RECOMMENDATIONS

from the Eliminate Hepatitis C San Diego County Initiative to the San Diego County Board of Supervisors

December 20, 2019



Cover photo: End Hep C San Diego Team at the 2019 Live Well San Diego 5K

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This document was developed through a public private partnership with the County of San Diego and community stakeholders that started in November of 2018 and ended in November of 2019.

"By joining forces and strengthening our local efforts, we expect to eliminate this curable disease as a public health threat and improve longevity and quality of life for people living with hepatitis *C.*"

> Wilma Wooten, MD, MPH, County of San Diego Health & Human Services Agency

"Hepatitis C (HCV) has long been a neglected disease affecting many marginalized populations. In keeping with San Diego County's motto – 'The noblest motive is the public good' – now is the time to deliver curative HCV treatment to those who need it most."

- Christian B. Ramers, MD, MPH, AAHIVS, Family Health Centers of San Diego

"Hepatitis C has been a part of my life since birth, I hope to help see it to its end before my own, let's End Hep C San Diego!

- Rick Nash, patient advocate and MPH student

"Scale-up of harm reduction and HCV treatment for those at risk of transmission are critical tools to preventing HCV infection and achieving HCV elimination."

 Natasha Martin, DPhil, Division of Infectious Diseases and Global Public Health, Department of Medicine, at University of California San Diego

"It is vitally important not to leave any community behind. While working with community members I have been reminded that these people are mothers and fathers, sons and daughters, neighbors, friends and advocates. Now is the time to make a difference, to be the change."

- Tara Stamos-Buesig, RADT, Family Health Centers of San Diego



Eliminate Hepatitis C San Diego County Initiative Recommendations

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EXECUTIVE SUMMARY

INTRODUCTION

It is now possible to eliminate hepatitis C as a public health threat due to treatments that cure the disease. In the past five years, a growing number of hepatitis C elimination projects have emerged at the international, national, state, and local levels. It is the mission of the World Health Organization (WHO) to eliminate viral hepatitis as a global public health threat by 2030. In 2017, the National Academies of Science, Engineering, and Medicine released *A National Strategy for the Elimination of Hepatitis B and C*, outlining a set of recommendations to eliminate these diseases. The growing Hepatitis C Virus (HCV) elimination projects in New York State, New York City, and San Francisco have inspired the County of San Diego (County) to replicate similar efforts. As a result, local public health officials – in collaboration with a diverse coalition of public and private sectors – have coalesced around the idea that this is the right time to pursue hepatitis C elimination in San Diego County.

The *Eliminate Hepatitis C San Diego County Initiative* (*Initiative*) was approved by the San Diego County Board of Supervisors in November 2018, with the Board asking the Health and Human Services Agency (HHSA) to return in twelve months with recommendations, which are provided in this report.

The HCV infection is a chronic liver disease spread to others through contact with the blood of a person infected with the virus. HCV profoundly impacts San Diego County, with nearly 54,000 individuals currently living with the virus. HCV infection can cause significant liver damage that may lead to disability, cancer, and death.

HCV can be easily identified with available blood tests and oral treatment, with few side effects, can cure nearly all infected patients. Unfortunately, most individuals with HCV are not aware that they are infected, and most are not being treated, according to the Centers for Disease Control and Prevention (CDC). With resources available now, identifying San Diegans living with HCV and connecting them to curative care and treatment could substantially reduce HCV-related illness and death, prevent future infections, and ultimately eliminate HCV in our county.

The tools are now available to eliminate HCV. One set of powerful tools is antiviral medications. Depending on the drug combination, viral genotype, prior treatment, and occurrence of cirrhosis, the duration of standard treatment could range from 8-12 weeks. In alignment with the WHO definition, the local *Initiative* defines elimination as a state where HCV no longer poses a public health threat in San Diego County. This means that those who become infected with the virus quickly learn this has occurred and access curative treatment without delay, preventing the spread of disease.

Targets

In alignment with the WHO recommendations, the proposed targets, based on the best current estimates, are to achieve:

- 80% decrease of incidence of chronic HCV by 2030, and
- 65% reduction of HCV mortality by 2030.

METHODOLOGY

To ensure success in meeting this goal, this initiative embraced a public-private partnership and used a collective impact model for both its structure and approach to community engagement. Key stakeholders were engaged from 65 organizations representing all impacted segments and populations in San Diego County. These member organizations, clinical practices and governmental agencies are on the forefront of HCV testing, linkage, treatment, and advocacy in San Diego County. The five committees established were:

- 1. *Advisory Committee:* This committee made critical decisions regarding the governance, vision, and cross-cutting activities of the initiative.
- 2. *Steering Committee:* This committee acted as the coordinating committee of the initiative.
- 3. **Research and Surveillance Committee (HCV Burden of Estimate)**: This group broached the question of how to estimate local HCV burden and monitor HCV elimination progress.
- 4. Access, Testing, Treatment and Prevention Committee (Barriers to Prevention and Cure): This committee was largely comprised of clinicians, pharmacists, and other direct service staff who work for agencies that offer HCV prevention and/or community-based HCV testing, treatment and linkage services.
- 5. **Consumer Committee (Faces of Hepatitis C):** This committee provided input to all committees and serves as a voice for those affected or at greater risk of being exposed to HCV.

FINDINGS

Over the 12-month period, from November 2018 to November 2019, the American Liver Foundation has served as the facilitating agency for the initiative. Early on, the committees established several core values to guide their collective work. These values include broad community outreach and surveillance, access to the most effective treatment integrating into our current medical system so that all at risk will know their status, and no community will be left behind.

Summary of Key Committee Findings

1. Research and Surveillance Committee (San Diego County HCV Burden Estimate)

This committee made significant strides in defining San Diego County reporting capabilities, capturing a more comprehensive report of individuals with HCV in San Diego County, and generating a breakdown by subpopulations. There is still substantial uncertainty in the burden estimation, a lack of data on HCV chronic prevalence and a need for epidemic modeling to inform treatment, prevention and monitoring of hepatitis C. Enhancements to the surveillance system will be included in the next phase of the *Initiative* planning work.

