



Federal Implementation Progress Report  
for the  
Action Plan for the Prevention, Care, and  
Treatment of Viral Hepatitis



Combating the Silent  
Epidemic of Viral Hepatitis  
**Action Plan for the Prevention,  
Care & Treatment of Viral Hepatitis**

This report was prepared under the direction of the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS). Information contained in the report was provided by the Viral Hepatitis Leads from various HHS agencies, the Department of Veterans Affairs, the Department of Justice's Bureau of Prisons, and the Department of Housing and Urban Development. Ms. Corinna Dan, R.N., M.P.H., Viral Hepatitis Policy Advisor in OHAIDP and Ms. Michelle Moses-Eisenstein, M.P.H., Public Health Analyst, coordinated development of this report. Ms. Tanesha Burley, M.P.H., Ms. Alaysia Phillips, M.P.H., Mr. Roy Quini, Ms. Deborah Finette of Altarum Institute and Mr. Steve Holman, M.B.A., all working under contract to OHAIDP, assisted OHAIDP staff in compiling and formatting the report.

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September 2014

## An excerpt from Presidential Proclamation on World Hepatitis Day 2014

Through the Affordable Care Act, my Administration has made major strides in expanding access to viral hepatitis prevention, care, and treatment. New health plans must now cover hepatitis C routine screening for individuals at high-risk and one-time screening for adults born between 1945 and 1965. These preventive services will allow more Americans to know their status and seek treatment.

Earlier this year, my Administration updated our Nation's first-ever comprehensive Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis. Alongside Federal, private, and non-profit stakeholders across our country, we will continue to strengthen our Nation's response. Together, we can raise awareness, reduce the number of new cases, and save lives.

Thanks to the tireless leadership of researchers and advocates, we are beginning to break the silence surrounding viral hepatitis. Today, we once again raise our voices, educate our at-risk communities, and support those living with this disease.

**—President Barack Obama**  
World Hepatitis Day Proclamation  
July 25, 2014

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## Background

On May 12, 2011, the U.S. Department of Health and Human Services (HHS) issued *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis* (Action Plan). This national Action Plan detailed more than 150 actions to be undertaken over the course of 3 years by agencies and offices across HHS and partners at the Department of Justice's (DOJ) Federal Bureau of Prisons (FBOP) and the U.S. Department of Veterans Affairs (VA). These actions were designed to improve the prevention, diagnosis, and treatment of viral hepatitis in the United States.

The Action Plan put a spotlight on this silent epidemic and its growing impact in the United States, where as many as 5.3 million persons are living with chronic hepatitis B virus (HBV) or hepatitis C virus (HCV) infection, and tens of thousands are at risk of infection. While viral hepatitis was previously addressed by various federal research, prevention, care, and treatment programs, much of this work was conducted independently, sometimes in isolation from related efforts. Following the Institute of Medicine's (IOM) 2010 report, *Hepatitis and Liver Cancer*, which recommended steps to reduce the threats posed by HBV and HCV, Assistant Secretary for Health Dr. Howard Koh convened an interagency workgroup composed of subject matter experts from various HHS agencies to review the IOM recommendations and develop a comprehensive strategic Viral Hepatitis Action Plan (VHAP) that would do the following:

- Address IOM recommendations for viral hepatitis prevention, care, and treatment.
- Set forth actions to improve viral hepatitis prevention and ensure that infected persons are identified and provided with quality care and treatment.
- Improve coordination of all activities related to viral hepatitis across HHS and promote collaborations with other government agencies and nongovernmental organizations.

Stakeholders from other federal agencies, professional societies; and state, tribal, local, and community partners also provided critical input into the Action Plan. The steps set forth in the Action Plan represented efforts to be undertaken in calendar years 2011–2013. Some actions outlined in the Plan could be accomplished using existing resources through improved coordination and integration, while others were subject to the availability of funds.

Following the Action Plan's release, agencies and offices across HHS began working to implement the actions assigned to them in the Action Plan. To support these efforts, HHS convened a Viral Hepatitis Implementation Group (VHIG) and charged it with coordinating, supporting, and overseeing activities related to the Action Plan. The VHIG comprises representatives from across HHS and other federal departments and is chaired by Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases. Members of the VHIG have met repeatedly during the 3 years of implementing the Action Plan and have served as representatives within their respective agencies and offices on matters related to viral hepatitis. Read more about the Action Plan at <http://aids.gov/hepatitis>.

## Introduction

This third progress report features select highlights of progress made in implementing the Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis during 2013. Compiled by the HHS Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), the report spotlights several key accomplishments under each of the Action Plan's six priority areas. These highlights were reported by the federal partners engaged in implementing the Action Plan but are only a sampling of the numerous activities that the partners undertook during 2013.

One recurrent theme across the Action Plan is the need for additional evidence to guide policy and practice at every level. Throughout 2013, federal partners again made important contributions to addressing gaps in our understanding of the prevention, care, and treatment of viral hepatitis and shared this information through articles published in peer-reviewed literature along with the development of reports and other technical documents. These contributions, many of which are featured in this report, help to advance efforts to develop and implement evidence-based programs, clinical services, and policies.

All of the described activities support progress toward the four overarching goals that the Action Plan envisions will be achieved by 2020:

- An increase in the proportion of persons who are aware of their HBV infection, from 33 percent to 66 percent.
- An increase in the proportion of persons who are aware of their HCV infection, from 45 percent to 66 percent.
- A 25 percent reduction in the number of new cases of HCV infection.
- Elimination of mother-to-child transmission of HBV.

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## Federal Partners in Implementing the Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis

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### HHS

- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health
  - National Vaccine Program Office (NVPO)
- Office of Disease Prevention and Health Promotion (ODPHP)
- Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)
- Office of Minority Health (OMH)
- Office of Population Affairs (OPA)
- Office of the Surgeon General
- Office on Women's Health (OWH)
- Regional Health Administrators (RHA)
- Office of the National Coordinator for Health Information Technology (ONC)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

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### U.S. Department of Housing and Urban Development (HUD)

- Office of Community Planning and Development (CPD)

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### Department of Justice (DOJ)

- Federal Bureau of Prisons (FBOP)

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### VA

- Office of Public Health, Veterans Health Administration (VHA), U.S. Department of Veterans Affairs (VA)

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### White House

- Office of National Drug Control Policy (ONDCP)
- White House Initiative on Asian Americans and Pacific Islanders (WHIAAPI)

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## Priority 1 Educating Providers and Communities to Reduce Health Disparities

### Goals

**1.1 Build a U.S. health care workforce prepared to prevent and diagnose viral hepatitis and provide care and treatment to infected persons.**

**1.2 Decrease health disparities by educating communities about the benefits of viral hepatitis prevention, care, and treatment.**

The lack of provider awareness and knowledge of current screening, management, and treatment for viral hepatitis remains a barrier to effectively identifying and caring for patients with chronic HBV and HCV. Increased provider knowledge has been shown to improve delivery of preventive services, a key component of efforts to address viral hepatitis, because of the large proportion of individuals who are undiagnosed and unaware of their infections. Additionally, the dynamic public health and clinical landscape has led federal partners, in collaboration with other stakeholders, to support the development and dissemination of updated recommendations for viral hepatitis testing, care, and treatment. This will maximize the benefits afforded by new scientific advances, as well as opportunities presented by the Affordable Care Act.

State and local community efforts are critical to addressing viral hepatitis health disparities but are often limited by resource constraints. Past efforts to reach disproportionately affected communities and the providers at all levels of the health systems that serve them, have also been hampered by low levels of awareness among community leaders and a dearth of culturally competent materials. Federal efforts have focused on developing evidence-based materials and partnering with organizations serving affected communities to educate and increase awareness of opportunities for viral hepatitis prevention, care, and treatment. By increasing awareness in communities and patients at risk for viral hepatitis, including Asian-Americans and Pacific Islanders (AAPI), African-Americans, HIV-infected persons, persons who inject drugs (PWID), men who have sex with men (MSM), and baby boomers (persons born during 1945–1965), in tandem with health care provider education efforts, we can improve the identification, management, and treatment of people who have chronic viral hepatitis in the United States.

