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

Updated

2014-2016

Combating the Silent Epidemic of Viral Hepatitis

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This digital version of the *2014-2016 Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis*-- originally released in spring 2014-- was updated March 2015. The revisions to this version involve the data sources that will be used to monitor progress toward the Action Plan's first and second goals (pages 71, 72, and 75) as well as an addition to the list of members of the inter-agency Viral Hepatitis Implementation Group beginning on page 77.

This Action Plan was prepared under the direction of the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS). The plan was developed collaboratively with input from representatives of all the participating federal agencies and offices from across HHS as well as from the Department of Veterans Affairs, the Department of Justice's Federal Bureau of Prisons, and the Department of Housing and Urban Development. Ms. Corinna Dan, RN, M.P.H., Viral Hepatitis Policy Advisor in OHAIDP, coordinated development of this plan. Ms. Antigone Dempsey, M.Ed., Ms. Kelly Stevens, Ms. Deborah Finette, and Mr. Roy Quini of Altarum Institute and Mr. Steve Holman, M.B.A., all working under contract to OHAIDP, assisted OHAIDP staff in developing and formatting the plan.

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Introduction

Viral hepatitis remains a silent epidemic in the United States. Most of the 3.5–5.3 million Americans living with viral hepatitis do not know that they are infected, placing them at greater risk for severe, even fatal, complications from the disease and increasing the likelihood that they will spread the virus to others. Viral hepatitis can persist undetected for many years before manifesting as chronic liver disease, cirrhosis (scarring of the liver) or even liver cancer. As a result, viral hepatitis is a leading infectious cause of death and claims the lives of 12,000–18,000 Americans each year. It is the leading cause of liver cancer and the most common reason for liver transplantation. In 2007, deaths due to viral hepatitis outpaced deaths due to HIV. Despite these facts, awareness of viral hepatitis remains very low in the general public and among at risk populations. Even health care providers can lack knowledge and awareness about these infections.

To confront this significant cause of morbidity and mortality, the U.S. Department of Health and Human Services (HHS) led the development of a cross-agency action plan. Released in 2011, *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis* articulated robust and dynamic steps for improving viral hepatitis prevention and the care and treatment available to infected individuals. In the 3 years since its release, offices and agencies across HHS have been joined by partners from the U.S. Department of Housing and Urban Development (HUD), the U.S. Department of Justice's Federal Bureau of Prisons (FBOP), and the U.S. Department of Veterans Affairs (VA) as well as state and local health departments and academic and community-based partners to implement these steps, bringing new energy to the nation's response to this heretofore silent epidemic.

> ***"Viral hepatitis is a silent epidemic, and we can only defeat it if we break that silence. Now is the time to learn the risk factors for hepatitis; talk to family, friends, and neighbors who may be at risk; and to speak with healthcare providers about strategies for staying healthy…. [L]et each of us lend our support to those living with hepatitis and do our part to bring this epidemic to an end."***
>
> ***—President Barack Obama***
> ***World Hepatitis Day Proclamation***
> ***July 26, 2013***

In May 2013, reflecting on their progress to date and encouraged by emerging opportunities for even greater progress resulting from the promise of emerging hepatitis C treatments as well as the expansion of access to viral hepatitis prevention, care, and treatment offered by the Affordable Care Act, the partners agreed to propel these efforts further by renewing the Action Plan for another 3 years by outlining specific actions for 2014–2016.

Nonfederal stakeholders were strongly supportive of this renewal effort and played a critical role in providing input into the process. All agreed that the updated plan should explicitly embrace the vital contributions of both federal and nonfederal stakeholders in achieving the national goals for the prevention, diagnosis, care, and treatment of viral hepatitis in the United States.

Goals and Priority Areas

This renewed plan maintains the goals set forth in the original Action Plan:

- Increase the proportion of persons who are aware of their hepatitis B virus (HBV) infection from 33 percent to 66 percent,
- Increase the proportion of persons who are aware of their hepatitis C virus (HCV) infection from 45 percent to 66 percent,
- Reduce the number of new cases of HCV infection by 25 percent, and
- Eliminate mother-to-child transmission of HBV.

