where the rate of HCV is 10 times higher than among older individuals of other races in the United States. In addition, HCV-related illness and death are higher among African Americans than among people who identify with other races.

Nationally, American Indian/Alaska Natives have the highest rates of acute HCV[26] and a rate of death related to HCV that is 2.7 times higher than non-Hispanic whites.[27] A recent analysis by the Northwest Portland Area Indian Health Board found that, during 2006-2012 in Washington State, American Indian/Alaska Native residents had a higher rate of HCV-associated death when compared to non-Hispanic whites.[28]

Stigma Experienced by People Living with Hepatitis C

Because of the relationship between HCV transmission and drug injection, people living with and those cured of HCV report social challenges telling people about their status. They report concern that they may be perceived as having injected drugs, whether they have or not, and therefore treated poorly in their communities, including by health and social service providers. Stigma may lead to isolation and withdrawal from medical care.[29]

During two community events held in May 2019, one in Seattle and one in Spokane, participants spoke powerfully about their experiences living with HCV. The selected quotes provided below underscore the importance of addressing HCV-related stigma and offering opportunities for people affected by HCV to discuss their experiences and learn from each other.

There is a stigma that only certain people get HCV — anyone can get it.

- *"You kept [HCV] quiet, you didn't say anything."*
- *"I'm co-infected [with HIV and HCV] and I got treated [and cured for HCV] and got re-infected… It was a lot harder to talk to my provider a second time… I felt their disappointment."*
- *"[When I first found out I was living with HCV] I told my husband… it was scary."*
- *"There is a stigma that only certain people get HCV — anyone can get it."*
- *"I didn't tell anyone — I was ashamed big time. I told my mom because she had it. I went to [a substance use treatment program] and talked to a counselor and that helped."*
- *"You can feel really lousy after addiction and some providers treat you crappy."*
- *"I had co-infection with HIV and hep C. It really sucked. I would talk to someone [living] with HIV online, but when I told him I also had hep C I got turned down [for a hook up] and rejected so I stopped disclosing the hep C… I stopped telling anyone about hep C."*
- *"People are really uneducated about hep C. My sister didn't want to share my soda or my soap in the shower. It hurt."*
- *"Everyone wanted to know how I got [HCV] and I didn't know. I just told everyone I was a child of the 70s — sex, drugs, and rock n roll."*
- *"I had neck surgery and got hooked on Dilaudid and eventually started injecting [heroin]. It was devastating to find out I had hep C… I got a massage… and told the massage therapist I had headaches related to my hep C treatment and that's why I was there. She walked out and came back and said, 'My supervisor says it's okay to touch you… Do you have any open sores?' I felt like I had the plague. I'm so ashamed because of my addiction. I haven't really told anyone except one of my daughters… My self-esteem is in the toilet."*
- *"It was embarrassing and I'm ashamed of what I did to my life and I'm really grateful for being treated [for HCV]. I don't feel like I'm worth it."*

Hep C Free Washington — The State Hepatitis C Elimination Initiative

Hepatitis C elimination is defined as a state where HCV is no longer a public health threat and where those few people who become infected with HCV learn their status quickly and access curative treatment without delay, preventing the spread of the virus. There is a global conversation about HCV elimination occurring, both at the World Health Organization[30] and in a number of countries (e.g., Georgia[31], Australia[32], Scotland[33]). While the United States does not have a federally supported national HCV elimination strategy, the National Academies of Sciences, Engineering & Medicine released **A National Strategy for the Elimination of Hepatitis B and C** (2017),[34] and the U.S. Department of Health & Human Services developed the **National Viral Hepatitis Action Plan, 2017–2020**.[35] In addition, a number of Tribal Nations (e.g., Lummi Nation[36], Cherokee Nation[37]) and state and local jurisdictions (e.g., San Francisco[38], New Mexico[39], New York State[40]) are working on HCV elimination strategies.

The tools exist to eliminate the public health threat of HCV in Washington, but currently resources are not available at the level needed to achieve this goal.

The clock is ticking as HCV-related illness and death rise. Almost all people living with HCV can be cured with a short-course, well-tolerated, all-oral treatment. Scaled up HCV treatment paired with prevention of infection and re-infection (e.g., access to sterile injection equipment and medication treatment, such as buprenorphine and methadone, for opioid use disorder) can lead to HCV elimination. The tools exist to eliminate the public health threat of HCV in Washington, but currently resources are not available at the level needed to achieve this goal.

The federal response to HCV has been very different from the response to similar public health threats like HIV and sexually transmitted infections. These conditions receive much more robust federal funding through agencies like CDC and the Health Resources Services Administration.

In Washington State, given the lack of resources for HCV, most local health jurisdictions do not have staff dedicated to working on HCV. The Washington State Department of Health leverages limited federal and state funds to support some local community efforts including: rapid HCV antibody screening in community settings, an HCV health education program, Project ECHO (a virtual clinical consultation program to train primary care providers to treat HCV), and a few screening programs in local county jails and federally qualified health centers. In addition, the Department of Health supports a number of syringe service programs throughout the state. These programs play a critical role in supporting people who inject drugs to prevent infection and re-infection, and helping connect them to healthcare and social services. The resources available through the Department of Health are not sufficient to meet the need for these services throughout the state. In most cases, these community efforts must also look for support from other partners (e.g., local governments, private donors).

Because medications can cure almost everyone living with HCV, it is imperative to identify, link, and cure everyone living with HCV as quickly as possible. For Baby Boomers, the peak of HCV-related complications (e.g., cirrhosis complications, liver cancer, liver transplants, and deaths) is estimated to be around the year 2030. Among younger people, acute HCV is increasing due to the opioid crisis and increased injection drug use.

Failure to increase testing and treatment means the HCV epidemic will continue and there will be more preventable illnesses and deaths. In addition to the human value of providing treatment, recent studies show that HCV treatment is cost effective and creates a clear economic benefit. Preventing new infections and linking people living with HCV to treatment will reduce Washington State's expenditures in the long term by reducing health care costs.[41]

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In September 2018, Governor Inslee issued **Directive of the Governor 18–13** (the Directive), "Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach" (**Appendix B**).

One part of the Directive calls for the Washington State Health Care Authority[42] to secure innovative methods to purchase HCV direct acting antiviral medication and ensure timely access for Washingtonians living with HCV. According to the Health Care Authority, about 30,000 people living with HCV in Washington are covered by state-purchased health care insurance and programs, including Washington Apple Health (Medicaid), the Public Employees Benefits Board Program, the Department of Corrections, the Department of Labor & Industries, and the Department of Social & Health Services (state hospitals).[43]

Through participation in the State Medicaid Alternative Reimbursement and Purchasing Test for High Cost Drugs (SMART-D) collaborative, the Health Care Authority released a request for proposals for drug manufacturers to bid on January 22, 2019, and on April 25, 2019 announced AbbVie US LLC (AbbVie) as the apparently successful bidder (the bidder advanced to the next step in the process to engage in contract negotiations). AbbVie was chosen because they provided the best overall portfolio to assist Washington with eliminating HCV. They offer a product that is clinically appropriate for about 97% of all people living with HCV and they have demonstrated a commitment to partner with the Health Care Authority to eliminate HCV through its investment in the Hep C Free WA initiative. The Health Care Authority finalized the contract with AbbVie on July 1, 2019.

Another of the Directive's major components is the establishment of a committee comprised of a broad array of stakeholders, including people personally affected by HCV. The committee's charge was to draw on existing efforts, best practices, and community knowledge to develop a comprehensive strategy to eliminate the public health threat of HCV in Washington by 2030.

Hep C Free Washington

Our vision: A world free from hepatitis C.

Our mission: Working together to eliminate hepatitis C in Washington State by the year 2030.

Our values:

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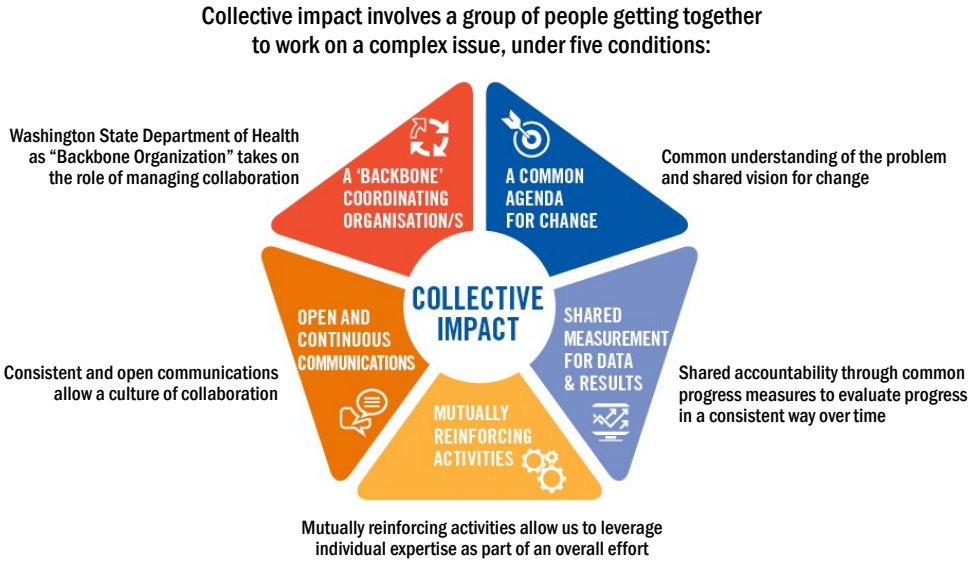
- **Innovative solutions**. Hep C Free WA seeks new and creative ideas to address hepatitis C by centering the voices of those disproportionately impacted and pairing community wisdom and strengths with the best available data.

Figure 3: Collective Impact Model



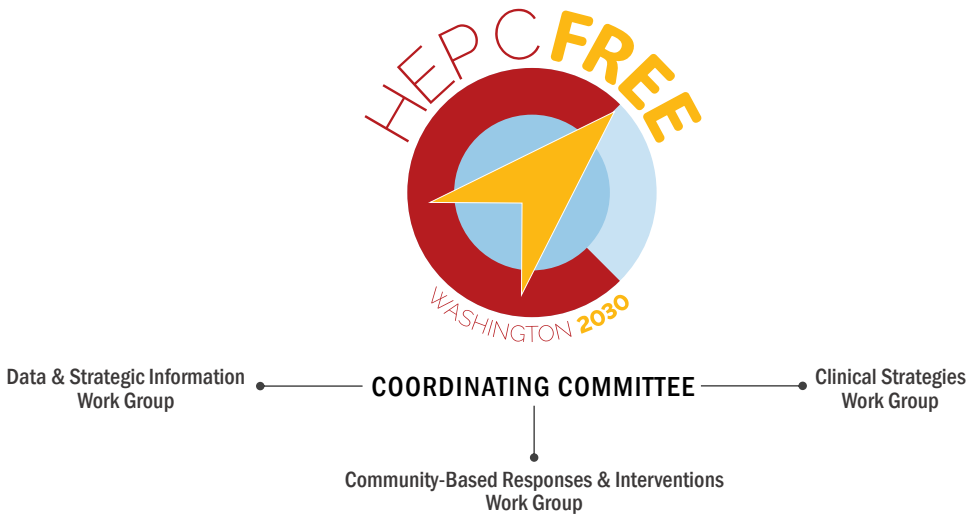
Using the principles of collective impact,[44] in October 2018, the Washington State Department of Health brought together multisector partners for the first meeting of what became the Hep C Free Washington (WA) Coordinating Committee. The committee has met monthly since. Members include representatives from state agencies and offices (e.g., the Health Care Authority, Department of Corrections, Department of Labor and Industries, Office of Financial Management, Office of the Insurance Commissioner, and the Department of Health), Tribal health centers, local health jurisdictions, federally qualified health centers, community-based organizations, syringe service programs, opioid treatment programs, academic institutions (University of Washington, Washington State University), health plans, professional organizations, and people affected by HCV.

The Department of Health acts as the "backbone organization" for Hep C Free WA. In the collective impact framework, the backbone organization pursues six common activities to support and facilitate collective impact, distinguishing this work from other types of collaborative efforts. Over the lifecycle of an initiative, the backbone organization:

1) Guides vision and strategy;
2) Supports aligned activities;
3) Establishes shared measurement practices;
4) Builds public will;
5) Advances policy; and
6) Mobilizes funding.

The Committee established three work groups, Data & Strategic Information, Clinical Strategies, and Community-Based Responses & Interventions, to draft recommendations based on their specific expertise.

Figure 4: Hep C Free WA Coordinating Committee Workgroups



The Data & Strategic Information Work Group reviewed existing data sources for the Hep C Free WA initiative to set baselines for measuring progress and to evaluate data strengths and limitations. The Work Group was charged with developing recommendations related to data, outcomes, and monitoring, including developing indicators for the initiative, and recommending improvements to data systems to capture needed baseline information.

The Community-Based Responses & Interventions Work Group was charged with developing recommendations to address HCV community health education and awareness, preventive services, testing, linkage to care, case management, and access to curative treatment in non-clinical (community-based settings that do not traditionally provide clinical services), high-impact settings (settings that serve a high proportion of clientele who inject drugs, such as outreach sites, syringe service programs, substance use disorder treatment facilities, opioid treatment programs, organizations serving people experiencing homelessness) to reach populations disproportionately impacted by HCV.

The Clinical Strategies Work Group was charged with developing recommendations related to clinically based HCV services, including: Health care provider education; testing and treatment in primary care; linkage from primary care to specialty care when needed; treatment and cure of HCV; treatment adherence and medical support services; and follow up care (e.g., liver cancer surveillance in people who are cured, but have advanced fibrosis).

The recommendations developed by the Hep C Free WA Coordinating Committee and Work Groups follow, along with a description of next steps as we enter the implementation and evaluation phase.

Recommendations

Below are the Hep C Free WA recommendations approved by the Hep C Free WA Coordinating Committee. Each recommended goal includes several action items.

Overarching Coordination Goal

The Hep C Free WA Coordinating Committee identified an overarching goal and funding and activities needed to ensure coordination and implementation of the recommendations contained herein.

Goal 1. Ensure implementation of the Hep C Free WA recommendations in order to achieve HCV elimination by 2030.

