



FEDERAL IMPLEMENTATION PROGRESS REPORT

The Action Plan for
the Prevention,
Care & Treatment
of Viral Hepatitis



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

2015

This report was prepared under the direction of the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), the Office of the Assistant Secretary for Health (OASH), and the 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 U.S. Department of Veterans Affairs, the U.S. Department of Justice’s Federal Bureau of Prisons (FBOP), and the U.S. Department of Housing and Urban Development (HUD). The report was developed under contract #HHSP233201400468G and finalized under contract #HHSP233201600350G.

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Letter From the Director

Since the release of our nation's first Viral Hepatitis Action Plan in 2011, agencies and offices from across the U.S. Department of Health and Human Services and partners from the U.S. Departments of Justice, Housing and Urban Development, and Veterans Affairs have sharpened their focus on viral hepatitis prevention and on improving the care and treatment provided to people diagnosed with chronic hepatitis B and hepatitis C. Building upon the progress achieved under that original Action Plan, a renewed plan was developed and released in 2014, detailing additional strategic actions to be undertaken through 2016. As this 2015 annual progress report demonstrates, our national progress continues.

Despite these efforts, however, some indicators are getting worse, we are not seeing progress on others, and still too many people are falling through the cracks. We are missing key opportunities to prevent disease, diagnose people, treat them, and save their lives; if we do not act now, things will only continue to get worse. With an estimated 4.4 million Americans infected, the number of new hepatitis C infections increasing by close to 300 percent from 2010-2015, and approximately 20,000 preventable viral hepatitis-related deaths occurring each year, we must intensify our efforts.

I commend and thank my colleagues from across the participating federal agencies who actively responded to the Action Plan's ambitious call to action for better education, treatment, and prevention and who have all been working to implement the strategies detailed in the Plan. The progress highlighted in this report strengthened the foundation on which we built the [National Viral Hepatitis Action Plan \(2017–2020\)](#), the current roadmap for our national response to hepatitis B and C, infectious diseases that continue to affect millions of Americans from all walks of life.

This report highlights examples of important work by federal partners—both individually and in collaboration with each other—as well as many activities undertaken collaboratively with a variety of stakeholders in communities across the nation. Given its federal focus, however, this report does not address the many incredibly important actions that [nonfederal agencies and organizations also undertook in 2015](#) to help advance us toward our national viral hepatitis goals. We are grateful for the contributions toward our national progress by those state and local health departments, healthcare providers and systems, community-based organizations, researchers, and others. Federal action by itself will not get us to our goals; it will require all of us doing our part.

We now have the knowledge and tools to save lives and win the fight against viral hepatitis and, as this report indicates, we continue to make progress each year in our nation's response. The National Viral Hepatitis Action Plan is our battle plan that puts us on the path to eliminate viral hepatitis in the United States. We must not let up on our commitment to this fight, and we must continue to pursue it vigorously until we have achieved our goals.

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BACKGROUND

Originally released in 2011, and updated in 2014, the Action Plan for the Prevention, Care & Treatment of Viral Hepatitis (Action Plan) was developed to raise awareness of the silent epidemic of viral hepatitis in the United States. The current version of the plan spans 2014 to 2016 and details more than 150 actions to be undertaken by federal agencies and offices across the U.S. Department of Health and Human Services (HHS) and partners at the U.S. Department of Housing and Urban Development, the U.S. Department of Justice's Federal Bureau of Prisons, and the U.S. Department of Veterans Affairs. All of these actions contribute to improving the prevention, diagnosis, and treatment of viral hepatitis in the United States.

According to the Centers for Disease Control and Prevention, an estimated 4.4 million Americans are living with viral hepatitis. Most people with chronic hepatitis B virus (HBV) or hepatitis C virus (HCV) do not have symptoms until the later stages of the infection, at which point significant liver damage may be present. As a result, many Americans living with viral hepatitis do not know they are infected or that they are at risk for serious liver disease, liver cancer, and even death. The development, updating, and implementation of the Action Plan has brought increased attention to both the burden of viral hepatitis and to the numerous opportunities to halt its growing impact in communities across the nation. The Action Plan has enabled further collaboration, resulting in advances in:

- ❖ Addressing Institute of Medicine recommendations for viral hepatitis prevention, care, and treatment;
- ❖ Setting forth actions to improve viral hepatitis prevention and ensuring that infected persons are identified and provided with quality care and treatment; and
- ❖ Improving coordination of all activities related to viral hepatitis across the federal government and promoting collaborations with state, tribal, local government agencies, and nongovernmental organizations.

In support of the efforts across HHS and its partners to implement the Action Plan, the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) convenes a Viral Hepatitis Implementation Group (VHIG) charged with coordinating, supporting, and monitoring activities related to the Action Plan. The VHIG is chaired by Dr. Richard Wolitski, Director of OHAIDP, and members include representatives from across HHS and other federal agencies and departments. VHIG members meet regularly during the implementation of the Action Plan and serve as representatives within their respective agencies and offices on matters related to viral hepatitis.

This progress report is an outcome of their collaborative federal efforts to implement activities to address viral hepatitis. Read more about the Action Plan, progress reports, and updates at <https://www.hhs.gov/hepatitis>.

INTRODUCTION

OHAIDP is charged with coordinating implementation of the Action Plan. In support of this charge, it has compiled several key accomplishments under each of the Action Plan's six priority areas:

1. Educating Providers and Communities to Reduce Health Disparities,
2. Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer,
3. Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease,
4. Eliminating Transmission of Vaccine-Preventable Viral Hepatitis,
5. Reducing Viral Hepatitis Caused by Drug Use Behaviors, and
6. Protecting Patients and Workers from Health Care-Associated Viral Hepatitis

These highlights were reported by the federal partners engaged in implementing the Action Plan and reflect a sampling of the numerous activities that partners undertook during 2015.

This report features examples of the tremendous work by federal partners as well as many activities undertaken collaboratively with a variety of stakeholders, such as:

Supporting capacity-building among HBV coalition partners;

- ❖ Promoting viral hepatitis training and technical assistance for health centers and other healthcare providers;
- ❖ Increasing participation in the annual observances of Hepatitis Awareness Month in May and World Hepatitis Day on July 28;
- ❖ Developing culturally and linguistically appropriate materials for communities experiencing high rates of chronic viral hepatitis (including African Americans, American Indians/Alaska Natives, and Asian Americans and Pacific Islanders);
- ❖ Supporting the development of testing and linkage to care programs; and
- ❖ Further exploring the use of new HCV therapies in special populations and HBV therapies to reduce perinatal transmission.

A common theme across the field of viral hepatitis is the need for additional evidence to guide policy and practice at every level. Throughout 2015, federal partners made important contributions to addressing gaps in our understanding of the prevention, care, and treatment of viral hepatitis through peer-reviewed journal articles, as well as the development of reports and other technical documents. These publications help to advance efforts to develop and implement evidence-based programs, clinical services, and policies; they are compiled in Appendix A and described throughout this report.

All of the aforementioned 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; and
- ❖ Elimination of mother-to-child transmission of HBV.

FEDERAL PARTNERS IN IMPLEMENTING THE ACTION PLAN FOR THE PREVENTION, CARE, AND TREATMENT OF VIRAL HEPATITIS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

- ❖ Agency for Healthcare Research and Quality (AHRQ)
- ❖ Center for Faith-Based and Neighborhood Partnerships (CFBNP)
- ❖ 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 (OASH)
 - National Vaccine Program Office (NVPO)
 - Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)
 - Office of Minority Health (OMH)
 - Office of Population Affairs (OPA)
 - Office of the Surgeon General (OSG)
 - 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)

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

- ❖ Office of Community Planning and Development (CPD)

U.S. DEPARTMENT OF JUSTICE (DOJ)

- ❖ Federal Bureau of Prisons (FBOP)

U.S. DEPARTMENT OF VETERANS AFFAIRS (VA)

- ❖ Veterans Health Administration (VHA)

WHITE HOUSE

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

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PRIORITY AREA 1: Educating Providers and Communities to Reduce Health Disparities

Goals

- 1.1 Build a U.S. healthcare 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.

Everyone has a role to play in the national response to viral hepatitis and the fight against hepatitis stigma and discrimination. Activities that support engagement across communities help break the silence around viral hepatitis and educational campaigns that raise awareness and encourage testing for those at risk are critical elements of a comprehensive response to viral hepatitis. Equally important is the training and capacity-building support for healthcare providers which will ensure that those who need care and treatment can get it, and that those who experience hepatitis-related discrimination can learn how to seek federal protection.

