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A New Epidemic
Hepatitis C



A New Epidemic: Hepatitis C

San Diego County Implements a Plan to Eliminate Hepatitis C by 2030 BY ROBERT G. GISH, MD

THE LEADERSHIP OF THE Public Health Services (PHS) department in the County of San Diego Health and Human Services (HHSA) saw the opportunity to use the playbook from the Getting to Zero Initiative to develop a similar strategy for hepatitis C (HCV). “Working with community partners is how public health goals are achieved,” said Wilma Wooten, MD, MPH, County Public Health Officer. “This initiative is one of three elimination initiatives currently being implemented by the local public health department, in collaboration with many community partners. It is yet another example of how collective impact can be achieved when the County of San Diego Health and Human Services collaborates

with community partners, including the healthcare sector and others.”

The planning process to develop the *Eliminate Hepatitis C San Diego County Initiative* started in November of 2018 after the County of San Diego Board of Supervisors authorized HHSA’s PHS staff to develop the initiative with community stakeholders. This effort resulted in the board approving the recommendations in March of 2020 and approving an implementation plan in July 2021. HHSA contracted with the Liver Coalition of San Diego County to serve as the convener of the partnership. The primary outcome of the *Eliminate Hepatitis C San Diego County Initiative* is to achieve an 80% decrease of incidence of chronic HCV and a 65% reduction in HCV mortality by 2030.

The plan has nine overarching recommendations (www.endhepcsd.org):

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).



care implements such as razors or toothbrushes. The CDC estimates that before the implementation of screening of the blood supply and the wave of universal precautions after the HIV epidemic, there were >300,000 incident cases per year in the U.S. Population-based surveys have shown that baby boomers (those born between 1945 and 1965) have an HCV seroprevalence that is three- to five-fold higher than the general population. Hence the CDC's recommendation in 2020 to offer all adults a one-time screening for HCV without prior acquisition of risk. [1] This was followed by California State Law (AB 789), signed in October 2021, that mandates offering HCV testing to all adults.

Since 2000 in San Diego County more than 2,500 cases per year of chronic HCV have been reported, and an estimated 55,000 individuals with a history of HCV infection are currently living in San Diego County. [2] From 2015 to 2020, HCV was listed as an underlying cause of an average of 60 deaths per year in San Diego County.

In recent years, fueled by the opioid epidemic, >80% of new infections occur in people who inject drugs (PWID). The result is a very different looking epidemic: a bimodal age distribution with one peak in the 20- to 30-year-old range, and another in baby boomers, currently aged 54-74 years. Parallel to the increase in HCV infection in women of child-bearing age is the recent increase in number of newborns who acquire the infection from their mothers. [3] It is believed that only 50% of the estimated 3 million prevalent infections have been diagnosed. [4] Through the lens of a cascade of care, the large drop from those suspected of having HCV to those diagnosed indicates we will not reach our elimination efforts by 2030. This cascade of care concept applies to children and adolescents as well as to adults; all infants born to high-risk mothers should be screened for HCV, given that about 5% of infected mothers transmit to their offspring. [5] Despite the great advances in HCV therapies, with cure rates of over 98%, if patients are not identified and linked into care and treatment, then they cannot benefit from the cure, no matter how simple, safe, and

effective the treatment. The time to act is now for all primary care providers to become involved with HCV testing and linkage to care. Pharmacists are also a cornerstone of HCV testing and linkage.

Historically, HCV treatment relied on interferon and ribavirin, and in 2010 the addition of a protease inhibitor, a course that typically lasted a year, came with many potentially severe side effects requiring careful patient selection and intensive monitoring, and with cure rates of only 50-70%. Because of the intensity of side effects and necessary patient support, typically only those with advanced liver fibrosis were offered therapy, and only highly specialized centers were able to handle the complexities of triaging, prescribing, and managing these therapies. [6] This meant that a basic component of treatment evaluation was a liver biopsy — an expensive, invasive, specialized procedure that many patients declined. It is no surprise that estimates of the HCV care cascade showed only 16% of people with HCV infection received treatment and only 9% were cured as of 2014. [4] Liver biopsies are rarely performed today as fibrosis stage can easily be evaluated with imaging and blood tests such as the aspartate aminotransferase to platelet ratio index (APRI) and fibrosis-4 (FIB4) index from liver enzymes and platelet counts, as well as proprietary testing such as the enhanced liver fibrosis (ELF) test and FibroSure/Fibrotest.

A Changing Diagnostic and Therapeutic Landscape

Enter two profound innovations that have dramatically changed the clinical and treatment landscape and made HCV treatment primed for adaptation to primary care: noninvasive fibrosis assessment via liver elastography, and short-course DAA treatment regimens.