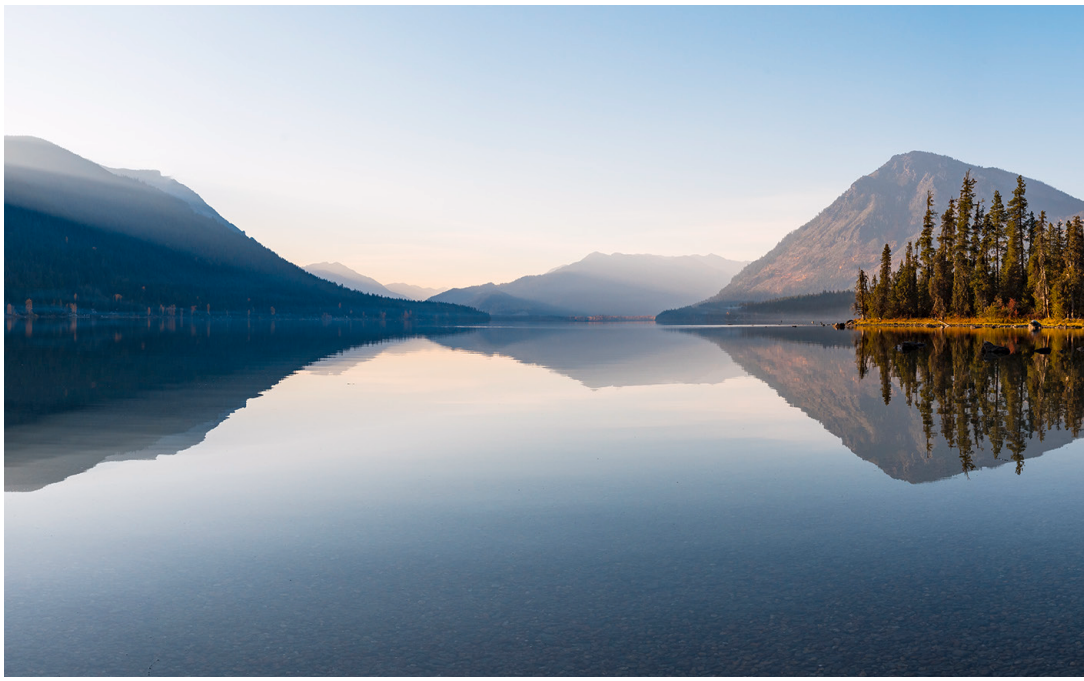
1.1 **Allocate funding to the Department of Health, the backbone organization for Hep C Free WA, to facilitate coordination of the Hep C Free WA initiative and coordinate implementation of the Hep C Free WA recommendations with other state agencies (e.g., Health Care Authority, Department of Corrections) and other public and private partners (e.g., Tribal nations, local health jurisdictions, community-based organizations, health care organizations).**

1.2 **Define governance and provide resources (e.g., to employ staff to support the Coordinating Committee and Work Groups, to cover travel expenses of Coordinating Committee members to attend meetings, to host Hep C Free WA community engagement events) for the continuation of the Hep C Free WA Coordinating Committee and topic specific work groups to improve multi-directional communication among the community, local health jurisdictions, and state agencies in order to advise the Department of Health and other relevant state agencies on the implementation of the Hep C Free WA recommendations.**

1.3 Create Hep C Free WA work groups focused on how to address the HCV prevention, care, and treatment needs of communities disproportionately impacted by HCV as identified by Hep C Free WA data monitoring and analyses (e.g., people who inject drugs, women of transgender experience, men who have sex with men, Native Americans, African Americans). See action item 3.11.

1.4 Create Hep C Free WA community leadership opportunities (e.g., a community leadership program, community engagement events) for and promote the involvement of people affected by HCV and people from communities disproportionately impacted by HCV in the Hep C Free WA coordinating committee and work groups to ensure ongoing engagement in the implementation and refinement of the Hep C Free WA plan over time.

1.5 Align the Hep C Free WA plan with the End AIDS Washington plan[45], the state Opioid Response Plan[46], and other strategic documents related to the syndemics (braided epidemics) of HCV to ensure coordination and communication among these related efforts.



Data and Strategic Information Goals

Goal 2. Identify data sources and strategies to strengthen the characterization of HCV disease burden within Washington State.

2.1 Mandate the reporting of non-positive HCV RNA (viral load) tests to local health jurisdictions, as well as positive ones, to allow tracking of spontaneous HCV clearance and successful HCV curative treatment.

Background: Reactive HCV antibody tests and positive HCV RNA tests must be reported by health care providers, facilities, and laboratories to the local health jurisdiction and to health authorities in Washington State as stated in Washington Administrative Code (WAC) 246-101[47]. The purpose of this reporting is to identify sources of infection and to prevent further transmission from such sources; identify new groups at risk and reduce further cases; inform cases about treatment options; educate cases and contacts about transmission of HCV and how to reduce the risk of transmission; and better understand the epidemiology of HCV infection and the burden of morbidity from chronic infection. The Department of Health is currently working on WAC revisions regarding reporting of negative test results, which would be used to determine when a previously reported case becomes non-infectious; to identify newly acquired infections through identification of a seroconversion window; or to provide information critical for assignment of a case definition. The Department of Health received some push back from labs and the public on reporting of negative antibody tests due to the volume and privacy concerns. A separate system may be needed to house negative test results (similar to the model being used in the state of Utah[48]). Labs could submit aggregate data for screening tests in order for public health to calculate screening rates. Ongoing leadership from entities interested in this policy change is needed as opportunities for public comment on this issue arise in the late summer and fall of 2019.[49]

2.2 Use the All Payer Claims Database and Department of Health HCV surveillance data as primary data sources for statewide monitoring and reporting.

Background: The Washington All Payer Claims Database (WA-APCD) is a health care claims data source, which includes all claims data for Medicaid, Medicare, the Public Employees Benefit Board (PEBB) plan, and about half of private payers. For private payers, the WA-APCD includes all claims for the individual market, but most claims for self-insured plans are not included. The School Employees Benefit Board plan will begin submitting data to the WA-APCD in 2020. The CDC have developed a methodology for using claims data to create an HCV care cascade and Washington should explore creating such a cascade with data from the WA-APCD.[50] The WA-APCD has some limitations. Data from the WA-APCD can allow us to quantify the number of HCV tests conducted and the number of direct-acting antiviral treatments provided, but does not provide information on test results, so we cannot determine if someone is living with HCV or if treatment has resulted in cure.

Department of Health HCV surveillance data are housed in a person-based system within the Washington Disease Reporting System (WDRS). It includes all reported cases of acute, chronic, and perinatal HCV infection in Washington. A proportion of labs that report electronically also submit negative RNA results, which are uploaded into WDRS.

2.3 Use other novel data sources, such as vital records, cancer registries, other infectious disease registries, and data from the Department of Corrections, to strengthen the development of a care cascade for the state and for specific priority populations.

Background: Birth and death records can be matched with the HCV surveillance registry to strengthen the Department of Health's ability to develop an accurate prevalence estimate for Washington and to assist in perinatal HCV case follow up. The Washington State Cancer Registry should be matched with the Department of Health's HCV surveillance records annually in order to illustrate the burden of the progression of HCV to hepatocellular carcinoma in Washington. A routine match between the HCV registry and other relevant infectious disease registries (e.g., HIV and HBV) should be done to understand the burden of co-infections. Because the Department of Corrections provides data on testing and lab results to the Department of Health and fully captures demographic data, including race/ethnicity data (which is often missing from case reports submitted by other facilities), the Departments of Health and Corrections should work together to complete an annual focused analysis in order to create a care cascade for the prisons and to analyze health disparities issues.

Goal 3. Obtain resources and build capacity for continuous data monitoring, evaluation, quality improvement, and reporting.

3.1 Employ a multiagency approach to monitoring progress (including the Health Care Authority, the Department of Health, the Office of Financial Management, the Department of Corrections, the Department of Social & Health Services, the Health Benefit Exchange) and identify and resource an agency (e.g., the Department of Health) to employ staff to analyze all state data and develop an annual HCV data report.

3.2 Add resources and build capacity at the local health jurisdiction level to strengthen data quality and completeness and timeliness of HCV case reporting.

3.3 Add resources for a staff member at the Department of Health to handle increased HCV case reports from local health jurisdictions and link laboratory and case report data.

3.4 Build capacity to allow local health jurisdictions to produce HCV reports to independently create data analytics with prescribed methodology.

3.5 Ensure that all developed metrics will have baseline data, are evaluated at discrete benchmarks, and are monitored continually (see Goals 4 and 5).

3.6 Apply identified metrics, where appropriate and as resources allow, to different populations and sub-populations including the state, Accountable Communities of Health, counties, incarcerated populations, and priority populations (e.g., people who inject drugs, Native Americans, people who are pregnant, men who have sex with men, people born in high prevalence countries).

3.7 Use metrics to develop care cascades for the above populations. Metrics collected and evaluated will be used to develop statewide, Medicaid, Department of Corrections, and other sub-population care cascades.

3.8 Resource a modeling project every other year to track the number of patients needing to be treated annually to achieve 80% elimination by 2030, given current HCV prevalence, incidence, and mortality.

Background: In 2019, the Department of Health received one-time in-kind support from the Association of State & Territorial Health Officials to work with the Center for Disease Analysis Foundation to do this modeling, findings of which are summarized in the table below and provided in full in the report in Appendix A. Resources will be needed to repeat this modeling over time and evaluate progress.

The Center for Disease Analysis Foundation created two treatment scenarios for Washington: 1) Base scenario, the current standard of care assuming a near 40% drop in treatment between 2017 and 2020; and 2) Accelerated Elimination, the levels of intervention necessary to eliminate the disease burden by 2025. The elimination scenario is based on the World Health Organization's (WHO) Elimination Targets, defined as an 80% reduction in new infections, 90% diagnosis of all infections, and a 65% reduction in liver related mortality. This strategy requires the following numbers of people to be diagnosed and treated for HCV:

Scenario	Model parameters	2018	2019	2020	2021	≥2022
Base, WHO targets by 2030	Incident (new) infections	3,000	2,700	2,400	2,300	2,100
	Treated	7,300	7,000	4,900	4,900	4,900
	Newly diagnosed	5,600	5,600	3,900	3,900	1,800
Accelerated, WHO targets by 2025	Incident infections	3,000	2,700	2,200	1,400	800
	Treated	7,300	7,000	5,100	5,100	5,100
	Newly diagnosed	5,600	5,600	3,900	3,600	1,200

Under the base scenario, the number of Washingtonians with HCV peaked in 2000 and will continue to decline by 85% between 2017 and 2030, resulting in 10,700 (95% uncertainty interval, 200-26,700) Washingtonians with HCV by the end of 2030. Liver-related deaths, hepatocellular carcinoma (HCC) (liver cancer), and decompensated cirrhosis will also decrease by 90% as the population ages and a high level of treatment is maintained. Incident cases of HCC will decrease from 280 in 2017 to 20 in 2030 (90% decrease). Incident decompensated cirrhosis cases will decrease from 220 in 2017 to 20 in 2030 (90% decrease). Given the current standard of care in Washington, there would be 340 fewer liver-related deaths by 2030, a 90% decrease from 2017.

Under the World Health Organization elimination scenario, an average of 5,100 patients would need to be treated per year between 2020 and 2025 in order to achieve a 65% reduction in liver related deaths by 2025. Additional harm reduction efforts (i.e., improved access to sterile injection equipment and medication treatment for opioid use disorder) would also be needed to achieve an 80% reduction in new infections by 2025. Doing so would avert 5,800 new infections, 20 cases of decompensated cirrhosis, 25 cases of HCC and 35 liver-related deaths by 2025; and 9,400 new infections, 110 cases of decompensated cirrhosis, 130 cases of HCC and 190 liver-related deaths by 2030 compared to the base scenario.

The report by the Center for Disease Analysis Foundation underscores the need to focus efforts on people who inject drugs and other people at risk for or living with HCV who may be unengaged with health care services. Washington has largely addressed HCV among those easiest to engage in health care and who have access to HCV treatment. Efforts must evolve to address the challenging work ahead in order to ensure HCV elimination efforts reach all disproportionately affected communities.

3.9 Identify and collect qualitative data from populations who may experience barriers to care due to stigma. Collected data will help strengthen our understanding of how stigma impacts individual health outcomes and develop innovative strategies to reduce bias among service providers.

3.10 Develop an interactive dashboard through the Washington Tracking Network[51] to provide publicly available data on HCV and progress toward elimination at the county and Accountable Communities of Health levels.

3.11 Support, where possible, community epidemiological studies to determine the HCV seroprevalence in communities disproportionately impacted by HCV and who experience some of the greatest health inequities in Washington (e.g., women of transgender experience, people engaged in sex work, men who have sex with men, people who inject drugs, Native Americans, African Americans).

3.12 Strengthen bi-directional exchange of HCV surveillance data between healthcare delivery systems, payers of services, and public health systems to support evaluation and strengthen service delivery.

Background: The Department of Health currently provides rapid HCV antibody test kits to the cycle of the Washington-based National HIV Behavioral Surveillance (NHBS) focused on people who inject drugs. Funding permitted, the Department of Health should resource all cycles (e.g., men who have sex with men, high-risk heterosexuals, women of transgender experience) with rapid HCV antibody test kits in order to determine baseline prevalence of HCV antibodies in these communities, as well as support linkage to care services for people who test antibody reactive. Note that successful linkage to care means, at minimum, people living with HCV have attended a first medical appointment for evaluation or treatment.

3.13 Improve coordination among the Department of Health, local health jurisdictions, and community partners to strengthen HCV disease intervention and to assess levels of service needed to optimize outreach services.

3.14 Modernize data collection systems to track the number of unique people accessing services at syringe service programs throughout Washington in order to better understand the use of such programs by people who inject drugs and track improvement in access over time.

Goal 4. Identify and track data metrics using currently available data.