2. Access, Testing, Treatment and Prevention Committee (Barriers to Prevention and Cure)

A countywide Organizational Practices Survey was conducted to provide key insights. Findings were incorporated into the *Initiative* recommendations. The survey findings highlight substantial barriers and opportunities that exist in the areas of HCV awareness, provider and patient education, access and linkage to care, as well as funding.

3. Consumer Committee (Faces of Hepatitis C)

People living with HCV were eager to participate in this *Initiative* because they felt this work would have a significant impact on their lives. Representative profiles showed a cross-section of marginalized and general members of the population affected by the virus. These profiles helped raise awareness to the stigma that exists with diagnosis and treatment of HCV for the population that will greatly benefit from HCV elimination.

RECOMMENDATIONS

Based on stakeholder interviews, key findings and extensive committee working sessions, the stakeholders identified the following nine consensus driven recommendations to reach HCV elimination in San Diego County by 2030:

- 1. Promote awareness of HCV as a major public health concern.
- 2. Implement prevention strategies in alignment with current best practices.
- **3.** Screen for HCV in line with the recommendations of the U.S. Preventive Services Task Force (USPSTF), Centers for Disease Control and Prevention (CDC), and best practices.
- 4. Ensure all individuals with HCV are linked to care and treatment.
- 5. Build capacity within the existing workforce to treat patients in diverse health care environments.

- 6. Ensure individuals with HCV have access to direct-acting antivirals (DAAs).
- 7. Ensure adequate surveillance, evaluation and monitoring.
- 8. Pursue policies in alignment with WHO/CDC that will help achieve elimination.
- 9. Support HCV research, implementation science and operation research.

RECOMMENDATIONS

from the

Eliminate Hepatitis C San Diego County Initiative

INTRODUCTION

Background

It is now possible to eliminate hepatitis C as a public health threat due to treatments that cure the disease. In the past five years, a growing number of hepatitis C elimination projects have emerged at the international, national, state, and local levels. It is the mission of the World Health Organization (WHO) to eliminate viral hepatitis as a global public health threat, by 2030. In 2017, the National Academies of Science, Engineering, and Medicine released a *National Strategy for the Elimination of Hepatitis B and C*, outlining a set of recommendations to eliminate these diseases. The growing hepatitis C virus (HCV) elimination projects in New York State, New York City, and San Francisco have inspired the County of San Diego to replicate similar efforts. As a result, local public health officials – in collaboration with a diverse coalition of public and private sectors – have coalesced around the idea that this is the right time to pursue hepatitis C elimination in San Diego County.

The *Eliminate Hepatitis C San Diego County Initiative (Initiative)* was approved by the San Diego County Board of Supervisors, in November 2018, with the Board asking the HHSA to return in twelve months with recommendations, which are provided in this report.

The HCV causes inflammation of the liver. Infection with the HCV is a chronic liver disease spread to others through contact with the blood of a person infected with the virus. The disease can range in severity from a mild illness lasting a few weeks to a lifelong illness. Hepatitis C can be either "acute" or "chronic." Acute HCV infection is a short-term illness that occurs within the first 6 months after exposure to HCV. In most cases, acute infection leads to chronic infection with HCV. Untreated, the majority of HCV infections become chronic, leading to long-term negative outcomes, including scarring of the liver, cirrhosis, liver cancer, liver failure, and death.

HCV profoundly impacts San Diego County, with nearly 54,000 individuals currently living with the virus. HCV infection can cause significant liver damage that may lead to disability, cancer, and death. HCV can be easily identified with available blood tests and oral treatment, with few side effects, which can cure nearly all infected patients. Unfortunately, most individuals with HCV are not aware that they are infected, and most are not being treated, according to the Centers for Disease Control and Prevention (CDC). With resources available now, identifying San Diegans living with HCV and connecting them to curative care and treatment could substantially reduce HCV-related illness and death, prevent future infections, and ultimately eliminate HCV in our county.

The tools are now available to eliminate HCV. One set of powerful tools is antiviral medications. Depending on the drug combination, viral genotype, prior treatment, and occurrence of cirrhosis, the duration of standard treatment could range from 8-12 weeks. In alignment with the WHO definition, the *Initiative* defines elimination as a state where HCV no longer poses a public health threat in San Diego County. This means that those who become infected with the virus quickly learn this has occurred and access curative treatment without delay, preventing the spread of disease.

Targets

In alignment with the WHO recommendations, the proposed targets for the Initiative, based on best current estimates, are to achieve:

- 80% decrease of incidence of chronic HCV by 2030, and
- 65% reduction of HCV mortality by 2030.

Burden Overview

Overview of HCV Burden: International

Globally, an estimated 71 million people have chronic HCV infection. The WHO estimated that in 2016, approximately 399 000 people died from HCV, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer).

Overview of HCV Burden: National

HCV infection is the most commonly reported bloodborne infection in the United States, causing substantial morbidity and mortality and costing billions of dollars annually. According to the CDC, an estimated 2.4 million people in the United States are living with HCV. An estimated 44,300 acute HCV cases occurred in 2017.

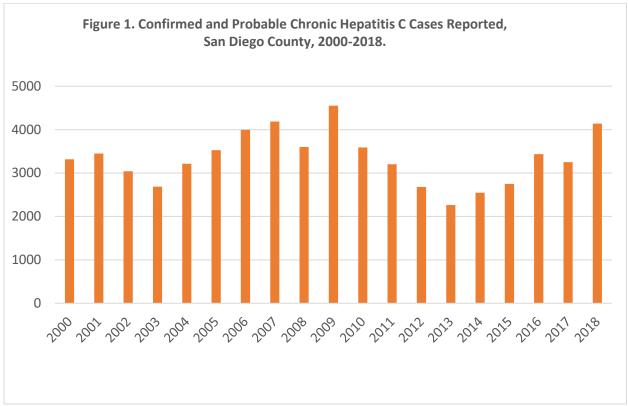
Overview of HCV Burden: California

Even in microscopic amounts of blood, HCV is highly infectious and easily transmitted. Today, transmission of hepatitis C is primarily through sharing needles, syringes or other drug injection equipment. An estimated 400,700 Californians live with chronic HCV, but many do not know they are infected. This is one of the most frequently reported communicable disease in California. Almost half of HCV cases reported in California are baby boomers (born from 1945-1965). In addition, the number of hepatitis C cases among young people ages 15-29 has more than doubled from 2012 to 2016.