In addition, the renewed plan maintains the six original priority areas around which its actions are grouped:

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

Developing the Renewed Viral Hepatitis Action Plan

Using this framework as a foundation, in the latter half of 2013, federal partners worked within their respective agencies and offices to identify strategic actions to be undertaken beginning in 2014 and continuing through 2016. Members of the cross-agency Viral Hepatitis Implementation Group (VHIG) led these efforts (see appendix A for a list of VHIG members), but many federal staff contributed to the development of the actions contained in this plan (see Appendix B for a list). Valuable input about these actions was obtained from nonfederal stakeholders via three scheduled teleconferences, and a formal Request for Information that was published in the *Federal Register* on June 5, 2013. More than 100 thoughtful comments and suggestions were received from stakeholders representing health departments, community groups, patient advocacy groups, providers, and academic researchers. Many of these ideas are reflected, directly and indirectly, in this renewed plan. After they had been received, reviewed, and discussed with members of the VHIG, the proposed actions were consolidated and refined by the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) at HHS, the office responsible for coordinating the implementation of the Viral Hepatitis Action Plan.

Background

Viral Hepatitis: The Silent Epidemic

Viral hepatitis is caused by infection with any of at least five distinct viruses: hepatitis A virus (HAV), HBV, HCV, hepatitis D virus (HDV), and hepatitis E virus (HEV). Most symptomatic viral hepatitis infections in the United States are attributable to HAV, HBV, and HCV. All three of these unrelated viruses can cause severe illness in newly infected individuals, characterized by nausea, malaise, abdominal pain, and jaundice. But many new infections cause only mild symptoms or, in some cases, no symptoms at all. HBV and HCV can progress to chronic infections, but many who are chronically infected manifest no obvious signs or symptoms for decades—until they present with cirrhosis, end-stage liver disease, or hepatocellular carcinoma (a type of liver cancer).

Because chronic viral hepatitis B and C infection can persist for decades without symptoms, 65–75 percent of infected Americans remain unaware of their infection status and are not receiving necessary care and treatment.[1] As a result, viral hepatitis is a leading cause of liver disease in the United States and the most common reason for liver transplantation.[2] In the decade to come, more than 150,000 Americans are expected to die from viral-hepatitis-associated liver cancer or end-stage liver disease[3] unless steps are taken to increase awareness, diagnosis, and access to necessary care, and treatment, including curative treatment for HCV.

Viral-Hepatitis-Related Health Disparities

Liver cancer and other liver diseases resulting from long-term liver damage secondary to untreated viral hepatitis (e.g., cirrhosis) affect some U.S. populations more than others, resulting in substantial health disparities. In the United States, HBV disproportionately affects Asian Americans and Pacific Islanders (AAPI). In fact, 1 in 12 AAPIs lives with hepatitis B, representing half of all HBV-infected persons in the United States. Sadly, these health disparities are reflected in viral hepatitis-associated morbidity and mortality; liver cancer incidence is highest among AAPIs. Other demographic groups bear a disproportionate burden of disease related to undiagnosed and untreated viral hepatitis. American Indian and Alaska Natives (AI/AN) were reported to have the highest incidence of acute HCV by race/ethnicity for the period 2000-2011[4]; and while African Americans represent about 12 percent of the U.S. population, they make up about 22 percent of the chronic HCV cases. Chronic liver disease, often hepatitis C-related, is a leading cause of death among African Americans ages 45–64. Another disproportionately affected population are the so-called "baby boomers," those individuals born between 1945 and 1965. Of the approximately three million adults infected with HCV in the United States, most are baby boomers. It is estimated that baby boomers are five times more likely to have hepatitis C than any other age group.[5]

Persons with certain risk behaviors, including men who have sex with men (MSM) and persons who inject drugs (PWID), also have very high rates of viral hepatitis. Despite the availability of a safe and effective vaccine for HBV, many MSM have not been adequately vaccinated against this virus, which can be sexually transmitted. In fact, approximately 15–25 percent of all new HBV infections in the United States are among MSM.[6] Exposure to contaminated blood through injection drug use is a primary risk factor for both HBV and HCV, both of which are bloodborne pathogens. Of new cases of

hepatitis C reported to the Centers for Disease Control and Prevention (CDC), injection drug use is the most commonly reported risk factor.