4.1 Identify the following metrics at baseline (i.e. reflecting the "current state") for recent years (e.g., 2017 and 2018) and then track prospectively during the 10-year period of the elimination effort (when possible national metrics and benchmarks, such as the Healthcare Effectiveness Data and Information Set and the National Quality Forum, should be used to make data comparable to other states and national data):

a. **HCV prevalence**. The estimated number of people living with HCV per 100,000 population.

b. **Acute HCV incidence**. The number of newly diagnosed acute HCV cases per 100,000 population.

c. **Chronic HCV incidence**. The number of newly diagnosed chronic cases per 100,000 population. This metric is an approximation, as it relies on newly reported cases (e.g., newly reported cases could have been diagnosed in years prior and may not actually be incident cases).

d. **Number of HCV antiviral treatment regimens**. The number of antiviral treatment regimens prescribed each year (or each six-month period).

e. **Estimated number of HCV cures**. The number of people with lab data to suggest successful HCV treatment (a positive RNA test followed by at least two consecutive negative RNA tests at least 30 days apart).

f. **HCV-associated mortality**. The number and rate of deaths in Washington each year attributed to HCV infections.

g. **All-cause mortality in people living with HCV**. The number and proportion of all-cause deaths in Washington each year among people living with HCV.

h. **Cost of HCV treatment for patients**. Average out-of-pocket costs paid per patient for HCV treatment.

Goal 5. Determine metrics using data not yet available or accessible.

5.1 The following metrics require data that are not currently available and may require additional effort to obtain. As soon as these data are available, these metrics should be identified at baseline and then tracked prospectively:

a. **Number of HCV screenings**. The number of persons screened for HCV during each year (or six-month period).

b. **Number of people at risk for HCV who remain unscreened**. The number (and proportion) of people in Washington at risk for HCV (e.g., Baby Boomers and people who inject drugs) who remain unscreened.

c. **Screening coverage in high-impact settings**. Number of high-impact settings offering routine opt-out HCV screening.

d. **Access to confirmatory testing**. The number of clients who have tested reactive for HCV antibodies that receive a subsequent RNA confirmatory test within three months of their reactive antibody test.

e. **Access to HCV treatment**. The number of providers in Washington prescribing HCV treatment.

f. **Cost of HCV treatment**. The annual cost to the state of Washington and to private payers in Washington to treat HCV.

g. **Cost of HCV-related hospitalizations**. Hospitalization costs related to HCV on an annual basis.

Community-Based Responses and Interventions Goals

Goal 6. Improve access to and use of preventive and health care services in non-clinical settings through expansion and co-location of services.

6.1 **Support the expansion of syringe service programs and medication treatment for opioid use disorder in areas of the state with limited access to such services.**

Background: In order to eliminate HCV among people who inject drugs, access to sterile syringes, access to medication treatment for opioid use disorder (e.g., methadone, buprenorphine), and access to HCV direct-acting antiviral treatment for people who inject drugs all need to scale.[52] [53]

6.2 **Improve access to sterile syringes and other injection equipment by sufficiently resourcing syringe service programs so that they can optimize their open hours and implement needs-based supply access.**[54]

6.3 **Explore innovative strategies for improving sterile syringe access in rural and remote parts of the state, including a mail-order service.**

6.4 **Develop educational materials for community members and clinical stakeholders about the benefits of syringe service programs for individual, community, and population health.**

6.5 **Explore harm reduction interventions for people who inject stimulants.**

Background: "People who inject stimulants need sterile syringes and injecting equipment, although they may need different services from those typically provided by syringe [service] programs to individuals who inject opioids, given the different frequency of injection of these classes of drugs (e.g., injection drug use for stimulants can be periodic instead of consistent intervals such as the case with opioids). As such, [people who use stimulants] often feel that syringe [service] program staff and clients are biased to the needs of heroin/opioid injections and so [people who use stimulants] may elect not to use these vital services. Switching from injecting methamphetamine to smoking is a form of harm reduction and people may be interested in this option… Safer snorting information and equipment should also be provided to [people who use stimulants] to reduce the risks of this practice and/or so that people could consider snorting as a harm reduction option, especially if they frequently inject."[55]

6.6 **Expand the provision of clinical services, including HCV and other infectious disease screening and diagnostic testing (e.g., HIV testing, HBV testing, testing for sexually transmitted infections), linkage to care services, HCV treatment, vaccination (e.g., against HAV and HBV), wound care, overdose education and naloxone distribution in high-impact settings (settings that serve a high proportion of clientele who inject drugs, such as syringe service programs, substance use disorder treatment facilities, opioid treatment programs, organizations serving people experiencing homelessness).**

6.7 **Support strategies for opioid treatment programs to receive reimbursement or bill Medicaid and other health coverage programs for HCV counseling, testing, and linkage to care services.**

6.8 **Ensure non-clinical settings (e.g., syringe service programs, substance use treatment services, other community-based organizations) can secure Medicaid reimbursement for services such as testing, counseling, medical case management, and vaccination services, in order to scale and sustain HCV and related services in community settings.**

Background: This will require defining taxonomy and provider classification for these settings. This aligns with current work underway at the Health Care Authority, in collaboration with the Department of Health, to develop a State Plan Amendment for certain services delivered in the syringe service program setting to become Medicaid reimbursable.

6.9 **Provide resources, including financial resources for Medical Assistant-Phlebotomy training and staff, so that high-impact, non-clinical settings have access to onsite phlebotomy in order to perform immediate blood draws for confirmatory RNA testing for people who have a reactive test result from a point-of-care rapid antibody screening test.**

6.10 **Explore innovative and evolving approaches to HCV testing in non-clinical settings as new platforms receive approval from the Federal Drug Administration, such as dried-blood spot testing to detect RNA and point-of-care antigen testing.**

6.11 **Negotiate with commercial laboratories to reduce the cost of HCV diagnostic laboratory costs for community based organizations providing HCV testing in non-clinical settings.**

6.12 **Incentivize screening, confirmatory testing, and return for HCV care and treatment in high-impact settings, working with the impacted community to understand what incentives would be most meaningful and promote engagement throughout the testing and linkage to care process.**

Background: Research has shown that financial incentives promote testing, engagement, and treatment adherence for infectious diseases, including HCV.[56] [57] [58]

6.13 **Maximize opportunities to integrate HCV services into HIV prevention and care services, such as ensuring that agencies contracted with the Department of Health to provide HIV prevention and/or care services receive education about HCV and share that education with clients, including men who have sex with men, women of transgender experience, and people who inject drugs.**

Background: Evidence suggests that men who have sex with men[59] and women of transgender experience are at elevated risk of acquiring HCV and integrating HCV education into HIV services is an opportunity to raise awareness in these communities, including understanding of sexual transmission of HCV. A study from San Francisco found that women of transgender experience have an HCV prevalence that is nine times higher than San Francisco overall.[60]

6.14 **Ensure that agencies working with the Department of Health to provide non-clinical, rapid HIV antibody testing are trained and resourced to provide non-clinical rapid HCV antibody testing, including resources to provide confirmatory RNA (viral load) testing and HCV linkage to care services; gonorrhea, chlamydia, and syphilis testing and linkage to care services; and HAV and HBV vaccination where feasible.**

6.15 Recognizing the significant impact of homelessness and the lack of housing opportunities for many people experiencing poverty, implement strategies for medication storage in community settings (e.g., at syringe service programs, substance use treatment programs) so that people with no or unstable housing can safeguard their HCV direct-acting antiviral prescriptions and other medications.

6.16 Work with housing providers (e.g., shelters, supportive housing programs, subsidized housing) to ensure supportive policies that permit residents to possess syringes and to offer access to onsite sharps disposal to promote the use of sterile syringes and proper disposal.

6.17 Ensure HAV and HBV vaccine and vaccination capacity are available in high-impact settings.

6.18 Work with housing providers and organizations serving people experiencing homelessness to support people who inject drugs with education and resources to prevent transmission and acquisition of viral hepatitis, including HAV, HBV, and HCV.

Background: Recent outbreaks of HAV and HBV in Washington have disproportionately impacted people experiencing homelessness and people who inject drugs. People living with HCV who become infected with HAV or HBV are at an increased risk of death due to the synergistic impact of living with multiple forms of viral hepatitis. In addition, people who inject drugs living in close quarters need access to information and resources to prevent transmission and acquisition of viral hepatitis.

Goal 7. Improve access to and use of clinical care and supportive services by sufficiently scaling coverage and widening the scope of community-based navigation and case management programs.

7.1 Develop community navigator programs to empower people who have experienced living with HCV and being cured to support members of their community living with HCV to be linked to HCV care and achieve cure.

Background: Community navigators can help people locate and access community and clinical resources, develop relationships that promote community inclusion, and support people in implementing their individualized plans for addressing HCV and related health and social service needs. Because community navigators come from the population of focus, they can provide culturally relevant services in language their fellow community members understand.

7.2 Expand Title XIX Medical Case Management to HCV, which allows those receiving Medicaid benefits to receive holistic wrap-around services.[61]

7.3 Allocate funding for case management in high-burden counties and/or high-impact settings to support people diagnosed with HCV who are also experiencing mental health issues, challenges with substance use, and/or histories of trauma and incarceration.

7.4 Provide community-based medical case managers in high-impact settings.

7.5 Develop strategies that focus on re-entry community navigators to assist people through the transition between correctional care to community care for HCV and substance use disorder treatment (e.g., the navigator could meet with a person a few weeks prior to reentry to provide connection back into community and to stay connected as they navigate to care services).

7.6 Develop strategies that support people living with HCV who are incarcerated to enroll in Medicaid in order to receive HCV treatment and other health care and social services in the community upon release (e.g., create bridge hubs for re-entry so that people may go to a central location after their release date for comprehensive services such as housing and job placement, primary care, and linkage to substance use disorder treatment and harm reduction services).

7.7 Develop standards for HCV case management, including assessing acuity and intensity of case management needed, and evaluation and documentation of services within and across health systems in order to track client outcomes and avoid duplication of services.

Goal 8. Increase HCV awareness, resources, and education, and reduce stigma.

8.1 **Develop a web-based, searchable HCV provider referral database for people affected by HCV and community navigators and case managers serving them as a centralized repository of health care providers in Washington who treat HCV.**

Background: People living with HCV and community navigators and case managers working with them need a tool to determine which health care providers in their area treat HCV. The database could use a symbol to indicate if a provider offers particular services or competencies (e.g., has specific training or is interested in serving people who use drugs). Resources permitting, the database should include information on where to find the nearest syringe service program, overdose education and naloxone distribution site, substance use treatment facility, and other relevant information that people at risk for or living with HCV might seek.

One option for the database is to expand the existing Washington Recovery Helpline (http://www.warecoveryhelpline.org) to include HCV providers.

8.2 **Support a centralized community education position to improve and sustain community awareness and knowledge of HCV throughout the state.**

8.3 **Establish an online clearinghouse for non-clinical social service providers (e.g., community health workers, HCV care navigators, HCV testing and linkage to care staff) containing training, resources, and technical assistance related to HCV education, prevention, testing, and linkage to care services.**

8.4 **Conduct focus groups and key informant interviews to better understand the impact of stigma on the health and wellbeing of people at risk for and living with HCV.**

8.5 **Develop and implement a standardized tool for measuring stigma towards people who inject drugs and people experiencing homelessness among clinical and support service providers.**

8.6 **Expand HCV, bloodborne infection, and harm reduction education for people experiencing incarceration, which includes the expansion of the peer-educator Project SHIELD (Self Help in Eliminating Life-threatening Diseases) into all prison facilities.**

Background: Initially as part of a research study, the Washington State Department of Corrections, in collaboration with the Hepatitis Education Project, piloted an evidence-based program to reduce drug, tattoo, and sexual risk factors within hard to reach populations both during incarceration and after release. The CDC's HIV risk reduction program, Project SHIELD, was modified to include HCV and was tailored for the correctional setting. The model relies on peer networks to reduce risk behaviors. Participants are trained by 1-2 facilitators to be peer educators during six interactive small-group sessions that involve role-plays, demonstrations, and group discussions. Participants are asked to improve their own health behaviors and promote risk reduction among their social networks and community contacts. The pilot program involved one session at each of four facilities where it was very well received with excellent feedback from participants, prison health staff, and administrators. This modified version of SHIELD, coordinated by Hepatitis Education Project, continues in two Department of Correction facilities.

8.7 **Develop comprehensive HCV community health education materials (e.g., online, printed materials, videos) designed for people at risk for and living with HCV that explain how HCV is transmitted, how HCV is prevented, HCV testing and the difference between antibody and RNA testing, the direct-acting antiviral treatments, and that anyone living with HCV (regardless of substance use or level of fibrosis) is eligible to be treated through Medicaid in Washington.**

8.8 **Resource an HCV social marketing campaign to raise awareness about HCV and promote HCV prevention, testing, and treatment messages.**

8.9 **Provide comments and/or testify on legislation that impacts people at risk for or living with viral hepatitis, including proposed legislation that directly or inadvertently criminalizes people at risk for or living with viral hepatitis.**

8.10 **Ensure approaches to substance use focus on public health approaches and minimize criminalization of people who use drugs (e.g., provide comments on any future proposals related to paraphernalia in the Revised Code of Washington, criminal penalties for drug possession), because criminalization increases risk for infectious diseases, including HCV.**[62]

Clinical Strategies Goals

Goal 9. Improve access to and use of clinical care for marginalized populations at risk for or living with HCV through innovative service delivery models.

9.1 **Support the development of fixed clinical sites where the focus is on delivering interdisciplinary clinical services to people with extensive personal and social barriers to care.**

Background: Models like the MAX Clinic, at Harborview in Seattle, for people living with HIV could be adapted to serve people living with HCV. In addition to flexibility with walk-in hours and robust social and health services, resources are provided to support peoples' attendance at the clinic (e.g., outreach support, financial incentives, snacks, meal vouchers, cell phones, bus passes). Adapting the MAX Clinic model to ensure holistic care to address some of the unique needs of people who inject drugs, such as wound care, podiatry, and dental care, would act as a draw for attracting clientele who would benefit from onsite HCV testing, education, and treatment.

9.2 **Support mobile health clinics where a focus is on meeting people where they are, building trust and rapport, and providing necessary HCV and related infectious disease testing, assessment, and treatment and other health care services in areas with high burden and in remote communities with a lack of access to clinical services.**

9.3 **Explore strategies for incentivizing clinics to serve people who inject drugs referred by syringe service programs for care, including HCV treatment.**

Background: Syringe service programs need adequate referral networks to refer participants to health care services. Clinics may be disincentivized from working with syringe service program participants because of the competing social challenges that may make it difficult for some participants to keep medical appointments. Clinics need to receive reimbursement for missed appointments or some other type of incentive for keeping appointment slots open for syringe service program participants.

