2016 PROGRESS REPORT

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, the Office of the Assistant Secretary for Health, 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, and the U.S. Department of Housing and Urban Development. The report was developed under contract HHSP233201400468G and finalized under contract HHSP23320160035OG.

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October 2018

Message from the HHS Office of HIV/AIDS and Infectious Disease Policy

October 2018

Using the Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis (2014–2016) (Action Plan) as a road map, throughout 2016, 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 continued their individual and collective efforts to improve viral hepatitis prevention, and the care and treatment provided to people living with hepatitis B and hepatitis C. This report, compiled by our office, highlights key 2016 accomplishments within each of the Action Plan's six priority areas. It provides highlights of the work done by partners from across the federal government to address viral hepatitis, which continues to affect millions of Americans from all walks of life.

With this third and final report documenting federal progress on our nation's second Action Plan (2014–2016), we also look back on that plan. We are proud to report that federal partners completed more than 90 percent of the actions they had set forth in the second plan. Over the past three years, they also were able to capitalize on new opportunities that emerged, as well as expand and strengthen collaborations among agencies and with community partners. The Action Plan has clearly continued to galvanize our national response to viral hepatitis, spurring greater awareness, attention, initiative, and collaboration.

As we reflect on this progress, we also look to the future. The progress highlighted in this report strengthened the foundation on which our work continues today. Indeed, a significant 2016 accomplishment was the joint effort by the federal partners to thoughtfully assess our progress and the opportunities before us, collect input from a variety of stakeholders, and develop a renewed three-year Action Plan. The result of that effort, the National Viral Hepatitis Action Plan (2017–2020), was released at the beginning of this year and continues to serve as the road map for our collective response to hepatitis B and C. It sets forth ambitious goals that are achievable through strategic efforts that make the best use of available financial and human resources, and establishes indicators that will be used to assess our progress.

Although this is a federal progress report, we must acknowledge the tremendous support and commitment of a broad mix of nonfederal stakeholders from various sectors, both public and private, whose work also contributed substantially to our national progress in 2016. The Action Plan is a national plan. It emphasizes that all sectors of society have roles to play if we are to achieve our national goals and prevent disease and death, and reduce costs for the health care system. As our progress faces new threats, especially from the opioid epidemic, we must find new ways to work together with all stakeholders to sustain our achievements and continue to advance toward our national viral hepatitis prevention and care goals.

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BACKGROUND

The Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis (Action Plan) was developed to raise awareness of the silent epidemic of viral hepatitis in the United States. The nation's first Action Plan was released in 2011. Building on the progress achieved under the original Action Plan, a renewed plan was developed and released in 2014, detailing additional strategic actions to be undertaken through 2016. That second Action Plan detailed 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 (HUD), the U.S. Department of Justice's Federal Bureau of Prisons, and the U.S. Department of Veterans Affairs (VA). All of these actions contribute to improving the prevention, diagnosis, and treatment of viral hepatitis in the United States.

Viral hepatitis is a group of viral infections that cause inflammation of the liver, including hepatitis A, B, C, D, and E. The most common types of viral hepatitis in the United States are hepatitis A, B, and C. Millions of Americans from all walks of life are chronically infected with hepatitis viruses. The numbers of new hepatitis C infections have increased by 350 percent between 2010 and 2016, and approximately 20,000 preventable viral hepatitis-related deaths occur each year. Most people infected with viral hepatitis do not know it. People can live with the infection for decades without symptoms or feeling sick. 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. Today, we have the knowledge and tools to save lives and win the fight against viral hepatitis. The Action Plan has enabled further collaboration, resulting in advances in:

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

In support of the efforts across HHS and other federal departments to implement the Action Plan, the HHS Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) convenes a Viral Hepatitis Implementation Group (VHIG) charged with coordinating, supporting, and monitoring implementation of the Action Plan. Chaired by the Director of OHAIDP, VHIG members include representatives from across HHS agencies and other federal agencies and departments engaged in the Action Plan. Members meet regularly to confer about the state of hepatitis B and C in the United States, advance implementation of the actions detailed in the Action Plan, and address new opportunities and challenges. The members have served as representatives from 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.

CONTENTS

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. 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 2016.

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

- Promoting viral hepatitis training and technical assistance for health centers and other health care providers.
- Supporting linkage to care programs and the development of testing.
- Further exploring the use of new hepatitis C therapies in special populations and hepatitis B therapies to reduce perinatal transmission.
- Supporting integrated behavioral health and hepatitis services.

A common theme across the field of viral hepatitis is the need for additional evidence to guide policy and practice at every level. Throughout 2016, through peer-reviewed journal articles and the development of reports and other technical documents, federal partners made important contributions toward addressing gaps in our understanding of the prevention, care, and treatment of viral hepatitis. These publications help advance efforts to develop and implement evidence-based programs, clinical services, and policies. A list of these publications appears in Appendix A, and they are described throughout this report.

The described activities support progress toward the four overarching goals that the Action Plan set forth to achieve by 2020:

1. An increase in the proportion of persons who are aware of their hepatitis B virus (HBV) infection, from 33 percent to 66 percent,
2. An increase in the proportion of persons who are aware of their hepatitis C virus (HCV) infection, from 45 percent to 66 percent,
3. A 25 percent reduction in the number of new cases of HCV infection, and
4. Elimination of mother-to-child transmission of HBV.

This report is organized by the Action Plan's six priority areas within which priority area goals/strategies and actions are grouped as shown in the graph on the following page.

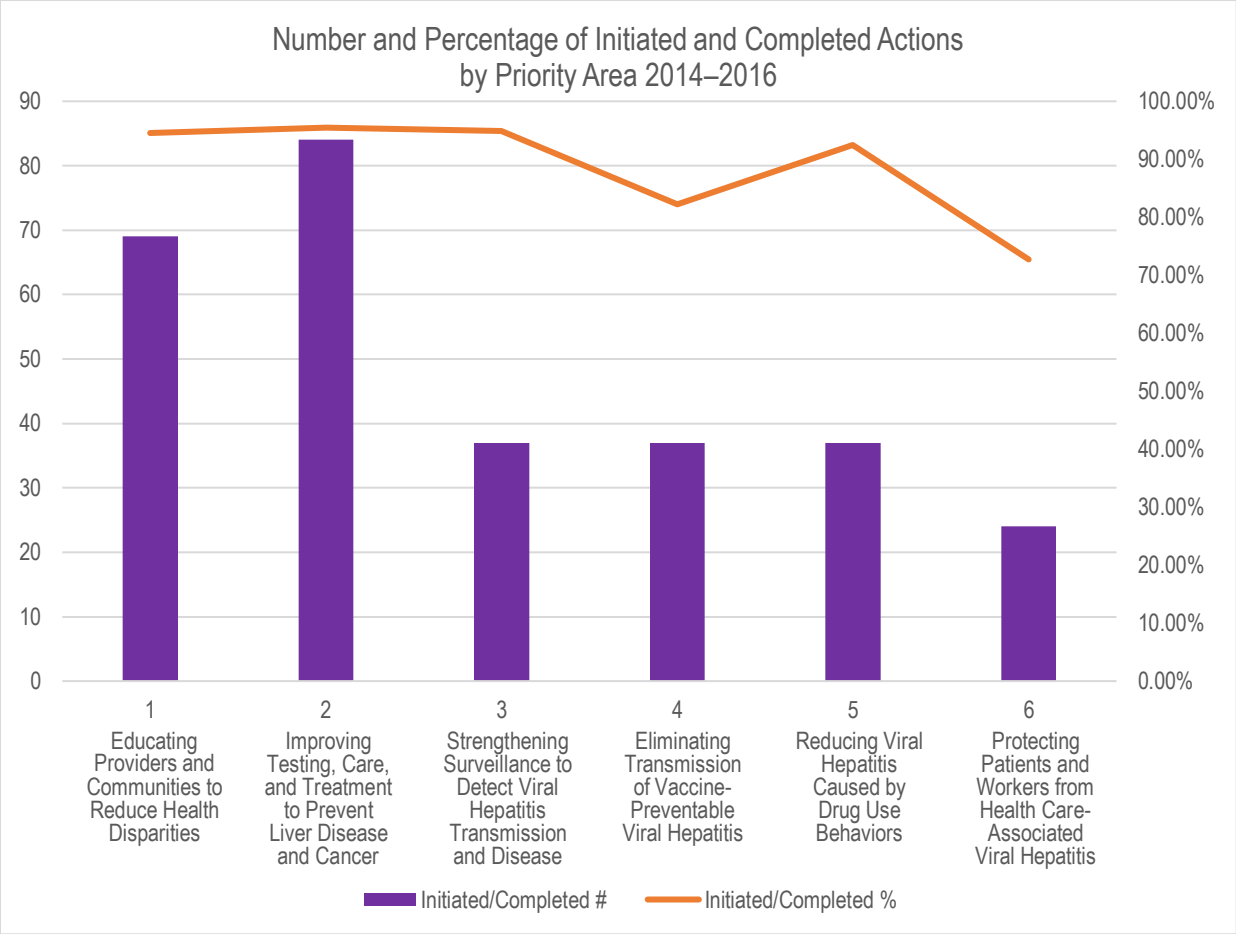
This report represents the final progress report that will be developed based on the Action Plan for 2014–2016, including:

- An assessment of the proportion of all actions undertaken during the three-year timeframe,
- A breakdown of the number and percentage of actions undertaken within each priority area, and

- An assessment of whether the core measures (correlated to the four overarching goals) and additional measures of progress identified are on track to meet the 2020 target, not expected to meet the 2020 target, or there is insufficient data to assess progress.

Federal Viral Hepatitis Actions Completed 2014–2016

The Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis contained a total of 318 actions due by 2016; of those, overall, 91 percent (288) were initiated/completed. The graph below illustrates initiated/completion number and rate within each of the six priority areas.



These data reflect the status of each federal action to which they committed in the Action Plan as reported by VHIG members through the data collection process for the 2016 Progress Report as follows: completed, partially completed, or not initiated. It should be noted that, in many cases, actions continuing past 2016 were reported as partially completed (i.e., ongoing grant programs through the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention; ongoing research efforts at the National Institutes of Health), thus these categories were combined to reflect the total shown.

FINAL PROGRESS REPORT FOR THE 2014–2016 ACTION PLAN

On Track to Meet 2020 Target

GOAL 2 ■ Increase the proportion of persons who are aware of their chronic HCV infection from 45% to 66%.