Persons living with HIV/AIDS (PLWHA) also are disproportionately affected by viral hepatitis. Because HIV, HBV, and HCV share common modes of transmission, on average, one-third of HIV-infected persons are co-infected with HBV or HCV, though certain groups, like PWID, have even higher rates of co-infection. Research shows that of PLWHA in the United States, about 25 percent also live with hepatitis C and about 10 percent live with hepatitis B.[7] The progression of viral hepatitis is accelerated among persons with HIV; therefore, persons who are co-infected experience greater liver-related health problems than non-HIV-infected persons.[8] In fact, liver disease caused by hepatitis B and C has become a leading cause of non-AIDS-related deaths in PLWHA in the United States.[9]

Viral Hepatitis Transmission Associated with Health Care Delivery

Transmission of HBV and HCV can occur in a wide variety of health care settings. Dramatic progress has been made in reducing the risks of transfusion-associated HBV and HCV infections; estimated residual risk of HBV transmission through transfusion is approximately 1 per 600,000-700,000 blood units, which remains higher than those of HIV and HCV at less than 1 per million units. However, outbreaks continue to occur as a result of breakdowns in basic infection control, sharps injuries, and other unsafe health care practices. Outside of confirmed outbreaks, unrecognized health care-related exposure to HBV and HCV is believed to occur sporadically, most often associated with injection of medication and hemodialysis.[10] Notably, changes in health care delivery methods that may contribute to transmission include the increased volume of health care delivered in ambulatory care settings where increasingly complex procedures are performed and where older adults who are more likely to have had past exposure to viral hepatitis are receiving care. Reductions in health care transmission are partially due to the availability of single-use needles, syringes, and medication vials; safety-engineered technologies and strategies such as prefilled syringes with tamper-proof packaging; and improved labeling. Enhanced infection control practice, education, oversight, and enforcement are critical strategies to further reduce transmission of viral hepatitis in health care settings.

The Preventable Costs of Viral Hepatitis

In addition to causing substantial morbidity and mortality, viral hepatitis infection has adverse economic consequences. End-stage treatments for viral hepatitis (e.g., liver transplants) are expensive: The lifetime health care costs for a person with viral hepatitis can easily total hundreds of thousands of dollars.[11] These costs usually do not occur in isolation; viral hepatitis may contribute to the costs of care for co-occurring conditions such as HIV, substance abuse disorders, etc. Research has shown that compared with other patients of similar age and sex, managed-care enrollees with HCV are hospitalized more frequently (24 percent for HCV-infected persons versus 7 percent for other patients). Hepatitis C also increases other societal costs: A study of 339,456 workers revealed that employees with HCV had significantly more lost workdays than other employees, resulting in lost productivity.[12] However, hepatitis C therapy can lead to a cure that has been shown to reduce liver-related disease and deaths[13, 14] as well as deaths due to all causes in individuals with chronic HCV. The prevention of liver disease caused by HCV naturally reduces the costs associated with caring for individuals experiencing consequences of untreated HCV such as

cirrhosis, end-stage liver disease, and liver cancer. Hepatitis B therapy has also been shown to reduce liver disease progression, thus reducing the high costs of these same consequences of untreated infection.[15] Vaccination for hepatitis B is a cost-saving intervention, as it effectively prevents chronic hepatitis B in almost all individuals who complete the series of three shots, thereby preventing the vast majority of HBV-related liver disease and death.

The Epidemiology of Viral Hepatitis

Hepatitis B

In the United States, an estimated 800,000–1.4 million persons are chronically infected with HBV. In 2011, there were approximately 2,890 new cases of hepatitis B infection reported to the CDC.[16] Due to underreporting, the CDC estimates that there are actually 6.5 new infections for every reported case, leading to an estimated 18,800 new cases of HBV in 2011. Hepatitis B is a vaccine-preventable disease; immunization programs for infants and adolescents have resulted in substantial declines in the incidence of HBV infection in young people.[17] HBV is spread in several distinct ways: from mother to infant at the time of birth, through incidental household exposures to blood, through injection drug use, and through sexual contact.[18, 19, 20] Globally, inadequate infection control in health care settings represents a significant mode of viral hepatitis transmission. Rates of HBV infection are highest among adults, reflecting low hepatitis B vaccination coverage among persons at risk.[21, 22, 23, 24] About 20 percent of all new HBV infections in the United States are among MSM.

