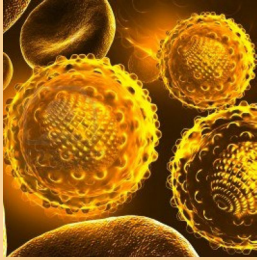


## What is hepatitis?

A viral condition, hepatitis causes mild to severe liver inflammation and can lead to cirrhosis and even cancer. Because hepatitis is usually asymptomatic, many people never seek treatment and develop chronic disease, which worsens over time.



3D rendition of the hepatitis virus

Hepatitis A (HAV) is generally transmitted when people ingest food or drink handled by an infected person. Its severity can vary from mild to acute, but people often recover without treatment. Due to the HAV vaccine and better hygiene, infections are decreasing in the U.S.

Hepatitis B (HBV) is spread through blood or other bodily fluids. Intravenous drug users, sexually active gay men and children born to HBV-infected mothers are particularly at risk. In its chronic form, Hepatitis B can be deadly. The HBV vaccine has reduced new cases of the disease; however, there are still many adults with chronic HBV, many of them undiagnosed.

Hepatitis C (HCV) is also spread through blood or other bodily fluids and infection can be acute or chronic. The virus is the most common chronic, blood-borne infection in the United States and the leading cause of liver transplants. Intravenous drug users, health care workers and people who received blood transfusions before 1992 are most at risk. HCV is a particularly significant public health concern because there are potentially millions of infected people who do not know they have the disease. As a result, public health officials are updating HCV testing recommendations to include populations that were not previously thought to be at-risk. (See Public Policy on page 2).

Source: Centers for Disease Control and Prevention

## An Emerging Health Crisis

Viral hepatitis is often called the silent epidemic. While more than 5 million people are infected with chronic Hepatitis B (HBV) and Hepatitis C (HCV) nationwide, symptoms may take decades to manifest and many may not be aware they are infected. That, combined with the stigma associated with hepatitis, has muted concern and endangered public health.

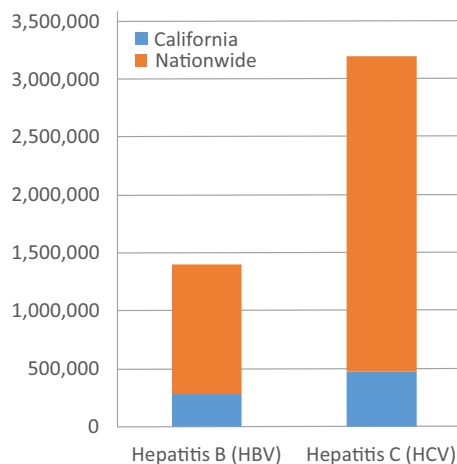
Hepatitis puts people at increased risk for cancer and is causing a rapid rise in liver transplants. Liver cancer rates are expected to increase nearly 60 percent in the next twenty years, particularly among Hispanics, Asian Americans and Pacific Islanders. During that same period, medical costs for HCV treatment are expected to increase by nearly 200 percent.

Public health officials estimate there are at least 475,000 people in California who are infected with HBV or HCV, and another 280,000 are infected with HBV. Many of those most at risk lack health insurance and do not seek care, so actual figures could be much higher. Hospitalizations for HBV- and HCV-related liver disease, liver cancer, and liver transplants in California in 2007 totaled \$1.916 billion.

Nationwide, an estimated 800,000 to 1.4 million people have chronic HBV. Due to routine childhood vaccination, new cases of HBV among young people born in the U.S. are declining. However, many adults with chronic HBV acquired the virus at birth and subsequently immigrated to the United States. HBV rates are particularly high among people from Asia, Africa, Eastern Europe and the Pacific Islands.