The following actions were among those undertaken by federal partners in 2015 to build a strong workforce of providers trained to diagnose and manage viral hepatitis and educate communities.

Enhancing public educational materials for viral hepatitis. In 2015, the Centers for Disease Control and Prevention (CDC) released the third phase of the [Know More Hepatitis C](#) national education campaign designed to encourage people born from 1945 to 1965 to get tested for HCV. This initiative supports CDC's overall efforts to improve HCV testing, linkage to care, and treatment. The campaign has garnered more than 6.7 billion audience impressions, worth an estimated \$23 million of media time.



Increasing public awareness. Many federal partners took steps to increase public awareness and education about viral hepatitis.

- ❖ National Institutes of Health (NIH) Institutes and Centers promoted on their websites events such as Hepatitis Awareness Month, Hepatitis Testing Day, and World Hepatitis Day. They also provide educational materials on viral hepatitis to the public through the websites for [National Institute of Allergy and Infectious Diseases \(NIAID\)](#) and [National Institute of Diabetes and Digestive and Kidney Diseases \(NIDDK\)](#), among others.

- ❖ U.S. Department of Housing and Urban Development's (HUD's) Office of Special Needs Assistance Programs distributed a Hepatitis Awareness Month message to more than 30,000 individuals via its listserv to grantee and staff networks, reinforcing the association between homelessness and increased risk for viral hepatitis and providing information about resources and how to get more involved in raising awareness.
- ❖ Substance Abuse and Mental Health Services Administration's (SAMHSA's) Center for Substance Abuse Treatment released a Dear Colleague Letter to certified outpatient treatment programs about hepatitis awareness and National Hepatitis Testing Day.
- ❖ The U.S. Department of Veterans Affairs (VA) Viral Hepatitis Community Advisory Board worked to advocate, increase knowledge, raise awareness, and empower patients affected by HCV. This work was accomplished through better education, awareness, training and commitment to improve treatment, communications, and information through patients, providers, national service, and community organizations.
- ❖ VA supported HCV awareness campaign during the month of May 2015, which included HCV testing outreach across the VA's healthcare system with a focus on increasing awareness among homeless veterans.
- ❖ HCV was the subject of the national radio show Native America Calling twice in 2015, which featured Indian Health Service (IHS) official representation.

Increasing community engagement in viral hepatitis observances. July 28, 2015 marked the fifth annual World Hepatitis Day, an opportunity to raise awareness about viral hepatitis, share successes, and continue work toward improved access to treatment, better prevention programs, and focused government action. The event, hosted by OHAIDP in partnership with the White House Office of National AIDS Policy (ONAP) and Office of National Drug Control Policy (ONDCP), featured remarks from then-Acting Assistant Secretary for Health Dr. Karen DeSalvo, followed by three panels. The first panel discussion underscored the White House's commitment to addressing viral hepatitis with ONAP, ONDCP, and the White House Initiative on Asian Americans and Pacific Islanders (WHIAAPI). The second panel, featuring CDC, Food and Drug Administration (FDA), IHS, and VA highlighted federal agency activities on viral hepatitis. The third panel provided perspectives on viral hepatitis from state and national partners, including the National Viral Hepatitis Roundtable, Massachusetts Department of Public Health, Hep B Foundation, and the Association of Asian Pacific Community Health Organizations. OHAIDP worked with federal and community partners to broadly disseminate the live stream invitation via social media. In addition to the approximately 90 in-person participants, close to 400 viewers joined the observance via webcast.

Strengthening HCV efforts in African American communities. In March 2015, OHAIDP convened a two-day forum focused on strengthening the response to HCV in African American communities and included participation from more than 30 organizations from across the country. Federal and African American community leaders, including media, presented on the impact of HCV in African American communities and identified strategies, best practices, gaps, and specific opportunities to increase engagement and awareness of the importance of HCV prevention, diagnosis, care, and treatment. To support the participation and engagement of many partners, the [HHS Forum on Hepatitis C in African American Communities report](#) was released

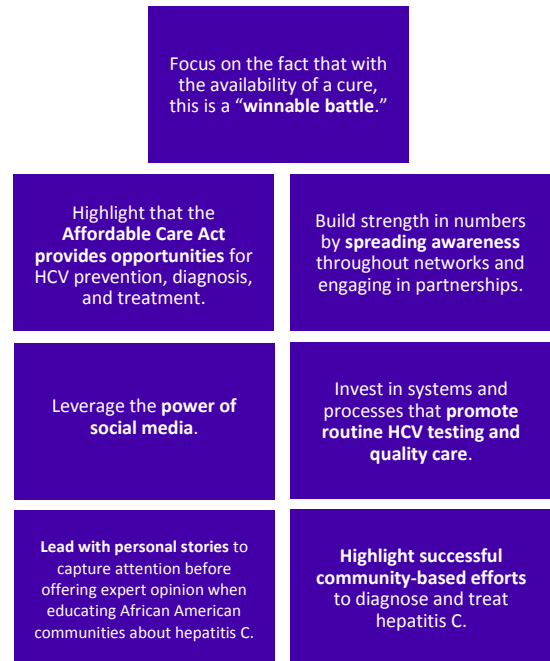
that included themes and strategic considerations that all stakeholders can use to address the important health disparity of HCV among African Americans in the United States.

Supporting health centers in addressing viral hepatitis. In May 2015, to coincide with Hepatitis Awareness Month, the Health Resources & Services Administration (HRSA) launched a viral hepatitis [webpage](#) on the Bureau of Primary Health Care (BPHC) website that offers quick links to guidelines and recommendations on screening, vaccination, and treating patients with HBV and HCV along with links to patient education materials as well as training resources for clinicians.

Disseminating training and technical assistance opportunities. HRSA’s BPHC worked closely with HHS operating and staff divisions, national partners, and key stakeholders to promote viral hepatitis training and technical assistance opportunities (e.g., webinars, publications, tools) for Health Center Program participants. Through the weekly Primary Health Care Digest, with a distribution list of over 18,000 contacts, BPHC distributed relevant updates, announcements and training opportunities.

HRSA’s BPHC supports the provision of training, technical assistance, and information dissemination to health centers through its [National Cooperative Agreements](#) partners. Partners that worked to address HBV and HCV in 2015 include: the Association of Asian Pacific Community Health Organizations, the National LGBT (Lesbian, Gay, Bisexual and Transgender) Health Education Center, and The National Center for Farmworker Health. Examples of specific activities and resources are listed below:

- ❖ The Association of Asian Pacific Community Health Organizations (AAPCHO) supports health centers in addressing the healthcare needs of Asian Americans, Native Hawaiians, and other Pacific Islanders. Given the disproportionate burden of HBV in this community, AAPCHO provided direct training and technical assistance to health centers around HBV on an ongoing basis in addition to providing national webinars and toolkits. Specific activities included a [webinar](#), “Strategies in Implementing USPSTF Hepatitis B Recommendations,” detailing the U.S. Preventive Services Task Force (USPSTF) screening guidelines for HBV, implementation strategies, and how two health centers are addressing HBV screening; and the development of a provider [checklist](#), “Checklist for Hepatitis B Services and Resources Within your Health Center,” to assist clinicians in assessing the HBV services and resources their health centers provide and what additional services could be added.
- ❖ The National LGBT Health Education Center sponsored a national [webinar](#), “New Era in HCV Management: Primary Care Innovations,” discussing the role primary care can play in HCV screening and management, current recommendations for treatment in HCV



mono-infected and HCV-HIV co-infected individuals, and how to overcome challenges of integrating HCV into health centers and other primary care settings.

- ❖ The National Center for Farmworker Health produced Hepatitis Focused Health Tips/Consejos de Salud, which is a bilingual, quarterly [publication](#) that focuses on health topics and issues prominent to the farmworker and the general Hispanic population. It makes use of low-literacy and culturally appropriate terminology to present the latest, most updated information on health topics.

Sharing viral hepatitis strategies and successes across jurisdictions. OHAIDP launched the Viral Hepatitis Prevention Coordinators (VHPCs) spotlight blog series on AIDS.gov in April 2015. The series was designed to showcase the work of the CDC-funded Viral Hepatitis Prevention Coordinators and help disseminate best practices and strategies being used by state and local health department staff toward achieving the goals of the Action Plan. Blogs describe innovative strategies in prevention, testing, care, and treatment; unique partnerships; and other creative opportunities being implemented by Viral Hepatitis Prevention Coordinators, including those in [Hawaii](#) and [New York](#).