Mother-to-child transmission of HBV is especially concerning, because it is preventable Tragically 90 percent of HBV-infected newborns will develop chronic infection, remaining infected throughout their lives, and up to 25 percent of these children will die of cirrhosis, liver failure, or liver cancer later in life. Of adults newly infected with HBV, only 5 percent go on to become chronically infected with the disease.[25]

To improve health outcomes for those living with hepatitis B in the United States, the CDC developed and issued guidelines that emphasize the need for testing of persons at high risk for the disease, educating patients, and administering U.S. Food and Drug Administration (FDA)-approved treatments for hepatitis B.[26] In addition, the standard of care for pregnant women includes an HBV test during each pregnancy, since effective interventions are available to prevent transmission to an infant in almost all cases.

Hepatitis C

In the United States, it is estimated that as many as 3.2 million persons may be chronically infected with HCV.[27] Because HCV is primarily spread through contact with infected blood, PWID are at increased risk for HCV infection.[28, 29, 30, 31] Much less often, HCV transmission occurs among HIV-positive MSM as a result of sexual contact with an HCV-infected partner. Among persons with HIV who report a history of injection drug use, nearly three-quarters are also co-infected with HCV.[32] For the past several years, the CDC has estimated relatively stable HCV incidence; but in 2011, there was an increase of 45 percent in reported new HCV infections. This increase was among predominantly White adolescents and young adults with histories of injection drug use and previous use of prescription opioids such as oxycodone, mostly in nonurban areas.[33]

In terms of chronic HCV infection, research shows that of all people living with HCV in the United States, 75 percent were born between 1945 and 1965. To address HCV in the baby boomer population, in 2012 and 2013, the CDC and the U.S. Preventive Services Task Force (USPSTF), respectively, issued guidelines recommending that one-time screening for the virus be offered to all persons born between 1945 and 1965,[34, 35] regardless of risk history. HCV transmission can also occur through breaches in infection control practices in health care facilities[36] and, rarely, from mother to child at the time of birth.

HAV, HDV, and HEV

In addition to HBV and HCV, at least three other pathogens can cause viral hepatitis in the United States: HAV, HEV, and HDV.[37] Spread by the fecal-oral route, HAV is largely transmitted by person-to-person contact and through exposure to contaminated food and food products.[38, 39] Hepatitis A is vaccine-preventable, with childhood vaccination contributing to substantial declines in hepatitis A incidence[40]; however, adults at risk for hepatitis A have low rates of vaccination and, as a result, the highest incidence of disease.[41] A combination HAV/HBV vaccine is available and can be useful in increasing vaccination rates among vulnerable adults at risk for both infections.

Also spread by the fecal-oral route, HEV represents the leading cause of viral hepatitis in South and Central Asia, Sub-Saharan Africa, and the Middle East.[42] Although clinical cases of hepatitis E are rarely reported in the United States, serologic surveys suggest that a substantial number of persons have been exposed in the past[43]; additional data are needed to explain this discrepancy.

The hepatitis D virus is unique in that it can replicate only in the presence of HBV; therefore, it is only found in co-infection among persons who are chronically infected with HBV.[44, 45] Thus, hepatitis B vaccination is protective against both HBV and HDV infection.

History of the Viral Hepatitis Action Plan

The original 3-year *Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis*, released in 2011, was developed in response to a January 2010 report from the Institute of Medicine (IOM). In that report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*,[46] the IOM identified viral hepatitis as an underappreciated health concern for the nation and outlined multiple barriers impeding efforts to prevent and control viral hepatitis transmission and disease. In its 2010 report, the IOM provided 22 specific recommendations to help improve disease surveillance, knowledge and awareness of viral hepatitis among the public and providers, access to vaccination, and delivery of viral hepatitis prevention and care services. See appendix C for a summary of the IOM recommendations.

In response to the IOM report, Assistant Secretary for Health Dr. Howard Koh convened a cross-departmental working group to respond to the IOM recommendations by developing a comprehensive strategic viral hepatitis action plan that would

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

After conferring with expert panels comprised of representatives of various HHS agencies and offices; consulting federal colleagues from other government departments whose work addresses viral hepatitis; and soliciting input from nonfederal stakeholders including professional societies, community-based organizations, and other members of the public, the working group produced *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis*. Released in May 2011 by Dr. Koh, the Action Plan has enhanced collaborative federal efforts to address viral hepatitis and served as a foundation for strengthening partnerships with stakeholders outside of government. The cross-departmental VHIG has met regularly to monitor progress and has released two progress reports featuring highlights from actions undertaken in 2012 and 2013.