Overview of HCV Burden: San Diego County

The California Department of Public Health (CDPH) Office of Viral Hepatitis Prevention (OVHP) estimates that, in 2017, there were almost 37,000 San Diego County residents living with a diagnosis of probable or confirmed chronic hepatitis C (herein referred to as "chronic hepatitis C"). The case definition for chronic hepatitis C has changed over time. With surveillance practices still evolving, establishing a consistent estimate of those diagnosed has been difficult. More than

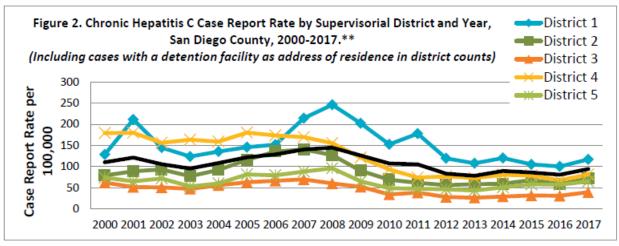
2,000 cases of chronic HCV are reported each year in San Diego County (see *Figure 1*). From 2014 to 2018, approximately 1,400 San Diego County residents died with chronic HCV listed as an underlying cause of death on the death certificate. Reported chronic HCV cases in San Diego County affect both men and women in a ratio of almost 2-to-1, with about 63% of reported cases age 45 and older at time of report.



Data are subject to change as additional information becomes available. Cases are grouped into CDC disease years on the basis of the earliest of the following dates: onset date, laboratory specimen collection date, diagnosis date, death date, date report was received. For hepatitis C, this is most often the specimen collection date. Per CDPH confirmed chronic cases have both antibody positive and detectable viral load; probable cases have antibody positive and unknown viral load status. Includes cases that may have been reported previously in another jurisdiction and those that are incarcerated.

Data from the CDPH OVHP report, *California Local Health Jurisdiction Chronic Hepatitis Data Summaries*, indicate rates of chronic hepatitis C have increased in San Diego County across all age groups in females, and in males under 40 years of age. Whites are over-represented in the chronic hepatitis C cases, that is, a greater percentage of the cases are white than are found in the general population, while Asians and Pacific Islanders are underrepresented.

The OVHP estimate, of 37,000 residents, includes only those who are diagnosed and reported. In a separate exercise, the *Initiative's* Research and Surveillance Committee used multiple data sources to generate an estimate of the total number of residents with a history of HCV (past or current) who are undiagnosed or diagnosed, of nearly 54,000 individuals in San Diego County (see Key Findings for methods and limitations). In *Figure 2*, the rates of hepatitis C by Supervisorial District is provided. The overall rate is just under 100 cases per 100,000 population, with all Districts below the overall rate, except district 1, which encompasses the South Region.



**Rates are rate of newly reported cases, not incidence nor prevalence; date of case report may not correspond with date of infection or diagnosis. Data are provisional and subject to change as additional information becomes available. Grouped by CDC disease years. Supervisorial districts calculated based on zip code, grouped into the district with the highest proportion of the zip code population. Cases missing address (12%) not included.

Hepatitis C Strategic Approaches

International and National HCV Strategy

HCV is a global issue. In 2015, the 2030 Agenda for Sustainable Development was adopted by the General Assembly of the United Nations (UN), with Sustainable Development Goal (SDG) committing the UN to combating viral hepatitis. In 2014, the World Health Assembly requested the WHO to examine the feasibility of eliminating HCV. WHO modelled options and found that an 80% reduction in new chronic HCV infections, and a 65% reduction in HCV-related deaths could be achieved worldwide 2030 if the response included:

- Comprehensive, high quality screening of blood donations;
- A significant increase in distribution of sterile syringe/needle sets for people who inject drugs (PWID);
- Diagnosis of HCV in 90% of people living with the disease; and
- Treatment of at least 80% of those eligible for treatment.

HCV kills 20,000 Americans per year, which equals more than HIV, TB and 58 other infections combined. A highly effective cure, in the form of an oral regimen of 8-12 weeks duration, exists for HCV with few side effects. The development of this cure led the CDC, the U.S. Department of Health and Human Services (DHHS), and the National Academies of Sciences, Engineering, and Medicine (NASEM) to determine that eliminating hepatitis C in the United States is now possible. To achieve this goal, NASEM developed *A National Strategy for the Elimination of Hepatitis B and*

C, a report recommending several actions on the part of federal, state, and local governments, private businesses and others.

Key recommendations from the report are to:

- Identify best practices for screening at-risk populations;
- Expand access to syringe exchange and opioid agonist therapy*;
- Remove HCV treatment restrictions, based on liver disease severity;
- Build primary care capacity for HCV treatment;
- Develop a national system of care/support for patients with HCV;
- Implement screening/treatment in prison system; and
- Establish government purchase of license/patent of DAA's for use in public treatment settings.

* Opioid Agonist Therapy (OAT) is an effective treatment for addiction to opioid drugs.

The DHSS will soon release its updated Viral Hepatitis Action Plan, developed as the nation's battle plan to fight hepatitis B and C in the United States.

Citizens, community groups, and governments in many areas of the country have begun pursuing HCV elimination. In 2014, New York City launched *Hep Free NYC*, and San Francisco followed, in 2016, with the *End Hep C SF initiative*. Currently, community stakeholders in Los Angeles, Alameda, Philadelphia, and here in San Diego County are organizing themselves to develop community approaches to HCV elimination. In addition, some states have started planning for statewide action and include Hawaii, Illinois, Maryland, Massachusetts, New Mexico, New York, Pennsylvania, and Washington.