Enhancing hepatitis C outreach to public health professionals. OHAIDP, CDC, and Office of Minority Health (OMH) convened a [special session](#) at the American Public Health Association Annual meeting, in November 2015. The session, [*The Changing Epidemiology of Viral Hepatitis: Hepatitis C Emerging Trends and Disparities*](#), provided attendees of the largest national public health meeting with highlights of the latest viral hepatitis epidemiology, the impact of HCV among African Americans, and the way forward as we implement the Action Plan.

The following table contains highlights of additional activities to train and educate health professionals conducted during 2015.

Agency or Office	Health Professional Training and Education Activities
CDC	University of Alabama at Birmingham's National Hepatitis Training Institute (a CDC grantee) developed a free educational, six-module web-based resource for health professionals to improve understanding of viral hepatitis prevention, diagnosis, management, and treatment.
HRSA	Throughout 2015, HRSA-funded AIDS Education and Training Centers continued to provide clinical training and clinical consultation on HBV and HCV for co-infected people living with HIV, including Partnerships for Care (P4C) co-infection webinars .
HUD	HUD's Office of Special Needs Assistance Programs and the Office of HIV/AIDS Housing, in collaboration with the U.S. Interagency Council on Homelessness and HHS, made available remote and onsite technical assistance focused on improving program participant access and effective use of mainstream healthcare services at the systems level. These efforts are designed to ensure effective coordination of linkages between housing and healthcare services to maximize care coverage and increase access to comprehensive health care and supportive services. This technical assistance is available to grantees, sub-recipients and project sponsors of the following programs: Continuum of Care (CoC), Emergency Solutions Grants (ESG), and Housing Opportunities for Persons with AIDS (HOPWA).
HUD	HUD's Office of Special Needs Assistance Programs began assessing available health education materials on viral hepatitis targeted for homeless individuals and homeless assistance providers by reaching out to local public health departments, healthcare providers that care for homeless individuals, and grantees. HUD also asked CoC, ESG, and HOPWA grantees, and their partners to share training resources and community- and program-level promising practices being used to prevent, test, and/or treat infectious diseases, such as viral hepatitis, tuberculosis, and HIV/AIDS.
IHS	Training to clinicians and facilities was provided in 2015 via multiple national webinars (Grand Rounds), more than 40 site visits, and in-person trainings via partnerships with academic institutions (University of California, San Francisco and the University of New Mexico). Telehealth clinics on HCV occur several times a month, and an increasing number of IHS sites are participating. Multiple, national, web-based trainings for patient benefits coordinators and pharmacists on patient assistance programs were also completed.

Agency or Office	Health Professional Training and Education Activities
HHS Regional Health Offices	<p>Under the directions of the Regional Health Administrators, the Regional Resource Consultants (RRCs) established ongoing communication and partnerships with state health departments' VHPCs to obtain information on viral hepatitis activities/events, data and resources. RRCs participated in numerous community events to provide HIV/HCV education about the benefits of viral hepatitis prevention, care, and treatment.</p> <p>For example, RRC in Region IV hosted regional HIV/HCV meetings, and, to ensure healthcare providers' participation, established a partnership with the Southeast AIDS Education and Training Center to provide continuing medical education credits.</p>
SAMHSA	<p>SAMHSA's Center for Substance Abuse Prevention (CSAP) provides viral hepatitis and HIV prevention training via webinars and other educational efforts to community-based organizations. In particular, trainings were provided to CSAP's grantees that are already providing HIV/AIDS and other infectious disease prevention services. Webinar attendees learned about the benefits of educating providers and communities about infectious disease to improve screening, counseling, treatment, and vaccination in various programs.</p>
SAMHSA	<p>SAMHSA provided education to providers in high-risk communities and on college campuses on the benefits of viral hepatitis prevention, care, and treatment using evidence-based programs, practices, and strategies, including environmental strategies and social media campaigns.</p> <p>SAMHSA updated professional education programs, materials, and tools addressing known gaps and needs concerning the prevention of viral hepatitis, identification of infected persons, and provision of care and treatment.</p>
VA	<p>VA developed new provider education materials distributed through the Internet and intranet and revised older provider education materials.</p> <p>Several VA regional and local Hepatitis Innovation Teams developed or expanded Extension for Community Healthcare Outcome models for providers in rural areas, clinics in urban areas without sufficient treatment providers, and others outside of specialty HCV care to expand the scope of HCV treatment across the system.</p>

PRIORITY AREA 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. infected persons.

Hepatitis B and C are silent and deadly diseases, often without symptoms, and viral hepatitis is a leading cause of liver cancer in the United States. Today, we have the knowledge and tools to save lives and win the fight against viral hepatitis. Ensuring that prevention, education, and testing efforts are reaching those who need them will help turn the tide on viral hepatitis and improve health outcomes.

The following actions were among those taken by federal partners in 2015 to improve testing, care, and treatment of viral hepatitis to prevent liver disease and cancer.

Setting a path towards viral hepatitis elimination. Since the Cherokee Nation launched its HCV elimination effort in fall 2015, CDC has provided extensive technical assistance to support the “Path Toward Elimination of HCV” project. Successful completion of this project will improve the health of the Cherokee Nation and also inform similar programs to move toward eliminating HCV infection in other American Indian and non-American Indian populations.

CDC continued to collaborate with the Alaska Native Tribal Health Consortium in a multi-year study that aims to improve efforts to prevent hepatitis A (HAV) and HBV through vaccination and study interventions to reduce mortality and morbidity from chronic HBV and HCV.

Supporting networks and linkages to care. CDC partnered with [Hep B United](#), a national coalition of community-based organizations that work in communities serving Asian Americans who are disproportionately affected by HBV, and the [National Viral Hepatitis Roundtable](#), a national coalition of national and community-based organizations, state health departments, and private industry working on viral hepatitis prevention and control, especially with those disproportionately affected by HCV. These partnerships support CDC’s overall efforts to improve HBV and HCV testing, linkage to care, and treatment as well as support local outreach efforts, including those targeting non-English speakers.

Strategies to Improve the Care Cascade

Several federal agencies undertook activities to improve the HBV and HCV continuum of care with projects that focused on viral hepatitis testing as well as linkage to care and treatment.

Testing

- ❖ In collaboration with CDC, the Office of the National Coordinator for Health Information Technology (ONC) electronically specified three Physician Consortium for Performance Improvement HCV clinical quality measures and developed three sharable electronic clinical decision support artifacts to help providers make appropriate screening recommendations/decisions. This work was completed in January 2016.
- ❖ IHS reported that HCV screening of persons born 1945–1965 has increased 400 percent to a total of 37 percent of this population being screened. This increase is due in part to procedural developments and program support.
- ❖ NIH’s National Institute on Minority Health and Health Disparities (NIMHD) supports a community-based participatory study in Korean churches that examines the effectiveness of two dissemination strategies for implementing the evidence-based HBV intervention in-person training and technical assistance, and e-training and technical assistance of community health workers to increase HBV screening and vaccination rates among Korean Americans. This study was initiated in 2008 and completed in 2017.
- ❖ In 2015, 69.9 percent of the veterans in VA care born between 1945 and 1965 were screened for HCV.

Linkage to Care

- ❖ CDC’s Viral Hepatitis Program, working under a center cooperative agreement, is conducting modeling projects to inform increased testing and best practices for the care cascade.
- ❖ CDC awarded [three Community-Based Programs to Test and Cure Hepatitis, PS14-1413](#), to develop partnerships with primary care clinics to improve testing, linkage to care, and treatment of patients with HCV from September 2014 to September 2018. All awardees have developed provider education programs to train primary care providers on the delivery of HCV-directed services to HCV infected patients. As of February 12, 2016, a total of 114 providers had completed the training programs.
- ❖ CDC conducted HCV birth cohort testing trials as part of the Birth-cohort Evaluation to Advance Screening and Testing for Hepatitis C Studies (BEST-C) at three of the retrospective healthcare centers using variations of the randomized controlled trial design. These interventions evaluated the feasibility and effectiveness of three distinct interventions designed to increase HCV testing and linkage to care. An article on the trials, [Uptake of Hepatitis C Screening, Characteristics of Patients Tested, and Intervention Costs in the Best-C Study](#), was published in the journal *Hepatology*.
- ❖ IHS assisted more than 40 sites with drug access navigation for referrals and linkage to HCV care. An estimated 20 IHS facilities are now treating HCV patients in-house, with telehealth support. Local reports on sustained virologic response (SVR) are limited, but suggest SVR targets are being met.
- ❖ Using a community-based participatory approach, NIH’s NIMHD supports a project conducting needs assessments and focus groups. NIMHD is developing pilot testing of culturally proficient health information technology (HIT) intervention strategies to

improve HBV vaccination, screening rates, and linkages to care among underserved Asian Americans attending a community clinic. This study was initiated in 2013 and completed in 2016.