9.4 **Support the integration of HCV testing and treatment in opioid treatment programs and office-based buprenorphine treatment programs, and encourage providers to offer medications for HCV in conjunction with medications for opioid use disorder early in the course of substance use treatment.**

Background: Studies suggest that offering HCV treatment has benefits for substance use-related outcomes, and conversely, patients who receive medications for substance use disorder have good HCV treatment outcomes.[63 64 65]

Goal 10. Build the capacity of the health care workforce to diagnose and treat HCV.

10.1 **Scale the availability of easily accessible and low-barrier (e.g., free or low cost, brief) medical education regarding HCV for non-specialist providers and primary care providers, with a special emphasis on screening, diagnosis, treatment, and reinfection education through approachable and easy to understand platforms that offer educational credits to all applicable providers.**

10.2 **Educate providers about risk factors for HCV and encourage providers to implement CDC's updated screening guidance related to both risk-based and routine HCV testing, available at https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm, as well as CDC's updated refugee health guidelines which note, "It is reasonable to screen all adults (≥ 18 years of age) who originated from or have lived in countries with high moderate (2% to 5%) or high (≥ 5%) HCV infection prevalence."[66]**

10.3 **Develop easily accessible and low-barrier provider education materials and information to confront bias and prejudice toward people who use drugs in the medical community, including information on why HCV testing and treatment for people who inject drugs is effective and critical to achieve HCV elimination.**

Background: In 2018, a survey of 1,839 Washington State-licensed medical providers was conducted to assess provider awareness of treatment guidelines and HCV testing and prescribing practices. A primary finding of the survey was that while 1,089 (68%) of respondents had people who inject drugs in their practice, only 739 (68%) provided HCV testing and considered current injection drug use a risk factor for testing. In addition, of the 762 (41%) providers with people who inject drugs living with HCV in their practice, 637 (84%) had heard of direct-acting antivirals, of whom only 46 (13%) had prescribed direct-acting antivirals to a patient who injects drugs in the last three years. Approximately half (48%) were uncomfortable discussing alcohol or drug use during treatment. The most common concern about prescribing direct-acting antivirals to people who inject drugs was not being a specialist/trained (54%). Approximately half (58%) were aware that primary care providers in Washington can prescribe direct-acting antivirals and (52%) that treatment is recommended regardless of risk behavior.[67]

10.4 **Administer an annual or biennial HCV provider survey, like the one described above, to all health care provider types whose scopes of practice include prescribing authority and clinical care management to identify learning opportunities for health care providers and the methods of education preferred.**

10.5 **Develop a provider training program that couples training for prescribing medication treatment for opioid use disorder with training about HCV testing and treatment.**

Goal 11. Improve diagnosis of HCV in primary care settings.

11.1 **Work with all health care systems to implement prompts in their electronic medical records to screen people according to the CDC[68] and United States Preventive Services Task Force (USPSTF) recommendations.[69]**

11.2 **Through opportunities for public comment to the CDC and USPSTF, express Hep C Free WA's support for the expansion of one-time antibody screening for all adults and all people who are pregnant regardless of risk, with follow up RNA testing for anyone who is reactive, and encourage payers to cover this screening.**

Background: Currently the age cohort recommended for a one-time HCV test in the CDC and USPSTF recommendations is Baby Boomers. In addition, while the CDC and USPSTF do not currently recommend HCV testing for all people who are pregnant (only based on risk factors), the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America recommend that all people who are pregnant should be tested for HCV infection, ideally at the initiation of prenatal care (and again in the third trimester for people engaged in behaviors that put them at risk for acquiring HCV). Transmission to children during pregnancy occurs at an overall rate of 5% to 15%, with the number that progress to chronic HCV infection being 3% to 5%.[70] Hep C Free WA anticipates that the CDC and USPSTF recommendations may change in the coming year to include one-time testing for all adults.

11.3 **Work with all labs in Washington that receive specimens for HCV testing to implement reflex testing, ensuring that all specimens that are reactive for HCV antibody are immediately tested for RNA in order to streamline the diagnosis process.**

11.4 **Ensure all HCV antibody testing ordered in health care settings includes a reflex to RNA testing to ascertain current versus past infection and any reactive point-of care test includes an immediate blood draw for performing the RNA test.**

11.5 **Develop a statewide HCV treatment referral management system for primary care providers unable or unwilling to treat HCV in order to refer their patients to HCV treaters, including telemedicine providers, and include such information in the Health Care Authority's master contracts.**

11.6 **Incorporate HCV testing and linkage to care into the Health Care Authority's common measure set[71] so they can be considered for inclusion as value-based quality of care indicators for provider reimbursement through the Health Care Authority.[72]**

Goal 12. Improve HCV disease intervention services.

12.1 **Identify resources to strengthen the scale and scope of public health disease intervention services, to include HBV and HCV, at local health jurisdictions, and ensure that local health jurisdictions are sufficiently staffed with disease intervention specialists to adequately respond to HCV and other infectious diseases (e.g., HIV, STDs, HAV, HBV) and to identify outbreaks.**

Background: Local health jurisdictions receive reports of notifiable conditions from health care providers and laboratories. Given the volume of HCV case reports, no local health jurisdiction in the state has the capacity to investigate newly reported cases and work with people to link them to care and provide testing services to their social networks (e.g., working with a person identified with HCV to understand the settings where they interact with people who inject drugs and/or share injection equipment and to identify sexual partners who may benefit from testing). Only a few local health jurisdictions have any staff specifically tasked to work on HCV disease intervention activities and investigate high-priority cases (e.g., acute cases, cases in people under the age of 30, cases in people who are pregnant).

12.2 **Explore strategies for linking entire social networks into HCV testing and treatment (e.g., injection networks), such as using the support of Epidemic Intelligence Service Officers from the CDC.**[73]

Goal 13. Improve access to HCV treatment and comprehensive health care.

13.1 **Simplify the HCV direct-acting antiviral prior authorization process in Medicaid (Apple Health).**

Background: The Health Care Authority recently released an updated HCV policy that removes some previous restrictions, including a requirement for specialist consultation in order for primary care providers to treat HCV (Appendix C). Some additional strategies for future consideration include:

- Creating a streamlined or expedited prior authorization process for HCV.
- Limiting genotype testing to treatment-experienced patients and those with cirrhosis.[74]
- Reviewing reasons for prior authorization denials and consider removal of prior authorization in the future.

13.2 **Encourage third-party payers to approve HCV treatment for people at high risk of transmitting HCV.**

Background: Most patients who start direct-acting antiviral medication will have an undetectable viral load after four weeks of treatment, which likely means they are not able to transmit the virus to others. Approving treatment for people at high risk of transmitting HCV (e.g., people who inject drugs, men who have sex with men) after a single detectable and quantifiable HCV RNA test (>15 IU/mL) within the last six months, so they can achieve cure as soon as possible, has both an individual and public health benefit.

13.3 **Work with third-party payers to recognize non-physician providers (e.g., NPs, PAs, PharmDs) as prescribers.**

13.4 **Encourage health plans to enroll pharmacists as providers in order to allow for pharmacists to bill for HCV testing, treatment, and prevention counseling.**

13.5 **Support the development and implementation of telehealth models and address policy barriers to telehealth expansion, such as payer requirements for face-to-face visits.**

13.6 **Develop statewide standards of care including, but not limited to, clear guidelines for treating people who inject drugs, information that treatment will be covered for people who experience re-infection, and provider education about re-infection prevention and linkage to supportive services, such as medication treatment for opioid use disorder and syringe service programs.**

13.7 **Improve treatment access and continuity of care for people who are institutionalized (e.g., in jail, prison, state hospitals), such as leveraging the purchasing of HCV medications for jails and a centralized place to deliver medications to jails to ease financial and administrative burden (e.g., this could involve pairing opioid treatment and HCV treatment through these channels), and/or including HCV in the Health Care Authority's 1115 waiver proposal[75] to the U.S. Centers for Medicare & Medicaid Services to continue Medicaid coverage for medication to treat opioid use disorder for people while they are in jail.**

Background: When people are institutionalized their Medicaid coverage is suspended. Washington needs to explore strategies for ensuring people living with HCV can receive HCV direct-acting antivirals during institutionalization, whether they are mid-treatment when institutionalized or start treatment during institutionalization.

13.8 Identify a funding mechanism that provides support for HCV care and treatment for people who are underinsured or uninsured, with a special emphasis on supporting care and treatment for those unable to acquire insurance due to immigration status.

13.9 Ensure people at risk for and living with HCV have access to comprehensive health care, including oral health care, behavioral health services, and hygiene services to improve overall wellness and linkage and retention to HCV services.

Goal 14. Improve the ability of people taking HCV direct-acting antivirals to complete treatment.

14.1 Modify state pharmacy regulations to allow opioid treatment programs to store and administer HCV medications so that they can provide directly observed therapy (DOT) in conjunction with medications to treat opioid use disorder.

14.2 Encourage the use of strategies/tools to improve peoples' ability to take direct-acting antiviral therapy as directed and complete all aspects of treatment (e.g., financial incentives, DOT in opioid treatment programs, smartphone apps for video-DOT, ingestion sensors that confirm treatment was taken, medication storage, etc.).

14.3 Encourage Accountable Communities of Health to offer more flexible policies in care transition (e.g., see the example of the Healthier Here transitional care project[76]).

Goal 15. Improve follow-up clinical care for people who have completed HCV treatment.

15.1 Develop systems to ensure that all patients with cirrhosis receive appropriate follow-up care, which includes screening for hepatocellular carcinoma and portal hypertension.

15.2 Ensure those with risk factors for re-infection are monitored post-cure (e.g., people who currently inject drugs who have been cured should be counseled about reinfection prevention and receive RNA testing annually).

Implementation Phase and Next Steps

The development of the "Hep C Free WA Plan to Eliminate Hepatitis C by 2030" marks the beginning of Washington's efforts to eliminate the public health threat of HCV by the year 2030. Now that this initial planning phase is complete, the Hep C Free WA initiative moves into the implementation phase.

The Hep C Free WA Coordinating Committee, with support from the Department of Health as the backbone organization, will continue meeting on a quarterly basis. The Committee will focus on:

1. Disseminating best practices and identifying promising approaches and potential demonstration projects;
2. Shared accountability, an important tenet of collective impact initiatives, including monitoring implementation of the recommendations, evaluating progress toward elimination, and refining the plan over time as efforts evolve;
3. Reviewing progress on the recommendations, producing an annual, written progress report, and revising recommendations as necessary;
4. Refining its structure and defining governance, including how to ensure effective communication with the Governor, Secretary of Health, and other relevant state leaders to ensure bi-directional communication and to discuss progress and roadblocks toward realization of the Governor's Directive (Appendix B); and
5. Investigating opportunities for raising funds to support activities to help Washington achieve HCV elimination.

The three Hep C Free WA topic-specific work groups — Data & Strategic Information, Community-Based Responses & Interventions, and Clinical Strategies — will also meet on a quarterly basis, to ensure accountability related to their group's recommendations. At the quarterly Coordinating Committee meetings, each work group will report back on opportunities and challenges. An additional work group focused on community engagement and outreach will form and meet monthly to build leadership among people affected by HCV and from communities disproportionately impacted. This group will also coordinate Hep C Free WA community engagement events throughout the state.

The tools exist to eliminate the public health threat of HCV in Washington, but we must act swiftly and provide the resources necessary to achieve this goal.

Conclusion

Hepatitis C is a public health crisis in Washington State. Illness and death among aging Baby Boomers from HCV-related causes is on the rise. New infections are occurring at alarming rates among younger people who inject drugs, largely related to increases in opioid and other drug injection. Stigma and lack of accurate knowledge about HCV among affected communities and healthcare providers impede appropriate preventive services, testing, diagnosis, linkage to care, and treatment. The tools exist to eliminate the public health threat of HCV in Washington, but we must act swiftly and provide the resources necessary to achieve this goal. By working together to implement the Hep C Free WA recommendations, we can fulfill the Governor's Directive to eliminate the public health threat of HCV by 2030.

Appendices

Appendix A

Report by the Center for Disease Analysis Foundation, Public health impact of a population based approach to HCV treatment in Washington

Appendix B

Directive of the Governor 18-13

Appendix C

Washington State Health Care Authority, Hepatitis C Clinical Policy

Appendix D

Glossary

Public health impact of a population based approach to HCV treatment in Washington

This is a summary of the key outcomes of a hepatitis C virus (HCV) disease burden analysis undertaken by the CDA Foundation's Polaris Observatory, in collaboration with ASTHO, CDC and the Washington State Department of Health

This analysis was funded by a CDC cooperative agreement with ASTHO.

Contents

Executive Summary and Key Recommendations

Hepatitis C virus (HCV) is a blood borne infectious disease that causes substantial liver related morbidity and an increased risk of liver cancer and liver-related death.[1] HCV is often known as a "silent disease", as there are few noticeable symptoms, especially in early stage infection.[2] Because of this, many infected individuals are unaware of their HCV status until more serious, late stage complications arise. Treatment is available for HCV, with success measured by the sustained viral response (SVR) rate at 12-24 weeks post treatment. Prior to 2014, an average of 48-70% of patients achieved SVR with the available therapies; however, recent therapeutic advances mean that SVR rates in 2018 have increased to more than 95%.[3] Achieving SVR can reverse the effects of early stage fibrosis and slow the progression of cirrhosis into decompensation or hepatocellular carcinoma (HCC).[4,5] This reduces liver related mortality by 20-fold and all-cause mortality by 4-fold.[6] Transmission of HCV can be prevented by avoiding direct exposure to contaminated blood or blood products, including objects that may have come in contact with contaminated blood, such as needles and syringes.