California's End the Epidemics Strategy

End the Epidemics: Californians Mobilizing to End HIV, HCV, and STDs is a coalition of over 140 community public health leaders calling on elected officials to end these epidemics now. This year the coalition was successful in getting California to appropriate \$5 million for HIV prevention, \$5 million for sexually transmitted diseases (STD) prevention and \$5 million for HCV prevention. The CDPH is currently working on a scope of work and set of terms and conditions for funded Local Health Jurisdictions (LHJs) that is consistent with the authorizing statute.

- Local Health Jurisdictions expectations include:
 - Public health surveillance and case follow up;
 - Testing, treatment, navigation and linkage services;
 - Collaborations and coalitions to further HCV prevention, testing, linkages, care, treatment; and
 - Partnership with CBOs in implementation of HCV activities.
- Community Based Organizations expectations include:
 - Collaboration with LHJs to support data to care, where appropriate;
 - Testing, linkage to care, navigation, care, and treatment services;

- o Collaborations and coalitions to further HCV activities; and
- Partnership with LHJs in implementation of HCV activities.

The CDPH worked with stakeholders from across the state to create the <u>California Viral Hepatitis</u> <u>Prevention Strategic Plan, 2016-2020</u>, which can serve as a reference document for local efforts in San Diego County. They have also recently launched an effort to develop an integrated HIV, STD, and HCV ending the epidemics plan, which can inform future elimination activities.

San Diego County Hepatitis C Elimination Strategy

In December 2016, Public Health Services identified hepatitis C elimination as a priority. As the San Francisco initiative's plan was finalized, the American Liver Foundation Pacific Coast Division approached the County of San Diego HHSA to organize a local hepatitis C initiative. An initial preplanning effort was convened of 12 members, from February to November 2018, to map out a strategy to submit a Board Letter to the Board of Supervisors. The *Initiative* was approved by the San Diego County Board of Supervisors, in November 2018, with the Board asking the HHSA to return in 12 months with recommendations, which are provided in this report.

METHODOLOGY

Facilitation and Committee Structure

Upon approval by the Board of Supervisors, a Steering Committee was formed to map out the way forward to develop the initiative. Overall guidance was provided by the Advisory Committee. Three working committees were formed to generate the recommendations for this initiative.

The American Liver Foundation (ALF) was selected to serve as the facilitating agency. ALF was selected because of their focus on promoting liver health and disease prevention through research, education and advocacy including viral hepatitis. In addition, their ability to work with unserved and underserved communities to access care and treatment made them an ideal partner. Finally, as a non-profit 501(c)3 entity, ALF was able to seek revenue support for the initiative, unburdening the county government and other partners from this task.

For the planning phase of the initiative, funding was secured through unrestricted educational grants from a coalition of organizations including the Alliance Healthcare Foundation, AbbVie Inc,, and Gilead Sciences. The initiative is also supported by Ryan Clary, a technical consultant who is the former Executive Director of the National Viral Hepatitis Roundtable (NVHR).

Organizational structure was determined by the Steering Committee, based on approaches from other initiatives. The approach of *Getting to Zero* was also reviewed and served as a roadmap for this elimination project.

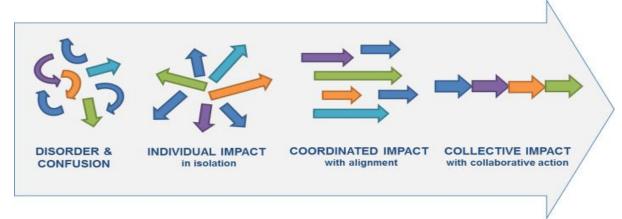
Strategic Approach

Following the example of San Francisco's *End Hep C SF initiative*, a collective impact model utilizing public and private partners was seen as essential, (<u>http://www.fsg.org/approach-areas/collective-impact</u>). It is important to note that the collective impact model is also a foundational principle for *Live Well San Diego*. This model involves a group of people getting together to work on a complex issue, under five conditions:

- 1. Common Agenda: We agree on our vision, mission, values, and strategies.
- 2. **Shared Measurement:** We jointly determine shared measures to demonstrate the success of this initiative, for which all the different partners can collect data.
- 3. **Mutually Reinforcing Activities:** Instead of acting uniformly, the participants in the initiative strategically coordinate a wide variety of activities that mutually reinforce the common agenda.
- 4. **Continuous Communications:** Constant communication exists not only within the Steering Committee and between partners but also with the community.
- 5. Backbone Support: There is someone/a group identified to hold all the pieces together.

As seen in *Figure 3* below, a collective impact with collaborative action is achieved when all stakeholders, or partners, are doing what they do best to move the needle on a mutual goal. The most effective results are seen when there is collaborative action driving the collective impact.

Figure 3. Collective Impact.



Source: John Kania and Mark Kramer. Collective Impact. Stanford Social Innovation Review, Winter 2011.

KEY FINDINGS

After submitting a Board Letter to the San Diego County Board of Supervisors, in November 2018, the *Eliminate Hepatitis C San Diego County Initiative* received Board authority to conduct planning activities throughout the year with a Board action to return in 12 months with recommendations for the initiative.