In 2013, the following were among the actions undertaken by federal partners to educate communities about viral hepatitis and build a strong workforce of viral hepatitis providers:

**Expanding national hepatitis education activities and campaigns.** In 2013, the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) continued developing and implementing two national educational campaigns to inform the general public, persons at risk, and health care providers about the serious consequences of unrecognized viral hepatitis. The campaigns encourage testing of persons at risk and linkage to care for persons who test positive for viral hepatitis. CDC continued promotion and dissemination of campaign messages and tools for the *Know More Hepatitis* campaign, which launched in 2012 and encourages adults born during 1945–1965 to get tested for hepatitis C. The targeted multimedia campaign, which comprises news media outreach, print and broadcast ads, transit ads, radio public service

announcements, airport dioramas, magazine ads, a Web presence, and social media such as Facebook and Twitter, enhanced its outreach to baby boomers, for whom one-time HCV screening is recommended by both CDC and the U.S. Preventive Services Task Force. In June 2013, CDC launched a new national public awareness campaign, *Know Hepatitis B*, the first national multilingual, multiyear communications campaign encouraging screening for hepatitis B among Asian Americans and Pacific Islanders (AAPIs), a population disproportionately affected by HBV infection. *Know Hepatitis B* is a partnership between CDC and Hep B United, a nationwide coalition of community organizations working to increase hepatitis B awareness and testing. Hep B United receives support from the Office of Minority Health (OMH). The *Know Hepatitis B* campaign delivers culturally relevant messages in multiple languages, including English, Chinese, Korean, and Vietnamese, through a wide range of channels. The official launch of the new hepatitis B campaign was held at HHS headquarters in June 2013 and featured remarks by Dr. Howard Koh, Assistant Secretary for Health; Dr. John Ward, Director of DVH; Deputy Assistant Secretary for Minority Health Dr. Nadine Gracia; Ms. Kiran Ahuja, Executive Director of the White House Initiative on Asian-Americans and Pacific Islanders; and Hep B United leaders Ms. Joan Block and Mr. Jeff Caballero.

**Raising awareness in highly affected communities.** The HHS Regional Health Administrators (RHAs) in Public Health Regions II, V, VII, VIII, IX, and X supported or participated in various activities across the nation that promoted the Action Plan and helped increase public awareness about viral hepatitis, particularly within communities that are highly impacted by the disease. For example, RHA staff in Region IX met with clinic and hospital consortia in an effort to improve HBV screening rates among AAPIs and build public awareness around viral hepatitis in correctional facilities. Several RHAs and HIV/AIDS Regional Resource Coordinators actively engaged in partnering with community-based organizations and others to raise public awareness around viral hepatitis. They presented in Detroit, Michigan, about the impact of viral hepatitis on minority populations, as well as in Chicago, Illinois, on the impact of the Affordable Care Act on prevention, care, and treatment of viral hepatitis.

**Educating the public about viral hepatitis via the Internet and social media.** Many federal partners engaged in public and provider outreach via websites, blogs, and social media to raise awareness of the benefits of viral hepatitis prevention, screening, care, and treatment. For example, the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), which administers AIDS.gov, shared 45 viral hepatitis-related blog posts via [blog.aids.gov](http://blog.aids.gov) on a variety of topics including: viral hepatitis-related health disparities among racial and ethnic minority populations; efforts by state health departments to address viral hepatitis; observances, including Hepatitis Awareness Month, Hepatitis Testing Day, and World Hepatitis Day; and guest posts from federal partners, including FDA, CMS, and NIH, and several nonfederal community partners. To expand dissemination to additional audiences, CDC, OHAIDP, OMH, Office of Women's Health (OWH), and several Regional Health Offices used Twitter and Facebook to share new guidelines, publicize informational resources, and to promote events and observances.

**Training health professionals in viral hepatitis.** Several agencies and offices led trainings or created other opportunities to educate health care professionals and improve quality of care for persons with viral hepatitis. The table below summarizes the trainings, webinars, briefings, and resources from partners across government.

Agency or Office	Health Professional Training Product
<b>CDC</b>	<p>In 2013, CDC continued working with academic partners, the University of Washington, Seattle (UW) and the University of Alabama, Birmingham (UAB). UW continued to update and maintain <a href="http://www.HepWebstudy.org">www.HepWebstudy.org</a>, which houses case studies, slide libraries and glossary. UW also produced <a href="#">Hepatitis C Online</a>, a comprehensive online training for clinicians on HCV covering topics from screening and diagnosis to treatment of special populations and special situations. UAB continued to produce webinars for frontline workers and also worked on developing competency-based hepatitis curricula for the entire spectrum of medical education, both housed at <a href="http://www.KnowHepatitis.org">www.KnowHepatitis.org</a>.</p>
<b>HRSA</b>	<p>HRSA's Bureau of Primary Health Care developed a Grantee Spotlight on a health center that serves a predominately AAPI population in Seattle, Washington, titled <a href="#">"Using Video Storytelling and Community Health Workers To Provide Health Education Across 52 Languages."</a> The Spotlight highlights their provider's innovative approach to educating the multilingual community on hepatitis B and their work within the health center to develop clinical guidelines and train staff on managing chronic hepatitis B.</p> <p>The National LGBT Health Education Center and the National Association of Community Health Centers, both National Cooperative Agreement partners of HRSA, developed a toolkit titled <a href="#">"Taking Routine Sexual Histories: A System-Wide Approach for Health Centers."</a> The toolkit is designed to develop and implement systems for collecting routine sexual histories of patients and opportunities to educate and counsel patients about HIV, STDs, and viral hepatitis. It includes resources to connect patients to treatment and care.</p> <p>The National Center for Health in Public Housing and the National Center for Health and the Aging, both National Cooperative Agreement partners of HRSA, hosted webinars on viral hepatitis related to their respective target audiences.</p> <p>The National Health Care for the Homeless Council, also a HRSA National Cooperative Agreement partner, on March 14-16, 2013, hosted two trainings on hepatitis C at the National Health Care for the Homeless Conference and Policy Symposium: "Investigating Patient Attitudes Towards Hepatitis C (HCV) to Guide Implementation of Primary Care-Based HCV Treatment" and "Talking About Hep C: How To Give Clear, Compassionate, and Up-to-Date Information."</p> <p>The National Association of Community Health Center's Annual Policy and Issues Forum included two training sessions: "Board Members: Learning About Health Care for LGBT People and National Strategies on HIV and Hepatitis," hosted by the National LGBT Health Education Center; and "The Health Center Response to Hepatitis C, the New Public Health Crisis."</p>

Agency or Office	Health Professional Training Product
<b>OWH</b>	In collaboration with OMH, NVPO, and OHAIDP, OWH led a webinar on <a href="#">hepatitis and Hispanics</a> . OWH led a webinar with OHAIDP on <a href="#">hepatitis in women</a> . The webinars are available on the <a href="#">OWH YouTube channel</a> .
<b>RHAs</b>	<p>RHAs briefed selected state health officers on priority public health issues, including the VHAP.</p> <p>The Regional Resource Network Programs (RRNP) in Regions I and II led the development and coordination of the first RRNP viral hepatitis national webinar series in partnership with RRNP in Regions V, IX and X and the Latino Commission on AIDS. The Latino Commission on AIDS hosted the webinar series as part of Hepatitis Awareness Month and National Hispanic Hepatitis Awareness Day. This four-part webinar series, “Viral Hepatitis Today: Taking Action To Overcome the Challenges of Communities of Color,” was launched in May 2013. The series featured webinars focused on the VHAP, racial and ethnic communities, and vulnerable populations, and reached more than 800 participants.</p> <p>In July 2013, the Region VIII Federal National HIV/AIDS Strategy Workgroup hosted a webinar to further inform advocates of the latest developments in screening, testing, and treatment for viral hepatitis. Partners included Hep C Connection, Denver Health, the Colorado Department of Public Health and Environment, SAMHSA, and OHAIDP. As a result of this webinar, the focus of the 2014 RRNP regional meeting was viral hepatitis.</p>
<b>SAMHSA</b>	The Center for Substance Abuse Prevention (CSAP) produced webinars, technical assistance trainings, and conference calls for grantees. CSAP’s Minority AIDS Initiative programs provided preventive services in communities disproportionately affected by HIV/AIDS, viral hepatitis, and other infectious diseases. Webinars highlighted the benefits of HIV/HCV prevention efforts, including counseling, treatment, and vaccination.
<b>VA</b>	<p>VA organized monthly calls on national HIV/HCV issues for frontline VA providers, as well as a live meeting lecture series on viral hepatitis featuring experts and offering continuing education units.. Lecture series topics included emerging clinical issues and psychosocial issues around transplantation.</p> <p>In 2013, VA funded postdoctoral fellowships in clinical psychology at nine VA Medical Centers. The fellowships emphasize the behavioral health, mental health, and substance use treatment of Veterans with HIV/HCV infection and include weekly national didactic seminars that are open to the entire VA healthcare system.</p>

## Priority 2 Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer

### GOALS

**2.1 Identify persons infected with viral hepatitis early in the course of their disease.**

**2.2 Link and refer persons infected with viral hepatitis to care and treatment.**

**2.3 Improve access to and quality of care and treatment for persons infected with viral hepatitis.**

**2.4 Advance research to facilitate viral hepatitis prevention, and enhance care and treatment for infected persons.**

Timely diagnosis of HBV and HCV and better provision of care and treatment to those who are infected can decrease the burden of cirrhosis and liver cancer, reduce the need for liver transplantation, and reduce the number of deaths due to viral hepatitis in the United States. Many federal partners are working to improve health outcomes through policies and programs to reduce viral hepatitis-related health disparities experienced by baby boomers, African Americans, AAPI, MSM, PWID, HIV-infected persons, and other populations. Further evaluation and dissemination of effective models of care are critical to achieving the Action Plan goals.