Over the last 14 years, the HCV epidemic has drastically changed in the US. Originally a disease affecting "baby boomers" (people born between 1945 and 1965), HCV has reemerged as a syndemic with opioid misuse, overdose and HIV.[7] In 2010, approximately 3.5 million Americans were infected with chronic HCV[8] and, according to CDC data; HCV now kills more Americans than any other infectious disease.[9] Additionally, HCV is the leading cause of cirrhosis and liver cancer, and the most common reason for liver transplantation in the US.[10] In 2013, HCV-related deaths surpassed the total combined numbers of deaths from 60 other infectious diseases reported to the CDC, including HIV and tuberculosis; and in 2014, HCV-related deaths reached an all-time high with more than 19,600 deaths reported.[11] At the same time, there has been a marked simultaneous increase in the number of persons newly diagnosed with HCV across the US, particularly among people with a history of injection drug use.[12] Increases in acute HCV and hospital admissions for opioid injection were seen between 2004 and 2014, with the number of persons newly diagnosed with HCV more than doubling between 2010 and 2014.[13]

National-level programs to control the burden of HCV have focused primarily on the older cohort of previously infected individuals. These programs include screening for HCV in the baby boomer birth cohort (1945-1965) as well as programs through the Veteran's Administration (VA) to diagnose and cure all veterans infected with HCV. Despite these efforts, barriers to treatment still exist at the state Medicaid level, as evidenced in many states by fibrosis requirements that preclude treatment for patients with early stage liver disease.[14] Universal procedures exist to prevent HCV transmission in medical settings across the US (though localized outbreaks may still occur when procedures fail). However, the recent opioid crisis presents a new challenge for HCV prevention efforts. At present, policies to prevent transmission among drug users are entirely state-specific, and in many states these policies are non-existent.[15]

This report presents the outcomes of a multi-stakeholder collaboration to assess the HCV disease burden in the state of Washington. This work follows a standard methodology (modified Delphi process) developed and facilitated by the CDA Foundation's Polaris Observatory staff. It engages local stakeholders, including the Washington State Department of Health, doctors from the Department of Veterans Affairs and University of Washington, local health jurisdictions (Tacoma Pierce County Health Department and Public Health – Seattle & King County), the Washington State Department of Corrections, the Hepatitis Education Project, the Washington State Office of Financial Management and Washington State Health Care Authority, to ensure the data used in the analysis represent the best available and to develop momentum and consensus toward a common goal. The tool used in this work is a Microsoft Excel based

Markov model, populated with consensus estimates, which can answer the basic questions needed for HCV policy development.

Key Insights and Recommendations

Who is affected?

- At the beginning of 2018, there were 59,100 (95% uncertainty interval 32,500-71,500) HCV-RNA+ (viremic) infections in Washington. Approximately 80%, of infections were diagnosed previously (n= 46,500) with 5,600 infections diagnosed annually, and 12% of persons infected (n=7,330) were initiated on treatment annually. There were an estimated 2,950 new infections annually, an incidence rate of 39.9 per 100,000 in 2018.
    - 52% of total infections were in the 1945 to 1965 birth cohort*
    - 18% of total infections were among women of child bearing age*
    - 25% of total infections were among people who inject drugs*
    - 5% of the HCV infected population were among incarcerated people
    - The percent of the HCV infected population on Medicaid was unknown

    *Percentages do not sum to 100% because overlap exists across groups and not all subpopulations are considered here

What is the impact of current policies?

- If currently policies continue and there is no change to the HCV treatment paradigm in Washington, the total number of HCV infections will decline 85% by 2030; liver related deaths, hepatocellular carcinoma (HCC), and cirrhosis will decrease by 90% as the infected population ages.

What needs to be done to eliminate HCV in Washington?

- Under the current standard of care, Washington is projected to eliminate HCV (defined by the WHO as an 80% reduction in new infections, 90% diagnosis of all infections, and a 65% reduction in liver related mortality) by 2030. Between 2019 and 2030, a total of 61,400 treatments are needed, an average of 5,100 patients annually.
- Eliminating HCV on an accelerated timeline (2025) would require 1,500 *fewer* total treatments than in the base scenario but at a slightly higher rate in years 2020-2025. Additionally, prevention efforts would need to continue to lower the incidence rate from 39.9 per 100,000 cases in 2018 to around 6.6 per 100,000 by 2030.
    - As discussed below, Washington already has some prevention programs in place providing access to sterile needles and syringes and treating persons who are actively injecting drugs.

Background

HCV globally

Today, an estimated 71 million individuals globally are infected with Hepatitis C, a curable disease that can lead to cirrhosis, liver cancer, and liver related death. Approximately 400,000 people die each year from causes related to HCV, which can be eliminated through coordinated efforts for prevention and treatment. Unfortunately, as of 2017, only 20% of those infected patients have ever been diagnosed, and, currently, only 2% of total infected patients are being treated for the disease annually.

The CDA Foundation and the Polaris Observatory

The CDA Foundation (CDAF) is a non-profit organization that specializes in the study of complex and poorly-understood diseases in order to provide countries and states with the data and information to create and implement successful elimination strategies. The Polaris Observatory, an initiative of CDAF, provides epidemiological data, modeling tools, training and decision analytics to support eliminating Hepatitis B and C globally by 2030. The observatory offers the most up-to-date estimates for the HCV, hepatitis B virus disease burden and economic impact, and offers strategies for elimination of each virus, along with financing options. An independent advisory board with representatives from global health organizations, academia, civil societies and donors oversees the activities of the observatory. The Polaris Observatory's teams of epidemiologists work directly with stakeholders in over 100 countries to assess the current – and future – disease burden of hepatitis, model economic impact, and develop strategies that can achieve country or state-defined targets to eliminate it. By developing partnerships at country and regional levels, the observatory collects and analyzes data for its platform and publishes key findings to enable policies around hepatitis elimination.

How this model has been used globally

This work has resulted in the adoption of national hepatitis elimination strategies in countries such as Egypt and Mongolia. In Egypt, this included an economic analysis that accounted for both direct costs (healthcare, screening, diagnostic and antiviral therapy costs) and indirect costs (costs based on disability-adjusted life years). The analysis showed that it would cost Egypt US$90 billion over a 15-year period if the government kept the status quo. A plan of action was then developed beginning in 2014 with a goal of treating 300,000 patients annually, including cost subsidies for four years. After seeing successes, the plan continued each year. In 2016, Egypt treated 577,000 patients and the plan expanded to include patients at all stages of disease, even those without any HCV-related consequences.

In Mongolia, CDAF and its Polaris Observatory team worked with the World Health Organization's Regional Office for the Western Pacific (WPRO) to first design an economic analysis and understand the disease burden. Working with partners including WPRO, the president of the Mongolian Association on Study of Liver Diseases, a physician professor and a group of other researchers, the team developed the co-payment method based on income level. The Mongolian government subsidized part of drug treatment and as prices declined, treatment became even less expensive for patients. CDAF also worked with the WPRO to develop a national screening program in urban and rural areas after reaching the conclusion that, even if the prevalence of HCV goes down in the next decade, there will still be more transmission and deaths unless there is an increase in screening and diagnosis.

How this model has been used in the United States

In 2014, this work expanded to include state-based analyses within the US. Through collaborations with a combination of state health departments, the CDC Foundation, Association of State and Territorial Health Officials (ASTHO) and state collaborators this model has been used to encourage the removal of Medicaid fibrosis restrictions (Colorado), to publish the HCV epidemiology and an elimination scenario (Rhode Island) and to inform the development of state elimination strategies (District of Colombia and New York, *in progress*). Additionally, the results for ten states (California, Colorado, Georgia, Iowa, Louisiana, New Mexico, Pennsylvania, Rhode Island, Tennessee and Washington) are included on the Polaris Observatory Website (http://cdafound.org/polaris-hepC-dashboard/). Ongoing analyses include collaborations with ASTHO, CDC and state partners to identify the disease burden and associated elimination strategies in Washington.

Hepatitis C related disease burden – Washington

Washington is a Pacific Northwest US state that is larger than average both geographically and in population size. Washington has demonstrated the capacity to treat as many as 7,900 HCV patients in a year, has implemented some of the nation's first harm reduction programs among high-risk populations and has developed a funding mechanism for future statewide treatment scale-up.[16]

The analysis presented here represents the work of stakeholders from the Washington State Department of Health, the Department of Veterans Affairs, the University of Washington, local health jurisdictions (Tacoma Pierce County Health Department and Public Health – Seattle & King County), the Washington State Department of Corrections, the Hepatitis Education Project, the Washington State Office of Financial Management and Washington State Health Care Authority, ASTHO, CDC and CDAF. The primary objectives were to quantify the current and future disease burden of HCV in Washington and identify the level of effort necessary to eliminate HCV in the state.

Based on the Edlin et al. adjustments of NHANES data, scaled specifically to Washington, it was estimated that 1.1% (range 0.8%-1.5%) of the population of Washington was chronically infected (RNA positive) with HCV in 2010. This equates to approximately 77,100 (range 55,000-103,500) infected individuals in 2010. [17]

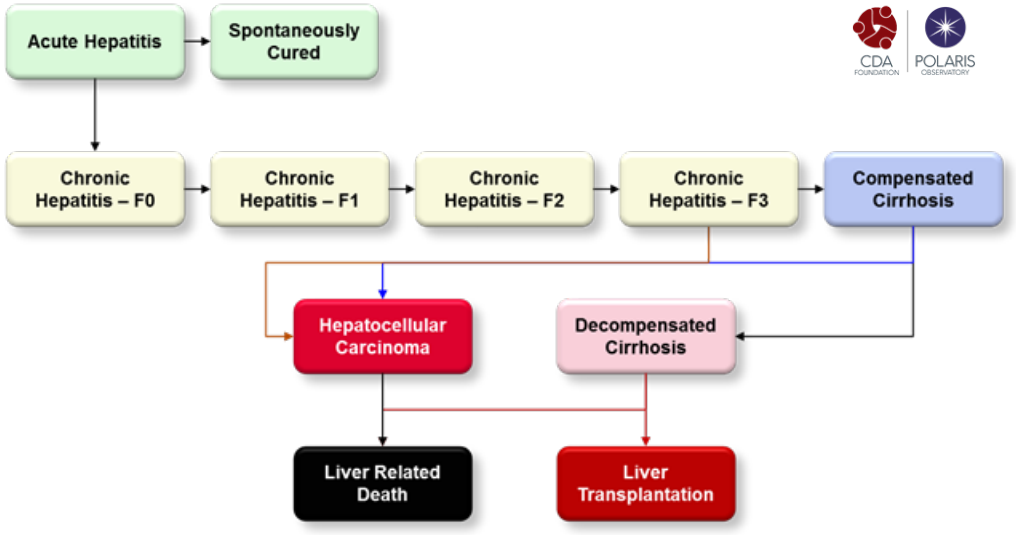
Achieving a sustained virologic response (SVR) to HCV treatment can reverse the effects of early stage fibrosis and slow the progression of cirrhosis into decompensation or HCC.[18,19] This reduces liver related mortality by 20-fold and all-cause mortality by 4-fold.[20] Direct acting antivirals (DAA) can achieve SVR in >95% of patients with HCV.

Similar to the United States as a whole, in Washington, almost 70% of individuals infected have genotype 1 (unpublished surveillance data from the Washington DOH).[21] Though previously genotype 1 chronic infection was the most difficult to treat, DAAs have become the standard of care and are safe for the treatment of genotype 1 patients. For this modeling exercise, based on input from expert meetings, we assumed an SVR rate of 95% for all genotypes.

The model

The mathematical model is an Excel based disease progression model which was calibrated using reported, state-specific, epidemiologic data. The progression is as follows (Figure 1):

Figure 1.



The details of the model have been described previously in Blach 2016.[22] Briefly, a Markov disease progression model grounded in population, mortality, and state-specific HCV data was developed. The model captures new (acute) infections by age and sex starting in 1950, and then follows the annual progression from acute to spontaneous clearance or through the stages of chronic infection. Additionally, the model accounts for age-specific mortality as well as patients who maintain a sustained virological response (SVR). Based on state-specific inputs, the model is used to forecast the disease burden by HCV-sequelae, including fibrosis, cirrhosis, decompensated cirrhosis, hepatocellular carcinoma (HCC), and liver related death from 1950-2030.

Input data

The following epidemiologic data were input into the model (Table 1):

Table 1.