GOAL 4b ■ Hepatitis B vaccine "birth dose" coverage.

MEASURE 1 ■ Reduce mortality related to hepatitis B infection.

MEASURE 2 ■ Reduce mortality related to hepatitis C infection.

Not Expected to Meet 2020 Target

GOAL 3 ■ Reduce the number of new cases of HCV infection by 25%.

MEASURE 3 ■ Reduce occupational transmission of viral hepatitis.

No Progress Data

GOAL 1 ■ Increase the proportion of persons who are aware of their chronic HBV infection from 33% to 66%.

GOAL 4a ■ Number of infants perinatally infected with HBV.

Monitoring Progress Toward Goals and Related Measures: Viral Hepatitis Action Plan

Measure	Baseline Estimate (Source)	Year of Baseline Estimate	2016 Status	Percent of 2020 Target*		2020 Goal
CORE MEASURES						
GOAL 1 ■ Increase the proportion of persons who are aware of their chronic HBV infection from 33% to 66%.						
Proportion of persons with HBV infections who know that they are infected	**33%** (REACH Survey)	**2009**		n/a	⊘	66%
GOAL 2 ■ Increase the proportion of persons who are aware of their chronic HCV infection from 45% to 66%.						
Proportion of persons with HCV infections who know that they are infected	**45%** (NHANES)	**2010**	**59%** (2014)	66.7%	↗	66%
GOAL 3 ■ Reduce the number of new cases of HCV infection by 25%.						
Number of reported and estimated acute hepatitis cases in the United States	**1,229** (NNDSS)	**2011**	**2,967** (2016)	-316%	✗	922
GOAL 4 ■ Eliminate mother-to-child transmission of HBV.						
4a. Number of infants perinatally infected with HBV	**747** (NVSS)	**2009**		n/a	⊘	No cases*
4b. Hepatitis B vaccine "birth dose" coverage	**64.1%** (NIS)	**2010**	**73.3%** (2015)	56%	↗	85%
ADDITIONAL MEASURES TO MONITOR PROGRESS						
MEASURE 1 ■ Reduce mortality related to hepatitis B infection.						
Number and age-adjusted mortality rate of hepatitis B listed as the underlying or a contributing cause of death in the United States	**0.5** per 100,000 people; **1,844** (Ly, et al., 2013)	**2010**	**0.45**; **1,698** (2016)	10%	↗	To be developed
MEASURE 2 ■ Reduce mortality related to hepatitis C infection.						
Number and age-adjusted mortality rate of hepatitis C listed as the underlying or a contributing cause of death in the United States	**4.6** per 100,000 people; **16,627** (Ly, et al., 2013)	**2010**	**4.45**; **18,153** (2016)	3%	↗	To be developed
MEASURE 3 ■ Reduce occupational transmission of viral hepatitis.						
HBV vaccination among health care workers	**64.3%** (NHIS)	**2008**	**64.8%** (2015)	1.9%	✗	90% (*Healthy People 2020*)

* Percentage of progress from baseline toward 2020 goal or percentage improvement if no goal has been developed.

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
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- 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 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 (OSG)
  - Office on Women's Health (OWH)
  - Regional Health Offices (RHOs)
- Office of the National Coordinator for Health Information Technology (ONC)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- U.S. Food and Drug Administration (FDA)

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

- Office of Community Planning and Development (CPD)

U.S. DEPARTMENT OF JUSTICE (DOJ)

- Civil Rights Division
- Federal Bureau of Prisons (FBOP)

U.S. DEPARTMENT OF VETERANS AFFAIRS (VA)

- Veterans Health Administration (VHA)

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This list reflects VHIG members as of the release of this report.

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PRIORITY AREA 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.

Everyone has a role to play in the national response to viral hepatitis and the fight against hepatitis stigma and discrimination. There are serious health disparities in viral hepatitis. Reaching populations experiencing disparities can be enhanced by nontraditional partnerships, tailored messaging, and improved cultural competence. 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 health care providers, which will ensure that those who need care and treatment can get it.

The following were among the actions undertaken by federal partners in 2016 to educate communities and build a strong workforce of providers trained to diagnose and manage viral hepatitis.

Building capacity to identify people infected with chronic hepatitis. In 2016, the **Centers for Disease Control and Prevention (CDC)** began work on a cooperative agreement, Viral Hepatitis Networking, Capacity Building, and Training (CDC-RFA-PS16-1608), that supports projects to increase the identification of people with chronic hepatitis B and hepatitis C infection. The five-year projects are funded at approximately $648,000 per year. Activities will include (1) leading and growing a national coalition to address the public health challenge of chronic viral hepatitis through training and technical assistance to conduct culturally competent outreach, extending the reach of CDC's national campaigns and enhancing testing and linkage to care in high-risk communities, and (2) developing up-to-date, comprehensive, web-based hepatitis materials, resources, and trainings for health professionals.

Targeting health disparities in viral hepatitis. In 2016, the **Office of Minority Health (OMH)** awarded 12 subcontracts of up to $35,000 per subcontract, equally distributed across targeted minority populations: Blacks/African Americans; Latinos/Hispanics; American Indians/Alaska Natives; and Asians, Native Hawaiians, and Pacific Islanders. The goals of the social marketing campaign subcontracts include:

- Developing and implementing a social marketing campaign that supports increased awareness of the co-infections of HIV and hepatitis.
- Increasing HIV testing and hepatitis screening, with referrals to care for minority and hard-to-reach communities.

Social marketing campaign examples include:

- GALA Guam – Take Control of Your Health, a one-minute public service announcement (PSA)
- Hepatitis B Initiative of Washington, DC
- Asian Health Services – Get Informed: HIV/AIDS and Hepatitis

As of March 2017, the 12 subcontracted agencies conducting social marketing campaigns reported the following:

Social Media Marketing Campaigns' Indicators & Outcomes	
Indicators	**Total**
1. Community outreach events conducted	313
2. PSAs produced (audio, video, billboards, bus ads, posters)	186
3. Venues or events where PSAs played	665
4. Printed materials distributed	110,079
5. New peer educators recruited	70
6. Peer educator training workshops held	46
7. Workshops on HIV and hepatitis prevention held	173
Outcomes	
1. People reached through community outreach events	52,569
2. People exposed to PSAs	1,335,297
3. People trained through program (includes peers trained)	5,874
4. People tested for HIV	7,794
5. People tested for hepatitis B	1,415
6. People tested for hepatitis C	3,454

Numbers reflect activities undertaken in 2016 through March 2017.

Supporting hepatitis nondiscrimination efforts. The **U.S. Department of Justice** reached an agreement in 2016 with a moving company to resolve allegations that it violated the Americans with Disabilities Act when it refused service because of a customer's hepatitis C. The agreement required the moving company to adopt a series of nondiscrimination training and policy reforms, pay the victim $10,000 in compensation, and pay a $3,500 civil penalty to the United States. The Disability Rights Section of the Civil Rights Division continues to receive and review referrals of potential hepatitis-based discrimination through direct calls and online at http://www.ADA.gov.

Integrating community health worker training to reach priority populations. The **OMH Resource Center (OMHRC)** developed a hepatitis training module to accompany its community health worker trainings. This module provides training in HIV, viral hepatitis, health insurance benefits and system navigation, the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care, and other topics that support the implementation of HHS initiatives. Subject matter experts developed materials and implemented capacity-building strategies related to competency on these health topics.

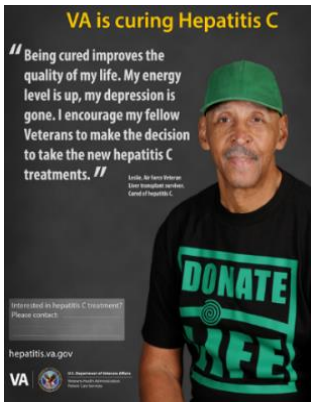
Convening tribal leaders to identify HCV priorities and actions. The **Indian Health Service (IHS)** and **Regional Health Office** in Region VI participated in the Southwest Hepatitis C Tribal Summit on March 2–3, 2016, in Albuquerque, NM, with more than 100 people in attendance representing a cross-section of Southwest Native Americans. The Regional Resource Consultants (RRCs) led a small group discussion to provide information on the updated Action Plan. This discussion was designed to prepare group members for the final sessions of the summit, when they identified national tribal hepatitis C priorities and created an action plan to address the priorities.

Partnering to develop updated, culturally competent materials. The **OMH Resource Center** partnered with three national and regional community organizations—the Association of Asian Pacific Community Health Organizations (AAPCHO), the National Health IT Collaborative for the Underserved (NHIT), and the Asian and Pacific Islander American Health Forum (APIAHF)—to develop updated HIV and viral hepatitis materials.

- AAPCHO updated a fact sheet and developed guidelines for physicians. AAPCHO developed a co-infection (HIV/AIDS, tuberculosis [TB], and hepatitis B) fact sheet in 2008 that included information on each infectious disease, its impact, and related statistics on the Asian American and Pacific Islander community. The revised fact sheet included hepatitis, TB, and HIV/AIDS patient-centered strategies for Asian Americans, Native Hawaiians, and Pacific Islanders.
- NHIT coordinated with OMHRC to convene an in-person Hepatitis Awareness Month roundtable event. NHIT worked with subject matter experts to modify available or develop culturally and linguistically appropriate educational material for underserved communities, including a one- to two-page fact sheet per target population and marketing materials to support distribution. NHIT's Hepatitis Awareness Initiative culminated with a comprehensive project report in August 2016 that included a summary of online and social media reach, as well as outcomes, lessons learned, and detailed recommendations from the roundtable event for future initiatives.
- APIAHF conducted an environmental scan of available national and state surveillance and survey reports containing hepatitis, HIV, sexually transmitted disease (STD), and TB-related data. The results of the scan were used to assess how Asian American, Native Hawaiian, and Pacific Islander data are currently categorized in these reports. APIAHF developed and electronically disseminated a report on the current state of Asian American, Native Hawaiian, and Pacific Islander hepatitis, HIV, STD, and TB-related data at the national and state levels.