In 2013, the following were among the actions undertaken by federal partners to improve testing, care, and treatment to prevent liver disease and cancer:

**Supporting development and dissemination of updated U.S. Preventive Services Task Force (USPSTF) HCV screening recommendations.** In June 2013, USPSTF issued a new recommendation for screening for hepatitis C infection in persons at high risk for infection as well as offering one-time screening for HCV infection to adults born between 1945 and 1965. The Task Force is an independent group of national experts that works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, or preventive medicines. AHRQ is authorized to convene the Task Force and provides it with ongoing scientific, administrative, and dissemination support. The new [USPSTF recommendation statement on HCV screening](#) aligns with the [CDC's Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965](#), issued in 2012. Creating more standard, consistent federal recommendations on hepatitis C testing was one of the strategies articulated in the VHAP. These aligned recommendations from USPSTF and CDC send a clear signal to health care professionals, policymakers, and the public that screening for HCV is effective and should be offered to patients. This alignment of recommendations is a step toward reducing confusion among health care providers, increasing awareness of the importance of hepatitis C screening, improving testing rates and ultimately identifying millions of Americans previously unaware of their infection status, and preventing the associated liver disease and deaths attributable to undiagnosed chronic HCV infection.



Many federal agencies and offices worked to adopt and raise awareness of the new USPSTF HCV screening recommendation after it was issued, revising policies or sharing information with providers and the public via blog posts, web pages, social media, training opportunities, and other means. For example, in November 2013, the VHA's Preventive Medicine Field Advisory Committee voted to approve a new Clinical Preventive Services Guideline recommending birth cohort HCV testing. The VHA National Center for Health Promotion and Disease Prevention released guidance on this recommendation in January 2014. These recommendations encourage one-time testing for all veterans within the 1945–1965 birth cohort, in addition to all veterans who have known HCV risk factors. Additionally, in 2013, SAMHSA's medical director sent a letter to agency grantees notifying them of the updated screening recommendations. In July, the medical director of IHS sent a "Dear Colleague" letter regarding the new HCV screening recommendations to all clinical directors within the Indian Health Service care system.

**Supporting development of recommendations for healthcare providers on HCV testing, management, and treatment.** In 2013, investigators from NIH, in collaboration with CDC, participated in the development of clinical [Recommendations for Testing, Managing, and Treating Hepatitis C](#). The guidelines, developed by a panel of HCV experts convened by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, were published online in January 2014. The recommendations cover four broad topics: HCV testing and linkage to care, initial treatment of HCV infection in patients starting treatment, retreatment of persons in whom prior therapy has failed, and unique patient populations. CDC led the development of guidelines for screening, testing, and linkage to care. The recommendations will be expanded and updated on an ongoing basis as warranted by new findings and developments in the field. In late 2013, VHA convened a panel of nationally recognized VHA experts in the treatment of hepatitis C. They developed [Chronic HCV Treatment Considerations](#), which are based on the available medical evidence. These Treatment Considerations are updated as new medications are approved by the FDA and as new data become available. They are nationally recognized and available to the public.

**Exploring opportunities to expand coverage for viral hepatitis testing.** In September 2013, CMS initiated a national coverage determination (NCD) for HCV screening after the release of the USPSTF recommendation. An NCD is a national policy statement granting, limiting, or excluding Medicare coverage for a specific medical item or service. CMS is authorized to add coverage of "additional preventive services" that have been recommended with a grade of A or B by the USPSTF and are found, through the NCD process, to be reasonable and necessary and appropriate for the Medicare population. The final NCD was issued in June 2014 expanding coverage for screening for HCV in primary care settings for beneficiaries who are at high risk and who were born from 1945 through 1965.

**Increasing HCV screening and hepatitis awareness in minority communities.** OMH funded six grantees located in several diverse communities across the nation with disproportionately high rates of hepatitis to support hepatitis awareness and access to testing, care, and treatment. Activities included piloting the offering of rapid HCV screening onsite and at public events and venues, facilitating access to care for people who tested positive for HCV, engaging local officials in hepatitis awareness activities, and hosting a bilingual Twitter chat on Latinos and viral hepatitis. OMH supported the following grantees: Dominican Sisters Family

Health Service, Inc. in Bronx, New York; Community Education Group in Washington, District of Columbia; Latino Commission on AIDS in New York, New York; FACES NY, Inc. in New York, New York; Long Island Association for AIDS Care, Inc. in Long Island, New York; and Hep B United in Oakland, California.

**Demonstrating effective HBV and HCV testing and linkage to care model programs.**

Beginning in 2012 and throughout 2013, CDC funded 34 viral hepatitis testing and linkage-to-care demonstration sites. Ten sites focused on testing individuals at risk for HBV and 24 sites were supported to test persons for HCV. From October 2012 through March 2014, three sites that participated in an initiative to identify foreign-born persons with HBV infection and link them to care tested a total of 4,727 persons, of whom 310 (6.6 percent) were HBV surface antigen (HBsAg)-positive. These findings show that community-based and refugee clinic-based HBV testing initiatives can identify substantial numbers of persons with chronic HBV infection, inform them of their HBV infection, and provide preventive counseling.

In 2013, three additional demonstration sites were funded by the CDC Foundation's Viral Hepatitis Action Coalition to test persons for viral hepatitis and refer them to care. One site in Birmingham, Alabama, focused on HCV testing and linkage to care for baby boomers. With a relatively modest investment of approximately \$239,000, the program began HCV testing in September 2013. After the first 6 months of operation, a total of 3,600 baby boomers had been tested for HCV. Of those, 444 (12.3 percent) had a positive antibody result; and of those, 354 persons were tested further to determine whether they had active (chronic) HCV infection. Results of this testing showed that 251 persons (or 71 percent of those who received a confirmatory test) have active HCV infection. This revealed that more than one of every 15 baby boomers tested learned of their infection as a result of this project, providing them the information needed to seek lifesaving care and treatment.

**Using electronic health record tools to improve HCV screening for American Indians and Alaska Natives.** IHS has been innovative in using computer technology to capture clinical data while improving patient care since the emergence of electronic health records (EHR). In 2013, IHS disseminated an EHR clinical reminder module that prompts clinicians to screen baby-boomer patients for HCV. Mid-year analysis covering July–December 2013 showed that at participating sites, 23 percent of active patients in the baby-boomer cohort were screened for HCV. This was a significant improvement from the pilot year, in which only 11 percent of eligible patients were screened.

**Using health information technology (HIT) to monitor and improve viral hepatitis services in health centers.** HRSA-support health centers provide comprehensive, culturally competent, quality primary health care services to medically underserved communities and vulnerable populations. In 2013, two national organizations that receive support from HRSA to provide technical assistance to health centers undertook activities to improve the use of health information technology to address viral hepatitis-related health disparities:

- The Association for Asian Pacific Community Health Organizations (AAPCHO) received a [3-year grant](#) totaling more than \$700,000 from NIH to develop new HIT strategies that increase screening for chronic hepatitis B and reduce the impact of hepatitis B among high-risk AAPI populations. To pilot and assess the HIT strategies designed to improve HBV outcomes for



underserved AAPIs receiving care in community health centers, AAPCHO is partnering with International Community Health Services, a community health center located in Seattle, Washington.

- The International Association of Providers of AIDS Care, in partnership with the Alliance of Chicago Community Health Services and the National Association of Community Health Centers, developed an EHR-based approach to integrating hepatitis C clinical management into community health center settings. The hepatitis C EHR module will be piloted across the 11-state EHR system network maintained by the Alliance, which manages almost 400,000 patients annually.