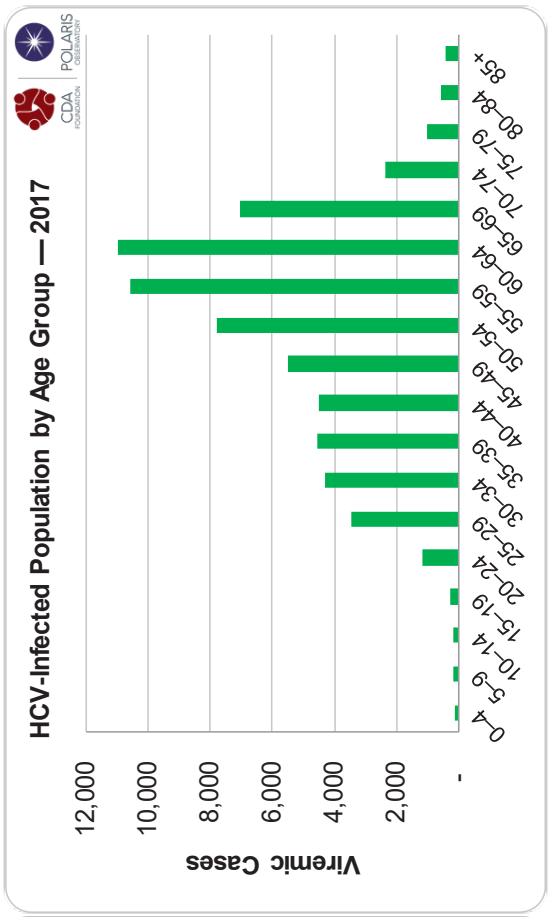
Historical Input	Estimate (Range)	Estimate Year	Source	Source Description
HCV-RNA+ Infections	77,100 (55,000-103,500)	2010	[23]	Edlin 2015
Anti-HCV Prevalence by Age and Sex	See Figure 2	2017	[24,25]	Notification data provided by the Washington State Department of Health scaled to the WA prevalence population
HCV-RNA Prevalence by Age and Sex	See Figure 3	2017	[26]	Notification data provided by the Washington State Department of Health scaled to the WA prevalence population
HCV Genotype	See Table 2	2018-2019	[27]	Unpublished surveillance data from the WDOH
Total Diagnosed (HCV-RNA)	33,294	2010	[28,29]	Based on analyses of NHANES data, ~45% of the US infected population has been previously diagnosed, scaled to the WA population
Annual Newly Diagnosed (HCV-RNA)	7,889	2017	[30]	Notification data provided by the Washington State Department of Health
Annual Number Treated	7,957	2017	[31]	All Payers Claims Data provided by the Washington State Office of Financial Management

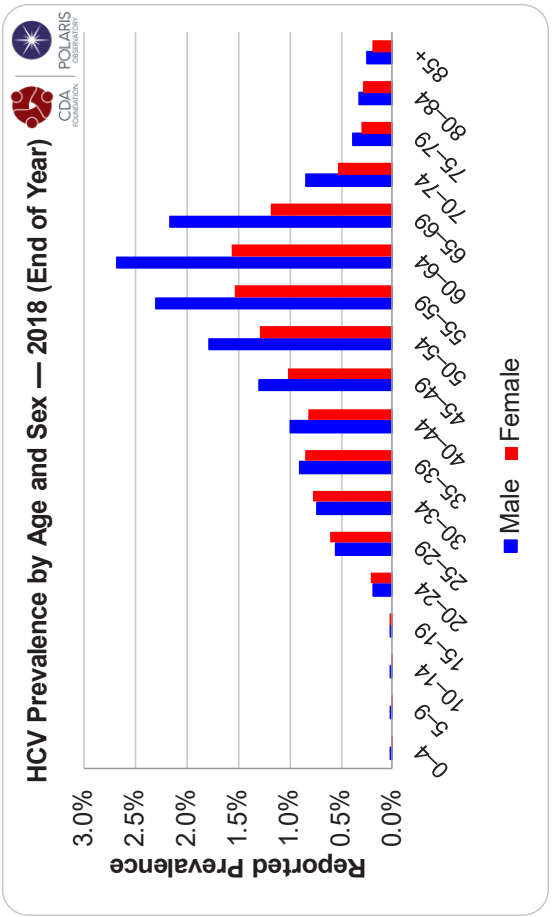
HCV Prevalence

Prevalence of HCV in Washington was estimated for 2010 based on adjustments made to the National Health and Nutritional Examination Survey (NHANES) data. Edlin et al. details several high-risk groups (such as incarcerated, homeless, active military, etc.) that were excluded from the NHANES data, and based on this analysis, it was estimated that 1.1% (range 0.8%-1.5%) of the population, or approximately 77,100 (range 55,000-103,500) individuals, were chronically infected with Hepatitis C in 2010. [32] Uncertainty intervals from Edlin et al. were used in the sensitivity analysis.

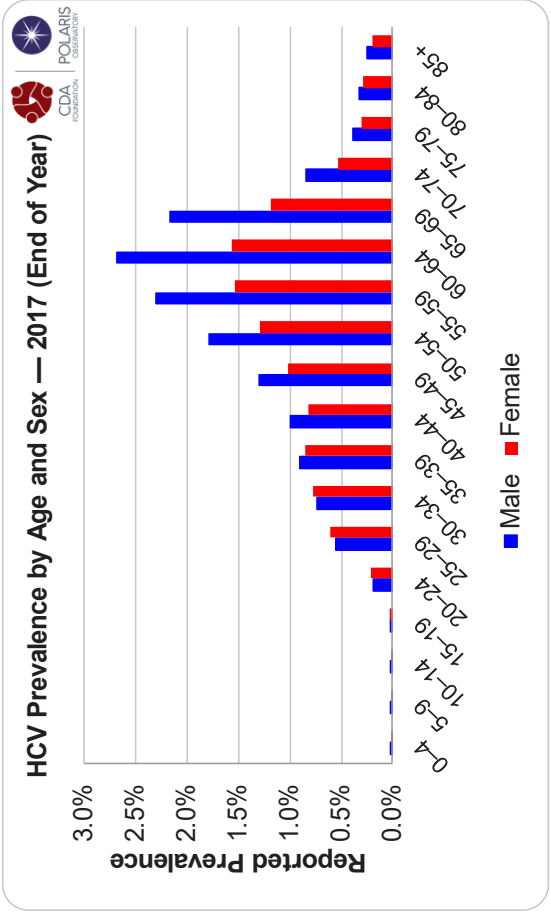
The historical age and sex distribution of the infected population in Washington was estimated using state notification data by age and sex collected from 2000-2017.[33] The data were aggregated and aged over time while adjusting for viremia (75%, except for 2016-2017 where actual RNA+ cases were reported), age- and sex-standardized mortality rates, and the number of patients cured each year (in total, 40,475 treated and 32,190 cured). Next, this distribution was scaled to match the overall number of HCV infections estimated in 2017 (Figures 2a and 2b). The resulting prevalence by age curve was bell-shaped in 2006 with a peak in 50-54 year olds (model output). This was similar to the US as a whole according to data reported from NHANES 2003-2010.[34]

The distribution of total viremic patients by age group for Washington in 2018 can be seen in Figure 3a. As the opioid epidemic grows in the United States, we see an increase in the number of infected individuals between the ages of 25-39. More so, in Figure 3b, we see that females are slightly more likely to be infected than males in ages younger than 35 years.





Figures 3a and 3b.



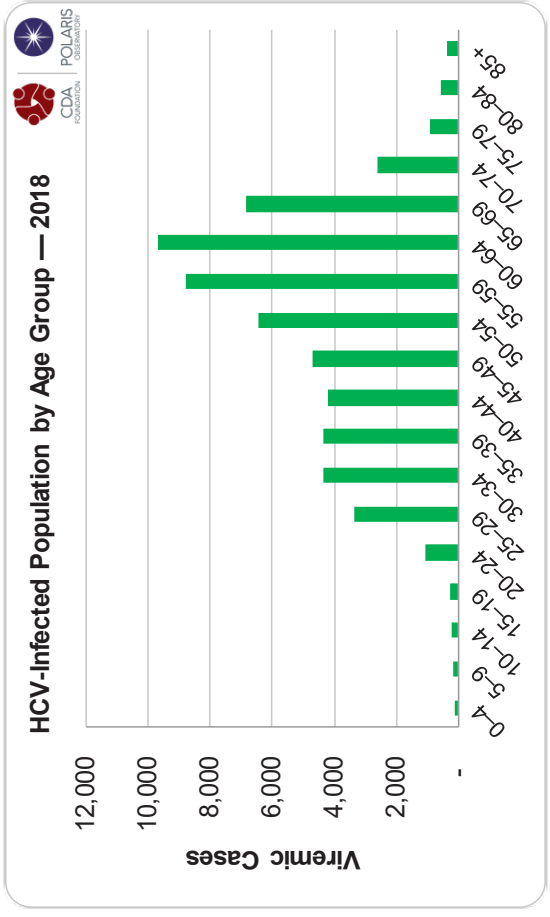


Figure 2a and 2b.

Genotype

The genotype distribution in Washington was based on unpublished surveillance data collected from 2018-2019 and provided by the WDOH (n=5,423). [35]

Table 2.

Genotype	G1	G2	G3	G4	G5	G6	Mixed/ Other
WDOH (2018-2019)	66.0%	14.9%	17.3%	0.9%	0.0%	0.5%	0.4%

Incidence

Prior to 2007, the incidence trend in Washington was assumed to mirror that of the entire United States. [36] Starting in 2008, it was then assumed that incidence increased to reflect increasing use of drugs by injection and sharing of injection equipment in Washington.

Diagnosis

According to US national estimates, ~45% of the infected population was diagnosed by the end of 2009.[37,38] This rate was applied to the Washington infected population in 2010, resulting in an estimated 33,300 previously diagnosed cases in that year. After 2010, WDOH notification data was used to inform the number of patients annually diagnosed.[39]

In 2017 alone, WDOH received reports of 8,813 Washingtonians who tested positive for HCV, and 7,889 of those patients were also confirmed to be RNA+.[40]

Treated

The number of patients treated each year between 2008 and 2014 was estimated using annual US treatment rates applied to the Washington population. The Washington State Office of Financial Management was able to provide Washington-specific All Payers Claims Data (APCD) which reported number of treatment initiations in years 2015-2017 stratified by Medicaid, Medicare and commercial.[41] Adjustments were made to these data to account for employees of large companies (e.g. Microsoft, Amazon, etc.) and those who are self-insured by applying the commercial treatment rate from the APCD to this population. Additionally, data on the number of prisoners treated were provided by the Washington State Department of Corrections and added to the adjusted APCD. Other potential points of care for treatment of HCV that would not be captured by the APCD include the Department of Veterans Affairs and tribal health providers, however these data could not be collected. According to these estimates, which were agreed to by expert consensus, 7,960 patients were treated in 2017.

Subpopulations

Approximately 30% of the total population of Washington is currently on Medicaid.[42] The prevalence of HCV in the Medicaid population was unavailable at the time of the analysis.

Routine opt-out screening for anti-HCV in the prison populations began in 2010 for all incoming men and women.[43] In 2018, almost 90% of the intake population was screened for anti-HCV with a 23.7% positivity rate for HCV exposure with an estimated 11-14% living with chronic infection.[44] About 7,000-8,000 people enter the Washington prison system each year and at any one time the prison population is estimated at 19,000.[45] The number of people who are incarcerated being treated for HCV has been increasing annually. Whereas ~90 people received treatment in 2015, over 250 will be treated in fiscal year 2019.[46]

There were an estimated 33,300 people who inject drugs (PWID) in Washington in 2017 (0.5% of the population). Based on the National HIV Behavioral Survey in 2016, it was assumed that approximately 66% of this population was anti-HCV positive. [47]

In 2017, approximately 23% of the total population in Washington was women of child bearing age (WoCBA) (females aged 15-49 years). The prevalence of HCV in this population was unavailable at the time of this analysis but could be estimated by the HCV disease burden model.

Results

Past and Present Burden of Disease

Annual incidence was modeled with expert input to peak in 1989, around the time systematic blood screening began. It was then modeled to increase again in 2007 in order to capture the increase in transmission of HCV due to high rates of unsterile opioid use in Washington. In 2018, it was estimated that there were approximately 2,950 Washingtonians who acquired HCV (39.9 per 100,000).

At the beginning of 2018, 79%, or 46,500, of the 59,100 (95% uncertainty interval 32,500-71,500) viremic infections were diagnosed. Of the total infected population, 12% (7,300) were treated. Of the 7,300 treated, 95% (7,000) were cured. This cascade of care in 2018 can be seen in Figure 4. The distribution of Washingtonians with HCV by fibrosis stage, which is calculated by the model, can be seen in Figure 5. Almost 30% of patients in 2018 were estimated to be fibrosis stage F1, while more than 40% were F2, F3, or cirrhotic.

The prevalence in subpopulations was also considered. Within the incarcerated population there close to 2,700 RNA+ infections in 2018. This was calculated by applying the anti-HCV prevalence (23.7%) and a viremic rate (71%) to the number of incarcerated persons (16,000). At the start of 2018, 4.6% of all viremic infections (2,700/59,100) were among persons who are incarcerated.

The prevalence among people who inject drugs (PWID) was also estimated. Assuming 33,300 total PWID in Washington and applying an anti-HCV rate of 66% and a viremic rate of 75% there would be a total of 16,500 HCV-RNA+ PWID, approximately 25% of all viremic infections at the beginning of 2018. [48]

The model was used to calculate the prevalence among WoCBA and in baby boomers (persons born in the 1945 to 1965 birth cohort). The prevalence by age in the WoCBA population ranged from 0.05%-0.92% in 2018, with the peak prevalence in those aged 45-49. In total, 18% of all viremic infections at the start of 2018 were estimated to be WoCBA. The prevalence by age in the baby boomer population ranged from 0.88%-2.03% in 2018. In total, 52% of all viremic infections in the same year were estimated to be among baby boomers.

Figure 4.

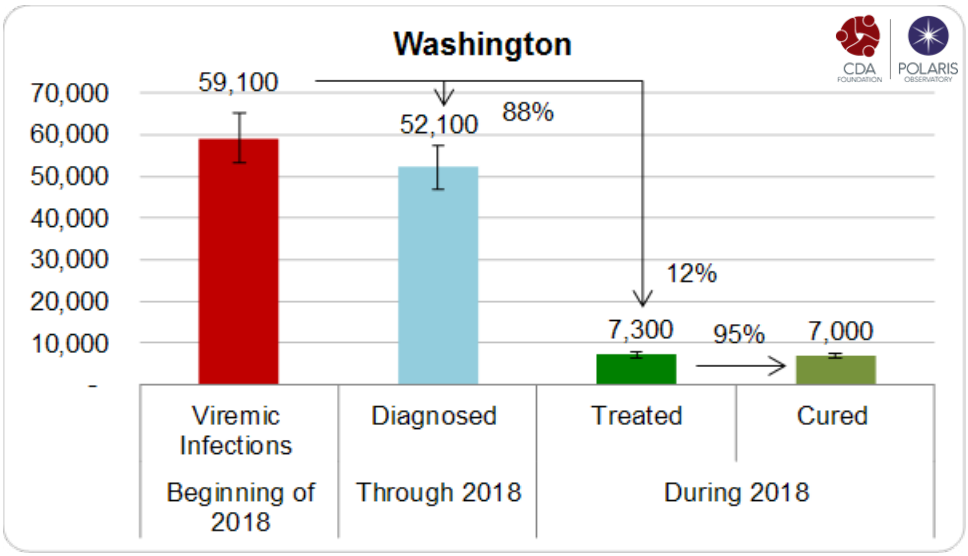
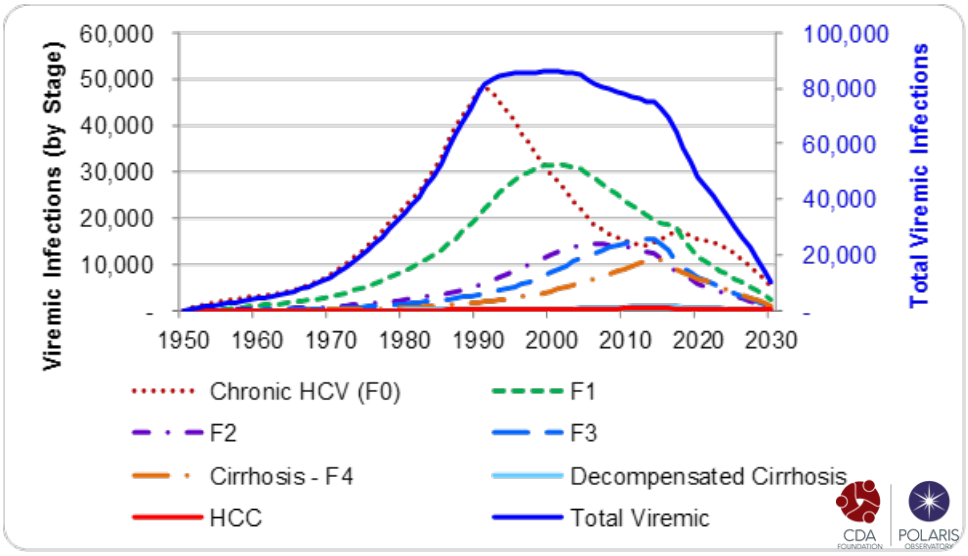

Washington
CDA FOUNDATION
POLARIS OBSERVATORY
70,000
60,000
50,000
40,000
30,000
20,000
10,000
-
59,100
52,100
88%
12%
7,300
95%
7,000
Viremic Infections
Beginning of 2018
Diagnosed
Through 2018
Treated
Cured
During 2018

Figure 5.