- ❖ In 2015, 73 percent of Veterans in VA care who had ever been diagnosed with HCV were linked to HCV care. Also in 2015, VA established 19 regional HCV Innovation Teams to work on redesigning care to increase access to HCV testing and treatment through dissemination of strong practices and building high-performing networks.

Integrated HIV/HCV Testing and Linkage to Care

- ❖ HRSA staff enhanced coordination and the availability of federal, state, and community resources in Scott County, IN, to provide linkage to HIV/hepatitis care and prevention services. Through the AIDS Education and Training Center, training was provided to a Scott County based private physician and to the local health department staff on HIV testing, outreach, and case monitoring.
- ❖ HRSA's Ryan White HIV/AIDS Program-funded clinical providers screen, link, and treat people living with HIV who are co-infected with HBV and HCV, in accordance with the national guidelines.
- ❖ HRSA's BPHC, in collaboration with CDC, in support of both HIV and viral hepatitis, funded the [Partnerships for Care \(P4C\) project](#), which is a three-year project awarded in September 2014 to support the integration of high-quality HIV services into primary care through innovative partnerships between the health centers and state health departments. Given the high levels of co-infection among people living with HIV, this project also includes support for HBV and HCV screening and referrals to care. As part of training and technical assistance for this program, a webinar was hosted in October 2015, "Drug Interactions in Managing HIV/HCV Co-Infection."
- ❖ OMH's HIV/AIDS Health Improvement for Re-Entering Ex-Offenders (HIRE) program grantees established partnerships with organizations that provide comprehensive healthcare services, substance abuse and behavioral/mental health treatment programs, education/general equivalency development programs, job placement/training programs, housing assistance, public assistance programs, and family services. HIRE clients are linked into a continuum of care within 30 days. Through systems navigation and case management services, HIRE clients were linked to and retained in a continuum of care within 30 days of testing positive for HIV. Clients are also screened and tested for viral hepatitis and linked to medical treatment. The HIRE Program ended in 2016.
- ❖ OMH's HIV/AIDS Initiative for Minority Men (AIMM) program addresses the unmet needs of young racial and ethnic minority men who have sex with men (MSM) between the ages of 18 and 29 and young minority males living with HIV/AIDS or at high risk for HIV infections. The AIMM grantees have established comprehensive Integrated Centers for Care and Supportive Services to address the gaps and fragmentation of HIV/AIDS treatment, reduce HIV/AIDS stigma and barriers to culturally and linguistically appropriate care, improve clinical outcomes of MSM and young minority males living with HIV or at high risk for HIV infections, and increase screening and testing for HCV and linkage into care. A total of 185 program participants were screened and tested for

HCV and eight individuals tested positive and were linked to care. The AIMM grant project period is September 1, 2014 to August 31, 2017.

Improving Viral Hepatitis Treatment and Cure

Encouraging coverage of HCV medications. In February 2015, HRSA issued a [program letter](#) to Ryan White HIV/AIDS Program Part B AIDS Drug Assistance Programs (ADAP) encouraging the inclusion of new HCV medications (direct-acting antivirals) in the state ADAP formularies.

Increasing treatment options for chronic HCV. In 2015, FDA approved two new regimens for treatment of chronic HCV.

- ❖ Daklinza® (daclatasvir) was approved in July 2015 for use with sofosbuvir to treat HCV genotype 3 infections. Daklinza in combination with sofosbuvir was the first regimen that demonstrated safety and efficacy to treat genotype 3 HCV infections without the need for co-administration of interferon or ribavirin.
- ❖ HARVONI®, a fixed-dose combination of ledipasvir, an HCV NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, was approved in October 2014. It was indicated for the treatment of chronic HCV genotype 1 infection in adults.
- ❖ TECHNIVIE™, a fixed-dose combination containing ombitasvir, paritaprevir, and ritonavir, was approved in July 2015. The product was indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic HCV infection without cirrhosis. TECHNIVIE in combination with ribavirin was the first regimen to treat genotype 4 HCV infections without the need for co-administration of interferon.

Developing HCV treatment guidelines. Staff from the intramural research program of NIH's NIDDK continued to participate in the ongoing development and evolution of clinical guidelines for testing, managing, and treating HCV under the auspices of the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America. These [guidelines](#) are updated every three months.

VA's nationally recognized [Chronic HCV Infection: Treatment Considerations](#) are continually updated to ensure that VA providers have the most current, objective, evidence-based information about HCV treatment regimens, drug interactions, and co-morbidity management to inform high-quality clinical decisions in caring for those living with chronic HCV.

Advancing Research, Knowledge and Tools to Improve Hepatitis Prevention, Treatment, and Cure

Advancing research on hepatitis prevention. In 2015, NIH's NIAID supported research on multiple novel strategies for prevention of viral hepatitis infection. The availability of small-animal models provides an enormous resource to research the pathogenesis, prevention, and treatment of HBV and HCV. Several such models have been developed by investigators funded by NIH's National Cancer Institute (NCI), NIAID, and NIDDK and are being used in studies of

both viral infections. Mice with humanized livers can be infected with HBV or HCV, which allows the study of the early events that occur in the liver during infection that lead to cell injury, recovery, or chronic infection.

Improving HCV testing and diagnosis. CDC's Viral Hepatitis Program completed an evaluation of a commercial HCV core antigen test. The program also conducted studies using MarketScan claims data and national commercial laboratory data to evaluate the impact of screening recommendations and other policies on HCV testing.

Exploring existing diagnostic HCV tests. FDA's Division of Microbiology Devices, Center for Devices and Radiological Health (CDRH), worked with manufacturers of HCV diagnostic tests to consolidate diagnostic and viral load claims for molecular HCV devices. CDRH stressed with manufacturers the need for a dual claim test, and the benefits to laboratories and HCV testing overall.

In October 2015, Roche Molecular Systems, Inc. obtained the first dual-claim HCV RNA assay that can be used for both quantitative (viral load) testing as well as diagnosis for its HCV test on its new Cobas 6800/8800 platform. Subsequently, in February 2016, Roche added the diagnostic claim to its existing HCV real-time viral load assay.

Enhancing liver disease evaluation. A commercial ultrasound elastography system has received FDA approval and is being evaluated prospectively in multiple NIH-funded clinical studies on HCV (intramural NIDDK), HBV (Hepatitis B Research Network, including HIV co-infection), and hepatitis delta virus (HDV) (NIDDK Intramural). Other biomarkers are included in these studies and are compared directly to liver biopsy.

Understanding viral hepatitis progression and liver cancer markers. NIH worked to support and conduct research to better understand the progression of viral hepatitis and improve detection of liver disease and cancer.

- ❖ Intramural researchers at NIH's NIAID, NIDDK, NCI, and the NIH Clinical Center conduct ongoing translational research studies on the molecular mechanisms of pathogenesis of acute and chronic liver disease (with a focus on cirrhosis and hepatocellular carcinoma [HCC]) aimed at investigating the role of hepatitis viruses in liver carcinogenesis. Other ongoing studies include elucidating the role of host and viral factors in hepatitis virus infections, identifying new diagnostic and prognostic biomarkers for HCC, and using large patient cohorts to validate previously discovered predictive markers for the progression of HCV to cirrhosis.
- ❖ NIH's NCI funded 28 projects relating to some aspect of viral hepatitis and HCC. These projects focus on basic science, genetics, biomarker development, and health disparities. For example, NIH's NCI funded two U01 center [grants](#) in 2015 in response to an initiative relating to detection of pathogen-induced cancer. Additionally, in 2015, NCI released two funding opportunities, through the [R01](#) and [R21](#) mechanisms, relating to advancing understanding of the risks, development, progression, diagnosis, and treatment of malignancies in individuals with underlying HIV/AIDS. One of the applications selected for funding through these initiatives focuses on HIV co-infection, aging, hepatitis infection (among other pre-disposing conditions), and the development of HCC.