Emerging Trends and New Opportunities for Addressing Viral Hepatitis in 2014 and Beyond

Since the release of the Viral Hepatitis Action Plan in 2011, several important trends have emerged, along with significant new advances and opportunities that can be leveraged as part of national efforts to combat the silent epidemic of viral hepatitis in the United States.

Growing Awareness Among Disproportionately Affected Populations

Inspired in part by the Action Plan, recent years have seen increased awareness of the impact of viral hepatitis among racial and ethnic minority communities. The CDC has supported this trend by partnering with a national AAPI network to raise awareness of hepatitis B in the community through the "Know Hepatitis B" education campaign, which encourages AAPIs to talk to their doctors about getting tested for hepatitis B. Groups from African American, Hispanic, and American Indian and Alaska Native (AI/AN) communities are also working to engage their constituents, raise awareness, and collaborate to address viral hepatitis health disparities and are critical partners in developing culturally competent and linguistically appropriate messages and materials. Similarly, through its *Know More Hepatitis* campaign, the CDC has conducted targeted outreach to baby boomers to raise awareness of the recommendation for one-time HCV screening among this population. Supporting and expanding this growing awareness among these and other key affected populations in the United States and the providers who serve them will continue to be an important aspect of the renewed plan and related opportunities for expanded stakeholder engagement.

HCV Treatment Advances

It can be said that the dawn of a new era in treating HCV infection arrived at the same time that the original Viral Hepatitis Action Plan was released with the FDA's approval of the first two direct-acting antiviral agents (DAA) in spring 2011.* In late 2013, the FDA approved two additional DAAs,** including the first drug that has demonstrated safety and efficacy to treat certain types of HCV infection without the need for co-administration of interferon. These new drugs further advance the shift in the treatment paradigm for chronic hepatitis C, with higher cure rates, therapies of shorter duration, and simpler dosing regimens (e.g., those treatments that no longer require interferon), all of which can improve patient acceptance and adherence. A number of additional DAAs are currently in the drug development pipeline. Some of these could come to market during the 3-year period of this renewed Viral Hepatitis Action Plan. As such, the treatment

*, ** http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/ucm151488.htm

landscape for chronic HCV infection will remain dynamic during the ongoing implementation of the Action Plan, requiring the review and updating of important treatment information both for providers and consumers.

HCV Testing Advances

As awareness of viral hepatitis increases and treatment options become more effective and better tolerated, it is vital that we implement policies and best practices to improve the frequency, availability, and acceptability of viral hepatitis testing. A major contribution toward these aims came about in 2013 with the harmonization of the CDC and USPSTF recommendations for HCV screening.[47, 48] Both now recommend HCV screening in persons at high risk for infection as well as one-time screening for HCV infection in baby boomers. These aligned recommendations from USPSTF and the CDC send a clear signal to health care professionals, policy makers, and the public that screening for HCV is both effective and necessary. This alignment will serve to reduce confusion about conflicting screening guidelines that previously existed among some health care providers and payers, increase provider and public awareness of the importance of hepatitis C screening, and improve HCV testing rates, ultimately identifying millions of Americans previously unaware of their infection status and directing them to lifesaving care that can prevent serious complications from undiagnosed HCV disease. But accurate diagnosis relies on a follow-up HCV RNA test to confirm chronic infection. As reported by the CDC in 2013, as many as half of all adults who had a positive antibody (screening) test for HCV lacked the confirmatory HCV RNA testing.[49] This finding indicates that testing and reporting practices must improve in order to accurately detect all persons with current infection so that they can be linked to appropriate care and treatment.

Growing Trend of HCV Infection Among Young PWID

In recent years, an emerging epidemic of HCV infection has been detected among young PWID in rural and suburban settings in the United States. Several states have reported similar findings--rising rates of hepatitis C infection among young people, primarily White, both male and female, from suburban and rural settings, who inject drugs, and who started misusing prescription opioids (e.g., oxycodone) before transitioning to heroin injection.[50] There is growing concern that these increases could begin to reverse the decline in overall HCV incidence and prevalence observed by the CDC over the past two decades. It is clear that federal, state, local, and community partners need to take action if we are to mount an effective public health response. These efforts must include enhanced surveillance to better describe the scope of this problem, clinical and community-based research into effective strategies to intervene, and the development of age-appropriate prevention and treatment services.