Engaging cancer prevention stakeholders. **CDC** entered into a supplemental cooperative agreement (PS13-1315) with its Division of Cancer Prevention and Control to work with the George Washington University Cancer Institute to create a variety of informational resources linking liver cancer and viral hepatitis. Deliverables included (1) 51 state and Washington, DC, cancer profile fact sheets disseminated and promoted for Liver Cancer Awareness Month in October 2017; (2) a fact sheet on the National Academy of Sciences report that shared the report findings, in the context of cancer and for use by the cancer community (e.g., state cancer control programs), disseminated during Hepatitis Awareness Month (May 2017) and on Hepatitis Testing Day (May 19); (3) a social media toolkit with sample liver cancer prevention messaging for Facebook and Twitter, disseminated in April 2017 (ahead of Hepatitis Awareness Month and Hepatitis Testing

Day); and (4) a policy, systems, and environmental case study on liver cancer for inclusion on the George Washington University Cancer Institute's policy map tool.



Expanding on best practice dissemination. The **Veterans Administration (VA)** implemented VA Pulse, an internal social networking site, to improve employee engagement and communication, and share promising practices across VA health centers. The Veterans Health Administration (VHA) developed a viral hepatitis-specific space to help improve communication with the field, share resources, and answer questions. Thirteen blog posts were developed, and more than 10 resources were shared. Building on this success, VHA added an additional collaboration group for the Veterans Integrated Service Network Hepatitis C Innovation Team to encourage open dialogue and problem solving.

Encouraging testing and highlighting effective treatment. **VA** developed new outreach methods in 2016, including a national hepatitis C awareness campaign focused on encouraging testing and treatment among veterans. The campaign features four veterans who were cured of hepatitis C while in VA care.

Educating communities about the benefits of viral hepatitis prevention through vaccination. The **National Vaccine Program Office**'s (NVPO) vaccines.gov website saw more than 300,000 unique views to its hepatitis A and hepatitis B webpages in 2016.

Enhancing public educational materials for viral hepatitis. In May 2016, **CDC** released the third phase of the Know More Hepatitis campaign. This phase included TV, radio, print, and digital banner ads in Chinese, Korean, and Vietnamese that were disseminated across the United States, delivering more than 19 million impressions. In addition, CDC collaborated with Hep B United to identify speakers for radio and TV interviews on ethnic media stations. This collaboration allowed local Hep B United coalitions to establish their presence in local communities.

Considering hepatitis elimination goals for the United States. In partnership with OMH, **CDC**'s Division of Viral Hepatitis commissioned the National Academies of Sciences, Engineering, and Medicine to determine whether elimination goals for hepatitis B and hepatitis C in the United States are feasible and to identify possible critical success factors. The Phase One Report was released in 2016 and explored the barriers that must be overcome to eliminate hepatitis B and hepatitis C in the United States. The report also concluded that hepatitis elimination can be achieved if the right resources, commitment, and strategy are in place. Work on the Phase Two Report was initiated immediately and continued through 2016, with the report released in March 2017.

Establishing expert guidelines for viral hepatitis treatment. Staff from the **National Institutes of Health's** National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Intramural Research Program continued to participate in the ongoing development of clinical guidelines for testing, managing, and treating hepatitis C in collaboration with professional medical organizations, such as the American Association for the Study of Liver Diseases (AASLD), which updates the guidelines every three months.

These are some highlights of additional 2016 activities for training and educating health professionals:

Agency or Office	Training and Education Activities for Health Professionals
CDC	In May 2016, CDC participated in the 5th Annual White Earth Hepatitis C Tribal Summit held on the White Earth reservation in Minnesota and organized by White Earth Public Health Services. At the summit, health and social services providers, together with community members, met to focus on the problem of hepatitis C, HIV, and IDU in American Indian communities.
Health Resources and Services Administration (HRSA)	HRSA's Bureau of Primary Health Care (BPHC) provides resources for Health Center Program providers regarding prevention, screening, and treatment of hepatitis A, B, and C on its webpage. BPHC has a cooperative agreement with the National Nurse-led Care Consortium (NNCC), which supports nurse-led clinics and provides training and technical assistance to health centers that provide primary care services to residents of public housing. NNCC conducts an HIV/HCV testing program called FOCUS, which provides routine HIV and hepatitis C testing and linkage to care in six health centers located in Philadelphia. BPHC awarded a contract to the University of New Mexico's Project ECHO (Extension for Community Health Outcomes) to develop and support an innovative training and technical assistance initiative for primary care teams at HRSA-funded health centers to reduce perinatal HBV transmission.
HUD	HUD's Office of Special Needs Assistance Programs (SNAPS) initiated work with technical assistance providers to develop educational materials that can be used by grantees to address viral hepatitis prevention, care, and treatment for homeless assistance grant beneficiaries.
IHS	Throughout 2016, IHS offered training opportunities and resources to more than 300 clinicians through in-person HCV clinical trainings (in collaboration with the University of California, San Francisco, and the University of New Mexico), HCV Grand Rounds, and regional and national conferences. IHS developed local models for HCV education of community health workers and is working to make this effort systematic and nationwide.
OMH	OMHRC conducted a five-part webinar series, "Fighting Hepatitis and HIV Co-Infection in Minority Communities," which focused on American Indian and Alaska Native, African American, African immigrant, and underserved communities.
OPA	The Office of Population Affairs (OPA) hosted a webinar, "What Title X Providers Need to Know About Viral Hepatitis," for the Title X network to educate the health care workforce about the prevention, diagnosis, and treatment of viral hepatitis. The National Clinical Training Center for Family Planning hosted a virtual coffee break, "Hepatitis A, B and C in Family Planning Settings," to address hepatitis. The virtual coffee break is a mechanism used to provide information to health care professionals and other clinical providers in a brief 30- to 60-minute prerecorded webinar that can be can be viewed at their convenience.

Agency or Office	Training and Education Activities for Health Professionals
Regional Health Offices	The RRCs established ongoing communication and partnerships with state and local leaders to disseminate information regarding viral hepatitis activities and events, data, and resources. RRCs participated in more than 15 meetings and events in regions across the country to discuss the benefits of viral hepatitis prevention, care, and treatment. For example, RRCs moderated the Regional Resource Network Program cosponsored event, "The Silent Epidemic: Increasing Access to Hepatitis C Treatment and Care," which was part of the Black Lives Matter health series. The day-long program of training and discussion with more than 90 participants explored new treatment regimens and the HCV care cascade in Chicago and nationally, and the event included interactive conversations regarding increasing advocacy efforts and access to testing and treatment.
Substance Abuse and Mental Health Services Administration (SAMHSA)	In 2016, the Ryan White National Grantee Conference included a training with three Minority AIDS Initiative (MAI) Continuum of Care (MAI-CoC) grantees, illustrating HIV services, hepatitis services for screening, vaccination, and linkage to care in behavioral health care settings. SAMHSA provided education about sexually transmitted viral hepatitis for key populations, including men who have sex with men (MSM), commercial sex workers, and high-risk heterosexuals. In addition, SAMHSA provided training to community-based organizations, health care providers, providers with buprenorphine waivers, individuals at risk, and the public. SAMHSA also provided community outreach and education on testing, transmission modes, and disease signs and symptoms for high-risk populations, such as people who inject drugs (PWID), MSM, and ethnic and racial groups. The SAMHSA/Targeted Capacity Expansion-HIV (TCE-HIV) grant program has the following requirement: All clients who are considered to be at risk for hepatitis B and C) (as specified by the U.S. Preventive Services Task Force recommendations for hepatitis B and hepatitis C screening) must be tested for hepatitis B and C in accordance with state and local requirements, either onsite or through referral. **Exactly five percent (e.g., $25,000)** of grant funds **must** be used for the following hepatitis testing and services: hepatitis B and C (antibody and confirmatory) testing, hepatitis A and B vaccination, purchase of test kits and other required supplies (e.g., gloves, biohazard waste containers), or training for staff related to viral hepatitis testing. Applicants must provide a plan for providing referrals and linkages to follow-up care and treatment for all individuals identified with hepatitis (B or C). In addition, the Center for Substance Abuse Treatment forwards viral hepatitis information from HIV.gov, through a listserv, to all TCE-HIV grantees.
VA	In 2016, the VA continued support for regional HCV Innovation Teams. These teams bring together field providers and system redesign experts to develop and disseminate strong practices in HCV care that increase access to HCV care and treatment, contribute to building high-performing networks, and engage VA employees.

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

Hepatitis B and C are silent and deadly diseases, often progressing for years without symptoms, and viral hepatitis is a leading cause of liver cancer in the United States. Addressing viral hepatitis in the United States requires a two-pronged approach that targets both the prevention of new infections and identifying and treating chronic infections. Today, we have the knowledge and tools to save lives and win the fight against viral hepatitis. Tailored viral hepatitis prevention, education, and testing efforts for priority populations and others at increased risk will help turn the tide on the viral hepatitis epidemic. In addition to identifying those infected, linking them to care, and improving access to treatment, advanced research efforts are needed.

The following were among the actions taken by federal partners in 2016 to improve testing, care, and treatment of viral hepatitis to prevent liver disease and cancer.

Strategies to Improve Quality of Viral Hepatitis Care

Several federal agencies undertook activities to improve outcomes for people with chronic HBV and HCV, including projects that focused on viral hepatitis testing, as well as linkage to care and treatment.

Testing

Reviewing HBV screening for Medicare beneficiaries. On January 21, 2016, the **Centers for Medicare & Medicaid Services (CMS)** initiated a National Coverage Analysis for Medicare beneficiaries on screening for HBV infection, which is recommended with grade A and grade B recommendations by the U.S. Preventive Services Task Force (USPSTF). CMS issued a proposed decision memorandum on July 7, 2016, and a final decision memorandum on September 28, 2016. As a result, CMS will cover an HBV infection screening test for asymptomatic, nonpregnant adolescents and adults at high risk for infection and for pregnant women at the first prenatal visit, including rescreening at the time of delivery for those with new or continuing risk factors. CMS will also cover screening for the first prenatal visit in subsequent pregnancies, regardless of previous HBV vaccination or previous negative hepatitis B surface antigen (HBsAg) results.

Supporting development of updated USPSTF HCV screening recommendations. The **Agency for Healthcare Research and Quality (AHRQ)** initiated a review of USPSTF recommendations on screening for HCV in general and on screening for HBV specifically among pregnant women. This is a multistep process that begins with drafting and finalizing the research plan, developing a draft review and recommendation statement, finalizing the evidence review, and releasing a recommendation statement.