- ❖ Intramural researchers in NIH's NIDDK developed a cohort of 200 patients with cirrhosis or advanced cirrhosis who will be treated with direct-acting antiviral drugs and followed with biomarkers and advanced imaging for evidence of liver cancer using genomic data.

Advancing approaches to HBV testing and treatment. NIH also supported research focusing on HBV vaccination, screening, and treatment.

- ❖ NIH's NIDDK supports ongoing studies through the [Hepatitis B Research Network](#), which has as its goal to advance understanding of disease processes and natural history of chronic HBV, as well as to identify effective approaches to treatment with currently available therapies. Through partnerships with industry and CDC, this multi-center network initiated two prospective cohort studies, with enrollment of approximately 2,000 patients, and three clinical trials with several supportive ancillary studies. Network investigators target special populations, including infected pregnant women, those with acute HBV infections, individuals co-infected with HDV, and chronically infected individuals experiencing disease flares. The Network also includes a cohort of adult patients with HBV-HIV co-infection that will allow for analysis of the separate contribution of HIV infection to the course and outcome of chronic HBV and will help define the optimal means of managing HBV in patients with HIV co-infection. The NIDDK released an [initiative](#) in 2014 to continue support for projects within the Hepatitis B Research Network, starting in 2015 for up to five years. Funding will continue for the Network through 2020.
- ❖ Hepatitis delta virus infection is a rare but important cause of severe liver disease and cirrhosis in individuals co-infected with HBV; there is currently no effective treatment for HDV. A [pilot clinical trial](#) conducted by scientists in NIH's NIDDK Intramural Research Program, in collaboration with an international group of investigators and the drug sponsor, provided the first evidence that a drug called lonafarnib may be safe and effective as the only dedicated treatment available for chronic HDV. This first human trial shows the promise of lonafarnib as a potentially groundbreaking new type of therapy for chronic HDV. Future studies will explore long-term therapy, dose adjustment, and combination with other drugs to increase the antiviral activity and reduce side effects. This group has initiated and fully enrolled a phase 2 trial of lonafarnib with results expected in 2017; plans are being made for a phase 3 multinational study in 2017–2018.
- ❖ NIH's NIDDK, together with the National Heart, Lung, and Blood Institute (NHLBI) and Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), supported initiatives such as the [New Technologies for Viral Hepatitis Small Business Technology STTR Grant](#) and [New Technologies for Viral Hepatitis Small Business Innovation Research SBIR Grant](#), released in 2015 to encourage small business companies to address viral hepatitis research opportunities. In response to one of these initiatives, NIH's NIDDK and NICHD are supporting a small business innovation research (SBIR) grant, awarded in September 2015, aimed at [developing a therapeutic vaccine for chronic HBV infection](#) that is designed to stimulate immunity strong enough to clear HBV from the body.

Advancing HCV research. NIH undertook a number of research activities addressing HCV treatment options.

- ❖ Two recently completed clinical trials conducted by intramural scientists in NIH's NIAID showed that new drug combinations could improve adherence by offering shorter treatment durations with good tolerability while maintaining excellent cure rates. The [first clinical trial](#), completed with the DC Partnership for AIDS Progress, showed that a 12-week course of the drugs ledipasvir and sofosbuvir cured chronic HCV in 49 of 50 participants and caused no serious side effects. The [second clinical trial](#) achieved HCV cure with a shorter six-week course of therapy of ledipasvir, sofosbuvir, and one of two experimental drugs, GS-9669 or GS-9451. All participants tolerated the treatment well, and all but two participants were cured. A third group of 20 volunteers who received just sofosbuvir and ledipasvir for 12 weeks were also cured. Importantly, the second clinical trial provides [compelling proof-of-concept](#) that two different three-drug regimens resulted in high cure rates after just six weeks.
- ❖ NIH researchers at NIAID and NIDDK have initiated several clinical research studies of oral regimens of therapy for acute and chronic HCV. These studies are focused on high-risk patients in vulnerable populations who are usually not included in industry-supported studies that lead to drug licensure. These populations include the uninsured, recent emigrants from Africa and Asia, racial/ethnic minority populations, persons with advanced liver disease and cirrhosis, and persons co-infected with HIV. Special groups include patients with HCV genotypes 2, 3, and 4; patients with drug-resistant HCV mutations; and patients who are co-infected with HIV ([SWIFT-C](#), A5327, ACTG 5329). Another trial [demonstrated](#) that a 12-week course of ledipasvir and sofosbuvir, a treatment combination that showed promise in those with HCV mono-infection, provided SVR in patients who were co-infected with both HCV and HIV. SVR is the standard measurement of HCV treatment efficacy.
- ❖ NIDDK's Intramural Research Program has an ongoing collaboration with the NIH National Center for Advancing Translational Sciences performing high-throughput screening to identify novel targets and molecules for HCV therapy. They [identified](#) one, a commonly used antihistamine called chlorcyclizine, which also has activity against HCV in cell and animal models. [Studies](#) are underway in humans with HCV with close monitoring for side effects and careful analysis of the effects on HCV levels and potential liver damage.
- ❖ Intramural researchers in NIH's NIAID conducted a case [study](#) of immunosuppression in three HCV patients who have already achieved SVR after treatment with IFN-sparing combinations of direct acting antivirals (DAAs). As the number of patients with HCV receiving host immune-suppressing or immune-modulating therapies during cancer treatment, organ transplantation, and autoimmune disease management grows, understanding the impact of these medications on concomitant HCV treatment outcomes has become important. Because immunosuppression after liver transplantation is a necessity, evaluating the use of DAA to prevent recurrent HCV infection is imperative. In the three patients who received immunosuppressive biologic or chemotherapeutic agents, there was no evidence of viral relapse at least 48 weeks after completion of DAA therapy.

PRIORITY AREA 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 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.

Surveillance and other health data are key components in the consideration of how best to allocate resources to meet the needs of those living with viral hepatitis and work towards combating viral hepatitis through prevention, care, and treatment services. Increased federal efforts in research, monitoring, and reporting have made an impact on surveillance to detect viral hepatitis transmission and disease. However, too many states lack basic resources to effectively track the epidemic and related deaths. While thousands of Americans are infected and even dying from viral hepatitis, current surveillance systems cannot detect all the cases.

The following actions are among those undertaken by federal partners in 2015 to strengthen surveillance to detect viral hepatitis transmission and monitor disease.



Responding to viral hepatitis outbreaks. In response to the HIV outbreak among people who inject drugs (PWID) in Scott County, IN, CDC developed Global Hepatitis Outreach and Surveillance Technology ([GHOST](#)) to assist in the response. Through the use of GHOST, it was revealed that greater than 90 percent of HIV-infected individuals also were previously infected with HCV.

A central coordinating team from across HRSA bureaus and offices and HRSA-Office of Regional Operations Region V staff responded to the outbreak of HIV/HCV in the rural town of Austin, IN, by convening the HHS Operating and Staff Divisions, HRSA offices and bureaus, Indiana State Department of Health, and regional HRSA-funded AIDS Education and Training Center to assess needs related to the outbreak and available resources. The team facilitated ongoing communication with partners and provided ongoing surveillance information to HRSA offices and bureaus about needs and response activities.

Identifying areas at high risk for a hepatitis outbreak. CDC conducted a vulnerability assessment to identify counties that may be at highest risk for an HIV/HCV outbreak caused by unsafe illicit drug injection practices. Subject matter experts from CDC, HRSA, and SAMHSA are available to any jurisdiction that would like to review the findings of the vulnerability assessment or request assistance.

Monitoring and measuring progression along the HCV care cascade. CDC collaborated with partners to identify data sources for federally qualified health centers and develop standardized definitions for the care cascade using secondary data. CDC also collaborated to initiate a monitoring plan for the HCV care cascade. CDC further developed standardized methods and

indicators for measuring progression along the HCV care cascade using a variety of secondary healthcare data sources, including claims and electronic health record data.

Reporting on HCV care quality. VA's HCV quality measures facility report provided VA healthcare facilities with an overview of their HCV quality measure rates in relation to national rates across VA.