Liver elastography is a technology similar to ultrasound that allows a clinician to assess liver damage at the bedside with a noninvasive, rapid, painless procedure that takes less than 10 minutes. The technology was developed and widely used in Europe more than a decade ago and has been available in the U.S. since 2012. DAA therapies were first used

7. Ensure adequate surveillance, evaluation, and monitoring.
8. Pursue policies in alignment with the World Health Organization (WHO)/CDC that will help achieve elimination.
9. Support HCV research, implementation science, and operation research.

Treatment for HCV Has Advanced Greatly and a Cure Exists

First described as “non-A, non-B” hepatitis in the 1980s, the hepatitis C virus is a blood-borne pathogen transmitted through contaminated blood transfusions, non-sterile medical procedures, tattoos, organ transplantation, intravenous drug use (IVDU), and rarely through sexual contact or sharing of personal



McAlister Institute's Medical Director, Dr. James Dunford, pictured with HR Operations Director Embrie Tapia (center) and Executive Director Marsa Varond (right).

Organized for Success

The Eliminate Hepatitis C San Diego County Initiative uses a collective impact model. The initiative has six committees: Steering Committee, Task Force Committee, Awareness and Prevention Committee, Linkage and Testing Committee, Surveillance Committee, and the Treatment Committee.

Join the Treatment Committee

The Treatment Committee, co-chaired by Christian Ramers, MD and Richard Dunford, MD, is largely composed of clinicians, pharmacists, and other direct service staff who work with agencies that offer HCV treatment. Of the nine overarching recommendations in the Implementation Plan, this committee focuses on two of the recommendations: (5) Build capacity within existing workforce to treat patients in diverse healthcare environments; and (6) Ensure individuals with HCV have access to direct-acting antivirals. The full Implementation Plan is available at [Eliminate-Hepatitis-C-Initiative-Implementation-Plan-Board-of-Supervisors-7.13.21.pdf](https://www.livercoalition.org/Implement-Plan-Board-of-Supervisors-7.13.21.pdf) ([livercoalition.org](https://www.livercoalition.org)).

The Treatment Committee meets monthly; visit www.endhepsd.org for more information.

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in 2013 in combination with interferon and ribavirin, but in the last 5 years have evolved into all-oral, highly effective, 8- to 12-week regimens with cure rates >98% in most cases, and safety profiles that often do not even require on-treatment monitoring. [7] They have rapidly become the standard of care and have enabled treatment to occur in primary care and other settings. These agents are approved for all, including those in the pediatric age group (3 years and older). [8] There are rare drug-drug interactions, and the dosing is eight–12 weeks with three tablets or one tablet per day.

These innovations coupled with steep drops in drug pricing and elimination of payer restrictions in California have allowed HCV to be safely and easily treated in the primary care setting. California's Department of Health Care Services initially had a policy restricting HCV therapies in the Medi-Cal program on the basis of liver fibrosis, provider specialty, as well as the presence of concomitant drug and alcohol abuse. The most recent iteration of this policy has entirely removed these restrictions [9] and allows HCV treatment to be started on the same day as diagnosis in many cases using HCV antibody testing and HCV RNA quantitative polymerase chain reaction (PCR). The need for genotype testing is now gone.

New and Emerging Models of Care

In response to this new epidemic and with new diagnostic and therapeutic tools at hand, the need for a new approach to screening and linkage to care, treatment algorithm simplification, and integration with other services was self-evident. Although electronic-health-record-based HCV testing prompts have proven largely successful for the older baby boomer cohort — the Veterans Administration (VA) health system has screened >85% of their age cohort — there has been less success in screening and diagnosis in the younger, more recently infected PWID. Many reasons may help explain this difficulty: the long clinically latent period, the often asymptomatic nature of this disease, their low rates of interaction with the medical care system, and other competing priorities such as homelessness, poverty, addiction, and mental health challenges.

Traditional models of care wherein



patients may be screened in primary care settings and referred to gastroenterology, infectious disease, or hepatology offices have significant limitations, particularly for the younger patients with HCV who have new infections. Several models have emerged in response to these new needs. Co-location of services at a primary care clinic is one model that allows patients to see a specialist in their patient-centered medical home and still benefit from an important array of integrated services. Another model, known as the “Project ECHO” model, uses telehealth to link a multidisciplinary academic subspecialty team to rural and underserved primary care clinics in weekly didactic and case conference sessions. The ECHO model supports primary care providers with ongoing subspecialty consultation to help identify patients that require in-person specialty consultation. In an evaluation of ECHO, patients treated in primary care clinics in rural New Mexico had statistically equivalent cure rates compared with those treated in specialty settings.

[10] We need the full involvement of primary care providers now in HCV care.