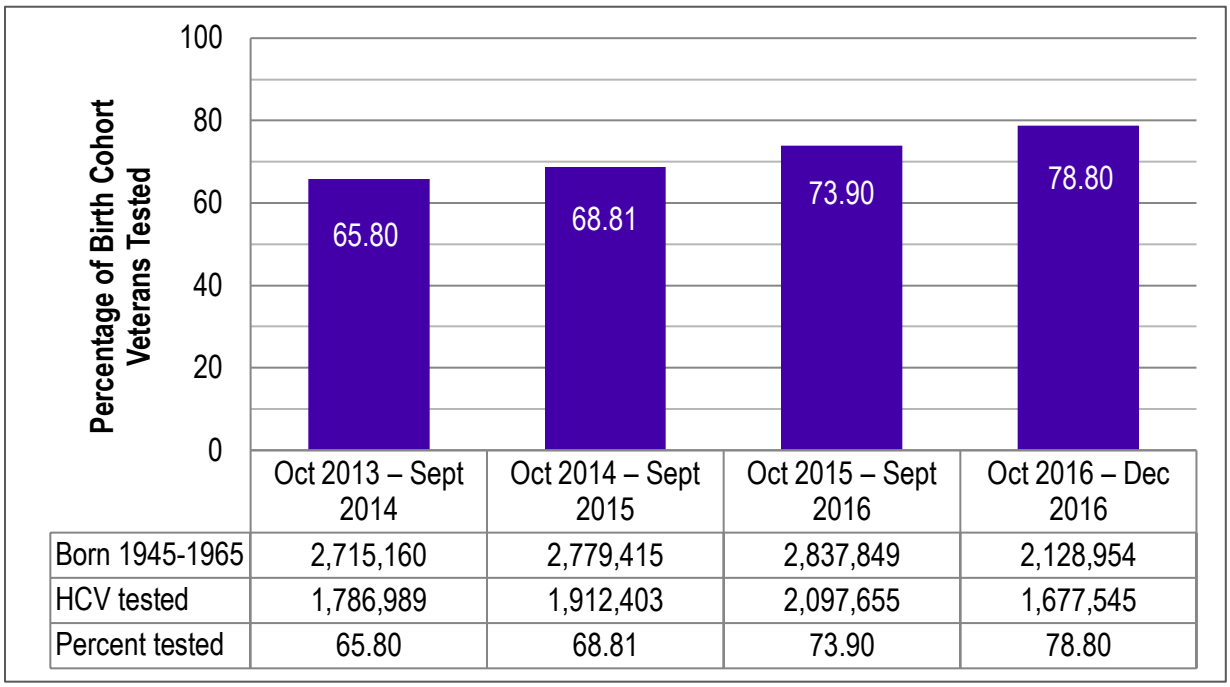
Developing practical and reliable algorithms for screening high-risk populations for chronic hepatitis B. **NIH**'s National Institute on Drug Abuse (NIDA) is supporting studies in progress to develop and evaluate mobile screening, prevention, and testing modules that can be used on a laptop or tablet in clinical settings.

Supporting the development of improved hepatitis diagnostic devices. In 2016, the **U.S. Food and Drug Administration**'s (FDA) Center for Devices and Radiological Heath (CDRH) identified and engaged with various hepatitis research consortiums and organizations to identify sources of patient samples to be used in support of premarket notifications for hepatitis diagnostic devices. Several manufacturers with approved devices have been successful in obtaining sufficient samples to support premarket application.

Increasing efforts to test high-risk populations. **SAMHSA**'s Center for Substance Abuse Prevention (CSAP) implemented viral hepatitis testing in high-risk community populations as part of its Capacity Building Initiative for Substance Abuse and its Minority Serving Institutions Partnerships with Community-Based Organizations. Through these efforts, 4,008 individuals were tested. In addition, SAMHSA's CSAP has been working with high-risk racial and ethnic minority communities as part of its MAI programs to share and promote hepatitis education and awareness. The SAMHSA CSAP MAI programs also provide up to 15 percent of grant funds to support hepatitis screening, vaccination, and linkage to medical care. Grantees of the **SAMHSA** Center for Substance Abuse Treatment (CSAT) MAI-funded Targeted Capacity Expansion-HIV Program are required to spend 5 percent of their funds on viral hepatitis testing and services. They may purchase test kits and other required testing supplies with these funds. SAMHSA's MAI Continuum of Care (MAI-CoC) grantees were also required to utilize 5 percent of their funds on viral hepatitis testing and services, in the main and partner sites, to educate clients and screen for hepatitis among individuals with mental and substance use disorders who are at risk for hepatitis. Across SAMHSA's three centers, in 2016, nearly 8,000 individuals were tested for viral hepatitis. Of those, 46 persons received positive hepatitis B results, 728 persons received positive rapid/antibody hepatitis C test results, and 149 persons received positive confirmatory hepatitis C test results indicating a chronic infection. Individuals who were confirmed positive were linked to health care for their chronic infection.

In 2016, **IHS** increased HCV screening coverage of baby boomers to 46 percent in federal facilities nationwide. Four facilities have screening coverage rates of more than 75 percent.

In 2016, **VA** HCV birth cohort screening rates increased to 79 percent from 74 percent in 2015.



	Oct 2013 – Sept 2014	Oct 2014 – Sept 2015	Oct 2015 – Sept 2016	Oct 2016 – Dec 2016
Born 1945-1965	2,715,160	2,779,415	2,837,849	2,128,954
HCV tested	1,786,989	1,912,403	2,097,655	1,677,545
Percent tested	65.80	68.81	73.90	78.80

Linkage to Care

Constructing hepatitis B disease state model. **CDC** is working with the University of California, San Francisco, to construct a Markov disease-state model depicting the natural history of acute and chronic hepatitis B and the impact of linkage-to-care interventions on reducing the burden of disease.

Integrated HIV/HCV Testing and Linkage to Care

Using social marketing to promote integrated HIV/HCV services. The **OMH Resource Center** has subcontracted with 12 organizations to implement an HIV and hepatitis social marketing campaign that supports increased awareness of the co-infections of HIV and viral hepatitis, and increases HIV testing and viral hepatitis screening with referrals to care among minority and hard-to-reach communities. These HIV and hepatitis network development subcontracts strengthen existing HIV/AIDS, viral hepatitis, and community health worker programs; combine HIV testing and viral hepatitis screening; and enhance viral hepatitis networks to increase referrals of racial and ethnic minority populations into care and treatment. Agencies and networks will demonstrate how they provide culturally competent care. Information will be evidence-based or informed and address sexual and reproductive health messaging and services to HIV-positive women and men.

Improving care and treatment of HCV in people living with HIV. **HRSA**'s HIV/AIDS Bureau initiated a contract, Identifying Barriers to Hepatitis C Care and Treatment Among People Living with HIV (PLWH), which will collect information from people living with HIV and hepatitis C about the treatment they received through the Ryan White HIV/AIDS Program. The purpose of the study is to (1) identify structural and/or provider/patient-level barriers to increasing hepatitis C care

and treatment for co-infected PLWH, and (2) inform communication with internal and external stakeholders on up-to-date data regarding system, provider, and patient-level barriers to addressing HCV in PLWH. The project started in July 2016, and ran through September 30, 2017.

In 2016, **HRSA**'s HIV/AIDS Bureau initiated a cooperative agreement, Jurisdictional Approach to Curing Hepatitis C Among HIV/HCV Coinfected People of Color. This effort included support from the Secretary's MAI fund and was provided to support Ryan White HIV/AIDS Program grant recipients. The approach increases jurisdiction-level capacity to provide comprehensive screening, care, and treatment for HCV among the program's clients who are co-infected with HIV/HCV, thus increasing the number of co-infected people who are diagnosed, treated, and cured of HCV infection. Three jurisdictions were funded from September 30, 2016, through September 29, 2019.

Improving Viral Hepatitis Treatment and Cure

Increasing treatment options for chronic hepatitis C. In 2016, **FDA** approved three new regimens for the treatment of chronic HCV.

- Zepatier is a fixed-dose combination product containing elbasvir, an HCV NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor. Zepatier is indicated for the treatment of adults with chronic HCV genotype 1 or 4 infection. It is indicated for use with ribavirin in certain patient populations.
- Epclusa is a fixed-dose combination of sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor. Epclusa is indicated for the treatment of adults with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis, with compensated cirrhosis, or, in combination with ribavirin, for decompensated cirrhosis.
- Viekira XR is an extended release tablet that includes dasabuvir, an HCV nonnucleoside NS5B palm polymerase inhibitor; ombitasvir, an HCV NS5A inhibitor; paritaprevir, an HCV NS3/4A protease inhibitor; and ritonavir, a CYP3A inhibitor. It is indicated for the treatment of adults with chronic HCV genotype 1b infection without cirrhosis or with compensated cirrhosis, and for use in genotype 1a infection without cirrhosis or, in combination with ribavirin, for compensated cirrhosis.

Encouraging coverage of HCV medications. As part of the shared commitment of **CMS** and state Medicaid programs to provide access to needed prescribed medications for Medicaid beneficiaries, in November 2015, CMS issued a letter to advise states on the coverage of drugs for Medicaid beneficiaries living with HCV infection. This letter addresses state policies regarding the coverage of FDA-approved direct-acting antiviral (DAA) drugs for the treatment of patients with chronic HCV infection on Medicaid.

Recognizing that manufacturers play a key role in ensuring access and affordability to these medications, **CMS** also sent a letter to the manufacturers of these HCV medications asking them to provide information regarding any value-based purchasing arrangements offered for these drugs, so that states might be able to participate in such arrangements. This effort by CMS may help identify cost-saving opportunities for state Medicaid programs and benefit Medicaid beneficiaries through increased access to curative HCV therapies.

FDA expedited the availability of oral (interferon-free) regimens for patients with difficult-to-treat chronic HCV infection, such as liver transplant or hemodialysis recipients and patients with decompensated liver disease, HIV co-infection, or chronic end-stage renal disease. Interferon-based regimens, the previously available standard of care, were either contraindicated or not well-tolerated in many of these subpopulations due to the adverse side effects associated with interferons. Interferon-free regimens have shorter treatment durations and have improved efficacy and safety profiles. Because of the FDA action, individuals previously ineligible to receive treatment or unable to tolerate interferon-based therapies were able to receive all-oral, interferon-free HCV regimens.