Committee Structure

Modeled after the work of *End Hep C San Francisco*, the following five committee were formed:

- 1. *Advisory Committee:* Co-chaired by Wilma Wooten, MD, Public Health Officer and Director Public Health Services for the County of San Diego Health and Human Services Agency, and Paul Hegyi, Chief Executive Officer for the San Diego County Medical Society. *This committee made critical decisions regarding the governance, vision, and cross-cutting activities of the initiative.*
- 2. *Steering Committee:* Co-chaired by Christian Ramers, MD, Infectious Diseases specialist and Assistant Medical Director of Family Health Centers of San Diego and Dean Sidelinger, MD, Interim Deputy Public Health Office and Child Health Medical Officer for the County of San Diego Health and Human Services Agency. *This committee acted as the coordinating committee of the initiative.*
- **3.** *Research and Surveillance Committee (Burden of Estimate):* Chaired by Natasha Martin, DPhil, Associate Professor Division of Infectious Diseases and Global Public Health, Department of Medicine University of California San Diego. *This committee broached the question of how to estimate local HCV burden and monitor HCV elimination progress.*
- 4. Access, Testing, Treatment and Prevention Committee (Barriers to Prevention and Cure): Chaired by Christian Ramers, MD, Infectious Diseases specialist and Assistant Medical Director of Family Health Centers of San Diego. This committee was largely comprised of clinicians, pharmacists, and other direct service staff who work for agencies that offer HCV prevention and/or community-based HCV testing, treatments and linkage services.
- 5. Consumer Committee (Faces of Hepatitis C): Co-chaired by patient advocate Rick Nash and Tara Stamos-Buesig, RADT, Case Manager II/SUD Counselor with Family Health Centers of San Diego. This committee provided input to all committees and served as a voice for those affected or at greater risk of being exposed to HCV.

The <u>Steering and Advisory Committees</u> worked to identify stakeholders from all possible sectors, to ensure that all impacted had an opportunity to participate in this initiative. Voices of all stakeholders were a critical part of the process – from health care providers to the county health department to consumers. As the committees were being formed, a list of all impacted groups – from Native Americans to the elderly to public and private insurers – was compiled and representatives from each of these groups were sought out and asked to join the Initiative. Ultimately, 65 stakeholder groups participated, representing all segments of the population and all HHSA's operational Regions of the County.

The committee structure enabled the various participants to contribute where their expertise was most relevant. Before the committees were formalized, the Steering Committee met with individual stakeholder groups to explain the purpose of the Initiative and gain a clear understanding of issues that impact HCV exposure and care in the county. For example, alcohol, drug and HIV service providers were asked to communicate their experiences and concerns. Additionally, consumers (individuals living with HCV, those cured of HCV, as well as affected partners and community-members) were integrated into all committees, rather than being isolated in one standalone committee. It was important that patients' observations be recognized in all aspects of the Initiative as well as in the final recommendations.

The <u>Advisory Committee</u> of the *Eliminate Hepatitis C San Diego County Initiative* developed and adopted value statements to guide the work of the committees. These were developed by committee members forwarding a value statement(s) that was important to them. Submissions that were similar were combined, resulting in seven unique statements. The value statements are as follows:

- No community left behind;
- All people at risk will know their hepatitis C status;
- All proven prevention strategies will be implemented;
- Anyone at risk of hepatitis C who wants a test will have free, available access to testing;
- All people with hepatitis C will have access to the most effective treatment, integrated primary care and payors will cover these treatments; and
- All people living with hepatitis C will have access to treatment for substance use disorders and behavioral health conditions.
- People living with hepatitis C will have access to resources available through a patientcentered navigation system.

San Diego County HCV Burden Estimate

The **<u>Research and Surveillance Committee</u>** undertook a process that was approved by initiative stakeholders to estimate the burden of HCV among adults in San Diego county. This was achieved

through synthesizing available published and unpublished data on population sizes at risk and HCV seroprevalence (anti-HCV positivity, a marker of past or current infection) in each group, obtained through systematic literature reviews and data requests from the California Correctional Health Care Services, San Diego Blood Bank, and the National HIV Behavioral Surveillance Survey. The mutually exclusive groups examined included people who inject drugs (PWID) in the community, men who have sex with men (MSM) in the community, the general population in the community excluding the aforementioned groups (stratified by age and sex), and prisoners (incarcerated in California with San Diego as their county of commitment). Due to a lack of data on HCV in children, this group was excluded from the analysis.

Based on this available epidemiological data, we estimated that in 2018 there were approximately 53,925 (95% confidence interval 25,261 - 89,914) adults aged over 18 with a history of HCV infection (HCV seropositive) in San Diego County (see *Table 1*). It is important to note the substantial uncertainty in this estimate, primarily driven by uncertainties in the size of the population of PWIDs and the HCV seroprevalence in the general population. See *Table 1* and *Table 2* for a breakdown of burden estimation by subpopulation.

Sub-population	Population size		HCV seroprevalence (anti-HCV)		Number individuals HCV seropositive	
	Point	95% confidence		95% confidence		95% confidence
	estimate	interval	Point estimate	interval	Point estimate	interval
People who inject drugs						
(community ^a)	25,935	8,976 - 43,678	0.6560	0.6140 - 0.6942	17,005	5,780 - 28,840
Men who have sex with						
men (community*)	88,735	67,376 - 110,061	0.0299	0.0252 - 0.0354	2,657	1,854 - 3,525
General population ^b						
(community ^a)						
Men 18-54	833,594	792,414 - 869,444	0.0072 ^c	0.0032 - 0.0118 ^c	6,053	2,696 - 9,814
Men 55-74 ^d	290,355	269,344 - 311,565	0.0470 ^c	0.0242-0.0808 ^c	13,769	7,225 - 22,395
Men 75+	76,566	69,489 - 83,691	0.0128 ^c	0.0018 - 0.0382 ^c	985	148 - 2,856
Women 18-54	838,611	817,451 - 860,791	0.0037 ^c	0.0018 - 0.0065 ^c	3,141	1,533 - 5,534
Women 55-74 ^d	345,081	324,071 - 366,751	0.0240 ^c	0.0122 - 0.0427 ^c	8,297	4,007 - 14,932
Women 75+	115,301	106,901 - 124,111	0	0	0	0
Prisoners ^d	8,793		0.2295	0.2218 - 0.2372	2,018	1,950 - 2,086
TOTAL					53,925	25,261 - 89,914

Table 1. San Diego HCV Burden Estimation, 2018.

Notes: ³Not incarcerated. ^bExcluding other risk populations above. ⁶Blood donor data adjusted by an inflation factor of 4.9 (95% Cl 2.2-7.7) for 'healthy donor effect' as per Facente et al. 2018. ^dClosest age groups in the ACS survey compared to to the aged 53-72 HCV birth cohort in 2018 ^ePrisoners are individuals incarcerated in 12/31/18 in California with San Diego as their county of commitment

Overall, among all infections the following trends were observed (see Table 2):

• Over 40% are estimated to be persons in the community general population aged 55-74 in 2018 (closest ages to the 1945-1965 HCV birth cohort [aged 53-72 in 2018] permitted with the binned American Community Survey data).