**Expanding health care provider capacity to effectively manage and treat HCV.** Project ECHO (Extension for Community Healthcare Outcomes) was developed in 2003 by the University of New Mexico's Health Sciences Center. Project ECHO seeks to build primary care capacity to treat HCV among rural, underserved populations through videoconferencing and case-based learning in telehealth clinics. The model program has been proven to improve HCV treatment outcomes of patients managed by primary care providers in community settings, with outcomes equal to—in some cases better than—those achieved by hepatitis C specialists at academic medical centers. In 2013, federal partners supported further development of HCV telehealth networks.

Beginning in September 2012 and throughout 2013, CDC funded Project ECHO programs in Arizona and Utah to improve patient access to primary care providers with the capacity to manage and treat HCV infection. In both states, Project ECHO was successfully implemented, training 66 primary care clinicians, predominantly from rural settings. Nearly all (93 percent) of the participating clinicians had no prior experience in care and treatment of HCV infection. For both states combined, 129 (46 percent) of 280 HCV-infected patients seen in teleECHO clinics received antiviral treatment, more than doubling the proportion of patients receiving HCV treatment in these clinics in the years prior to the introduction of the HCV telehealth program.

In 2013, the HRSA HIV/AIDS Bureau funded nine grant supplements for AIDS Education and Training Centers to expand hepatitis C and behavioral health treatment support in the Telehealth Training Centers Program (TTCP) demonstration program. The TTCP program expands access to and improves health care and health outcomes through telehealth technology by expanding support for providers who see a low volume of HIV patients. These efforts are targeted to rural areas to improve the management of hard-to-reach, HIV-positive persons residing in historically underserved communities.

The VA's Office of Specialty Care Services partnered with the Office of Primary Care, Office of Telehealth, Office of Nursing Service, Pharmacy, Office of Rural Health, Office of Public Health, and others to develop Specialty Care Access Networks (SCAN) across five regional sites, nationwide. Hepatitis C is one of the focus areas for the National SCAN Extension of Community Healthcare Outcomes (SCAN-ECHO). SCAN-ECHO uses video teleconferencing technology to simultaneously link mentoring specialists in hepatology to multiple primary- and specialty-care providers. SCAN-ECHO transforms health care delivery to veterans by enhancing communication between medical specialists and generalists. It also demonstrates the force-multiplier effects of shared specialist knowledge, skills, and resources locally, regionally, and across the country, which helps care systems responsibly manage fiscal

resources and generate cost-savings across the system. To date, there are six active Hepatitis C SCAN-ECHO centers that have mentored providers from 136 community-based outpatient clinics and VA Medical Centers in 18 of 21 Veterans Integrated Service Networks. As the program continues to evolve, it will increasingly focus on expanding access to specialty care among rural and highly rural veterans with HCV.

**Facilitating development, review, and approval of new drugs to treat viral hepatitis.** In 2013, the FDA engaged in several activities supporting advances in research to enhance care and treatment for persons living with HCV infection.

- Providing guidance for the clinical development of Direct-Acting Antivirals (DAA) for hepatitis C. The FDA released its draft [“Guidance for Industry Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment”](#) in October 2013. This revised draft guidance assists pharmaceutical sponsors in the clinical development of DAA drugs for the treatment of chronic hepatitis C. HCV DAA drugs are defined as drugs that interfere with specific steps in the HCV replication cycle through direct interaction with the HCV genome, its polyprotein, or its polyprotein cleavage products, representing significant advances in therapeutic efficacy. Although the guidance discusses the development of DAAs with and without interferon, the main focus is on the development of DAA drugs that can be used as part of interferon-free regimens.
- Expediting safe hepatitis C DAA research and development. The FDA’s Antiviral Information Management System database is a pooled database of de-identified clinical trial data from multiple pharmaceutical sponsors to be used for regulatory research. This pooled data was used in the research leading to establishment of sustained viral response to treatment regimens at 12 weeks after therapy instead of 24 weeks, as the primary efficacy endpoint for HCV clinical trials. In 2013, these findings decreased the HCV drug development timeline by 3 months, thus facilitating earlier access to safe and effective drugs.
- Approving new drugs to treat hepatitis C. In 2013, the FDA Center for Drug Evaluation and Research (CDER) approved two new DAAs for the treatment of chronic HCV infection. In November 2013, the FDA approved simeprevir, a protease inhibitor that blocks a specific protein needed by HCV to replicate, as a component of a combination antiviral regimen. Simeprevir (sold under the brand name Olysio<sup>®</sup>) was reviewed under the FDA’s priority review program, which provides for an expedited review of drugs that, if approved, would provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to available therapies. In December 2013, CDER approved a second new HCV treatment, sofosbuvir. Also a DAA, sofosbuvir (sold under the brand name Sovaldi<sup>®</sup>) was the first drug approved after demonstrating safety and efficacy to treat certain types of HCV infection without the need for co-administration of interferon. This was also the first regimen to be approved to prevent HCV recurrence post-transplant in a subgroup of the pretransplant population as well as the first approved regimen for HCV/HIV-1 co-infected population. Sovaldi is the third drug with breakthrough therapy designation to receive FDA approval. The FDA can designate a drug as a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may demonstrate a substantial improvement over available therapies for patients

with serious or life-threatening diseases. Sovaldi was also reviewed under the FDA's priority review program.

**Advancing the development of new therapeutic agents for viral hepatitis.** NIH supported a number of research activities on potential HBV and HCV therapies, including a randomized controlled trial of tenofovir with or without peginterferon in patients with immune active chronic hepatitis B. The study is funded as a cooperative agreement with participation from CDC. NIH researchers are engaged in an ongoing collaboration to identify novel targets and molecules for HCV therapy. Researchers in two NIH Intramural Research Programs have several ongoing clinical research studies of combinations of oral, direct-acting antiviral agents, with or without peginterferon and ribavirin, in patients with chronic hepatitis C. These studies are focused on high-risk patients in vulnerable populations, including uninsured and minority populations as well as persons with advanced disease and cirrhosis. In addition, the NIH supports clinical research studies of oral direct-acting agents in patients affected with both HIV and HCV.

**Advancing the science to improve prevention, care, and treatment of chronic viral hepatitis and liver cancer.** A project in the NIH funding announcement (FOA), "Biomarkers of Infection-Associated Cancers" includes a project that is investigating circular microRNAs as potential biomarkers to monitor people infected with hepatitis C virus for the development of liver cancer. A small animal model that is susceptible to hepatitis B and/or C would provide an enormous benefit for research into the pathogenesis, prevention, and treatment of hepatitis B and C. Extramural NIH-supported investigators have developed several new humanized mouse models of HCV infection by providing mice with the human genes responsible for entry of the HCV into liver cells. These mouse lines that are susceptible to HCV infection can be used to study immunity, recovery, and treatment of hepatitis C. A similar approach is being used to develop a mouse model for hepatitis B.

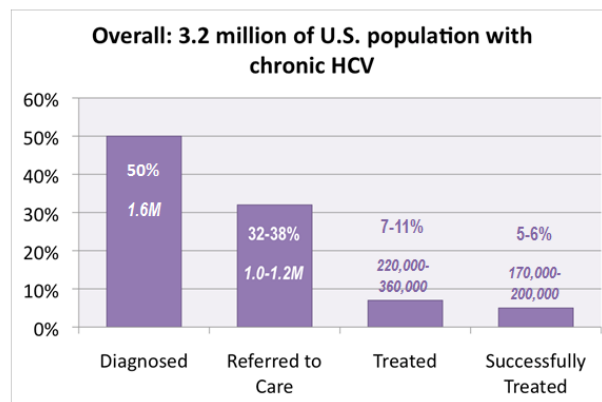
## Improving Testing, Care, and Treatment to Prevent Liver Disease

By John Ward, MD, Director, Division of Viral Hepatitis, National Center for HIV, Viral Hepatitis, STD and TB Prevention, Centers for Disease Control and Prevention

An estimated 3 million persons in the United States are living with HCV infection, of which about three-quarters<sup>1</sup> are baby boomers. However, at least 50 percent of HCV-infected persons in the United States are estimated to be unaware of their HCV infection.<sup>2</sup> Of the persons tested and aware of their infection status, only 32 to 38 percent are referred for care, 7 to 11 percent are treated, and 5 to 6 percent achieve virologic cure.<sup>3</sup> These data highlight gaps in the health care delivery system. In the absence of new interventions, the burden of HCV is projected to continue to increase in the United States.<sup>4</sup>

Priority area two of the VHAP focuses on reducing the burden of cirrhosis and liver disease caused by HCV, with detection of HCV infection through testing as the critical first step toward reducing HCV-related morbidity and mortality. In recent years, CDC, like other federal partners engaged in the Action Plan, has undertaken efforts to improve HCV prevention, testing, and linkage to care and treatment. For example, in Fiscal Year 2012, CDC awarded \$6.6 million in Prevention and Public Health Funds to demonstration sites, including community health, primary care, and substance abuse and prevention clinics to test persons for hepatitis B and C and to refer infected persons to appropriate care.<sup>5</sup> With that funding, CDC supported 35 sites in 19 states, the District of Columbia, and Puerto Rico. In 2013, three additional sites received support as a result of a public-private partnership under the auspices of the CDC Foundation's [Viral Hepatitis Action Coalition](#) (VHAC). The majority of the demonstration projects met targets for the number of persons receiving HCV testing and linkage to care for infected persons, but those at the

### U.S. HCV Treatment Cascade



(Holmberg et al., "Hepatitis C in the U.S." *N Engl J Med* 2013; 368: 1859-1861)

<sup>1</sup> Centers for Disease Control and Prevention. [Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945–1965](#). *Morbidity and Mortality Weekly Review*. 2012;61(RR04):1–18).