An estimated 3.2 million people in the U.S. have chronic HCV. While there is no vaccine for HCV, needle exchange programs and improved blood screening have lowered the rate of new infections. However, an August 2012 report by the Centers for Disease Control and Prevention (CDC) found that baby boomers (people born between 1945-1965) have a disproportionately high prevalence of HCV infection and related diseases. While less than four percent of the overall U.S. population is infected with hepatitis, more than 75 percent of those cases are in baby boomers. (See Public Policy on page 2).

Prevalence of HBV and HCV in California and Nationwide



Hepatitis puts people at increased risk for cancer and is causing a rapid rise in liver transplants. Liver cancer rates are expected to increase nearly 60 percent in the next twenty years, particularly among Hispanics, Asian Americans and Pacific Islanders.

Hepatitis poses serious health and economic challenges. Fortunately, federal and state government agencies, nonprofit advocacy and research organizations, academia and private sector innovators are working together to create new diagnostics and treatments and increase public awareness.

Sources: Centers for Disease Control and Prevention; California Adult Viral Hepatitis Prevention Strategic Plan

## Public Policy's Key Role in Preventing and Treating Hepatitis

Both HBV and HCV pose grave threats to public health. While the HBV vaccine has reduced the number of new cases, there remains a large reservoir of people who, due to lack of insurance, language barriers or other reasons, fail to get adequate treatment.

While there is no vaccine for HCV, education and community outreach programs have blunted the increase in new infections. However, because people with chronic HCV infection can remain symptom-free for decades, many people are unaware they are infected until they develop serious liver problems, such as cirrhosis (liver scarring) or liver cancer. As many as 3.2 million people in the United States have a chronic HCV infection and 15,000 die from the virus each year.

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The hepatitis virus is the most common chronic, blood-borne infection in the United States and the leading cause of liver transplants.

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To combat this threat, public health officials and advocacy organizations are increasing education and outreach to populations that have a disproportionately high number of HCV infections or are at high risk for the disease. The U.S. Preventive Services Task Force (USPSTF) and CDC now recommend that all baby boomers (people born between 1945 and 1965) get tested for HCV. Increased screening, combined with heightened HCV awareness amongst physicians, will alert many to their condition, reduce deaths from cancer and liver disease and prevent the disease from spreading.

Public officials are also acutely aware that HCV treatments must be improved. Until relatively recently, the immune booster interferon and the antiviral ribavirin were the favored treatment for HCV. However, these treatments can cause debilitating side effects and are poorly tolerated by many patients. Newer drugs have improved outcomes but still have significant side effects. As a result, the Food and Drug Administration (FDA) has been working to fast track next generation HCV treatments (see Diagnostics and Therapies on page 3).

## FIGHTING HEPATITIS WITH EDUCATION

Dr. Samuel So is a surgeon who wants to do fewer surgeries. Specifically, he wants to do fewer liver cancer procedures. He has seen the annual statistics on liver cancer deaths—695,000 worldwide—and recognizes the answer isn't surgery alone, it's preventing, diagnosing, managing and treating chronic viral hepatitis.

This is especially true for Asian Americans, who have significantly higher rates of liver cancer, often caused by chronic HBV. The virus is endemic in Asian countries, and roughly one in twelve Asian Americans is also infected. Many will die from liver cancer and liver cirrhosis if left undiagnosed and untreated.

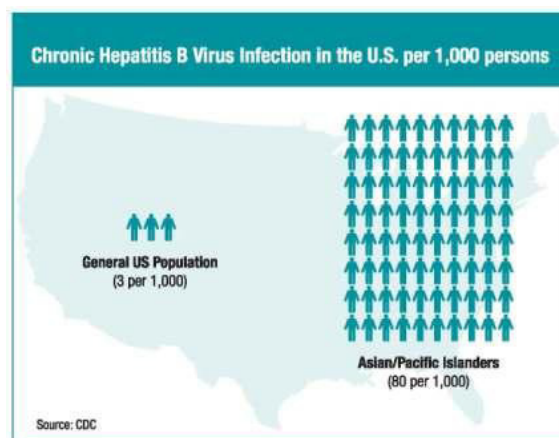
As a faculty member at Stanford University, Dr. So has witnessed this enormous health disparity firsthand. Many Asians and Pacific Islanders in the Bay Area are not even aware they have HBV, increasing the risks to themselves and their community.