Advances in the Science of Viral Hepatitis

Our understanding of all forms of viral hepatitis and their treatment has expanded significantly in recent years and will continue to evolve during the implementation of the renewed Viral Hepatitis Action Plan. This is due in part to the research activities conducted or supported by various U.S. federal agencies. These research activities improve our understanding of the transmission, prevention, treatment, and long-term consequences and complications resulting from viral hepatitis infection. The HCV treatment and testing advances referenced above are just two examples of the important progress in viral hepatitis science in recent years. During the

implementation of the renewed Viral Hepatitis Action Plan, a great variety of research activities will continue in numerous institutes across the National Institutes of Health (NIH), at the CDC, at the FDA, and in numerous academic and industry research facilities. Findings resulting from these activities will yield new information, interventions, therapies, or other tools that stakeholders will need to integrate into activities already underway to pursue the goals of the Viral Hepatitis Action Plan.

Opportunities Arising from the Affordable Care Act

The ongoing implementation of the Affordable Care Act provides multiple opportunities to support implementation of the renewed Viral Hepatitis Action Plan. The Affordable Care Act is improving access to health coverage and health care services through expansion of public and private insurance; reforms that eliminate discriminatory insurance practices and make insurance coverage more affordable; and significant investments in prevention, care coordination, and health workforce and infrastructure. Although barriers to access will likely remain, expanding access to high-quality health insurance coverage to millions of Americans will increase access to viral hepatitis vaccination, improve the timely identification of persons living with chronic viral hepatitis, and facilitate the provision of viral hepatitis care and treatment.

With the law's prohibition on denial of health coverage based on preexisting conditions, some people living with chronic viral hepatitis who had gone without health coverage will now be able to access it and thus access needed prevention, care, and treatment services. Others who may have been afraid to be tested for fear of being dropped from their coverage or denied future health insurance benefits may now feel more confident in seeking screening.

The Affordable Care Act requires health plans sold in the individual and small group markets as well as state-based Medicaid packages for newly eligible beneficiaries to cover 10 categories of "essential health benefits." These benefits include clinical preventive services recommended by the USPSTF (i.e., those graded "A" or "B"), which plans must cover without charging a copayment or coinsurance. The preventive services specific to viral hepatitis include hepatitis B screening for pregnant women at their first prenatal visit and immunizations recommended by the Advisory Committee on Immunization Practices (ACIP), such as those for hepatitis A and hepatitis B. The USPSTF-recommended HCV screening for persons at high risk for infection, and one time HCV screening for persons born between 1945 and 1965, will be added to this list in June 2014, 1 year after that recommendation was issued, so communicating that development to both providers and the affected population will be an important activity for all Action Plan stakeholders.

In addition, the law calls for a substantial investment in the HHS community health center program. Community health centers work to improve access to comprehensive, culturally competent, high-quality primary health care services for underserved populations, many of whom also have higher rates of chronic viral hepatitis. This vital health care safety net became an even more important source of care for millions of low-income people beginning in 2014, when millions of people gaining new access to health coverage entered the health care system. The ongoing investment in the expansion of these centers will better equip them to provide necessary prevention, screening, care, and treatment for viral hepatitis.

Action Plan Overview

Vision, Purpose, and Goals

The Viral Hepatitis Action Plan envisions a nation resolved to combat the silent epidemic of viral hepatitis. Supporters of the Viral Hepatitis Action Plan are committed to ensuring that new cases of viral hepatitis are prevented and that persons who are already infected are tested; informed about their infection; and provided with high-quality counseling, care, and treatment.

This commitment was evident in the original Action Plan released in 2011 and the myriad actions subsequently undertaken. The commitment is also evidenced in *Healthy People 2020*, the ambitious yet achievable 10-year agenda for improving the nation's health released in 2010, which, for the first time, identifies increasing awareness of viral hepatitis infection among infected persons as a formal objective.

This renewal of the Viral Hepatitis Action Plan helps further chart a course toward four overarching goals:

- Increase the proportion of persons who are aware of their HBV infection from 33 percent to 66 percent,
- Increase the proportion of persons who are aware of their HCV infection from 45 percent to 66 percent,
- Reduce the number of new cases of HCV infection by 25 percent, and
- Eliminate mother-to-child transmission of HBV.