<sup>2</sup> Denniston MM, Kleven RM, McQuillan GM, Jiles RB. Awareness of infection, knowledge of hepatitis C, and medical follow-up among individuals testing positive for hepatitis C: National Health and Nutrition Examination Survey 2001–2008. *Hepatology*. 2012;55:1652–1161.

<sup>3</sup> Holmberg SD, Spradling PR, Moorman AC, Denniston MM. Current status of hepatitis C in the United States. *New England Journal of Medicine*. 2013;368:1859–1186.

<sup>4</sup> Davis GL, Alter MJ, El-Serag H, Poynard T, Jennings LW. Aging of hepatitis C virus (HCV)-infected persons in the United States: a multiple cohort model of HCV prevalence and disease progression. *Gastroenterology*. February 2010;138(2):513–521.e6. doi:http://dx.doi.org/10.1053/j.gastro.2009.09.067.

<sup>5</sup> Centers for Disease Control and Prevention. *Viral hepatitis, early identification and linkage to care for persons with chronic HBV and HCV infections*. Atlanta, GA: Centers for Disease Control and Prevention; 2013.

University of Alabama at Birmingham<sup>6</sup> and The Johns Hopkins University in Baltimore, Maryland,<sup>7</sup> have been particularly successful. For example, in September 2013, UAB began offering HCV screening to all baby boomers seen in the hospital's emergency department. A total of 6,521 baby boomers were screened for HCV, of whom 691 (10.6 percent) had a positive test for HCV antibody. Of those who tested positive, 530 were given an additional test to determine whether they had current HCV infection, of whom 394 (74.2 percent) were confirmed to have chronic infection. One hundred ninety (48.3 percent) of the individuals with chronic infection were successfully contacted by phone and 91 (47.9 percent) of those contacted were linked to HCV care with an appointment. These data reveal that the prevalence of HCV in this population of ED patients was 6 percent or higher, far exceeding the expected 3 percent prevalence of HCV among baby boomers participating in national health surveys.<sup>8</sup> This project, which is the first CDC-funded HCV testing program implemented in the ED settings, demonstrates the potential of the ED to be a best practice setting for HCV testing and linkage to care.

The important work of the UAB project, as well as many other CDC research projects and programs, would not have been possible without the support of the private sector. The White House highlighted the importance of public-private partnerships as one of its priorities.<sup>9</sup> The VHAC is a success story for leveraging public- and private-sector partnerships to further progress toward achieving national public health goals for viral hepatitis. In addition to these demonstration projects, the VHAC provided funding to support the first U.S. longitudinal cohort study of individuals with chronic HCV, evaluation of the birth cohort HCV testing guidelines, and support for the increasingly important efforts to address HCV issues globally.

The collective actions of partners and stakeholders helped to disseminate CDC recommendations for HCV, evaluate strategies to implement testing in various care settings, increase awareness of viral hepatitis in key communities, and expand provider capacity to effectively manage and treat HCV. While these efforts show great promise, we cannot lose sight of how much more work remains: up to 60 percent of people living with viral hepatitis are still unaware of their status, reports of both incidence and mortality are increasing, and only about 5 percent of chronically infected persons have been successfully treated. We must continue to improve viral hepatitis testing, as well as care and treatment, if we are to stop new infections and prevent more people from becoming ill with or dying from liver disease. With commitment of governmental and non-governmental partners, the nation can markedly reduce HCV transmission and disease, setting the country on a course toward the elimination of hepatitis C.

<sup>6</sup> Galbraith JW, Franco RA, Rodgers JS, et al. Screening in emergency department identifies a large cohort of unrecognized chronic hepatitis C virus infection among baby boomers. Presented at the 64th Annual Meeting of the American Association for the Study of Liver Diseases, Washington, DC; November 1–5, 2013. Abstract LB-6.

<sup>7</sup> Falade-Nwulia O, Mehta S, Sulkowski M, Lasola J, Ghanem K, Chaulk P, Thomas D. Impact of rapid hepatitis C testing on receipt of hepatitis C results in an STD clinic. Presented at the 22<sup>nd</sup> International Conference on Retroviruses and Opportunistic Infections, Boston, MA; March 3–6, 2014.

<sup>8</sup> Centers for Disease Control and Prevention. [Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945–1965](#). *Morbidity and Mortality Weekly Review*. 2012;61(RR04):1–18.

<sup>9</sup> The White House, Community Partnerships Interagency Policy Committee. *Building partnerships: a best practices guide*. Washington, DC: Government Printing Office; 2013.



## Priority 3 Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease

### GOALS

**3.1 Build a network of state and local surveillance systems with sufficient capacity to monitor viral hepatitis transmission and disease.**

**3.2 Monitor viral hepatitis-associated health disparities.**

**3.3 Monitor the provision and impact of viral hepatitis prevention, care, and treatment services.**

**3.4 Develop and implement new technologies and laboratory procedures to improve viral hepatitis surveillance.**

Historically, the impacts of the viral hepatitis epidemic have not been well-quantified or well-understood. Surveillance data provides estimates of the prevalence and incidence of disease and can highlight trends in the burden of disease and disparities in health. Experts in the field are working to enhance existing methods and utilize novel data sources and analysis methods to improve surveillance and better target limited prevention and service resources. In the rapidly evolving health care field, with the increase in EHR use and the focus on data to monitor changes in health care use and outcomes, there are unprecedented opportunities to improve what we know about viral hepatitis to inform our national response.

In 2013, the following were among the actions undertaken by federal partners to strengthen surveillance to detect viral hepatitis transmission and monitor disease:

**Enhancing surveillance to better inform local viral hepatitis policy and community impact.** CDC released the report *Viral Hepatitis Surveillance United States, 2011* in August 2013. The report includes incidence data for 2011 and an analysis of changes from 2000 to 2011. Data are reported by age, sex, race or ethnicity, and state and are useful to a variety of policymakers, community advocates, and other stakeholders. Data reveal that deaths among persons diagnosed with HCV were highest among persons aged 55 to 64 years, American Indians and Alaskan Natives, and males.

This surveillance report was the first in which CDC used its revised and improved methods to estimate new viral hepatitis infections from cases reported to the CDC National Notifiable Diseases Surveillance System. CDC researchers adapted a model previously used to estimate the number of people who had pandemic influenza in 2009. Their revised model considers who developed symptoms, who sought care, and who was reported in hepatitis surveillance. This change in CDC's surveillance strategy will let state and local health authorities more accurately estimate acute cases of viral hepatitis on a jurisdiction level to inform their prevention activities.

CDC also published a paper on improving estimating methods related to infectious disease surveillance. "Estimating the Number of Persons Who Inject Drugs in the United States by Meta-analysis to Calculate National Rates of HIV and Hepatitis C Virus Infections" describes a

meta-analysis from four national probability surveys and deriving population size estimates from Census data.

**Monitoring advanced liver disease in veterans with chronic hepatitis.** All veterans in VA care known to have chronic hepatitis C are followed via the VA's National Hepatitis C Clinical Case Registry (CCR), an electronic database that captures clinical, laboratory, and pharmacy information on HCV care in the VA. VA CCR reports showed that out of 174,302 veterans with chronic hepatitis C in VA care, the incidence of patients newly diagnosed with cirrhosis remains stable at 2-to-3 percent over 2 years; the prevalence of cirrhosis among veterans with chronic hepatitis C in VA care in 2013 was 17 percent. In 2013, of veterans with chronic hepatitis C in VA care, 1,654 (0.9 percent) were newly diagnosed with hepatocellular carcinoma.