Treating and curing viral hepatitis. Throughout 2016, the **VA** treated 38,358 patients with HCV and cured approximately 94 percent of those individuals.

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

Understanding HCV treatment as prevention among PWID. **NIH**'s NIDA is supporting research modeling simulations to determine the impact of HCV treatment on prevention of HCV in networks of PWID.

Developing and testing novel viral hepatitis prevention interventions. The availability of a small-animal model provides an enormous benefit to research on the pathogenesis, prevention, and treatment of hepatitis B and C. Several such models are being developed by investigators funded by **NIH**'s National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), and NIDDK. Mice implanted with human liver cells can be infected with HBV or HCV, which allows study of the early events that occur in the liver during infection and subsequent cell injury, recovery, or chronic infection. Through a contract supported by NIAID, this mouse model was made available to researchers to evaluate anti-HCV and anti-HBV agents in development.

In 2016, **NIH**-sponsored investigators continued work toward uncovering the basic mechanisms of viral hepatitis infection. In real-world settings, investigators tested the effectiveness of all-oral treatment regimens for managing chronic hepatitis C. The NIDDK Intramural Research Program also conducted ongoing research to develop HCV entry inhibitors for prevention of HCV infection.

Developing improved diagnostics for viral hepatitis. In support of a rapid test for diagnosing hepatitis B and C, **FDA**'s CDRH engaged with device manufacturers at various conferences (AASLD's The Liver Meeting and the AASLD and European Association for the Study of the Liver "HBV Treatment Endpoints" workshop) to encourage them to send pre-submissions to obtain feedback on proposed study designs.

CDRH received feedback from the Association of Public Health Laboratories about the need for a dual claim for HCV viral load assays to enable diagnosis of active HCV infection, as well as management of patients undergoing treatment. The ability to diagnose HCV and obtain the viral load in one test reduces the amount of testing needed per patient and allows physicians to begin treatment more quickly. CDRH worked proactively with diagnostic manufacturers through the pre-submission process to develop a streamlined approach toward supporting the dual claim. Currently, three devices have the dual claim:

- Roche Cobas HCV
- Roche Cobas AmpliPrep/COBAS TaqMan HCV Test, v2.0
- Hologic Aptima HCV Quant Dx Assay

CDRH has approved the Siemens VERSANT HCV Genotype 2.0 Assay Line Probe Assay for genotypes 1 through 6. This is the first approved assay that can determine all six genotypes, allowing less testing per patient and more timely access to treatment.

Improving Treatments for Viral Hepatitis

Facilitating development of novel therapies for chronic hepatitis B and C. In 2016, **FDA**'s CDRH engaged in discussions with the FDA Center for Drug Evaluation and Research (CDER) and a multidisciplinary working group that included AASLD, the Forum for Collaborative Research, and several drug manufacturers. Clinical trial designs, efficacy endpoints, and the diagnostics needed to determine these endpoints were discussed to facilitate development of novel drug therapies for treatment of chronic hepatitis B and C.

Through a formal memorandum of understanding, CDER also collaborated with the Hepatitis C Therapeutic Registry and Research Network, which established a common research database for a longitudinal observational study to evaluate the use of approved DAA medications for the treatment of hepatitis C in clinical practice.

In May 2016, **FDA** issued a revised draft of the guidance for the development of DAA drugs for the treatment of chronic hepatitis C. The final FDA guidance was issued in November 2017.

Highlighting promising practices in hepatitis B treatment. **NIH**'s NIAID held the two-day workshop, "Cures for Chronic Hepatitis B," in April 2016. This important workshop was organized to highlight the challenges in novel drug development and to discuss the most promising current research in both pharmaceutical companies and academia.

NIH's NIDDK supports ongoing studies through the Hepatitis B Research Network, which has the goal of advancing the understanding of disease processes and the natural history of chronic hepatitis B, as well as identifying effective approaches to treatment with currently available therapies. The Network brings together clinical centers from throughout the United States and Canada. Through partnerships with industry and CDC, this multicenter network has initiated two prospective cohort studies (with enrollment of approximately 2,000 patients) and three clinical trials, two of which are now completed, and several supportive ancillary studies. Network investigators targeted special populations, including infected pregnant women, those with acute HBV infections, individuals co-infected with the hepatitis D virus, and individuals who have chronic infections and experience 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 hepatitis B, and the cohort will help define the optimal means of managing hepatitis B in patients with HIV infection. The Network is now completing a five-year study of long-term outcomes and the effects of hepatitis B therapy. It seeks to define the role, if any, of alpha-interferon and to investigate whether it is possible to clear HBV infection, allowing for stopping all antiviral

therapy and coming close to a cure for this daunting DNA virus-induced disease. Funding will continue for the Network through 2020.

NIH's NIDDK Intramural Research Program conducted ongoing research to develop model systems for the development of new drugs to treat chronic hepatitis B.

Researching chronic hepatitis C disease progression. Intramural researchers at the **NIH** Clinical Center and NIAID studied samples from 130 patients with chronic hepatitis C who were prospectively followed over time to determine the association between circulating microRNA levels and disease progression. The study demonstrated that six microRNAs were differentially expressed between patients with mild versus severe chronic hepatitis C, and that the strongest differences were in the let-7 family of microRNAs. Cross-sectional analysis showed that levels of let-7a, 7c, and 7d were inversely correlated with the degree of liver fibrosis by biopsy, FIB-4, and AST to platelet ratio index (APRI) scores. Longitudinal analysis of 60 patients with paired biopsies showed that let-7 levels markedly declined over time, in parallel to fibrosis progression. Hence, decreased levels of let-7 may serve as a surrogate marker for fibrosis progression.

Enhancing liver disease evaluation. A commercial, FDA-approved, ultrasound elastography system is being evaluated prospectively in multiple **NIH**-funded clinical studies on hepatitis C (NIDDK Intramural Research Program), hepatitis B and hepatitis B with HIV co-infection (Hepatitis B Research Network), and hepatitis D (NIDDK Intramural Research Program). Other biomarkers are included in these studies and are compared directly to liver biopsy.

Conducting studies of the efficacy and safety of new oral regimens for hepatitis C in specified populations. **NIH** researchers at NIAID and NIDDK have initiated several clinical research studies of oral regimens of therapy for acute and chronic hepatitis C. These studies are focused on high-risk patients in vulnerable populations who are not usually included in the industry-supported studies that lead to drug licensure. These populations include the uninsured, recent emigrants from Africa and Asia, racial and ethnic minority populations, persons with advanced liver disease and cirrhosis, and persons co-infected with HIV. Special groups include patients with genotype 2, 3, or 4; patients with drug-resistant HCV mutations; and patients who are co-infected with HIV (the studies include SWIFT-C, A5327, A5329, A5335, and STOP-CO). The NIAID STOP-CO trial is evaluating HCV treatment among people infected with HIV who are undergoing or in need of a liver transplant.

***Identifying potential new HCV therapies*.** **NIH** researchers in the NIDDK Intramural Research Program have an ongoing collaboration with the NIH National Center for Advancing Translational Sciences to perform high-throughput screening to identify novel targets and molecules for HCV therapy. One has been identified: the commonly used antihistamine chlorcyclizine, which has shown activity against hepatitis C in cell and animal models. Studies are underway in humans with hepatitis C, including close monitoring for side effects and potential liver damage, and careful analysis of the effects on HCV levels.

***Developing algorithms to increase the use of anti-HDV testing among persons with HBsAg in serum*.** **NIH**'s NIDDK Hepatitis B Research Network has tested all samples in its registry and is now testing them for hepatitis D (HDV) RNA, as well as using a new assay for anti-HDV to retest samples. HDV, for which there is currently no effective treatment, is a rare but important cause of severe liver disease and cirrhosis in individuals co-infected with HBV.

Encouraging development of targeted antiviral agents with activity against 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 the drug lonafarnib may be safe and effective as the only dedicated treatment available for chronic hepatitis D. This first human trial shows promise as a potentially groundbreaking type of therapy for chronic hepatitis D. Future studies will explore long-term therapy, dose adjustment, and combination with other drugs to increase antiviral activity and reduce the side effects of treatment (see Koh, et al.). Since finishing the phase 1 study, this group has initiated and fully enrolled a phase 2 trial of lonafarnib.

Advancing hepatitis E virus (HEV) research. In 2016, **NIH**'s NIDDK and NIAID supported clinical research on HEV, including studies of risk factors for HEV infection, HEV and decompensation of HCV cirrhosis, and HEV infection in U.S. women with HIV infection.

Supporting studies to prevent liver disease and cancer. Intramural researchers at **NIH**'s NIAID, NIDDK, NCI, and the Clinical Center are conducting ongoing translational research studies on the molecular mechanisms of the pathogenesis of acute and chronic liver disease (with a focus on viral 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 hepatitis C to cirrhosis.

Research by the NCI Early Detection Research Network at **NIH** examined changes in the viral genome during the progression to liver cancer. A study published in 2016 by a group from Taiwan identified HBV genetic variants in chronic carriers and correlated these variants with progression to HCC. The identification and monitoring of these viral mutations could be useful for monitoring HBV progression and for the early detection of liver cancer.

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 to work toward combating viral hepatitis through prevention, care, and treatment services. 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 cases.

The following are among the actions undertaken by federal partners in 2016 to strengthen surveillance that detects viral hepatitis transmission and monitors disease.

Monitoring and measuring progression along the HCV care cascade. In 2016, the **VA** supported a national collaborative to refine and disseminate a national hepatitis C dashboard. A working group was developed with the aim of providing guidance and information sharing using electronic tools for screening and treatment metrics to manage HCV within the VA. The dashboard allows for rapid identification of patients in the birth cohort, rapid identification of patients with known or suspected chronic HCV for evaluation and referral, tracking of patients undergoing DAA therapy, tracking local progress toward goals using an electronic scorecard, and sorting patients by clinic assignment, enabling primary care teams to participate in testing and referral-to-care efforts.

Collaborating with external partners to monitor the care cascade. **CDC** announced a project to build an electronic health record-based data system to measure HBV and HCV care cascades in federally qualified health centers and community health centers, and to test interventions to improve cascades. The project provides technical assistance to states to develop and maintain partnerships with federally qualified health centers and community health centers. As a result of this announcement, 46 states, three cities, and the District of Columbia were funded in 2017.