- Nearly 31.5% of infections are among community people who inject drugs, a key risk group for ongoing transmission.
- Nearly 20% of infections are among the community general population outside of these age groups, indicating the importance of surveillance in this group as well.

Summary of estimated HCV burden by subpopulation in San Diego County, 2018							
Subpopulation							
	Point estimate	95% confidence intervals		-% of all San Diego County HC seropositives			
PWID (community)	17,005	5,780	28,840	31.5%			
MSM (community)	2,657	1,854	3,525	4.9%			
General population aged 55-74*	22,066	11,232	37,327	40.9%			
General Population 18-54 and 75+	10,179	4,377	18,204	18.9%			
Prisoners	2,018	1,950	2,086	3.7%			

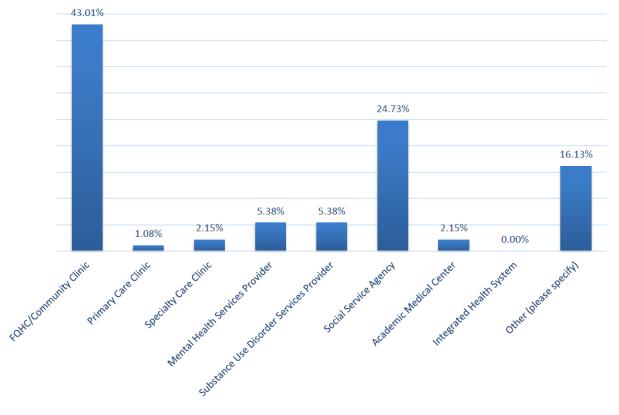
TABLE 2. Summary of HCV Burden Estimation by Subpopulation in San Diego County, 2018.

*Note: Due to American Community Survey data age groupings, we grouped ages 55-74 years, which is the closest age grouping to the HCV birth cohort (aged 53-72 in 2018)

The committee determined several key limitations and data gaps regarding the burden estimation and monitoring of future progress towards elimination. First, there is substantial uncertainty in the burden estimation, primarily driven by uncertainty in the size of the PWID population which is old (2007) and requires updating. Second, there is a lack of data on HCV chronic prevalence, which is essential in determining the number of individuals in need of HCV treatment in San Diego County and for monitoring elimination progress in the future. Third, epidemic modeling is required to determine the level of scale-up of treatment and prevention interventions and targeting of these interventions required to achieve the HCV elimination targets. Indeed, achieving HCV-related mortality reductions may require targeting individuals with more advanced liver disease (who are likely older and may no longer have ongoing transmission risk). Conversely, achieving the incidence reductions targets requires prioritizing interventions to those with ongoing risk, who may be younger with less advanced liver disease. Fourth, improved surveillance systems for chronic HCV and HCV-related mortality will reduce uncertainty and provide more robust evidence of progress towards elimination in the future.

Barriers to Prevention and Cures

The <u>Access, Testing, Treatment, and Prevention Committee</u> conducted an Organizational Practices Survey that assessed HCV awareness, practices, perceptions and needs. To ensure the survey was sent to relevant organizations that represented all HHSA operational Regions in the county, 211 San Diego was approached to distribute the electronic invite which included a link to SurveyMonkey[®] to obtain feedback. 211 San Diego maintains a comprehensive database of county-wide social services and medical programs that are shared with residents who call the three-digit dialing code 211 for a referral. Their database is routinely updated for accuracy. In total, 104 unique survey responses were received. This represented 41 organizations and 35 zip codes representing all Regions and included organizations such as community clinics, mental health services providers, substance use disorder services providers, social service agencies, and hospitals (see *Figure 4*). Survey data were reviewed by committee members and compiled in quantitative and qualitative summaries, focusing on key thematic elements (see *Table 3*).



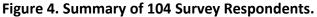


Table 3. Key Barriers Identified by Survey Respondents.

Theme	Key Findings
Population	Survey Respondents identified the following most at-risk
Characteristics	communities: substance users, homeless, baby boomers,
	incarcerated individuals and immigrants.
HCV Awareness	• 37% of respondents reported they did not receive updates on HCV transmission, risk factors and screening and treatment information.
HCV Provider and Patient Education	 41% reported lack of education or awareness as a major barrier. 52% of respondents reported that they did not routinely ask clients if they were ever tested for or diagnosed with HCV Many respondents expressed enthusiasm for increasing HCV activities such as displaying posters and educational materials (49%), staff training on HCV topics (33%), workshops on HCV prevention (32%) along with other interventions. Only 27% of respondents reported having posters visibly displayed regarding HCV transmission, screening or treatment 47% of respondents reported that they were not encouraged to talk the eligente object.
Access to Care	 to clients about HCV transmission risk. Only 50% of organizations offered hepatitis A and B vaccinations. Only 52% of respondents reported offering HCV screening. Only 46% of sites reported providing HCV treatment on site. Only 13% of respondents reported providing syringe access services on site. Only 29% of respondents reported providing Medication-Assisted Treatment on site. Only 5% of respondents felt that active drug or alcohol use should preclude HCV treatment.
Linkage to Care	 Less than half (47%) were able to link clients to on site HCV treatment. Most referrals to HCV care are passive referrals (flyer or phone number only). Very few respondents noted referral to care within 2 weeks
Overarching Barriers	 Major barriers identified by respondents included lack of funding, transportation, linkage and low access to services and treatment. The respondents identified the following needs in order to expand HCV related services: access to training, funding, increasing HCV screening, patient education, outreach navigators, etc. The triage and referral systems are dysfunctional and inefficient with some of the sickest clients waiting months to be seen.

Faces of Hepatitis C

The <u>Consumer Committee</u> shared the following profiles of individuals in San Diego County impacted by HCV. These represent a cross-section of communities that will benefit from this initiative. All consumer stakeholders whose stories are shared have provided input into the development of the recommendations. Some names have been changed at the individuals request.