Expanding research on perinatal HCV transmission. A multi-center observational [study](#) by NIH's NICHD Maternal-Fetal Medicine Units Network examined risk factors for HCV transmission from mother to baby and risk factors associated with HCV infection in pregnant women. The study describes the outcomes of pregnant women with HCV as well as the outcomes for their infants from birth to 18 months of age. It has enrolled 309 pregnant women with HCV infection and 370 pregnant women without HCV infection as comparison controls. The study aims to enroll 1,800 participants in each group. This study was initiated in 2012 with an estimated completion date of April 2019. Additionally, NIH's NICHD is supported by investigators working on advancing understanding of the immune mechanisms and factors that determine how HCV infection is transmitted from women to their offspring during pregnancy. This [study](#) began in 2014 with an estimated completion date of January 2019.

Exploring HDV diagnostics. CDC validated an in-house nucleic acid test based assay for detection of HDV infection and monitoring of viral load. NIH NIDDK's Hepatitis B Research Network conducted preliminary testing on all the samples in their registry of persons identified with hepatitis B surface antigen (HBsAg) in serum and are currently testing them for HDV RNA.

Considering the role of hepatitis E virus (HEV) infection in liver disease. In collaboration with NIDDK, the NIH Clinical Center's Department of Transfusion Medicine served as the testing laboratory for a study of the role of HEV infection in acute-on-chronic liver disease. Samples were tested from the HALT-C study comparing patients with hepatic decompensation to those with stable chronic liver disease. No temporal relationship was identified between HEV infection and the decompensation event (ascites, bleeding, and encephalopathy). Grants are funded to study anti-HEV rates in several populations, including HIV-infected persons, acute liver failure, acute liver injury attributed to herbal supplements, liver transplant recipients, and persons with HBV participating in the Hepatitis B Research Network.

PRIORITY AREA 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 and hepatitis B vaccination for vulnerable adults.
- 4.3 Design and test new or improved viral hepatitis vaccines and determine the indications for their optimal use.

Elimination of mother-to-child transmission of HBV is possible with currently available tools. We have safe and effective HBV vaccines, but not enough people get vaccinated. Testing all pregnant women and ensuring proper vaccination for infants and adults at risk can prevent infections and unnecessary deaths. After receiving all three doses, the [HBV vaccine](#) provides greater than 90 percent lifelong protection to newborns, infants, children, and adults immunized before being exposed to the virus. Federal partners worked diligently to ensure that elimination of mother-to-child transmission of HBV can become a reality. At the same time, efforts continued to increase vaccination for HAV and HBV, through provider education and engagement, and advance research towards an HCV vaccine.

The following actions are among those undertaken by federal partners in 2015 to eliminate the transmission of vaccine-preventable viral hepatitis.

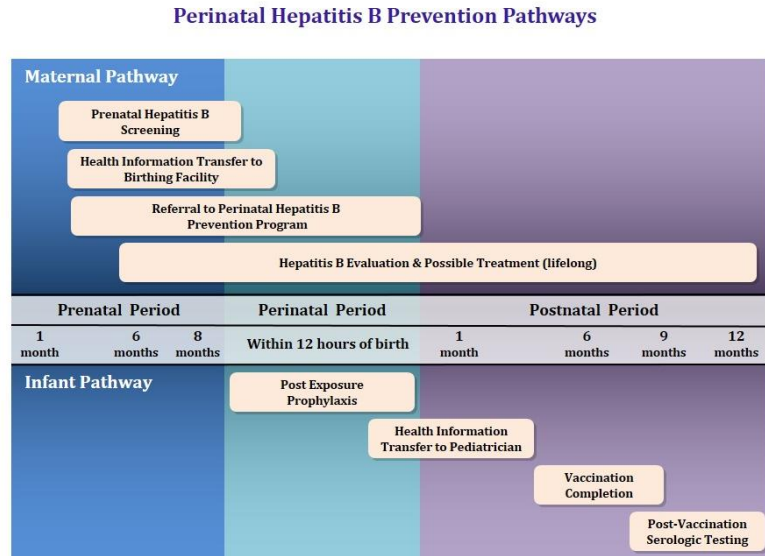
Providing guidance for providers on perinatal HBV screening and referral. In March 2015, CDC and the American College of Obstetrics and Gynecology (ACOG) co-branded an HBsAg screening guide and referral algorithm [tool](#) for pregnant women. The document has also been promoted by Perinatal Hepatitis B Prevention Programs within their jurisdictions, as well as on the [CDC](#) and [ACOG](#) webpages. The document provides guidance for providers on appropriate testing of pregnant women and recommends referral to a specialist during pregnancy for women with abnormal test results.

Enhancing identification of pregnant women with HBV. In September 2015, CDC developed a memorandum to all United States laboratories that offer an HBsAg assay, to recommend reporting of pregnancy status on positive HBsAg test results. The memorandum has been promoted by the Association of Public Health Laboratories and the American Society for Clinical Pathology to their memberships. Additionally, the document has been promoted by CDC's Perinatal Hepatitis B Prevention Program to increase support for this practice within funded jurisdictions.

Improving HBV prevalence estimates. To better estimate births to HBsAg-positive women in the United States, CDC's Viral Hepatitis Program revised the previous CDC model to incorporate both maternal country of birth and race/ethnicity, and updated data on HBsAg prevalence derived from the National Health and Nutrition Examination Survey 2007–2012 and CDC's Perinatal Hepatitis B Prevention Program. A manuscript documenting the new model methodology and results is in development.

Identifying strategies to improve perinatal HBV prevention and care.

In September 2015, OHAIDP convened a one-day [Technical Consultation on the Elimination of Perinatal Hepatitis B in the United States](#) to advance efforts toward the national goal of eliminating mother-to-child transmission of HBV. Bringing together more than 40 diverse experts and stakeholders, the consultation yielded a number of practical recommendations and identified model programs and policies that would, if widely implemented, reduce mother-to-child transmission of HBV. During the consultation, participants discussed approaches to improving outcomes at each stage of the perinatal HBV prevention pathway, beginning with identification of infected pregnant women, through to confirmation of vaccination and effective protection of their infants.



Engaging with community-based organizations on strategies for elimination of perinatal HBV. HRSA’s Bureau of Primary Health Care and Maternal and Child Health Bureau continued ongoing discussions initiated in 2014 with two national stakeholder organizations (Hep B United and Association of Asian Pacific Community Health Organizations) to discuss strategies to reduce perinatal HBV infections. Based on these discussions, HRSA is supporting, through a National Training and Technical Assistance Cooperative Agreement, the development of a comprehensive Perinatal Hepatitis B Toolkit that will focus on screening practices, linkage to care, and perinatal care and management. This resource is expected to feature such items as a provider checklist, needs assessment screening tool for providers and health educators, fact sheets containing best practices, and sample screening protocols for perinatal HBV in health centers.

Advancing research towards HBV transmission prevention. CDC and NIH collaborated to support the [Maternal Antiviral Prophylaxis to Prevent Perinatal Transmission of HBV in Thailand Study \(iTAP Study\)](#). The iTAP Study is an ongoing phase III, multicenter, placebo controlled, double-blind, randomized clinical trial to assess the efficacy and safety of tenofovir disoproxil fumarate given to HBV-infected pregnant women. Enrollment was completed in August 2015; 331 pregnant women were enrolled and randomized. The results of the study will help clarify the potential role of a short course of antivirals for the prevention of perinatal HBV transmission in women at high risk of transmission.

NIH’s Fogarty International Center and NICHD supported a [project](#) awarded in September 2015 focusing on improving birth outcomes by providing point-of-delivery prenatal test results, enabled by mHealth. This was done through the development and testing of the feasibility, acceptability, and usability of a web-based data platform and a medical decision model that is integrated with a community-based screening program for HIV, HBV, and the sickle cell

genotype. The model will store data in a secure web-based database, capture data in a chip imbedded “smart card,” and use a cell phone application to read the card to make data available at the point-of-delivery.

Collecting HBV vaccination data. ONC worked to improve HBV vaccination data collection by developing childhood vaccination screening measures that are eligible for collection by Certified Health IT, including HBV.