Viremic Infections (by Stage)
60,000
50,000
40,000
30,000
20,000
10,000
-
100,000
80,000
60,000
40,000
20,000
-
Total Viremic Infections
1950 1960 1970 1980 1990 2000 2010 2020 2030
Chronic HCV (F0)
F1
F2
F3
Cirrhosis - F4
Decompensated Cirrhosis
HCC
Total Viremic
CDA FOUNDATION
POLARIS OBSERVATORY

Treatment Scenarios

We created two treatment scenarios: 1) Base, the current standard of care assuming a near 40% drop in treatment between 2017 and 2020; and 2) Accelerated Elimination, the levels of intervention necessary to eliminate the disease burden by 2025. The elimination scenario is based on the WHO Elimination Targets, defined as an 80% reduction in new infections, 90% diagnosis of all infections, and a 65% reduction in liver related mortality. This strategy requires the following numbers of people to be diagnosed and treated for HCV:

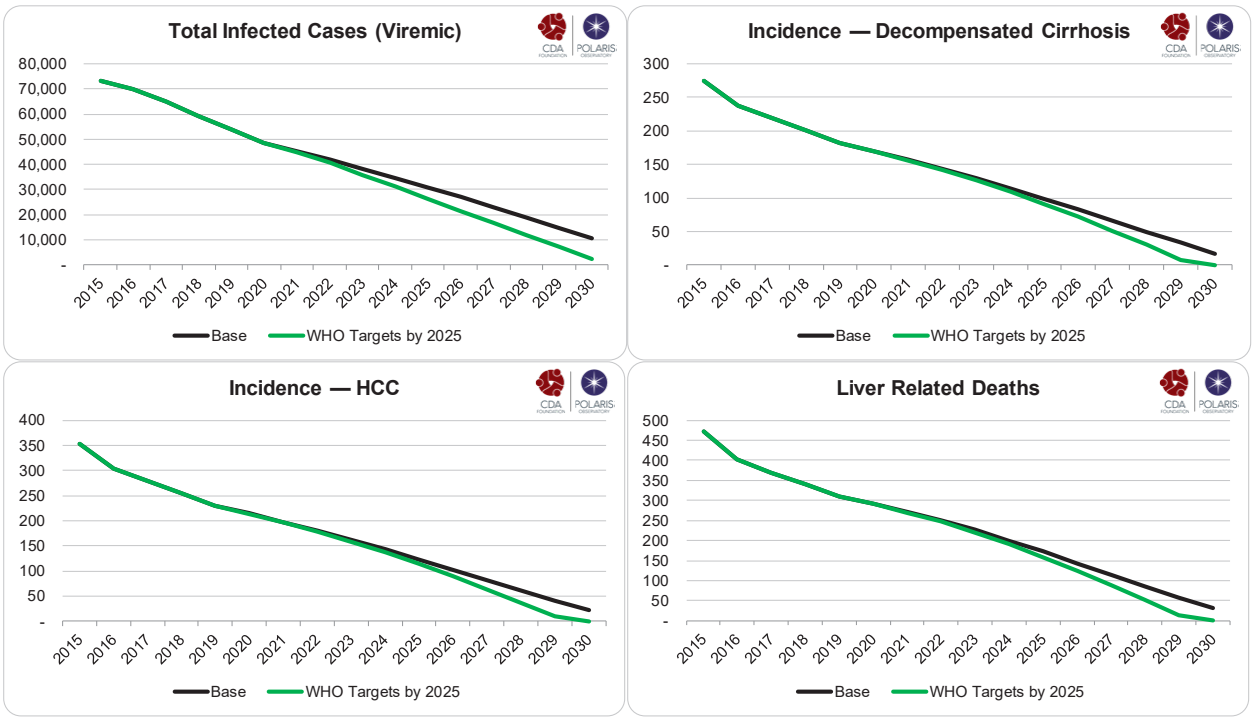
Table 3.

Scenario	Model Parameter	2018	2019	2020	2021	≥2022
Base	Incident Infections	3,000	2,700	2,400	2,300	2,100
	Treated	7,300	7,000	4,900	4,900	4,900
	Newly Diagnosed	5,600	5,600	3,900	3,900	1,800
	Fibrosis Stage	⩾F0	⩾F0	⩾F0	⩾F0	⩾F0
	Treated Age	15+	15+	15+	15+	15+
	SVR	95%	95%	95%	95%	95%
WHO Targets by 2025	Incident Infections	3,000	2,700	2,200	1,400	800
	Treated	7,300	7,000	5,100	5,100	5,100
	Newly Diagnosed	5,600	5,600	3,900	3,600	1,200
	Fibrosis Stage	⩾F0	⩾F0	⩾F0	⩾F0	⩾F0
	Treated Age	15+	15+	15+	15+	15+
	SVR	95%	95%	95%	95%	95%

Under the base scenario, the number of Washingtonians with viremic HCV peaked in 2000 and will continue to decline by 85% between 2015 and 2030, resulting in 10,700 (95% uncertainty interval 200-26,700) Washingtonians with HCV by the end of 2030. Liver related deaths, hepatocellular carcinoma (HCC), and decompensated cirrhosis will also decrease by 95% as the population ages and a high level of treatment is maintained. Incident cases of HCC will decrease from 350 in 2015 to 20 in 2030 (90% decrease). Incident decompensated cirrhosis cases will decrease from 280 in 2015 to 20 in 2030 (90% decrease). Given the current standard of care in Washington, there would be 440 fewer liver related deaths by 2030, a 95% decrease from 2015.

Under the WHO Elimination scenario, an average of 5,100 patients would need to be treated per year between 2020 and 2025 in order to achieve a 65% reduction in liver related deaths by 2025. Additional harm reduction efforts would also be needed to achieve an 80% reduction in new infections by 2025. Doing so would avert 5,800 new infections, 20 cases of decompensated cirrhosis, 25 cases of HCC and 35 liver related deaths by 2025 and 9,400 new infections, 110 cases of decompensated cirrhosis, 130 cases of HCC and 190 liver related deaths by 2030 compared to the base scenario.

Figure 6. Scenario Outcomes


Total Infected Cases (Viremic)
80,000
70,000
60,000
50,000
40,000
30,000
20,000
10,000
-
2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030
Base
WHO Targets by 2025
Incidence — Decompensated Cirrhosis
300
250
200
150
100
50
-
2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030
Base
WHO Targets by 2025
Incidence — HCC
400
350
300
250
200
150
100
50
-
2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030
Base
WHO Targets by 2025
Liver Related Deaths
500
450
400
350
300
250
200
150
100
50
-
2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030
Base
WHO Targets by 2025

Discussion

The ability to forecast the HCV disease burden in the presence and absence of interventions allows policy makers the ability to test hypotheses and quantify the impact of decisions. Using a Microsoft Excel based Markov model a team of state collaborators was able to develop consensus estimates to answer three primary questions - 1) Who in the state is most affected by HCV? 2) How do current policies positively or negatively impact indicators such as HCV prevalence, and HCV-related liver cancer and mortality? 3) What level of effort will be necessary to eliminate HCV?

Currently in Washington, it is estimated that more patients are being treated annually than are newly infected with HCV. Alongside increased mortality from an aging infected population, this means that the number of persons living with HCV is declining in the state. At the same time, the aging population is progressing to costly advanced liver disease, which can be prevented through timely treatment. Although the number of new infections occurring annually is low compared with the number of patients being treated, most people who are newly infected are not diagnosed for many years. While Washington has identified an estimated 80% of viremic infections, the remaining undiagnosed cases will be challenging to identify without an active screening campaign. If undiagnosed, they could remain silent carriers for decades, and may continue to transmit the virus and progress in their liver disease.

Overall, the disease burden in Washington is declining at a pace that is projected to achieve the WHO elimination targets by 2030 and almost by 2025 even with the expectation of a decline in treatment over the next several years. This is mainly due to a relatively high proportion of viremic cases previously diagnosed and high annual rates of diagnosis and treatment. Treating an annual average of 5,100 patients between 2020 and 2025 (36% less than the number treated in 2017) will achieve the targets.

Over the past several years Washington has treated HCV patients at high volumes, implemented harm reduction efforts such as needle exchanges and made efforts to open first-in-the-nation safe injections sites. Still, scale-up of these efforts would be required to achieve the goal of reducing new infections by 80% by 2025. The scale-up of treatment in the prison system would be another way to reduce new infections. Incarcerated people largely overlap with some of the most at-risk populations who are also the hardest to link to health care. Establishing a point of care in prisons would create an opportunity to prevent future infections through treatment of an otherwise difficult to reach population often with high transmission rates. Universal opt-out screenings upon intake are already conducted with an antibody test positivity rate of 24% in 2018.[49] Because the incarcerated population is very dynamic (mean length of stay is 15 months for women and 25 months for men), there is a constant flow of patients living with HCV and treatment opportunities.[50] Successfulness of such an intervention would thus need to be measured by treatment and cure statistics and not by prevalence rate at intake.

While Washington is currently on pace to meet the WHO Targets by 2030, future efforts are imperative to maintain the necessary diagnosis and treatment rates. Achieving these rates will become more challenging as the remaining infected population will consist primarily of those with limited access to care. Screening campaigns targeting at-risk communities and programs to address barriers to care will be necessary. Washington has taken significant steps towards eliminating HCV by removing treatment restrictions based on fibrosis stage in the Medicaid population, establishing harm reduction and test and treat programs and demonstrating the capacity to diagnose and treat high volumes of HCV patients. These strengths should not be taken for granted but should be maintained and bolstered moving forward in order to eliminate HCV in Washington.

Appendix A: Expert Panel Participants

The following individuals contributed to the content of this report through their participation in the expert panel discussions and in report revisions and we are grateful for their efforts:

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Jonathan Schmelzer, MPH	CDA Foundation

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JAY INSLEE
Governor

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DIRECTIVE OF THE GOVERNOR
18-13

September 28, 2018

To: Washington State Executive and Small-Cabinet Agencies

From: Governor Jay Inslee

Subject: Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach

This year, an estimated 65,000 Washingtonians are living with the chronic Hepatitis C Virus (HCV), but fortunately, we now have a cure. HCV is the leading cause of liver cancer and liver transplants. The virus also causes other health problems, including debilitating fatigue, which can significantly impact the quality of life of those affected.

HCV is the most common blood-borne disease in the United States, and in Washington, from 2012 to 2017, nearly 40,000 new cases of HCV were reported, increasing each year. And while deaths from other infectious diseases have steadily declined over the past decade, HCV-related deaths continue to rise, now exceeding all deaths from other reportable infectious conditions combined.

Newly acquired HCV-infection reports show a 126% increase in Washington between 2013 and 2017 when compared to the prior five years, an increase linked to the opioid crisis. And while the disease has historically impacted Baby Boomers (those born between 1945 and 1965), younger people are now contracting the disease with greater frequency, again related to opioid use. Ultimately, Washington's HCV-related hospitalization charges totaled $114 million between 2010 and 2014.

Confronting the HCV crisis is challenging because many Washingtonians living with HCV do not know they are infected. So, to reach affected communities, we must make enhanced public health efforts, including efforts to improve education, preventive services, and early detection of HCV to treat and cure existing infections and curb the onward transmission of the virus.

Fortunately, we see an opportunity to take action against HCV. In 2017, the National Academies of Sciences, Engineering, and Medicine released "A National Strategy" outlining how the United States can save nearly 30,000 lives from HCV-related deaths and eliminate HCV by 2030. Moreover, medications now exist to cure HCV in nearly all people appropriately linked to, and retained in, care. HCV drugs are expensive, but we can drive down costs by applying new purchasing strategies in which state agency health care purchasers collaborate with

manufacturers in combination with using key public health interventions to reduce the costs of treating and ultimately curing HCV.

In curing HCV, we can stem the tide of liver disease and liver cancer and save individuals the physical, emotional, and financial damage caused by HCV infection. Curing this disease will also support HCV-affected persons to engage in healthy behaviors, such as accessing treatment for opioid-use disorder, general primary care, and mental health services, which will help them live full, satisfying, and productive lives. This is an important part of the opioid response plan.