Reporting lab values and results. The **Office of the National Coordinator for Health Information Technology** ensured that electronic lab reporting from electronic health records to public health agencies and registries is required. Those reports are submitted using Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) or Logical Observation Identifiers Names and Codes (LOINC).

Responding to viral hepatitis outbreaks. **HUD**'s SNAPS Office deployed technical assistance providers that provided guidance and support to grantees managing hepatitis A outbreaks.

Coordinating to provide epidemiologic support in areas with increased viral hepatitis infection. In 2016, the **Regional Health Office** Region VIII RRC convened meetings with HRSA and SAMHSA colleagues and the Utah Department of Health to seek information about the viral hepatitis outbreak in Carbon County and to consider methods for preventing a viral hepatitis outbreak.

Collecting and utilizing HCV data. **IHS**, in collaboration with **CDC**, worked to compile HCV trends at the local and national levels to provide information to federal and tribal public health entities, as appropriate. This report was completed in 2017. IHS approved an HCV policy template for sites to customize and implement locally. HCV screening, per CDC and USPSTF recommendations, is a standardized national measure. Other elements of prevention, care, and treatment are not centrally reported, but the IHS Office of Clinical and Preventive Services offers HCV resources for prevention and care to all sites, often with the assistance of external experts, to increase the facility-level capacity for HCV detection, case management, and treatment. As one example, a tribal partner, using Native voice actors, recorded PSA radio text from the CDC Know More Hepatitis website. The PSA aired nationwide on Native America Calling at regular intervals.

Promoting development of quantitative assays for HDV RNA. **NIH**'s NIDDK is assessing these assays in studies, including intramural trials of lonafarnib, and prospectively through the Hepatitis B Research Network. NIH's NIAID Intramural Research Program is developing quantitative assays for HDV RNA.

Promoting development of quantitative assays for HEV RNA. **NIH**'s NIDDK Intramural Research Program, in collaboration with the NIH Clinical Center's Department of Transfusion Medicine and NIAID, is comparing commercial and research assays for HEV markers.

Promoting development of quantitative tests for HBsAg, HBeAg, hepatitis B core antibody, and hepatitis B surface antibody. In 2016, **NIH**'s NIDDK Intramural Research Program conducted ongoing clinical studies to assess new virologic assays for HBV. These assays also are being assessed in the prospective study of the NIDDK Hepatitis B Research Network.

Supporting engagement with providers, laboratories, and patients for improved surveillance. In 2016, **CDC** developed the Strengthening Surveillance in Jurisdictions with High Incidence of Hepatitis C Virus and Hepatitis B Virus Infections (CDC-RFA-PS17-1703) program. Funds provided through this cooperative agreement will be used to enable jurisdictions experiencing high rates of new cases of HCV or HBV infection to engage directly with providers, laboratories, and patients to obtain more complete case information. These statewide viral hepatitis surveillance data will be used to determine and document the burden of disease; identify outbreaks; identify groups that are at high risk of transmitting or acquiring the infections; and support the design, implementation, and evaluation of prevention services, including testing, linkage to care, and treatment.

***Reporting on viral hepatitis surveillance*.** **CDC** published the 2014 Viral Hepatitis Surveillance summary. In CDC's National Notifiable Diseases Surveillance System, viral hepatitis case reports are sent electronically from state and territorial health departments through CDC's National Electronic Telecommunications System for Surveillance, a computerized public health surveillance system that provides CDC with data on a weekly basis.

***Exploring improved viral hepatitis diagnostics*. CDC** received a Small Business Innovation Research award for development of an assay for hepatitis B core antigen. **CDC** also began development on a multiplex magnetic bead-based assay for simultaneous detection of various antibodies against HAV, HBV, HCV, HDV, and HEV.

***Creating new tools for improved hepatitis surveillance*. CDC** developed novel computational algorithms for probabilistic detection of HCV transmission and for distinguishing recent and long-term HCV infections. Work has been initiated to convert these algorithms into Global Hepatitis Outbreak and Surveillance Technology (GHOST) tools. GHOST is a cloud-based, public health research tool that helps state and local health departments more quickly detect and fight the spread of HCV. In addition, CDC conducted a one-week training in the HCV GHOST next-generation sequencing technology at the Tennessee public health laboratory; a three-day wet-lab workshop and GHOST next-generation sequencing training at CDC for public health laboratories from 10 states (Alaska, California, Kentucky, Michigan, Georgia, New York, Maryland, New Hampshire, New Mexico, and Tennessee); and began to pilot GHOST at four public health laboratories from Alaska, Michigan, New Hampshire, and New York.

***Exploring viral hepatitis care cascades*.** In 2016, **CDC** announced a funding opportunity: Improving Hepatitis B and C Care Cascades; Focus on Increased Testing and Diagnosis (PS17-1702). Awardees are required to conduct situational analyses to (1) describe jurisdiction-wide disease burden, epidemiologic trends, and laws/policies that impact the testing, care, and treatment of HBV and HCV infection; (2) identify high-prevalence areas; and (3) identify settings where testing should be conducted, as recommended by CDC and USPSTF.

***Improving our understanding of hepatitis C diagnostics*.** On September 8–9, 2016, **CDC** organized and hosted a Hepatitis C Diagnostic Summit, which focused on key areas of diagnosis and management; policy, practice, and data; diagnostics in global and resource-limited settings; new and improved technologies; and the role of public health.

***Supporting perinatal HCV reporting efforts*. CDC** worked in 2016 with the Council of State and Territorial Epidemiologists to develop a case definition for perinatal HCV.

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 perinatal hepatitis B infection is within our grasp using existing tools, including screening and preventive care. For individuals not vaccinated at birth, we also have safe and effective hepatitis B vaccines that can protect youth and adults, but not enough people get vaccinated. Testing all pregnant women and ensuring proper vaccination for both infants and adults at risk can prevent infections and unnecessary deaths. Receiving all three doses of the hepatitis B vaccine provides greater than 90 percent lifelong protection to newborns, infants, children, and adults if they are immunized before being exposed to the virus. Federal partners worked to eliminate mother-to-child transmission of hepatitis B, increase vaccination for hepatitis A and B, and advance research toward an HCV vaccination.

The following are among the actions undertaken by federal partners in 2016 to eliminate the transmission of vaccine-preventable viral hepatitis.

Enhancing identification of pregnant women with HBV. **CDC** developed a memorandum requesting that U.S. labs report the pregnancy status on HBsAg-positive reports. The memorandum was distributed by the Association of Public Health Laboratories and the American Society for Clinical Pathology to their respective members.

HRSA's Healthy Start program, in the Maternal and Child Health Bureau, targets communities with infant mortality rates that are at least one-and-a-half times the U.S. national average and aims to reduce disparities in birth outcomes. The program's 100 grantees are located in 159 counties in 37 states and Washington, DC. Healthy Start programs (e.g., community health centers, hospital-based) identify pregnant women with hepatitis B infection early in pregnancy and determine appropriate referrals for evaluation, care, treatment, and vaccination during pregnancy. Healthy Start grantees provide screening, referral, and follow-up services for pregnant Healthy Start participants. Healthy Start programs are required to use specific case management approaches to ensure completion of referrals and follow-up.

Tracking hepatitis B vaccination in infants. **CDC** achieved re-endorsement of National Quality Forum measure 0475 (hepatitis B vaccine coverage among all live newborn infants before hospital or birthing facility discharge). In addition, during the re-endorsement process, the measure calculation was changed, such that parent refusals will now be included in the denominator, thereby making the measure more robust for public health use.

Updating HBV vaccination recommendations. **CDC** updated recommendations for "Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices." The update included three main changes: (1) a recommendation for the hepatitis B vaccine birth dose within 24 hours of life for infants weighing 2,000 grams or more,

(2) removal of the permissive language for delaying the birth dose, and (3) an explicit recommendation for hepatitis B vaccination of persons with HCV infection (approved by the Advisory Committee on Immunization Practices in fiscal year 2017).

Supporting training and technical assistance at health centers for the elimination of perinatal hepatitis B. In 2016, **HRSA**'s BPHC awarded a contract (September 2016 – September 2018) to the University of New Mexico's Project ECHO (Extension for Community Healthcare Outcomes) to develop and support an innovative training and technical assistance initiative for 25 HRSA-funded health centers to reduce perinatal HBV transmission in the primary care setting. "HBV ECHO: Reducing Perinatal Transmission" supports primary care clinicians and care teams by providing ongoing mentorship and feedback from HBV specialists through didactic learning sessions, case-based guided learning, and care management. HRSA-funded health center participants present patient cases and learn promising practices to eliminate mother-to-child transmission of HBV through routine HBV screening during prenatal care; evaluation, care, and treatment of HBV-infected women during pregnancy; and HBV vaccination for at-risk women and infants.

Assessing the cost-effectiveness of HBV revaccination in infants. Through funding from the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention's Epidemiologic and Economic Modeling Agreement, **CDC** is working with Emory University on a cost-effectiveness analysis of single-dose HBV revaccination of infants.

Preventing perinatal transmission of hepatitis B. **NIH**'s *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), in collaboration with **CDC**, funded a cooperative agreement to conduct a clinical trial of tenofovir disoproxil fumarate (in addition to standard HBV immune globulin and vaccine) in Thailand for the prevention of HBV transmission from HBeAg-positive women to their infants. This phase III, placebo-controlled, double-blind, randomized clinical trial will assess the efficacy and safety of tenofovir in preventing perinatal transmission of HBV. The hypothesis of this study is that tenofovir, a potent antiviral, can decrease HBV load in pregnant women infected with HBV and thereby reduce the risk of perinatal transmission. Pregnant women participating in this study received tenofovir or a placebo during the last trimester of pregnancy and two months postpartum. The risk of perinatal transmission is being compared between the two groups. The results of the study will help define policy on managing the prevention of perinatal transmission from pregnant women infected with HBV.

In 2016, **CDC** awarded grants under Funding Opportunity Announcement PS16-1602, Perinatal Hepatitis B Prevention Program, Auxiliary Prevention Projects. Five awardees (state and local perinatal programs) are collecting data to inform the use of antiviral therapy among pregnant women infected with HBV, improve post-vaccination serologic testing, and increase identification of pregnant women who are infected.