Considering strategies to prevent HAV infection. CDC published a Morbidity and Mortality Weekly Report (MMWR), [Progress Toward Eliminating Hepatitis A Disease in the United States](#), emphasizing the large proportion of the U.S. adult population that is susceptible to acute HAV at ages when the risk for illness and death is greatest. Cost-effective analysis of HAV catch-up vaccination for adolescents was evaluated for any benefits to improve population protection, including for older adults over time. Catch-up vaccination for adolescents was determined to not be cost-effective with the current low disease incidence. A provider (family physician and pediatrician) survey on current practices on vaccination and feasibility of catch-up vaccination for HAV was funded by a grant from the CDC Special Interest Project through the Rocky Mountain Prevention Research Center.

Ensuring HAV and HBV vaccination. In 2015, HRSA’s Ryan White HIV/AIDS Program-funded clinical providers vaccinated people living with HIV against HAV and HBV, as clinically appropriate.

Routinizing hepatitis vaccination. The guidance followed by all Title X providers, [Providing Quality Family Planning Services \(QFP\): Recommendations of CDC and the U.S. Office of Population Affairs](#), includes recommendations for routine screening for HBV immunization in males and females and offering HBV vaccination to all unvaccinated adults who do not have a documented history of HBV infection. CDC/Office of Population Affairs (OPA) [QFP recommendations](#) note that testing for HCV and offering HBV vaccination are important parts of sexually transmitted disease services and preconception care.

The IHS Electronic Health Record includes provider reminders for HAV and HBV vaccine for routine childhood administration, catch-up vaccination for adolescents, adults who initiate the series, and a HBV vaccine reminder for adults 19–59 years with diabetes. Work is ongoing to develop a reminder for HAV and HBV vaccine for patients with chronic liver disease.

Developing an HCV vaccine. NIH’s NIAID is conducting a double-blinded, randomized, phase I/II [trial](#) to evaluate the safety, immunogenicity, and initial efficacy of a vaccine to prevent acute and chronic HCV infection in high-risk people. The study is expected to enroll approximately 540 participants and be completed in 2018.

Members of FDA’s Center for Biologics Evaluation and Research (CBER) developed a new [method](#) of reverse engineering HCV virus envelope epitopes to induce broader and more potent antibody responses following vaccination. CBER also assessed the [impact of recent discoveries](#) about HCV T-cell responses on vaccine development.

PRIORITY AREA 5: Reducing Viral Hepatitis Associated With Drug Use Behaviors

Goals

- 5.1 Ensure that persons who inject drugs have access to viral hepatitis prevention, care, and treatment services.
- 5.2 Mobilize community resources to prevent viral hepatitis caused by injection-drug use.
- 5.3 Provide persons who inject drugs 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.

People who inject drugs are at increased risk for viral hepatitis. More than 25 percent of new HBV cases and nearly 70 percent of new HCV cases indicated use of injection drugs. The opioid epidemic is fueling increases in new viral hepatitis infections, and, despite the growing opioid epidemic, many people do not have access to syringe service programs, medication-assisted treatment, and/or other services that can prevent infectious disease and overdose. Targeted efforts must ensure that viral hepatitis associated with drug use is addressed across the spectrum of prevention, care, and treatment.

The following actions were among those undertaken by federal partners in 2015 to reduce viral hepatitis associated with drug use behaviors.

Promoting viral hepatitis prevention and screening in behavioral healthcare settings.

SAMHSA's Minority AIDS Initiative Continuum of Care program supported hepatitis screening, testing, and vaccination among individuals in substance use and mental health disorder treatment programs in 34 grantee projects. The initiative is in the follow-up phase and is expected to be completed by the summer of 2016. SAMHSA's Minority AIDS Initiative Minority Serving Institutions with Community Based Organizations grants required grantees to use 5 percent of awarded funds for hepatitis testing, counseling, and referral to treatment on college campuses and in nearby communities.

In addition, SAMHSA funded Targeted Capacity Expansion-HIV grants:

- ❖ The 2012 TCE-HIV grant funded 52 substance use disorder treatment grantees (2012–2017) that had the option to use 5 percent of their funds for HBV and HCV testing.
- ❖ The 2013 TCE-HIV: Minority Women grant funded 35 substance use disorder treatment grantees that had the option to use 5 percent of their funds for HCV testing.
- ❖ The 2013 HCV Screening and Referral grant provided supplemental funding to nine SAMHSA certified non-profit opioid treatment program grantees that were focused on providing HCV screening, testing, and referral for care and treatment primarily for clients who inject drugs.

- ❖ The 2015 TCE-HIV grant funded 26 substance use disorder treatment grantees that have the option to use 5 percent of their funds for HBV and HCV testing.

Improving co-occurring behavioral health and hepatitis services. HRSA awarded \$94 million in Affordable Care Act funding to 271 health centers in 45 states, the District of Columbia, and Puerto Rico for the FY 2016 Substance Abuse Service Expansion. This will improve and expand the delivery of substance use disorder services provided by existing Health Center Program award recipients, with a focus on medication-assisted treatment in opioid use disorders. Award recipients can adopt an optional goal of increasing education, screening, care coordination, risk reduction interventions, and/or counseling on the availability of testing, treatment, and clinical management for patients with or at risk of HIV/AIDS, HCV, and other diseases associated with opioid use disorders.

VA continued to support a national postdoctoral training program for psychologists in integrated liver disease and HIV care with a focus on addressing substance use disorders among veterans with HCV.

Considering treatment models for HCV in PWID. CDC led a national stakeholder group to guide the Affordable Care Act-established Patient-Centered Outcomes Research Institute project: Patient-Centered Models of HCV Care for People Who Inject Drugs, running from 2015–2020.

Expanding workforce capacity to address the intersection of behavioral health and hepatitis. The University of California, San Francisco HCV Warmline for IHS was activated in 2015 for expertise that includes hepatitis care/treatment for PWID. Federal government policy changes on syringe exchange and substitution therapy was communicated to all IHS facilities. PWID gap analysis is underway to better understand needs and gaps in knowledge and care for PWID. IHS conducted three national webinars on harm reduction, overdose prevention, and syringe exchange policy to increase awareness of clinicians to engage PWID in prevention strategies. Treatment webinars and clinics routinely include information on special considerations for patients who are PWID.

In response to alarming increases in new HCV infections, primarily due to increases in the number of people injecting drugs, OHAIDP developed and hosted a webinar, "[Hepatitis C Virus Prevention Opportunities Among People Who Inject Drugs: Confronting the Growing Epidemic](#)." The webinar featured national experts in the field, nurse researcher Holly Hagan, and CDC scientist Jon Zibbell. OHAIDP worked with federal and community partners to disseminate the webinar invitation broadly, and nearly 800 people from across the United States participated.

The HRSA Office of Regional Operations Region VIII Pharmacy consultant worked with HHS regional representatives and state Regional partners to develop a webinar series on HCV screening, care, and treatment for the region. The partners identified young PWID as the most at-risk group to be addressed. Federal and state partners presented on the viral HCV webinar series, "IDU on the Rise in Young People."

- ❖ [Part I](#) described the rise of the viral hepatitis epidemic and the consequences for young people who inject drugs.
- ❖ [Part II](#) described substance use and overdose prevention, training and education.

- ❖ [Part III](#) reviewed treatment interventions, such as SBIRT, medication-assisted therapy, and cultural competency.

Enhancing HCV awareness and leadership in the recovery community. OHAIDP collaborated with ONDCP to develop a [World Hepatitis Day blog](#), authored by ONDCP Director Michael Botticelli, highlighting the relationship between infectious disease and substance use disorders and in particular, the importance of access to viral hepatitis education, prevention, testing, and treatment for HCV for people with substance use disorders and in recovery.

Representing public health and infectious disease prevention on the National Heroin Task Force. As directed by Congress, the U.S. Department of Justice and ONDCP co-chaired and convened the National Heroin Task Force in March 2015. Ronald Valdiserri and Corinna Dan were among invited members selected from over 25 federal agencies. The diverse group of public health, public safety, and legal professionals identified strategies to confront the heroin problem and curtail the escalating overdose epidemic and death rates. The Task Force developed [this report](#) outlining the steps being taken to address the opioid problem through a multifaceted approach of robust criminal enforcement, prevention efforts, and increased access to substance use disorder treatment and recovery services. The Task Force recommended that these efforts be enhanced and broadened, marshalling all of society—from local communities, the medical community, and public health organizations to federal, state, local, and tribal law enforcement agencies—to successfully address the heroin crisis in the United States.