Monica (Widow of a veteran who died from HCV complications; she gave birth while HCV positive)



Monica is a 59-year-old female who is antibody positive. She and her husband Carlos have been together since they were 14. Carlos enrolled in the service and served in the military. Over the years, they both began using IV drugs. Carlos was diagnosed during the mid-1990's and was not sure whether he had contracted during the service or via IV drug use. Carlos began working with Family Health Centers of San Diego (FHCSD) and was passionate about encouraging others to get

tested and get treated for HCV. Carlos worked alongside the local syringe exchange and substance use treatment to engage with individuals who might have been impacted by HCV. Monica was diagnosed during a pregnancy in 1996, and is antibody positive, HCV carrier with no viral load. Their child was tested and does not have HCV. Because of restrictions on treatment, Carlos's HCV eventually led to liver cancer and he was placed on transplant lists. Carlos and Monica worked closely with the VA to get ready for transplant, however, Carlos was unable to complete the process because of a return to substance use and lost his battle to liver cancer in December of 2018. Monica and her family continue to stay active in the community and work to bring awareness to the impact HCV can have on families. Monica has been drug-free and in recovery since 2011.



Kregg (Native American, HCV treated, tattoos, formerly incarcerated, former PWID, Baby Boomer)

Kregg is a 55-year-old male who has a history of incarceration and using IV drugs. Kregg was diagnosed with HCV in 2004 after asking to be tested. Kregg was aware that he had shared needles with someone who was HCV positive. He was told at the time that he was not eligible for treatment because his liver was not bad enough and told it was not something to worry about at the time. He continued to use and had little access to sterile injecting equipment. After several attempts, Kregg was able to stop using and was eventually referred

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to an infectious disease doctor (FHCSD, Dr. Ramers) who began the process of preparing him for HCV treatment. This process involved numerous drug screenings in order to meet the requirements at the time for 6 months of drug-free screenings. He worked closely with his provider, HCV navigators and his insurance company in order to be able to receive treatment. Kregg was eventually cleared of HCV after taking Harvoni for 12 weeks. Kregg noticed several weeks into treatment that brain fog had lifted, and he had more energy and less trouble focusing. Since treatment, he has met regularly with his infectious disease doctor to monitor other health issues, saying that "working with a trusted provider has allowed me to take care of both my physical and mental health, it gave me hope." He has remained drug free since 2012 and works closely with community partners to bring awareness to HCV.

Tara (Former PWID, formerly incarcerated, history of homelessness, gave birth while HCV positive, HCV cleared)

Tara is a 48-year-old former PWID who first tested positive in 2000. She was told at a routine prenatal exam that she was HCV positive and had a detectable viral load at that time. She struggled with homelessness and incarceration for several years and was told that she was not eligible to receive HCV treatment because she was still using drugs. Tara got sober in 2013 and was retested after giving birth to her daughter. She tested antibody positive with no viral load and was told she had cleared the virus on her own. Tara has 4 children who have been tested for HCV, all are negative. She currently works alongside local health officials and providers to bring awareness to substance use and HCV. Tara is employed as a substance use counselor and case manager and is a full-time social work student. She uses her voice and experience as a harm reduction specialist to advocate for impacted populations with local, state, and national harm reduction and HCV platforms.

Joey (Formerly incarcerated, tattoos, former PWID, HCV treated)



Joey is a 54-year-old male who has spent more than half of his life incarcerated. He used while in prison and shared that "there was often only one syringe for the entire facility, and it would be passed around between inmates." Joey found himself extremely ill during one of his prison terms and although jaundiced, was not tested for Hepatitis. During the time he spent in prison, he recalls only one brief educational presentation regarding hepatitis C, and they did not offer testing at that time. He is not sure when he contracted HCV but

tested positive in 1997 while in prison. He was not offered treatment for HCV, which at the time was acute. Joey was connected with a local drug and alcohol facility upon release and was linked to mental health and primary care. He worked closely with his doctor to be able to access treatment for HCV, and in 2017 was offered the opportunity to treat his HCV. Blood tests indicate that after treatment he has now been cured of HCV. Joey now works alongside of the Chula Vista

Police Department and the Homeless Outreach Team as a drug and alcohol counselor and continues to act as a role model for individuals who have been impacted by the criminal justice system.

Brad (Veteran, Baby Boomer)

Brad is a 66-year-old retired veteran who lives with a history of HCV. He is not sure how he contracted it, but knows he was originally tested for it during a pre-employment physical. His doctors at the time did a liver biopsy and said he would not need treatment. He has continued to be monitored over the years and receives his medical care through the VA.

Tim (Baby Boomer, tattoos, former PWID, treated for HCV three times)



Tim was born in 1952 and got his first tattoo when he was 14, long before HCV was even identified. He worked in the automobile industry and struggled off and on with drug use. Tim has a history of IV drug use and got sober in 1987. In 1995, he tested positive for HCV. He was told by doctors that he had several genotypes of hepatitis C and received treatment twice with medications that did not clear his HCV (interferon and ribavirin). After those first 2 attempts, his doctor had told him

he may never be able to get rid of the virus and would need to 'learn to live with it'. In 2017, his provider discussed newer treatment options and he was treated with DAA's and is clear of the virus today. He recently came out of retirement to work in the mental health field helping individuals who struggle with co-occurring disorders.

Rick (Vertical transmission, liver transplant, HCV cleared)



Rick was diagnosed with Hep C when he was 12 years old, and through his diagnosis, his mother was also diagnosed. Rick had received hepatitis C through vertical transmission (mother to child). His mother was cured in 2011 on her third treatment using earlier approved medications, which had lower cure rates. He was one of the 1% who received a liver transplant who had developed end stage liver disease. He would go on to need six treatments to finally achieve sustained virologic response (cure) in 2017, a year and a half after his transplant. He had a resistance associated variant (RAV) strain, which was harder to cure. Today, he's the director of education and outreach for a nonprofit and going to school for his Master's degree in public health.