Understanding perinatal viral hepatitis transmission. A multicenter observational prospective case-control study by **NIH**'s NICHD Maternal-Fetal Medicine Units Network is examining risk factors for HCV transmission from mother to baby and risk factors associated with HCV infection in pregnant women. The study also will describe the outcomes of pregnant women with HCV, as well as the outcomes of their infants up to 18 months. It will enroll 750 pregnant women with HCV infection and 500 pregnant women without HCV infection as comparison controls. **NIH**'s NICHD-funded investigators at the University of Colorado studied the integration and nature of multicellular

immune responses within the maternal-fetal interface to advance understanding of the immune mechanisms and factors that determine how HCV infection is transmitted from women to their offspring during pregnancy. Beginning in fiscal year 2016, **NIH**'s NICHD also supported new grant awards related to maternal hepatitis care and preventing mother-to-child transmission, including identifying the optimal strategy for preventing transmission in cases of maternal HIV-HBV co-infection, and a phase I trial evaluating the safety and pharmacokinetics of prenatal ledipasvir/sofosbuvir treatment in pregnant women with chronic hepatitis C.

Promoting hepatitis A and B vaccination. **IHS** actively distributed hepatitis A and B vaccination recommendations to all IHS, Tribal Health provider, and Urban Indian Health provider facilities. In addition, a clinical decision support algorithm was designed with support from VA experts on chronic liver disease. The algorithm will be pilot tested to determine its ability to increase vaccination coverage, per Advisory Committee on Immunization Practices guidelines.

Launched in early 2016, the NVPO National Adult Immunization Plan calls for developing strategies to increase hepatitis A and B vaccination rates among vulnerable adults and youth. NVPO also is supporting the production of a catalog of priority vaccine targets of domestic and international importance. Funded through a contract with the NIH's Fogarty International Center, the software tool is expected to be completed in 2017.

SAMHSA's MAI-CoC grantees, in the main and partner sites, educate clients and promote hepatitis A and B vaccination for individuals with mental and substance use disorders who are at risk for hepatitis. In 2016, 210 vaccinations were administered (52 of hepatitis A, 50 of hepatitis B, and 108 of the combined hepatitis A and B vaccine).

Routinizing hepatitis vaccination. **OPA** implemented the guidance "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs," which highlights that STD, HIV, and other preconception health services, including some hepatitis-related services, are considered family planning services because they improve women's and men's health and also can influence a person's ability to conceive or have a healthy birth outcome. In particular, the guidance recommends that routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents younger than age 19 and to all unvaccinated adults who do not have a documented history of hepatitis B infection.

Advancing HCV vaccine development. **NIH**'s NIAID is conducting a double-blind, randomized, phase I/II clinical trial to evaluate the safety, immunogenicity, and initial efficacy of a vaccine in preventing acute and chronic hepatitis C infection in high-risk people. All vaccine doses have been administered, and the study is now in the follow-up phase. The projected completion date of the trial is August 2019.

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.

PWID are at increased risk for viral hepatitis. Available data on identified risk factors indicate that more than 25 percent of new hepatitis B cases and 68 percent of new hepatitis C cases indicated use of injection drugs. The opioid epidemic that is gripping parts of the United States is fueling increases in new viral hepatitis infections. Without action, at least 220 counties may be at risk for outbreaks of viral hepatitis and HIV. Addressing the rapidly increasing new hepatitis C infections among PWID will require a comprehensive approach that includes prevention, screening, treatment, and harm-reduction strategies, such as syringe services programs.

The following were among the actions undertaken by federal partners in 2016 to reduce viral hepatitis associated with drug-using behaviors.

Acknowledging the link between opioid use and hepatitis. In August 2016, the **Surgeon General** of the United States issued a letter to medical providers, asking them to help solve the problem of opioid addiction in the United States. He acknowledged that increases in prescription opioid use disorder have contributed to increased heroin use and the spread of HIV and hepatitis C.

Supporting integrated behavioral health and hepatitis treatment. Throughout 2016, the **VA** supported:

- a postdoctoral training program in 10 facilities for psychology fellows who integrated mental health and substance use services into liver and HIV clinics;
- an academic detailing pilot project in which trainers provided onsite, evidence-based information and counseling messages to providers designed to increase the use of pharmacotherapy treatment for alcohol use disorder in HCV treatment clinics and access to treatment among veterans with problematic drinking; and
- three program improvement projects that integrated HCV treatment into substance use disorder clinics.

In March 2016, **HRSA**'s BPHC funded 271 health centers with a total of $94 million as part of a Substance Abuse Service Expansion to increase access to medication-assisted treatment (MAT) and general substance use disorder services. Service expansion included increases in the number of patients receiving substance use disorder services and the total number of health center providers

who can prescribe/dispense MAT, and support for models of integrated behavioral health and primary care. BPHC also supports technical assistance and training for health centers via Project ECHO for opioid use disorder, Substance Use Warmline for clinician-to-clinician telephone consultation, and the SAMHSA/HRSA Center for Integrated Health Solutions for behavioral health integration.

Increasing harm reduction and overdose prevention activities. **IHS** worked to increase overdose prevention and substitution therapy to address adverse addiction-related outcomes and opioid dependence. IHS also worked with tribal partners to increase awareness of tribal programs that engage in harm-reduction activities, such as syringe services programs. IHS and the Bureau of Indian Affairs established a memorandum of understanding addressing overdose prevention. Through this agreement, IHS provides training and naloxone doses to Bureau of Indian Affairs law enforcement for field use.

Providing guidance on the use of federal funds for harm reduction. On March 29, 2016, HHS issued implementation guidance to ensure that states and local communities were aware of the circumstances under which federal funds may be used to support certain components of syringe services programs for PWID. Such programs have been shown to be an effective component of a comprehensive approach to prevent HIV and viral hepatitis among PWID, and they do not increase drug use. The guidance details how state, local, territorial, and tribal health departments must first consult with **CDC**, including the Division of Viral Hepatitis (DVH), to request a determination of demonstrated need to use federal funds for the operational components of syringe services programs. This involves providing evidence that the jurisdiction is experiencing, or is at risk for, significant increases in viral hepatitis infections or an HIV outbreak due to IDU. Subsequently, **CDC, HRSA**, and **SAMHSA** published agency-specific guidance on syringe services programs for their respective grantees. By the end of 2016, more than 21 jurisdictions had made requests to CDC, and 17 of those had been approved.

Understanding viral hepatitis services provision among PWID. **IHS** and tribal partners conducted needs assessments and qualitative research among clinicians and PWID to improve services provision. IHS is collaborating with CDC on a county-level vulnerability assessment for bloodborne outbreaks related to IDU and other substance use.

Coordinating hepatitis efforts specific to PWID. To ensure that PWID are prioritized to receive HBV- and HCV-related interventions and services, **CDC**'s DVH formed a new unit, known as the Epidemiology, Surveillance, and Prevention Among Substance Users (ESPS) Unit, in mid-2016, which is now coordinating all of DVH's PWID-related work.

Working at the local and state levels to address the intersection of hepatitis and IDU. **CDC** is supporting the National Association of County and City Health Officials to work with local health departments in southwestern Virginia to develop a model plan for addressing the syndemics (synergist epidemics) of opioid abuse, HBV, HCV, and HIV through comprehensive, integrated prevention and harm-reduction services. Linkage to care and treatment for those in need also will be addressed. Through community engagement, the plan will address how services can be offered and adapted to meet the needs of rural and suburban communities. The result will be a model practice that can be adapted and implemented by local health departments across the country.

Kentucky held a viral hepatitis conference in July 2016 that was attended by **CDC**'s DVH staff. The DVH ESPS Unit collaborated with the Viral Hepatitis Technical Assistance Center to convene the Appalachian Regional Hepatitis Technical Assistance Meeting, at which eight state health departments gathered to discuss jurisdiction-specific and regional strategies for addressing the epidemic of HCV and HBV among PWID. While in Kentucky, DVH staff traveled to Hazard in Perry County to participate in the town hall, "What's Happening in Our Community? A Look at Injection Drug Use, Hepatitis C, and HIV in Eastern Kentucky." Hosted by the Kentucky Department for Public Health and Shaping Our Appalachian Region, the meeting engaged community, state, and national stakeholders in a discussion of viral hepatitis prevention strategies in Perry County and similar communities. A CDC article was published about the town hall meeting on November 1, 2016.

Expanding capacity to provide substance use disorder services. There are more than 150 participants from more than 80 health centers participating in the HRSA/BPHC-supported multidisciplinary Opioid Addiction Treatment ECHO (OAT ECHO), through a contract with Project ECHO (September 2016 – September 2018). OAT ECHO clinics are organized by five hubs: (1) western New York, (2) the Boston Medical Center, (3) the University of Washington, (4) the University of New Mexico, and (5) Billings, Montana. OAT ECHO provides training and educational resources, including updated prescriber guidelines, to assist health professionals with making informed prescribing decisions and to address the over-prescribing of opioids.

Through the Medicaid Innovation Accelerator Program, **CMS** provided technical assistance and other types of technical support to states interested in accelerating the development and testing of substance use disorder services delivery innovations.

SAMHSA supported training of primary care providers to become buprenorphine or naloxone opioid-dependence treatment providers. In 2016, 8,776 physicians were newly certified to prescribe buprenorphine through the waiver program under the Drug Addiction Treatment Act (DATA). Of these, 4,476 were certified to prescribe for 30 patients, 1,597 for 100 patients, and 2,703 for 275 patients. SAMHSA also collaborated with the Office of National Drug Control Policy through the Providers' Clinical Support System for Medication Assisted Treatment, and worked with the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Psychiatric Association, and the American Osteopathic Academy of Addiction Medicine to provide additional trainings in 2016 for physicians throughout the country to qualify for the DATA waiver to prescribe buprenorphine.

Improving health outcomes among the re-entry population. **OMH**'s Re-Entry Community Linkages (RE-LINK) program aims to improve health outcomes for minority and disadvantaged re-entrants, ages 18–26, in transition from jail to their communities. The RE-LINK program will demonstrate the effectiveness of multiple stakeholders within the public health system and other community support systems working together to implement a model transition process. Through the establishment of health and social services networks comprised of community stakeholders, RE-LINK projects will establish connections between the re-entry population and community-based organizations. In a culturally and linguistically appropriate manner for the populations being served, the networks will provide linkages to health care services (including behavioral health), coverage (including through the Health Insurance Marketplace and Medicaid), and other social services, such

as housing, adult education, and employment assistance programs. This program began on July 1, 2016, and ends on June 30, 2021.