The Viral Hepatitis Action Plan provides a framework and focus around which both federal and nonfederal stakeholders can engage in strengthening the nation's response to viral hepatitis and seeks to leverage opportunities to improve the coordination of viral hepatitis activities across federal programs and with the efforts of the wide variety of nonfederal stakeholders. The Action Plan also supports the public health and primary care infrastructures needed for viral hepatitis prevention, care, and treatment at the federal, state, and local levels.

Structure

The renewed Viral Hepatitis Action Plan is organized similarly to the original 2011 plan around six topic areas (referred to as priority areas), which correspond to the 2010 IOM recommendations. The many partners involved in developing and implementing the plan agree that concerted action in each of these priority areas will be necessary in order to achieve the goals set forth:

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

The updated Action Plan presents a brief rationale for each of the six priority areas and a narrative summary broadly characterizing the actions to be taken. A list of specific actions follows each summary section. The current plan presents 155 specific actions that the 14 agencies or offices from across four federal departments have committed to carrying out, often in collaboration with other partners.

This renewed plan also underscores that success cannot be achieved by federal action alone and requires the support and commitment of a broad mix of nonfederal stakeholders from various sectors, both public and private. Input from many nonfederal stakeholders informed the development of this renewed plan. In addition to shaping topics and particular actions in the plan, this input also led to the addition of a brief list, "Opportunities for Nonfederal Stakeholders" within each of the sections discussing the plan's six priority areas. This feature provides a sample of exemplary actions that nonfederal stakeholders from various sectors can undertake to complement the federal efforts detailed in the plan.

Implementation

The actions detailed in the plan will be carried out from calendar years 2014 through 2016 by the participating agencies and offices and many additional nonfederal partners across the nation. Some of these efforts are extensions of actions initiated as a result of the original Viral Hepatitis Action Plan, while others represent innovations in practice, technology, and treatment, requiring new strategic direction and commitment. Many of the actions detailed in the plan can be accomplished, at least in part, by leveraging existing resources whereas others are clearly subject to the availability of funds.

Successful implementation of the renewed Viral Hepatitis Action Plan will require sustained momentum and continued innovation within each federal agency or office while engaging the energy and expertise of new partners from both inside and outside of government. Furthermore, since reaching national viral hepatitis goals is a shared responsibility, we must redouble our efforts to broadly disseminate the Action Plan beyond the federal level to state, local, tribal, and community stakeholders who are serving populations at risk for or living with viral hepatitis. As clearly noted in both the original Viral Hepatitis Action Plan and this update, implementation of the Affordable Care Act will provide substantial opportunities to extend preventive, diagnostic and clinical services to vulnerable populations in need of viral-hepatitis-related services.

The cross-agency VHIG will continue to meet regularly to monitor progress, strategize about overcoming unexpected obstacles, and identify and capitalize on new opportunities or address emerging needs. Information about the Viral Hepatitis Action Plan and progress implementing it will be shared online via a special section of the AIDS.gov website (www.aids.gov/hepatitis) and in periodic blog posts at blog.aids.gov. The online resources of AIDS.gov are administered by OHAIDP, which also coordinates implementation of the Viral Hepatitis Action Plan.

Measuring Progress

The updated plan introduces several progress measures selected to support accountability and transparency as well as aid in monitoring and measuring the results of implementing the Action Plan. These include core measures of progress toward the Action Plan's four overarching goals as well as three additional indicators, two related to viral hepatitis-related mortality and one related to hepatitis B vaccination coverage among healthcare workers. These measures and the challenges of monitoring progress toward achieving the goals are discussed in a new section of the plan beginning on page 71.

These seven measures are not the only ones that can be used to monitor progress on implementing the Action Plan but they represent the best available national data that are regularly collected and can provide insight into progress on addressing viral hepatitis. As we continue to implement the Action Plan, additional measures will be considered. We encourage federal and nonfederal partners to consider these seven measures and how they may be used to monitor efforts to address viral hepatitis within states and community-based programs as well as to identify other sources of data that may be useful in monitoring progress in their work to combat viral hepatitis.

Priority Area 1:

Educating Providers and Communities to Reduce Health Disparities

Confront viral hepatitis by breaking the silence.