“Chronic hepatitis B is a terrible health crisis in the Asian community,” says Dr. So. “With surgery alone, there was only so much I could do. Fortunately, this is a disease we can prevent with a vaccine, diagnose with a one-time blood test and treat with a once-a-day oral drug. We need to educate and get people tested and treated.”

To make this happen, Dr. So founded the Asian Liver Center at Stanford University. By reaching out to physicians, employers, at risk populations and community organizations, the Center has raised awareness about chronic HBV, ensuring that people get vaccinated and, if necessary, treatment.



Dr. Samuel So, M.D., Founder, Asian Liver Center, Stanford University



The Center's efforts have expanded to public advocacy, both in Washington and Sacramento. In California, Dr. So helped mobilize the government to address this ongoing public health crisis. He also helped initiate the 2010 Institute of Medicine report (*Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*) that laid down the Department of Health and Human Service's plans to prevent and treat viral hepatitis.

### Asian Liver Center

Founded in 1996, the Asian Liver Center at Stanford University works to reduce chronic HBV and liver cancer. The Center focuses on raising awareness about HBV among Asians and Pacific Islanders, as well as the physicians who treat them. In addition, the Center seeks to prevent mother-to-child transmission and help exposed newborns get the care they need.

The fight against HBV requires a multipronged effort. The Center builds public/private partnerships; advocates for new legislation at all levels of government; conducts research to translate basic science into new treatments; and conducts rigorous education and outreach efforts to increase prevention.

Source: Asian Liver Center, Stanford University

# DIAGNOSTICS AND THERAPIES

Pharmaceutical, biotech and diagnostic companies in California and nationwide are leading innovative efforts to develop an array of diagnostic tools and treatments to curb the hepatitis epidemic. Because of the public health concerns associated with hepatitis infections, several new technologies are under review at FDA through special programs to facilitate and expedite development and review of promising new drugs.

## Abbott Laboratories

There are several different HCV strains, complicating treatment. Recently, FDA approved a genomic test from Abbott Labs that can identify the different strains, helping physicians and patients develop an appropriate care plan.



The RealTime HCV Genotype II is the first diagnostic of its kind in the United States. The test analyzes each patient's viral genome, personalizing care and providing physicians critical information to precisely diagnose the patient and select the most effective treatments.



Abbott's RealTime HCV Genotype II test

## AbbVie

In its efforts to fast track promising treatments, the FDA has designated AbbVie's direct-acting, multidrug HCV treatment (currently in Phase III clinical trials) a Breakthrough Therapy. Breakthrough therapy designation is intended to accelerate the development and review of drugs for serious or life-threatening conditions.



The drug combination, being tested with and without the antiviral ribavirin, has shown encouraging results in clinical trials, testing patients who had previously not received treatment (treatment-naïve) or whose virus had survived earlier therapies (null responders). In intent-to-treat analyses from the Phase II Aviator study, 99 percent of treatment-naïve patients achieved sustained virologic response 12 weeks post treatment (SVR12), with 96 percent achieving SVR24. In the same study, 93 percent of prior null responders achieved SVR12, and SVR24.

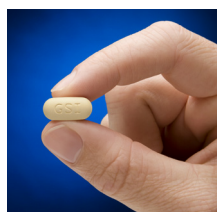
The drug is one of a new generation of oral HCV medications designed to treat the disease without the need for interferon.

## Gilead Sciences

In June 2013, the FDA granted priority review for Gilead's New Drug Application for the once-daily oral HCV medication sofosbuvir. Priority review designation is granted to medicines that may offer significant advances in treatment over existing options, and shortens the FDA's review time to six months from the standard 10 months.