**Providing guidance for hepatitis C testing procedures and policies.** In 2013, CDC published [“Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians”](#) in the *Morbidity and Mortality Weekly Report*. This critical update provided a simplified algorithm for HCV testing which was needed because of changes in the availability of certain commercial HCV antibody tests and evidence that many persons identified as reactive by an HCV antibody test might not subsequently be evaluated to determine whether they have current HCV infection. In addition, demand for HCV screening is expected to rise because of revised HCV screening recommendations as well as significant advances in the development of antiviral agents with improved efficacy against HCV.

**Improving surveillance through the development of new technologies.** In 2013, CDC engaged in a number of activities to develop and implement new technologies and lab procedures to improve viral hepatitis surveillance. These included significant laboratory capacity improvement for accurate, rapid, and cost-effective detection of disease transmission, especially during outbreak investigations. The application of powerful next-generation sequencing technologies capable of rapid identification and control of outbreaks, the development of novel computational approaches to viral hepatitis surveillance, and the development of multiplexing technologies for simultaneous detection of viral and immune markers of infection are being realized through laboratory capacity improvement .

**Advancing liver cancer surveillance.** Intramural investigators from NIH are studying mechanisms of viral hepatitis-mediated hepatocarcinogenesis and cancer stem cells in liver cancer. Molecular profiling and gene expression array studies comparing signatures of chronic liver diseases with hepatocellular carcinoma, revealed a molecular signature that separates patients for their risk of developing advanced disease. In addition, NIH, through the Early Detection Research Network, has a project for the surveillance and serial collection of serum and plasma from cirrhotic patients who are predominantly HCV positive. This biorepository will serve as an important resource for the future validation of markers for the monitoring and early detection of liver cancer.

## Priority 4 Eliminating Transmission of Vaccine-Preventable Viral Hepatitis

### GOALS

#### 4.1 Eliminate mother-to-child transmission of hepatitis B.

#### 4.2 Achieve universal hepatitis A virus (HAV) and HBV vaccination for vulnerable adults.

#### 4.3 Design and test new or improved viral hepatitis vaccines and determine the indications for their optimal use.

Hepatitis A and B are vaccine preventable, and expanded delivery of these vaccines has resulted in fewer new infections. From 2000 - 2012, new hepatitis A cases decreased by 88 percent. During the same period, new hepatitis B infections decreased by 64 percent. Although barriers to vaccination exist, the Affordable Care Act provides opportunities for expanding immunization access for adults at risk as well as enhancing perinatal hepatitis B prevention efforts. Establishing new and strengthening existing partnerships between organizations that serve groups at highest risk for viral hepatitis and health care providers who can administer vaccines is critical to increasing rates of vaccination, establishing effective programs, and ultimately eliminating new HAV and HBV infections in the United States.

In 2013, the following were among the actions undertaken by federal partners to eliminate the transmission of vaccine-preventable viral hepatitis:

**Supporting activities to eliminate mother-to-child transmission of HBV.** CDC funds Perinatal HBV Prevention Programs (PHBPP) through cooperative agreements with health department immunization programs. These programs are required to identify HBsAg-positive pregnant women and ensure that their infants receive post exposure prophylaxis by providing case management in 50 states, 6 cities, 5 territories, and the freely associated states. In 2013, CDC collaborated on a cost-effectiveness analysis of the PHBPP and worked with PHBPPs in Michigan and New York City to assess the rates of prenatal evaluation of HBV-infected women for care and treatment, evaluate novel strategies to increase identification of HBsAg-positive pregnant women, and determine the annual reporting of HBV birth dose coverage by birthing facilities in these jurisdictions. To further support the PHBPP, CDC collaborated with three large commercial laboratories to develop and implement a Special Laboratory Report. The report, which will be regularly provided to PHBPPs, lists confirmed HBsAg-positive test results from women who are likely to be pregnant with the objective of facilitating identification of pregnant women whose infants will require case management for prevention of mother-to-child HBV transmission.

**Validating a hepatitis B birth dose vaccination electronic clinical quality measure.** Clinical quality measures are tools that help measure and track the quality of health care services provided within the health care system. In 2013, CMS continued its partnership with CDC to convert CDC's quality measure "Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge" (NQF 0475) into an electronic clinical quality



measure format (e-specification). CMS used its existing Interagency Agreement with the HHS Office of the National Coordinator for Health Information Technology to e-specify the hepatitis B birth dose vaccination measure, which is now being piloted and evaluated in clinical settings to determine its feasibility for use in the Medicaid EHR Incentive Program.

**Increasing awareness of and access to hepatitis A & B vaccines.** In 2013, NVPO supported viral hepatitis prevention efforts via its website, [www.vaccines.gov](http://www.vaccines.gov), showcasing HAV and HBV vaccine information and featuring a homepage billboard during May's observance of Hepatitis Awareness Month. NVPO also maintains [Vaccine Finder](#), an online locator that enables individuals seeking protection from vaccine preventable diseases to search by ZIP code for health care providers and pharmacies that can provide HAV and HBV vaccine as well as flu and other vaccines.

VA's Office of Public Health expanded its scope of responsibility to include hepatitis B (as well as hepatitis C) through a formal directive, and drafted information for VHA clinicians on hepatitis B, particularly the importance of identifying candidates for immunization against hepatitis B.

**Supporting activities to achieve universal hepatitis A and hepatitis B vaccination for vulnerable adults.** In 2013, CDC engaged in a number of activities to further the goal of achieving universal hepatitis A and B vaccination for vulnerable adults, including the following:

- Collaborated with the DVH Laboratory Branch and American Red Cross in an ongoing project to determine the characteristics of hepatitis B virus vaccine breakthrough (when HBV infection occurs after an individual has been vaccinated for the disease) and occult HBV infection (the presence of HBV infection even when HBsAg is undetectable) by identifying cases through the screening of blood donors.
- Developed a project to conduct a prospective clinical trial determining the kinetics of hepatitis A vaccination seroconversion and immunogenicity among adults aged 40 years and up. The results will inform recommendations on the age limits for hepatitis A vaccination as post-exposure prophylaxis for hepatitis A exposure and support policy recommendations for providing vaccine or hepatitis A immunoglobulin in post-exposure situations.
- Published [CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management](#) in the CDC *Morbidity and Mortality Weekly Report*, providing updated guidance for evaluating health care personnel for hepatitis B protection for administering post-exposure prophylaxis.

**Supporting new vaccine development.** CDC is evaluating published data on novel hepatitis B vaccines for future consideration by the [Advisory Committee on Immunization Practices \(ACIP\)](#), a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States, including whether and how to include newly approved vaccines in [CDC's recommended immunization schedules](#).

## Priority 5 Reducing Viral Hepatitis Associated with Drug Use Behaviors

### GOALS

- 5.1 Ensure that people who inject drugs (PWID) have access to viral hepatitis prevention, care, and treatment services.
- 5.2 Mobilize community resources to prevent viral hepatitis associated with injection drug use.
- 5.3 Provide people who inject drugs (PWID) with access to care and substance abuse treatment to prevent transmission and progression of disease.
- 5.4 Expand access to and delivery of hepatitis prevention, care, and treatment services in correctional settings.
- 5.5 Advance research to improve prevention of viral hepatitis among persons who use drugs.

In 2011, after years of decreasing or stable rates of new infections, acute HCV infection rates in the US increased by 45 percent. Injection drug use continues to be the most common mode of transmission for HCV in the United States. The rise of new HCV infections is considered to be linked to the U.S. prescription opioid drug use epidemic, because individuals who become dependent on oral opioids very often transition to injecting drugs, thus creating opportunities for HCV transmission. To address this emerging trend, it is necessary to collaborate across sectors and form new partnerships to develop effective education and prevention programs; identify those infected and refer them into care; and explore opportunities afforded by new, more effective therapies.