Accordingly, I direct my health sub-cabinet and the health and human service state agencies under my authority to begin immediately to work with Tribal governments, local public health officials, and other partners across the state, to develop and implement a statewide HCV elimination plan. The Department of Health (DOH) shall lead the effort to develop the elimination plan as part of this comprehensive public health response. The Health Care Authority (HCA) shall lead and coordinate with DOH and other agencies and purchasers, in a corresponding effort to establish a comprehensive procurement strategy for the purchase of HCV medications that also includes financing the needed public health interventions to affordably eliminate HCV by 2030. Furthermore, I direct the following:

1. DOH, in collaboration with any other relevant state agencies that it identifies, shall convene and facilitate an HCV-elimination coordinating committee comprised of stakeholders from various sectors, including individuals personally affected by HCV. The committee shall draw on existing efforts, best practices, and community knowledge to develop, by July 2019, a comprehensive strategy to eliminate the public health threat of HCV in Washington by 2030. The strategy will address needed improvements to the public health systems to help ensure that all people living in Washington who have or are at risk for contracting HCV, have access to preventive services, know their status, and connect to care and ultimately the cure. The elimination strategy shall include a major public health communications plan financed, to the extent possible, by the funds saved through the purchasing strategy described below.

2. HCA shall collaborate with the Department of Corrections, Office of the Insurance Commissioner (OIC), Department of Labor and Industries, Department of Social and Health Services, Department of Veterans Affairs, DOH and Tribal governments, to initiate an innovative strategy to purchase curative HCV medications and ensure timely access to curative treatment for Washingtonians with HCV. Given that several state agencies each year purchase HCV treatment medications for over 4,000 people, by January 2019, HCA shall collaborate with these agencies and issue a single request for proposals for a joint value-based purchasing agreement for curative HCV medications from one or more pharmaceutical manufacturer(s). This joint purchasing agreement shall aim to reduce the costs of the drug(s) and incorporate key known public health strategies to address the needs described above.

3. HCA, in collaboration with DOH, shall request that the Centers for Medicaid and Medicare Services (CMS) enter into a shared-savings agreement for Medicare-program-cost avoidance resulting from the implementation of the state's HCV prevention and

treatment strategy. Our state program will save Medicare significant costs by not only treating people sooner, alleviating Medicare from needing to pay for HCV medications, but also the dire costs of liver disease and cancer and other health effects that would occur later in one's life while they are covered under Medicare.

4. HCA and DOH shall work with CMS, the Centers for Disease Control and Prevention, the Surgeon General, Veterans Affairs, other federal agencies, and Tribal governments to consider additional health care purchasing and disease elimination strategies, especially for rural and underserved populations—including Vietnam veterans living in rural areas—to address HCV in a cost-effective manner.

5. HCA, in collaboration with other state agencies shall, as the next phase of this plan, engage a multi-state or national organization to develop a strategy to assess the interest and ability of extending our purchasing and public health strategy to not only Washington's other major purchasers of health care and commercial insurers, but also other states or purchasers. As part of this next phase, HCA shall work with Washington's Health Benefit Exchange and OIC to explore purchasing options for the health insurance markets.

6. DOH and HCA shall also use data and information to detect cases of HCV, monitor HCV-related morbidity and mortality, monitor HCV-curative treatment access, and evaluate the impact of interventions and activities designated by this directive.

7. DOH and HCA shall develop a communications plan for this project. This communications plan shall include filing quarterly reports to my office and the health committees of the legislature to ensure the status and outcomes herein.

Washington State Health Care Authority

Antivirals - Hepatitis C Treatment

Medical policy no. 12.35.30.99 Effective July 1, 2019

Medical necessity

Drug	Medical Necessity
Preferred **Glecaprevir/pibrentasvir (MAVYRET)** *Non-preferred* Daclatasvir dihydrochloride (DAKLINZA) Elbasvir/grazoprevir (ZEPATIER) Ledipsvir/sofosbuvir (HARVONI) Ombitasvir/paritaprevir/ritonavir (TECHNIVIE) Ombitas/paritapr/riton and dasab pak (VIEKIRA) Sofosbuvir (SOVALDI) Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	Antivirals: Hepatitis C treatment may be considered medically necessary for the treatment of chronic Hepatitis C infection when the clinical criteria listed below are met. Non-preferred products will be considered on a case-by-case basis when treatment with Mavyret is not indicated. Requests for brand-name medications with a generic equivalent available must also meet the criteria described in the **Brands with Generic Equivalents** policy (Non-Clinical Policy No. 0001).

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Daclatasvir dihydrochloride (DAKLINZA) Elbasvir/grazoprevir (ZEPATIER) **Glecaprevir/pibrentasvir (MAVYRET)** Ledipsvir/sofosbuvir (HARVONI) Ombitasvir/paritaprevir/ritonavir (TECHNIVIE) Ombitas/paritapr/riton and dasab pak (VIEKIRA) Sofosbuvir (SOVALDI) Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	1. Patient has confirmed diagnosis of Hepatitis C and a quantifiable HCV RNA test >15 IU/mL within the last 12 months. 2. Required documentation and lab tests: a. HCV Genotype. b. Current HCV RNA Viral Load less than 12 months old. c. Fibrosis staging test (e.g. FibroScan® or FibroSURE®) to determine liver fibrosis level required to ensure the appropriate treatment regimen is used (e.g. patients with cirrhosis and/or decompensation may require longer treatment and/or ribavirin). Fibrosis staging test results must be less than 2 years old. d. Documentation of decompensation (or previous episodes of decompensation) if fibrosis level is F4 or cirrhosis. e. Documentation of treatment-experienced status including prior treatment regimen, length of treatment, response, and dates of treatment.

	f. Lab reports, if available, documenting presence or absence of resistant mutations in treatment-experienced patients. 3. Patients with the following conditions are not eligible for HCV treatment until the condition is resolved. Patients who: a. Are taking medications that are contraindicated with or that have a severe drug interaction with the prescribed HCV treatment. b. Are pregnant or planning on becoming pregnant. c. Have severe end organ disease and are not eligible for transplantation (e.g. heart, lung, kidney) d. Have a clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment. e. In the professional judgment of the primary treating clinician, would not achieve a long-term clinical benefit from HCV treatment (e.g. patients with multisystem organ failure, receiving palliative care, with significant pulmonary or cardiac disease, or with malignancy outside of the liver not meeting oncologic criteria for cure). f. Have a MELD score <20 and one of the following: i. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery ii. Malignancy outside the liver not meeting oncologic criteria for cure iii. Hepatocellular carcinoma with metastatic spread iv. Intrahepatic cholangiocarcinoma v. Hemangiosarcoma vi. Uncontrolled sepsis
	Criteria (Reauthorization)
	See treatment experienced dosing guidelines below.

Preferred therapies:

Drug Name	Preferred For:
Glecaprevir/pibrentasvir (MAVYRET)	**Patients with or without compensated cirrhosis (Child-Pugh A) that are:** • treatment naïve patients with genotypes 1, 2, 3, 4, 5, and 6; or • patients with genotypes 1, 2, 3, 4, 5, and 6 with prior treatment with peg-interferon, ribavirin, or sofosbuvir, but no prior treatment with an NS5A inhibitor or an NS3/4A protease inhibitor; or • patients with genotype 1 with prior treatment with an NS5A inhibitor but not an NS3/4A protease inhibitor; or • patients with genotype 1 with prior treatment with an NS3/4A protease inhibitor but not an NS5A inhibitor.

Sofosbuvir/velpatasvir (EPCLUSA) **Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)**	Will be considered on a case-by-case basis when treatment with Mavyret is not indicated.

Dosage and quantity limits

Drug Name	Dose and Quantity Limits

Glecaprevir/pibrentasvir (MAVYRET)	**Treatment Naïve Genotypes 1, 2, 3, 4, 5, 6**
	• 8 weeks without cirrhosis
	• 12 weeks with compensated cirrhosis
	
	Treatment Experienced
	• With peg-interferon, ribavirin, or sofosbuvir, but no prior treatment with an NS5A inhibitor or an NS3/4A protease inhibitor
	  ○ Genotypes 1, 2, 4, 5, 6
	  ▪ 8 weeks without cirrhosis
	  ▪ 12 weeks with compensated cirrhosis
	  ○ Genotype 3
	  ▪ 16 weeks with or without compensated cirrhosis
	• With an NS5A inhibitor without an NS3/4A protease inhibitor
	  ○ 16 weeks for Genotype 1 with or without compensated cirrhosis
	• With an NS3/4A protease inhibitor without an NS5A inhibitor
	  ○ 12 weeks for Genotype 1 with or without compensated cirrhosis

Sofosbuvir/velpatasvir (EPCLUSA) Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)	Will be determined on a case-by-case basis when treatment with Mavyret is not indicated.

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History

Date	Action and Summary of Changes
06-07-2019	• Updated policy for preferred therapies and formatting.

07-08-2019	• Placed in updated policy format • Removed prescriber specialty requirement • Removed proof of chronic HCV infection • Added all drugs to the policy • Mavyret only preferred agent • Added treatment regimens

Glossary

- **Accountable Communities of Health** (ACHs): Organizations that bring together leaders from multiple health sectors around the state with a common interest in improving health and health equity. As ACHs better align resources and activities, they support wellness and a system that delivers care for the whole person. There are nine ACHs. Their boundaries align with Washington's Medicaid regional service areas. (https://www.hca.wa.gov/about-hca/healthier-washington/accountable-communities-health-ach)
- **Baby Boomers**: People born between 1945 through 1965. According to the CDC, Baby Boomers in the U.S. are five times more likely than other adults to have HCV.
- **Backbone Organization**: The backbone organization pursues six common activities to support and facilitate collective impact which distinguish this work from other types of collaborative efforts. Over the lifecycle of an initiative, they: 1) Guide vision and strategy; 2) Support aligned activities; 3) Establish shared measurement practices; 4) Build public will; 5) Advance policy; and 6) Mobilize funding.
- **Collective Impact**: The commitment of a group of actors from different sectors to a common agenda for solving a specific social problem, using a structured form of collaboration. The concept of collective impact was first articulated in the 2011 Stanford Social Innovation Review article "Collective Impact," written by John Kania, Managing Director at FSG (https://www.fsg.org/areas-of-focus/collective-impact), and Mark Kramer, Kennedy School at Harvard and Co-founder FSG.
- **Centers for Disease Control & Prevention** (CDC): The CDC is one of the major operating components of the U.S. Department of Health and Human Services and the health protection agency for the nation. The CDC's mission is to work 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, the CDC fights disease and supports communities and citizens to do the same.
- **Direct-acting antiviral**: Current HCV treatments are made up of combinations of drugs called direct-acting antivirals (DAAs). DAAs directly target the hepatitis C virus in different ways to stop it from making copies of itself. DAAs have a cure rate of over 95%. For most people who take DAAs, treatment is eight to twelve weeks and there are few side effects.
- **Elimination**: In the case of HCV, elimination is defined as a state where HCV is no longer a public health threat and where those few who become infected with HCV learn their status quickly and access curative treatment without delay, preventing the forward spread of the virus.
- **Eradication**: Elimination is distinct from eradication. Eradication is reduction of the worldwide incidence of a disease to zero as a result of deliberate efforts, obviating the necessity for further control measures. True eradication usually entails eliminating the microorganism itself or removing it completely from nature.
- **High-impact settings**: Settings that serve a high proportion of clientele who are at high risk for acquiring or transmitting HCV (e.g., syringe service programs, substance use disorder treatment centers, opioid treatment programs, programs serving people experiencing homelessness, jails, prisons).

- **Linkage to care**: Ensuring that people with a reactive HCV antibody test receive an HCV RNA (viral load) test, and those with current HCV infection (HCV RNA positive) are linked to a health care provider who is prepared to provide counseling services and comprehensive curative treatment. Successful linkage to care means people living with HCV have attended a first medical appointment for evaluation or treatment.
- **Local health jurisdictions**: Washington has 31 county health departments, three multi-county health districts, and two city-county health departments, referred to as local health jurisdictions. They are local government agencies. Local health jurisdictions carry out a wide variety of programs to promote health, help prevent disease, and build healthy communities. They are an important part of the state's public health system.
- **Non-clinical settings**: Community-based settings, such as outreach sites, syringe service programs, non-medication-based substance use treatment programs, shelters, organizations serving people experiencing homelessness, supportive housing programs, social service programs, and other locations outside of a clinical setting. These are locations that are easy to access and useful for people who might not be willing or able to access medical services regularly.

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1. *Electronic reporting of negative results: Electronic reporting shall include negative as well as positive results for tests ordered for the following conditions: Chlamydia, Gonorrhea, Hepatitis A, Hepatitis B, Hepatitis C, including viral loads, Human Immunodeficiency Virus (HIV), including viral loads and confirmatory tests, Salmonellosis, STEC, Tuberculosis.*
2. *Negative test results reported for these conditions will be used for the following purposes as authorized in Utah Health Code Section 26-1-30(2)(c),(d), and (f):To determine when a previously reported case becomes non-infectious; To identify newly acquired infections through identification of a seroconversion window; or To provide information critical for assignment of a case definition.*
3. *Information associated with a negative test result will be retained by the Utah Department of Health for a period of 18 months. At the end of the 18 month period, if the result has not been appended to an existing case, personal identifiers will be stripped and expunged from the result. The de-identified result will be added to a de-identified, aggregate dataset which will be retained for use by public health to analyze trends associated with testing patterns* and case distribution, enabling identification and establishment of prevention and intervention efforts for at-risk populations, and assessment of trends over time in those populations, as authorized by Utah Health Code 26-1-30(2)(f).

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Hep C Free Washington Community Partners

To date, 16 community partners have signed on to the Hep C Free WA initiative. These partners have agreed that they share the goal of HCV elimination in Washington State, driven by broad-based prevention addressing social determinants of health, education, testing, linkage, and treatment strategies. Partners provide expertise and, in many cases, staff time in initiative meetings and Hep C Free WA events.

As a collective impact initiative, participation from representatives of these various organizations helps ensure Hep C Free WA is leveraging a variety of expertise in service of a common agenda for change.

Please email HepCFreeWA@doh.wa.gov if your organization would like to officially sign on to be a Hep C Free WA Community Partner.

HEP Hepatitis Education Project

Lifelong

NWIH Integrated Health

FHRA

pcaf

Providence Centralia Hospital

Public Health Seattle & King County

Spokane Regional Health District

Tacoma Needle Exchange — A Dave Purchase Initiative

Tacoma-Pierce County Health Department — Healthy People in Healthy Communities

Department of Corrections Washington State

Washington State Department of Health

Washington State Health Care Authority

washington healthplanfinder — click. compare. covered.

College of Pharmacy and Pharmaceutical Sciences — Washington State University

Yakima Valley Farm Workers Clinic — we are family