DISCUSSION

Several key conditions unique to San Diego County position the county for success in HCV elimination:

- A strong network of committed clinical champions;
- A rich network of community health centers dedicated to serving underserved populations throughout the county;
- A group of dedicated primary care clinician champions; and
- California Medi-Cal expansion broadening access to care and treatment, combined with the removal of restrictions to HCV treatment.

Through the effort of the working committees, nine recommendations were generated. Leveraging a collective impact concept, key stakeholders were recruited to participate in this effort to identify the burden of disease, barriers to prevention and cure, and give a face to the hepatitis C disease.

While significant progress has been made, to date, in capturing a more comprehensive estimate of HCV burden by subpopulation in San Diego County, substantial limitations and challenges still exist with the data. A more sophisticated HCV surveillance system must be developed to improve data quality and use to support HCV elimination going forward.

HCV awareness, provider and patient education, access and linkage to care, as well as lack of funding present substantial barriers to HCV elimination in San Diego County. These challenges must be addressed and incorporated into the next phase of the detailed implementation plan developed by the *Eliminate Hepatitis C San Diego County Initiative* partners.

Lastly, these individual profiles highlighted in this report help raise awareness about the populations living with HCV. Each of these participants were eager to participate in this work, because they recognize the substantial impact this initiative will have on the community. Reducing HCV-related stigma through enhanced education about the virus and those at risk of infection will help San Diego County reach its goals of HCV elimination.

RECOMENDATIONS

The committees of the *Eliminate Hepatitis C San Diego County Initiative* maintained a rigorous schedule that included over 80 committee meetings, presentations to seven community groups, an organizational assessment survey, and participation from 65 social service and provider organizations.

Through a collective impact approach, the Initiative developed the following nine recommendations to enable San Diego County to reach its HCV elimination goal by 2030:

1. Promote awareness of HCV as a major public health concern.

- Create a culturally and linguistically appropriate public awareness campaign.
- Develop a website that can provide patients with linkage to care and serve as a clearinghouse of patient-focused informational materials.
- Create opportunities for people to access information, referral and linkage to care 24/7.
- Educate decision makers and political leaders about HCV.

2. Implement prevention strategies in alignment with current best practices.

- Increase access to programs, services and activities to reduce harm.
- Increase availability and ensure access to substance use disorder and mental health treatment.
- 3. Screen for HCV in line with the recommendations of the U.S. Preventive Services Task Force (USPSTF), Centers for Disease Control and Prevention (CDC), and best practices.
 - Expand HCV screening.
 - Promote HCV RNA reflex testing.
 - Provide screening, diagnosis and results to individuals in nontraditional settings

4. Ensure all individuals with HCV are linked to care and treatment.

- Re-engage populations diagnosed with HCV but who have not accessed services or linked to care.
- Create a patient navigation program to provide assistance in accessing and remaining in treatment and other supportive services.
- Engage health care systems and individual providers to create HCV care cascades
- Develop population-specific strategies to engage and maintain individuals in treatment.
- Identify patients with advanced liver disease.
- 5. Build capacity within existing workforce to treat patients in diverse health care environments.
 - Engage and support providers in non-specialty settings.
 - Coordinate and streamline referral pathways to treatment providers.

6. Ensure individuals with HCV have access to direct-acting antivirals (DAAs).

- Advocate to streamline the prior authorization process for direct-acting antivirals.
- Work with health plans to limit out-of-pocket expenses for patients.
- Improve ease of access of patients in filling DAAs prescriptions.
- Ensure availability of DAAs in pharmacy inventories in all Regions of the county
- Bring treatment services to where patients are.
- Ensure the continuity of care for patients who enter/exit criminal justice system.

7. Ensure adequate surveillance, evaluation and monitoring.

- Establish a local HCV case registry using public health surveillance data for use in characterizing the HCV care cascade, assessing reinfection, implementing program evaluation, and supporting other initiatives.
- Conduct enhanced HCV surveillance among priority populations (e.g., people who inject drugs, transgender individuals, MSM, incarcerated individuals).
- Conduct modeling to inform service coverage targets and resource prioritization, and to predict impact of existing interventions on future HCV incidence and mortality.
- 8. Pursue policies in alignment with WHO/CDC that will help achieve elimination.
 - Continue education, collaboration and sharing with other aligned organizations.
 - Work with health care providers to implement polices to increase testing screening and treatment of HCV.
- 9. Support HCV Research, Implementation Science and Operation Research.
 - Collaborate with universities and other research institutions.
 - Facilitate sharing of information related to upcoming research opportunities, current studies and findings of completed studies.

CONCLUSION

NOW is the right time to move forward with planning for the elimination of HCV in San Diego. Through strong collaboration and multi-sector support, San Diego County is well-positioned to develop a comprehensive plan to implement the locally developed recommendations for the *Eliminate Hepatitis C San Diego County Initiative*.

The *Initiative* has been successful, to date, in achieving the critical first steps of diverse stakeholder engagement, commitment, and partnership that has led to achieving progress in HCV data collection, obtaining crucial information and feedback about the population and current barriers, and identifying a collective set of initial recommendations.

NEXT STEPS

The next phase of the project is to develop a detailed implementation plan with key strategies and tactics, public and private organizational commitments, and potential funding sources for execution of the recommendations. A crucial focus in the implementation phase will be the development of sophisticated surveillance system to monitor and report chronic HCV data.

As noted throughout this report, eliminating HCV will take a collaborative effort, combining resources from organizations and advocates throughout the county. The American Liver Foundation will continue as a facilitating agency during the next phase and, although the structure will change moving forward, all committee members will form an overarching

Hepatitis C Task Force. The Task Force will be focused on the development of the implementation plan. Through organized collaboration, San Diego can be on the forefront of successful HCV elimination.

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Catholic Charities

California Department of Public Health

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Note: This list of participating organizations includes organizations represented on the committees of the initiative.

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Alliance Healthcare Foundation AbbVie, Inc. Gilead Sciences

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