A growing body of scientific literature has documented successful programs in real-world primary care settings with high HCV cure rates. Recent recommendations from a consensus meeting endorse this approach of shifting HCV treatment to the primary care setting. Furthermore, the National Strategy for the Elimination of Hepatitis B and C notes in one of its key recommendations: *AASLD [American Association for the Study of Liver Disease] and IDSA [Infectious Disease Society of America] should partner with primary care providers and their professional organizations to build capacity to treat hepatitis B and C in primary care.* Pharmacists have taken a major role in medical care settings such as the VA. [11]

Experiences of Local Primary Care Providers

Jim Dunford, MD, is the medical director of McAlister Institute, a regional

substance treatment provider; emeritus professor of emergency medicine at UC San Diego; former medical director of the City of San Diego EMS system; and previous chair of the City of San Diego Clean Syringe Exchange Program. Dr. Dunford notes, “A recent longitudinal cohort study demonstrated the value of oral DAA on liver disease and mortality in a traditionally very difficult-to-reach population with HCV. [12] From 2006 to 2019, investigators followed 1,323 PWID (34% HIV-positive) in Baltimore as DAA became progressively more available. The HCV RNA positivity rate fell from 100% to 48%, and cirrhosis (based on serial elastography) decreased from 19% (2015) to 8% (2019). Undetectable HCV RNA was associated with an adjusted hazard ratio of 0.54 for all-cause mortality and 0.28 for cirrhosis. Remarkably, although the study did not provide treatment, 39% of the participants self-reported receiving HCV treatment by 2019. This study should cause all physicians who care for PWID to rethink their beliefs

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regarding the feasibility of significantly improving the health of even the most complex patients with HCV.”

Treatment in the primary care setting is likely to keep patients closer to other complementary services that may not be offered in specialty offices, such as addiction and mental health treatment and harm reduction services. The U.S. National Strategy for the Elimination of Hepatitis B and C further recommends: *The most effective way to prevent hepatitis C among people who inject drugs is to combine strategies that improve the safety of injection with those that treat underlying addiction. The strategy document further states: States and federal agencies should expand access to syringe exchange and opioid antagonist therapy in accessible venues* [11].

Dr. Adla Tessier, a family practice physician who practices at the La Maestra Health Centers of San Diego, in City Heights, treats HCV infection in her primary care practice. Dr. Tessier describes her experience this way: “It is very gratifying to be able to treat and cure hepatitis C in the primary care setting. Working closely with Dr. Robert Gish as a consultant as well as a mentor has expanded our knowledge to provide in-house specialty care and thereby improve timely access and linkage to care. Our Liver Clinic team works closely with our other departments, such as our addiction program and outreach programs, in facilitating much needed care for our vulnerable population. Having the ability to cure these patients and the feedback provided by our patients and family makes this a very rewarding experience.”

Primary and Specialty Care: Finding the Balance

The ECHO model is one specific way to define the relationship between primary care and specialty care, but the principles of collaboration need not be limited to one specific program. [13] At La Maestra, where I’m the medical director, we now have several providers offering treatment at multiple locations and can get patients in for an initial appointment within a week throughout the U.S. We can treat most patients immediately — from no fibrosis to compensated cirrhosis, but advanced liver disease and certain comorbidities definitely benefit from



liver specialist care, especially if liver transplant or liver cancer is part of the care spectrum. There are some innovative telemedicine opportunities that can help those patients that are in remote areas where specialty care is out of reach.

Dr. Kathleen Schwarz is a pediatric hepatologist on the staff of UCSD/Rady Children’s Hospital. She has played a national leadership role in developing treatments for children and adolescents with HCV. She is currently treating pediatric patients at the Rady Pediatric Liver Center but is happy to work with primary care physicians to provide advice regarding treatment in the primary care setting.

There are not enough liver specialists in the country to care for all the people who need HCV testing and the patients with HCV that need treatment. Given the safety and ease of HCV treatment in the DAA era, it makes sense for patients to be treated by their primary care physicians and pharmacists with whom they have had a long-term relationship. Shifting some of the burden of HCV treatment to primary care physicians and pharmacists will also allow patients with more advanced disease to access specialty hepatology care where proce-

dural and transplant expertise is really needed. We continue to educate patients and providers that liver function test (LFT) terminology has been updated. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) are not LFTs; these are liver enzymes that denote inflammation but not function. Albumin, bilirubin, and international normalized ratio (INR) are the key LFTs. Staging liver disease to start liver cancer surveillance is also key and diagnosing metabolic-associated liver disease (MAFLD, also known as non-alcoholic fatty liver disease [NAFLD] or non-alcoholic steatohepatitis [NASH]) is also essential alongside alcohol use disorder and substance use disorder for the more complete care of the liver patient.

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