The data submitted to the FDA support the use of sofosbuvir and ribavirin as the first-ever all-oral HCV treatment regimen for patients with genotype 2 and 3 HCV infection, and for sofosbuvir in combination with ribavirin and interferon for treatment-naïve patients with genotype 1, 4, 5 and 6 HCV infection. If sofosbuvir is approved, it could shorten the duration of therapy for HCV patients to just 12 weeks – half the time of currently available treatments. Most adverse events were mild to moderate in the Phase III sofosbuvir studies, and were consistent with the safety profiles of ribavirin and interferon. A decision from the FDA on sofosbuvir is anticipated by December 2013.



Gilead's sofosbuvir is an investigational agent

## Boehringer Ingelheim

Another HCV treatment showing success in clinical trials is Boehringer Ingelheim's compound faldaprevir. In a recent Phase III trial, faldaprevir was well tolerated and cured 80 percent of trial participants. In many cases, the therapy was so effective that participants stopped treatment early.



**Boehringer  
Ingelheim**

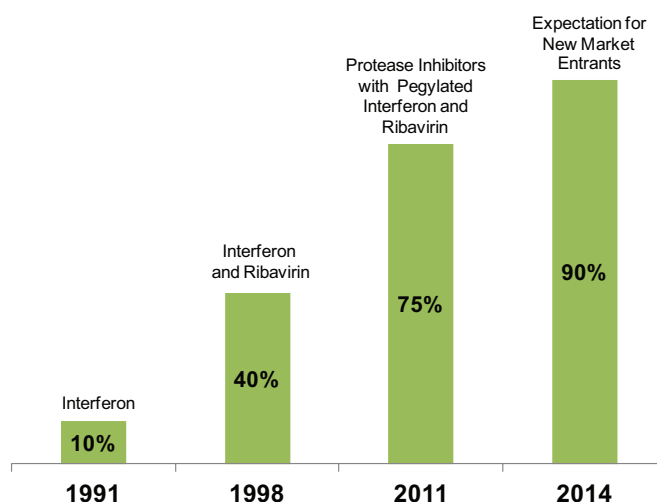
In another study, faldaprevir, combined with delebovir and ribavirin, cured 95 percent of participants.

## Hologic Gen-Probe

The first step in stopping any epidemic is preventing its spread. Because HBV and HCV are blood borne pathogens, it's essential that the blood supply be secure. Hologic Gen-Probe has been a leader in developing assays that detect hepatitis and HIV in donated blood. The company, in collaboration with Novartis Vaccines and Diagnostics, has developed the PROCLEIX assays, which has improved the safety of donated blood by detecting viral genetic material. As a result of this, and the use of other screening technologies combined with strict donor eligibility criteria, the chance of acquiring a dangerous disease by transfusion in the United States is roughly one in two million.



## Recognizing Rapid Innovation HCV Cure Rate Over Time



Source: Dr. David Bernstein. Hepatitis C: A 21st Century Oncology Success Story (Op-Ed). *Live Science*. 22 May 2013. <http://www.livescience.com/34606-hepatitis-treatment.html>

In the 1991, the cure rate for hepatitis C (HCV) was no more than 10 percent. By the late-1990s, cure rates increased to 40 percent with the addition of ribavirin to therapy. And in 2011, newly approved boceprevir and telaprevir in combination with earlier therapies produced cure rates as high as 75 percent. Given pipeline activity across the life sciences, we expect significant medical innovations by 2014 that promise similar or greater efficacy but with fewer side effects and a shorter treatment course.