Screening and referring people living with HIV for behavioral health disorders. HRSA's Ryan White HIV/AIDS Program-funded entities screened people living with HIV and HIV/viral hepatitis coinfection for mental and substance use disorders, and, if diagnosed, referred them for appropriate mental health and/or substance use disorder treatment. Ryan White HIV/AIDS Program funds were used to support those services.

Educating providers serving reentry populations. VA delivered provider education on reintegrating veterans back into VA care once released from prison. VA also increased capacity and expertise for mental health and substance use disorder treatment through training for psychology fellows. VA further increased the uptake of pharmacotherapy for alcohol use disorders and opioid safety measures in liver disease and HIV clinics through an Academic Detailing Pilot Program.

Using modeling to estimate impact of HCV interventions. In collaboration with colleagues in Chicago, FDA's CBER developed an agent-based [model](#) of HCV virus transmission in PWID. This model was used to predict the prevalence of HCV in this population, and will provide a basis for testing intervention techniques in an in silico population. Also in collaboration with colleagues in Chicago, CBER developed a mathematical [model](#) to assess the impact of treatment scale up on PWID. This work provided a prediction of the number of people in the Chicago population that would need to be treated with HCV antivirals in order to reduce prevalence over time. This work was initially reported in 2014; however, the study was published in 2015.

Improving our understanding of HCV infection in those with substance use disorders. NIH's National Institute on Drug Abuse (NIDA) funded several research studies on disease progression of HCV infection in drug-abusing populations, and also to test the efficacy of newly approved DAAs medications for the treatment of HCV infection in drug-abusing populations

with or without co-occurring infection of HIV. Successful treatment of HCV infection may serve as an exceptional prevention modality of HCV infections. Most of these research studies are in progress with clinically significant findings being published each year, including this 2015 [publication](#). Also in 2015, NIH staff presented talks on HIV/HCV or HCV in persons with substance use disorders at meetings of professional medical societies.

PRIORITY AREA 6: Protecting Patients and Workers From Healthcare-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.
- 6.3 Reduce occupational transmission of viral hepatitis.
- 6.4 Enhance understanding of the preventable causes of viral hepatitis transmission in healthcare settings.

Significant advances have been made in preventing transmission of viral hepatitis among patients and providers. However, continued consideration of the risk for acquiring HBV or HCV during healthcare interventions is critical to ensure the provision of safe health care and reduce the healthcare-associated transmission of viral hepatitis.

The following actions were among those taken by federal partners in 2015 to protect patients and health workers from healthcare-associated viral hepatitis:

Supporting a coordinated response to hepatitis outbreaks. CDC and its partners ensured rapid and coordinated surveillance, detection, and response to hepatitis outbreaks, information about which can be found on the CDC [website](#). CDC also provided consultation to health departments for approximately 25 suspected viral hepatitis healthcare-associated infection transmissions or other related queries.

Ensuring the safety of the blood supply. In addition to supporting investigator-initiated research on issues related to hepatitis and blood safety, NIH's NHLBI supported the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III). This support helped to find new ways to enhance transfusion safety and the practice of blood banking domestically and internationally. For example, the REDS-III Blood Donation Rules Opinion Study provided insight into non-compliance with certain current donor deferral policies, the motivations of at-risk individuals who donate, and attitudes and behaviors toward the donation screening process. Despite education efforts and risk screening, individuals with deferrable risks still donated blood, contributing to potential risk among recipients of transfusion-transmitted infections, including viral hepatitis. The results directly supported the formulation of the new FDA policy on deferral of blood donation by MSM.

FDA and NHLBI launched the Transfusion Transmissible Infections Monitoring System (TTIMS) to help ensure the continued safety of the U.S. blood supply and monitor the effects of FDA's policy change on deferral of MSM from blood donation. While the focus of TTIMS is HIV, the national blood surveillance system also includes monitoring of HBV and HCV virus infections among blood donors or donations.

Expanding our understanding of HBV reactivation. NIH's NIDDK and AASLD held a symposium on developing algorithms for screening for, and prophylaxis against, HBV reactivation in patients receiving immunosuppressive therapies or undergoing transplantation. The symposium was held in 2013 and a [summary](#) was published in 2015. The American Society

of Clinical Oncology published [recommendations](#) on this topic in 2015; however, more causes of reactivation are emerging, including new immune-modulating drugs for cancer treatment (e.g., infliximab, temozolomide, ustekinumab, imatinib, ibrutinib and romidepsin). Intramural researchers in NIH's NIDDK and NCI are preparing a review summarizing which drugs do and do not cause reactivation. FDA is investigating cases of reactivation caused by direct-acting antiviral treatment of HCV. These efforts will form the basis for guideline development.

APPENDIX A—PUBLICATIONS

Federal partners made important contributions to addressing gaps in our understanding of the prevention, care, and treatment of viral hepatitis through peer-reviewed journal articles and other technical documents. These publications help to advance efforts to develop and implement evidence-based programs, clinical services, and policies.

PRIORITY AREA 1: Educating Providers and Communities to Reduce Health Disparities

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PRIORITY AREA 2: Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer

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APPENDIX B – ACRONYMS

AAPCHO	Association of Asian Pacific Community Health Organizations
AAPI	Asian American and Pacific Islander
AASLD	American Association for the Study of Liver Diseases
ACOG	American College of Obstetrics and Gynecology
ADAP	AIDS Drug Assistance Programs
AETC	AIDS Education and Training Center (HRSA)
AHRQ	Agency for Healthcare Research and Quality (HHS)
AI/AN	American Indian/Alaska Native
AIMM	AIDS Initiative for Minority Men
ATTC	Addiction Technology Transfer Center (SAMHSA)
BPHC	Bureau of Primary Health Care (HRSA)
CBER	Center for Biologics Evaluation and Research (CDC)
CDC	Centers for Disease Control and Prevention (HHS)
CMS	Centers for Medicare & Medicaid Services (HHS)
CoC	Continuum of Care
CDRH	Center for Devices and Radiological Health (FDA)
CSAP	Center for Substance Abuse Prevention (SAMHSA)
DAA	direct acting antiviral
DOJ	U.S. Department of Justice
ESG	Emergency Solutions Grants
FBOP	Federal Bureau of Prisons (DOJ)
FDA	Food and Drug Administration (HHS)
GHOST	Global Hepatitis Outreach and Surveillance Technology (CDC)
HAV	hepatitis A virus
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HDV	hepatitis delta virus
HEV	hepatitis E virus
HHS	U.S. Department of Health and Human Services
HIRE	Health Improvement for Re-entering Ex-offenders Initiative
HIT	health information technology
HOPWA	Housing Opportunities for Persons with AIDS
HRSA	Health Resources and Services Administration (HHS)
HUD	U.S. Department of Housing and Urban Development
IHS	Indian Health Service (HHS)
LGBT	Lesbian, Gay, Bisexual and Transgender
MSM	men who have sex with men
NCI	National Cancer Institute (NIH)
NHLBI	National Health Lung and Blood Institute (NIH)
NIAID	National Institute of Allergy and Infectious Disease (NIH)
NICHHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NIH)

NIDA	National Institute on Drug Abuse (NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
NIMHD	National Institute on Minority Health and Health Disparities (NIH)
NIH	National Institutes of Health (HHS)
NVPO	National Vaccine Program Office (HHS)
OASH	Office of Assistant Secretary for Health (HHS)
OHAIDP	Office of HIV/AIDS and Infectious Disease Policy (HHS)
OMH	Office of Minority Health (HHS)
ONAP	Office of National AIDS Policy (White House)
ONC	Office of the National Coordinator for Health Information Technology
ONDCP	Office of National Drug Control Policy (White House)
OPA	Office of Population Affairs
OSG	Office of the Surgeon General
OWH	Office on Women's Health (HHS)
P4C	Partnerships for Care (HRSA and CDC)
PHS	U.S. Public Health Service
PWID	people/persons who inject drugs
REDS-III	Recipient Epidemiology and Donor Evaluation Study – III
RHA	Regional Health Administrator
RRC	Regional Resource Consultants
SAMHSA	Substance Abuse and Mental Health Services Administration (HHS)
SBIR	small business innovation research (grant)
SVR	sustained virologic response
TTIMA	Transfusion Transmissible Infections Monitoring System (NHLBI and FDA)
USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
VHIG	Viral Hepatitis Implementation Group
VHPC	State Viral Hepatitis Prevention Coordinator
WHIAAPI	White House Initiative on Asian Americans and Pacific Islanders