In 2013, the following were among the actions undertaken by federal partners to reduce viral hepatitis associated with drug using behaviors:

**Supporting viral hepatitis testing in behavioral healthcare settings.** In 2013, SAMHSA supported its grantees' expansion of HCV screening in substance abuse treatment programs. Included among these are 87 substance abuse treatment grantees under SAMHSA's Targeted Capacity Expansion-HIV (TCE-HIV) grant program, which supports substance abuse treatment for racial and ethnic minority populations at risk for HIV infection. SAMHSA awarded 35 new TCE-HIV grants in 2013. All 87 TCE-HIV grantees have the option to use up to 5 percent of their funds for hepatitis testing. In 2013, more than 60 percent of those grantees provided onsite HCV testing or referred the clients for hepatitis testing and treatment. In addition, SAMHSA's 2013 grant awards under the TCE-HIV minority women program funded 35 substance abuse treatment grantees that also have the option to use as much as 5 percent of their funds for hepatitis testing. During the first 6 months of those projects, most of those treatment facilities trained their staff on hepatitis testing and counseling and 2,020 HCV tests were provided, with an 11.5 percent HCV antibody positivity rate. Finally, SAMHSA's 2013 HCV Screening and Referral grant provided supplemental funding to nine SAMHSA-certified nonprofit

opioid treatment program grantees focused on providing an HCV screening test and, if results are antibody positive, referral for confirmatory testing and treatment. In the first 6 months of this grant program, more than 700 clients received HCV testing and 18 percent were screened antibody positive for hepatitis C.

**Convening national consultation on HCV infections among young persons who inject drugs.** In response to the emerging epidemic of HCV infection among young PWID documented in recent years in both rural and suburban settings, OHAIDP, CDC, NIDA, and SAMHSA collaborated to plan and convene a multidisciplinary technical consultation to discuss the existing evidence and to identify and define priorities for a comprehensive public health response. During the consultation, federal agency representatives, state health department officials, researchers, care providers, staff of community-based organizations, and other experts in the field shared presentations on key facts about the epidemiology of HCV infection among this population, the state of current research, and examples of innovative community responses to address this emerging issue. The participants explored factors fueling the epidemic and made recommendations about priorities for epidemiology and surveillance initiatives, prevention and care interventions, and research questions designed to curb the rising rate of HCV among young PWID in the United States. To further heighten awareness of this evolving epidemic and engage partners from across all sectors of society, OHAIDP produced and disseminated [a summary of the presentations and the groups' recommendations for key public health actions](#).

**Expanding efforts to address new HCV cases among young PWID.** CDC began a study in rural Wisconsin to better understand emerging clusters of HCV infections among young PWID in rural settings. This project expands CDC's efforts and research findings from a similar investigation in upstate New York, in which DVH assisted both the New York State Department of Health and the Cortland County Health Department in the investigation of an increase in new HCV infections in Cortland County, New York, among young PWID. In addition, CDC continued to provide funding to the Philadelphia Department of Health for a prospective follow up of new cases of HCV infection among young adults.

**Continued and expanded support of HIV/HCV psychology postdoctoral fellowships.** The VHA's HIV, Hepatitis, and Public Health Pathogens Programs, in collaboration with its Office of Academic Affiliations, funded additional postdoctoral fellowships in clinical psychology at five VA Medical Centers in 2013, in Long Beach, California; Miami, Florida; Providence, Rhode Island; Washington, District of Columbia; and West Haven, Connecticut. These joined the existing four sites at Houston, Texas; Jackson, Mississippi; San Francisco, California; and Seattle, Washington. This fellowship emphasizes the behavioral, mental health and substance use treatment of veterans with HIV and/or hepatitis C infection and the training of psychologists in this increasingly critical area to support the growing need within the VA to successfully treat veterans with HCV and care for veterans with HIV, as well as expand available mental health expertise within the system. Addressing the significant psychiatric needs of these patient populations promotes health, wellness, successful treatment, and disease management. Fellows receive specialty training in management of mental health aspects of HIV, HCV, and substance use disorders, as well as up to 20 percent protected time for research (depending on the site).

**Treating prisoners for hepatitis C in federal prisons.** In 2013, FBOP continued its HCV treatment initiative approving 250 patients for HCV treatment with boceprevir or telaprevir. Clinical pharmacy consultants reviewed treatment requests, monitored ongoing treatment, and collected data on patient outcome results. In addition, to inform policy and practice, FBOP collected and analyzed retrospective data on HCV treatment outcomes for patients with genotype 1 who were given dual therapy (peginterferon and ribavirin) in 2011 and began preparing the data and a manuscript for publication in a peer-reviewed journal.

**Funding research to improve HCV services for PWID.** In 2013, NIDA continued to support four major research studies on HCV among PWID. These research studies focus on clinical and treatment issues for PWID. Additionally, NIDA funded laboratory research on developing screening tests for HCV, which is critical for identifying HCV-positive PWID who are unaware of their status. NIDA also funded research using mathematical modeling of HIV/HCV co-infection that is being used to generate evidence to support optimal screening and treatment guidelines for PWID. Lastly, NIDA supported clinical studies examining the efficacy and practicality of providing rapid HCV, syphilis, and HIV testing kits at point-of-care clinics to improve medical care for PWID.

## Progress Addressing the Action Plan's Fifth Priority Area

*By Elinore McCance-Katz, M.D., Ph.D., Chief Medical Officer, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services*

Viral hepatitis is a major comorbidity among persons who inject drugs. It has been estimated that 11 percent of PWID are infected with hepatitis B and 64 percent are infected with hepatitis C.<sup>1</sup> It is also important to note the evolving epidemiology of hepatitis C in the United States, which includes increased HCV in young people who inject heroin and who initiated opioid use with prescription opioid analgesics.<sup>22</sup> In addition, other drug and alcohol use behaviors are also associated with viral hepatitis infection due to related high-risk behaviors. In the context of intoxication, risky behaviors, such as injection by those who do not regularly inject or engaging in high-risk sexual behaviors that can also result in viral hepatitis transmission, underscore the need to enhance our outreach, prevention, screening, and treatment efforts with all drug users.

To achieve the goals of the VHAP, we must reduce viral hepatitis associated with drug use behaviors as detailed in the Action Plan's fifth priority area. Prominent themes in priority area five include the development and implementation of prevention interventions to reduce the incidence of viral hepatitis and working to ensure that people who use drugs have access to treatment for both viral hepatitis and substance use disorders. The overarching goal of this priority area is to bring together federal and community partners and other key stakeholders to develop new, effective strategies for addressing viral hepatitis among drug users. Federal agencies have come together to develop new approaches, to construct a foundation that can be built upon, going forward, for viral hepatitis prevention, screening, testing, and treatment where necessary.

This foundation begins with improving the science and our understanding of what works to prevent, diagnose, care for, treat, and cure viral hepatitis in people who use drugs. To that end, colleagues at NIH, with NIDA leading the charge, are advancing research to inform improvements in HCV services for this important population.

An effective model, integrated care has been shown to have promise in providing for the multiple needs of patients in a single clinical setting. As part of the VHAP, SAMHSA, HRSA, and CDC have undertaken programs that integrate treatment of mental and substance use disorders with primary care. Building on this, SAMHSA developed a new model of collocation, where primary and HIV care are integrated into substance abuse and community mental health treatment programs. This pilot requires that a mandatory percentage of funds be utilized for viral hepatitis screening, testing, and vaccination, emphasizing the importance of viral hepatitis care in populations with substance use

<sup>1</sup>Rosenberg SD, Goodman LA, Osher FC, et al. Prevalence of HIV, hepatitis B, and hepatitis C in people with severe mental illness. *American Journal of Public Health*. 2001;91:31–37.

<sup>2</sup>Klevens RM, Hu DJ, Jiles R, et al.: Evolving epidemiology of hepatitis C virus in the United States. *Clinical Infectious Diseases*. 2013;55(Suppl 1):S3–S9.

**Priority 5:** Reducing Viral Hepatitis associated with Drug-Use Behaviors

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disorders and HIV. Another exciting outgrowth of integrated care is the development of new training materials for behavioral health providers on viral hepatitis, including treatment options. Similarly, clinical training programs developed by SAMHSA, and implemented by HRSA, CDC, and IHS will provide physicians with the knowledge/training needed to obtain a DOJ Drug Enforcement Administration waiver to provide office-based treatment of opioid dependence using buprenorphine.

These projects demonstrate only a few of the many innovative approaches being developed and implemented through ongoing partnerships between stakeholders and federal agencies in the service of those who have great clinical need but have traditionally been marginalized and unable to access essential treatment services. Through these and other initiatives, we aim to reduce the spread of viral hepatitis associated with drug use behaviors and realize the VHAP's goals.