## Community Resources:

American Liver Foundation  
[www.liverfoundation.org](http://www.liverfoundation.org)

California Hepatitis Alliance  
[www.calhep.org](http://www.calhep.org)

Centers for Disease Control and Prevention  
[www.cdc.gov/hepatitis/index.htm](http://www.cdc.gov/hepatitis/index.htm)

Clinical Trials  
[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Hep C Redefined  
[www.hepcredefined.com](http://www.hepcredefined.com)

Hepatitis B Foundation  
[www.hepb.org](http://www.hepb.org)

Hepatitis Education Project  
[www.hepeducation.org](http://www.hepeducation.org)

National Alliance of State & Territorial AIDS Directors  
[www.nastad.org](http://www.nastad.org)

National Institutes of Health  
[www.health.nih.gov/topic/Hepatitis](http://www.health.nih.gov/topic/Hepatitis)

National Viral Hepatitis Roundtable  
[www.nvhr.org](http://www.nvhr.org)

## DID YOU KNOW?

Baby boomers (people born between 1945-1965) make up 75% of those infected with hepatitis.



## In the Spotlight: Congressman Mike Honda



Congressman Mike Honda

Throughout his career in Congress, Representative Mike Honda (D-San Jose) has championed federal legislation to improve the detection, treatment and prevention of hepatitis. He was the first member to introduce comprehensive hepatitis legislation in the House of Representatives and is the founding co-chair of the bipartisan Congressional Hepatitis Caucus.

Rep. Honda has been honored by community advocates, health experts, industry professionals and the Obama Administration

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“Viral hepatitis is a silent killer, contributing to 15,000 American deaths each year...It is already more common than HIV/AIDS, but remains unrecognized as a serious threat to public health.” - Rep. Mike Honda

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for his commitment to hepatitis prevention and treatment. As a result of his work, hepatitis has become a leading issue in public health departments across the nation. He was also instrumental in encouraging President Obama to issue the first-ever presidential proclamation recognizing World Hepatitis Day, as well as urging the U.S. Preventative Services Taskforce to issue higher grade testing recommendations for hepatitis C (See Public Policy on page 2).

“Viral hepatitis is a silent killer, contributing to 15,000 American deaths each year,” says Rep. Honda. “It is already more common than HIV/AIDS, but remains unrecognized as a serious threat to public health. In addition, it disproportionately impacts racial and ethnic communities. Hepatitis C is twice as prevalent among African Americans, while Asian Americans and Pacific Islanders comprise more than half the known Hepatitis B cases. That is why I have fought for greater education and comprehensive solutions.”

## The Viral Hepatitis Action Coalition

The Viral Hepatitis Action Coalition (VHAC) is a public/private partnership developed by the CDC Foundation to help the Centers for Disease Control and Prevention (CDC) make meaningful advances in the prevention, screening and treatment of viral hepatitis. VHAC's members - including more than a dozen California companies CHI members - work collaboratively to link private sector innovation with CDC resources to combat hepatitis.

VHAC is spearheading a number of critical projects. *The Birth-Cohort Evaluation to Advance Screening and Testing for Hepatitis C* is evaluating the effectiveness of screening baby boomers based on their age, rather than other risk factors. *The Know More Hepatitis* campaign is raising awareness for providers, patients and people at risk. *The Chronic Hepatitis B and C Cohort Study* has adopted the data collection strategies that have worked in the fight against HIV/AIDS. Information about patients and treatments will help drive advanced therapies and new public health measures. VHAC is also creating fellowships to bring in vital expertise and advance research and outreach.

For more information, visit [www.viralhepatitisaction.org](http://www.viralhepatitisaction.org).

## CHI-California Healthcare Institute

CHI-California Healthcare Institute is a non-profit public policy research organization for California's biomedical R&D industry. CHI represents more than 275 leading medical device, biotechnology, diagnostics and pharmaceutical companies and public and private academic biomedical research organizations. CHI's mission is to advance responsible public policies that foster medical innovation and promote scientific discovery. CHI's website is [www.chi.org](http://www.chi.org). Follow us on Twitter @calhealthcare, Facebook, LinkedIn and YouTube.



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