Advancing research on HBV and HCV among PWID. In 2016, **NIH**'s NIDA, in collaboration with **CDC**, **SAMHSA**, and the Appalachian Regional Commission, issued funding opportunity announcements (RFA-DA-17-014 and RFA-DA-17-023) to support research on several aspects of HCV infection among PWID, including services for HCV screening and care, collateral services for HIV prevention and care, and screening for comorbid conditions, such as sexually transmitted infections. CDC is collaborating with NIDA to research strategies for the detection, investigation, and prevention of HBV and HCV (including perinatal transmission) among PWID in nonurban areas. CDC also initiated the development of NIDA RFA-DA-17-023 (Hepatitis C Virus Advanced Molecular Detection in Support of Systems for Prevention, Treatment and Control of HIV, HCV and Related Comorbidities in Rural Communities Affected by Opioid Injection Drug Epidemics in the United States (U24)) for establishing a first GHOST center.

NIH's NIDA funded several additional research studies on the disease progression of HCV infection in drug-abusing populations, as well as testing the efficacy of newly approved DAA medications for the treatment of HCV infection in drug-abusing populations with or without co-occurring HIV infection. Thus, successful treatment of HCV infection may serve as an exceptional prevention modality. In 2016, most of these research studies were in progress, with clinically significant findings being published each year (Carey, et al., Journal of Substance Abuse Treatment, 2016; Hajarizadeh, et al., Virology Journal, 2016; Solomon, et al., PLoS One, 2016; Page, et al., Open Forum Infectious Diseases, 2016; Lamoury, et al., BMC Infectious Diseases, 2016; Rodrigo, et al., Journal of Infectious Diseases, 2016; Bartlett, et al., Infection, Genetics and Evolution, 2016; Falade-Nwulia, et al., Journal of Viral Hepatitis, 2016). Also in 2016, NIDA staff presented talks on HIV/HCV and HCV infection in substance-abusing populations at meetings of professional medical societies (e.g., International Society of Addiction Medicine, Montreal, October 2016).

PRIORITY AREA 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.
6.3 Reduce occupational transmission of viral hepatitis.
6.4 Enhance understanding of the preventable causes of viral hepatitis transmission in health care settings.

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

The following were among the actions taken by federal partners in 2016 to protect patients and health workers from health care-associated viral hepatitis:

Reducing HBV transmission in clinical settings. In 2016, **IHS**, tribal, and urban clinicians were subject to annual qualifications on universal precautions to prevent the transmission of viral hepatitis in medical settings. Per IHS policy, all clinicians have documented HBV vaccination. IHS also initiated planning for a Grand Rounds on HBV, including the topics of transmission and high-risk settings, such as dialysis clinics.

Reduce iatrogenic transmission of viral hepatitis. Studies by **NIH**'s National Heart, Lung, and Blood Institute (NHLBI) are in progress. NHLBI-supported Recipient Epidemiology and Donor Evaluation Study-III continues to find new ways to enhance domestic and international transfusion safety and the practice of blood banking. The Transfusion-Transmissible Infections Monitoring System (TTIMS), supported by FDA and NHLBI, helps ensure the continued safety of the U.S. blood supply and monitors the effects of FDA's policy change regarding MSM blood donation deferrals. The national blood surveillance system monitors for HIV and hepatitis virus infections, specifically for HBV and HCV, among blood donors and donations.

Promoting safe organ transplantation. In 2016, **HRSA**'s Organ Procurement and Transplantation Network (OPTN) Ad Hoc Disease Transmission Advisory Committee (DTAC) modified OPTN Policy 15.4 to refocus on timely reporting of relevant cultures and pathology results, improve communication pathways, concentrate on recipient illness, and create specialized lists for donors and recipients. As a result, average monthly reports to the OPTN Ad Hoc DTAC have decreased since September 2016. The overall risk of unexpected donor-derived disease remains very low. Also in 2016, DTAC issued a policy notice stating that transplant programs must communicate any test results or information received posttransplant which indicate that donor-derived disease is possible. The policy details the requirements for discovery, reporting, and follow-up of a posttransplant discovery of donor disease or malignancy.

APPENDIX A – 2016 PUBLICATIONS

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

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

Beste, L. A., Mattox, E. A., Pichler, R., Young, B. A., Au, D. H., Kirsh, S. F., … Chang, M. F. (2016). Primary care team members report greater individual benefits from long- versus short-term specialty telemedicine mentorship. *Telemedicine Journal and E-Health, 22*(8), 699–706.

Yan, M., Ha, J., Aguilar M., Bhuket, T., Liu, B., Gish, R. G., … Wong, R. J. (2016). Birth cohort-specific disparities in hepatocellular carcinoma stage at diagnosis, treatment, and long-term survival. *Journal of Hepatology, 64*(2), 326–332.

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

Backus, L. I., Belperio, P. S., Shahoumian, T. A., Loomis, T. P., & Mole, L. A. (2016). Comparative effectiveness of ledipasvir/sofosbuvir ± ribavirin vs. ombitasvir/paritaprevir/ritonavir + dasabuvir ± ribavirin in 6961 genotype 1 patients treated in routine medical practice. *Alimentary Pharmacology and Therapeutics, 44*(4), 400–410.

Backus, L. I., Belperio, P. S., Shahoumian, T. A., Loomis, T. P., & Mole, L. A. (2016). Real-world effectiveness of ledipasvir/sofosbuvir in 4,365 treatment-naive, genotype 1 hepatitis C-infected patients. *Hepatology, 64*(2), 405–414.

Backus, L. I., Belperio, P. S., Shahoumian, T. A., Loomis, T. P., & Mole, L. A. (2017). Real-world effectiveness and predictors of sustained virological response with all-oral therapy in 21,242 hepatitis C genotype-1 patients. *Antiviral Therapy, 22*(6), 481–493.

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Evon, D. M., Wahed, A. S., Johnson, G., Khalili, M., Lisker-Melman, M., Fontana, R. J., … Hoofnagle, J. H. (2016). Fatigue in patients with chronic hepatitis B living in North America: Results from the Hepatitis B Research Network (HBRN). *Digestive Diseases and Sciences, 61*(4), 1186–1196.

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PRIORITY AREA 5 – Reducing Viral Hepatitis Associated with Drug Use Behaviors

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APPENDIX B – ABBREVIATIONS

AAPCHO	Association of Asian Pacific Community Health Organizations
AAPI	Asian American and Pacific Islander
AASLD	American Association for the Study of Liver Diseases
ACL	Administration for Community Living (HHS)
AETC	AIDS Education and Training Centers (HRSA)
AHRQ	Agency for Healthcare Research and Quality (HHS)
APRI	AST to platelet ratio index
ATTC	Addiction Technology Transfer Center (SAMHSA)
BPHC	Bureau of Primary Health Care (HRSA)
CDC	Centers for Disease Control and Prevention (HHS)
CDRH	Center for Devices and Radiological Heath (FDA)
CDS	Clinical decision support
CMS	Centers for Medicare & Medicaid Services (HHS)
CPD	Office of Community Planning and Development (HUD)
CSAP	Center for Substance Abuse Prevention (SAMHSA)
CSAT	Center for Substance Abuse Treatment (SAMHSA)
DAA	Direct-acting antiviral
DOJ	U.S. Department of Justice
DVH	Division of Viral Hepatitis (CDC)
eCQM	Electronic clinical quality measures
FBOP	Federal Bureau of Prisons (DOJ)
FDA	U.S. Food and Drug Administration (HHS)
HAV	Hepatitis A virus
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCC	Hepatocellular carcinoma
HCV	Hepatitis C virus
HDV	Hepatitis D 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
IDSA	Infectious Diseases Society of America
IDU	Injection drug use
IHS	Indian Health Service (HHS)
IPT/TA	Intervention in-person training and technical assistance
LGBT	Lesbian, gay, bisexual, and transgender
MAI-CoC	Minority AIDS Initiative Continuum of Care (SAMHSA)
MAT	Medication-assisted treatment
MMWR	Morbidity and Mortality Weekly Report
MSM	Men who have sex with men
NAT	Nucleic acid test
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

	(CDC)
NCI	National Cancer Institute (NIH)
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NHLBI	National Heart, Lung, and Blood Institute (NIH)
NIAID	National Institute of Allergy and Infectious Diseases
NICHD	*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)
NIH	National Institutes of Health (HHS)
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office (HHS)
OASH	Office of the Assistant Secretary for Health (HHS)
OCR	Office for Civil Rights (HHS)
OHAIDP	Office of HIV/AIDS and Infectious Disease Policy (HHS)
OMH	Office of Minority Health (HHS)
ONC	Office of the National Coordinator for Health Information Technology (HHS)
OPA	Office of Population Affairs (HHS)
OSG	Office of the Surgeon General (HHS)
OTP	Opioid treatment program
OWH	Office on Women's Health (HHS)
P4C	Partnerships for Care (HRSA and CDC)
PHS	U.S. Public Health Service (HHS)
PWID	People who inject drugs
RHA	Regional Health Administrator (HHS)
RRC	Regional resource coordinator
SAMHSA	Substance Abuse and Mental Health Services Administration (HHS)
USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
VHA	Veterans Health Administration (VA)
VHIG	Viral Hepatitis Implementation Group
VHPC	State viral hepatitis prevention coordinator
VISN	Veterans Integrated Services Network (VA)
VISN HIT	VISN hepatitis C innovation team

Description of Chart "Number and Percentage of Initiated and Completed Actions by Priority Area 2014–2016"

Bar chart showing number and percentage of initiated and completed actions by priority area, 2014-2016. The chart shows the following: 69 initiated/completed actions (94.52%) in priority area 1, "Educating Providers and Communities to Reduce Health Disparities"; 84 initiated/completed actions (95.45%) in priority area 2, "Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer"; 37 initiated/completed actions (94.87%) in priority area 3, "Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease"; 37 initiated/completed actions (82.22%) in priority area 4, "Eliminating Transmission of Vaccine-Preventable Viral Hepatitis"; 37 initiated/completed actions (92.50%) in priority area 5, "Reducing Viral Hepatitis Caused by Drug Use Behaviors"; and 24 initiated/completed actions (72.73%) in priority area 6, "Protecting Patients and Workers from Health Care-Associated Viral Hepatitis."