## Priority 6 Protecting Patients and Workers from Health Care-Associated Viral Hepatitis

### GOALS

- 6.1 Reduce transmission of viral hepatitis to patients resulting from misuse of medical devices and drugs.**
- 6.2 Reduce iatrogenic transmission of viral hepatitis associated with blood, organs, and tissues.**
- 6.3 Reduce occupational transmission of viral hepatitis.**
- 6.4 Enhance understanding of the preventable causes of viral hepatitis transmission in health care settings.**

Health care-associated viral hepatitis infections are much less common today than in decades past, before the routine screening of blood and the implementation of universal precautions. However, there remain opportunities to further reduce health care-associated transmission of viral hepatitis and ensure safety. Collaboration between the public and private sectors is critical to the success of educational campaigns, the consistent and comprehensive implementation of infection control practices, and the identification and investigation of suspected outbreaks as we strive to eliminate the risk of health care-associated viral hepatitis for patients and health care providers.

In 2013, the following were among the actions taken by federal partners to protect patients and workers from health care-associated viral hepatitis.

**Educating and promoting safe injection practices.** Throughout 2013, efforts continued to ensure patients are protected each and every time that they receive a medical injection. These include the [One & Only Campaign](#), a public health effort to eliminate unsafe medical injections by raising awareness of safe injection practices. The campaign was developed by the Safe Injection Practices Coalition, a partnership of health care-related organizations, patient advocacy organizations, industry partners, and other public health partners led by CDC. From June 2011 to June 2013, the Campaign offered a Medscape continuing medical education activity titled “Unsafe Injection Practices: Outbreaks, Incidents, and Root Causes,” which garnered more than 89,000 page views and served more than 58,000 learners and nearly 26,000 test takers. In 2013, the One & Only Campaign enhanced provider education by urging all health care professionals to know the difference between [single-dose and multiple-dose vials](#). The Campaign created a dynamic infographic that guides health care providers through the safe use of vials from various perspectives—providers, office managers, and patients—and concludes with a brief quiz to test the knowledge of medication vials.

**Enhancing blood transfusion safety.** In the past year, FDA has encouraged the development of increasingly sensitive tests for hepatitis B and C in blood donations to further reduce transfusion transmitted hepatitis. These tests are expected to become available in the coming years.

**Issuing updated guideline for reducing HIV, HBV, and HCV through organ transplantation.** In June 2013, HHS issued the updated U.S. Public Health Service (PHS) “PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation.” Published in *Public Health Reports*, the updated guideline recommends use of more sensitive tests so that patients can be informed of risks to the greatest extent possible and protected from unintentional infections caused by transplanted organs. The updated guideline is the result of the deliberations of an HHS-wide multidisciplinary workgroup. That group included transplant and infection prevention experts who conducted a systematic review of the best available evidence on reducing HIV, HBV, and HCV infection transmitted through organ transplantation. Subsequent to the release of this updated guideline, under direction of HRSA Division of Transplantation in fall 2013, the Organ Procurement and Transplantation Network (OPTN) began developing recommendations for revisions to current OPTN policies related to testing organ donors to be consistent with updated PHS guideline. OPTN’s goal is to promote transplant patient safety through updated policies that are consistent with PHS recommendations for testing organ donors and transplant candidates and recipients for hepatitis and HIV. This policy revision process will continue in 2014.

**Enhancing understanding of the preventable causes of health care-associated viral hepatitis.** In 2013, CDC updated their website with new resources: [Healthcare-Associated Hepatitis B and C Outbreaks Reported to the Centers for Disease Control and Prevention \(CDC\) in 2008–2013](#) to share information on known outbreaks and a [health care investigation guide](#) for use by state and local health departments to investigate possible health care-associated viral hepatitis transmission events, particularly those involving a single patient. Investigation of these single cases is an important public health response, as it can result in the identification of an outbreak or unsafe clinical practices that are putting additional patients at risk. Additionally, a [Patient Notification Toolkit](#) was developed and made available on the CDC website in 2013. This resource is intended to be used after a health department or health care facility decides to notify patients of their potential exposure to infectious organisms due to an unsafe practice or infection control breach. It offers resources and template materials to facilitate the notification process as well as essential tips and strategies.



## Looking Forward to a Promising Future

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This report reflects only a sample of the myriad activities undertaken by federal stakeholders in 2013 to help advance the Viral Hepatitis Action Plan's national goals. Together with a host of important efforts pursued by nonfederal stakeholders, these activities have strengthened the foundation for continued efforts to improve viral hepatitis prevention, diagnosis, care, and treatment across the United States.

Perhaps the most significant 2013 accomplishment was the decision by all federal partners engaged in the Viral Hepatitis Action Plan to re-commit to another 3 years of focused collaborative activity and the subsequent work to draft an updated action plan. Over the course of 2013, federal partners reflected on the progress of their agencies and offices and began considering strategic actions they could undertake from 2014 through 2016, independently and in partnership with other federal and nonfederal stakeholders, to move closer toward achieving the national goals. Importantly, we gathered critical feedback from nonfederal stakeholders that informed the development of a host of recommended actions for the coming years.

By the end of 2013, the updated Viral Hepatitis Action Plan was nearly complete and stakeholders turned their attention to the initial plans for rolling out the updated Action Plan, with an eye toward fostering even greater opportunities for engagement of nonfederal stakeholders. To this end, the [Stakeholder's Workbook](#) was developed to help all stakeholders identify actions they could take to join our national response to the epidemic of viral hepatitis (read more about the updated Viral Hepatitis Action Plan and the Stakeholder's Workbook at [www.aids.gov/hepatitis](http://www.aids.gov/hepatitis)).

This is an exciting time in the field of viral hepatitis. The updated Viral Hepatitis Action Plan (2014-2016) was released in April 2014. It seeks to take full advantage of the confluence of emerging opportunities for even greater progress resulting from the growing awareness of viral hepatitis—particularly among disproportionately impacted populations and those who serve them. The plan reflects the promise of effective hepatitis C treatments, and new recommendations regarding screening for hepatitis B and hepatitis C, as well as the expansion of access to viral hepatitis prevention, care, and treatment offered by the Affordable Care Act.

Much has been accomplished since the 2011 release of *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis*, the nation's first comprehensive plan to respond to viral hepatitis. Through partnerships inside and outside of government, we are finally breaking the silence on viral hepatitis.

## Appendix A. Citations of Publications by Priority Area

### Priority 1

Klevens RM, Moorman AC. Hepatitis C virus: an overview for dental health providers. *Journal of the American Dental Association*. 2013;144:1340–1347.

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## Priority 6

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## Appendix B. Abbreviations

AAPCHO	Association for Asian Pacific Community Health Organizations
AETC	AIDS Education and Training Center (HRSA)
AHRQ	Agency for Healthcare Research and Quality (HHS)
AAPI	Asian-American or Pacific Islander
BPHC	Bureau of Primary Health Care (HRSA)
CDC	Centers for Disease Control and Prevention (HHS)
CDER	Center for Drug Evaluation and Research (FDA)
CMCS	Center for Medicaid and CHIP Services (CMS)
CMS	Centers for Medicare & Medicaid Services (HHS)
CSAP	Center for Substance Abuse Prevention (SAMHSA)
DAA	direct-acting antiviral
DOJ	U.S. Department of Justice
DVH	Division of Viral Hepatitis (CDC)
ECHO	Extension for Community Healthcare Outcomes
EHR	electronic health record
FBOP	Federal Bureau of Prisons (DOJ)
FDA	Food and Drug Administration (HHS)
HAV	hepatitis A virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HEV	hepatitis E virus
HHS	U.S. Department of Health and Human Services
HIT	health information technology
HRSA	Health Resources and Services Administration (HHS)
HUD	U.S. Department of Housing and Urban Development
IHS	Indian Health Service (HHS)
IOM	Institute of Medicine
LGBT	Lesbian, Gay, Bisexual and Transgender
MSM	men who have sex with men
NCD	national coverage determination

NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NIH	National Institutes of Health (HHS)
NVPO	National Vaccine Program Office (HHS)
OHAIDP	Office of HIV/AIDS and Infectious Disease Policy (HHS)
OMH	Office of Minority Health (HHS)
ONDCP	White House Office of National Drug Control Policy
OPTN	Organ Procurement and Transplantation Network
OWH	Office on Women's Health (HHS)
PHBPP	Perinatal HBV Prevention Program (CDC)
PHS	U.S. Public Health Service
PWID	people who inject drugs
RHA	Regional Health Administrator
RRNP	Regional Resource Network Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SCAN	Specialty Care Access Network
TCE-HIV	Targeted Capacity Expansion-HIV
TTCP	Telehealth Training Centers Program
USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
VHA	Veterans Health Administration (VA)
VHAC	Viral Hepatitis Action Coalition
VHAP	Viral Hepatitis Action Plan
VHIG	VHAP Implementation Group



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