For too long, there has been silence on viral hepatitis. In order to achieve the goals of the Viral Hepatitis Action Plan, we must work to break this deadly silence on viral hepatitis both among health care providers, as well as other allies working with heavily affected populations, while addressing low levels of awareness of viral hepatitis in the general public.

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

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

Reducing the health disparities caused by viral hepatitis will require providers at all levels of the health care system to become more educated and aware of opportunities for prevention, care, and treatment. Providers must be able to recognize the diversity of patients at increased risk for viral hepatitis such as AAPIs, African Americans, PLWHA, PWID, MSM, baby boomers, immigrants and refugees from hepatitis B endemic areas, and homeless individuals and families. These diverse patients are cared for by an equally diverse group of providers, from community health workers in remote Alaskan villages and drug treatment providers in urban areas to midlevel providers in VA medical centers and HIV specialists in Ryan White HIV/AIDS Program-funded clinics. To be effective, any plan to improve provider education must encompass and engage a wide variety of health care providers.

While provider education is urgently needed, it is only part of the equation. The general public, especially members of priority populations, which includes all the at-risk groups above, as well as pregnant women, also needs to be knowledgeable and informed about how to prevent, diagnose, and treat viral hepatitis. Pregnant women are a priority because perinatal HBV prevention strategies are critical to eliminating HBV transmission.

Outlined next are the key activities that federal partners plan to take to educate providers and communities to reduce health disparities.

Strengthen the Capacity of the Health Care Workforce

Providers caring for people at risk for or living with viral hepatitis need to be knowledgeable about its prevalence, prevention, risk factors, and screening guidelines as well as aware of new treatment advances, various cofactors that can hasten the progression of liver disease (e.g., obesity, alcohol use), how to monitor patients for signs of disease progression, and when to refer patients for specialty care. Providers treating patients with viral hepatitis will need guidance regarding the use of more effective but rapidly evolving regimens, including decision support tools (e.g., standing

orders, electronic physician reminders, telemedicine consultations). As the implementation of routine viral hepatitis testing expands and therapeutic options for viral hepatitis become more effective and better tolerated, the need for a well-informed health care workforce will become paramount. Strengthening training systems and other forms of provider support is vital for expanding the U.S. health care workforce capacity to address viral hepatitis successfully.

Develop training and practice guidelines, and provide other types of support for health care providers and others. A key part of providing the right tools to the clinical and public health workforce is engaging in a process of assessing the landscape of current educational curricula and trainings. In response to identified gaps in educational tools about viral hepatitis prevention, care, and treatment, federal agencies will develop and disseminate new educational curricula, targeting multiple disciplines of health professionals. Similarly, high-quality existing tools will be identified and their dissemination expanded. Visual representations summarizing population gaps in prevention, diagnosis, linkage to care, and treatment for viral hepatitis can heighten awareness and support training for health care providers. Therefore, federal agencies will develop effective tools that demonstrate the continuum of care for both hepatitis B and C from diagnosis; linkage to care; successful treatment; and, where relevant, cure.

As more DAAs are approved, federal, professional, and community partners will need to update, revise, and disseminate clinical practice guidelines to improve the clinical management of hepatitis C infection using DAAs, including the management of drug interactions and any side effects. During the 3-year implementation of the renewed Action Plan, federal partners will update training curricula and guidance to reflect the most current approaches to diagnosis, treatment, and care.

Integrating viral hepatitis information into existing clinical and social service provider training activities will leverage existing federal training systems that engage and support providers who are already working with populations at high risk for viral hepatitis but who may not typically focus on infectious diseases (e.g., those working with refugees, new immigrants, homeless individuals and families). Many federal partners have committed to integrating viral hepatitis information into existing training activities so as to expand and enrich opportunities for education about the prevention, care, and treatment of viral hepatitis. These efforts will include developing networks to support specialty providers who are uniquely positioned and equipped to intervene with populations at high risk for viral hepatitis, resulting in expanded capacity for viral hepatitis services across several systems.

Enhance collaboration with professional organizations. Federal activities alone cannot reach the breadth and diversity of providers across the nation who must be engaged in order to successfully address the U.S. epidemic of viral hepatitis. Therefore, federal partners have identified several key collaborations with public health, medical, and other professional organizations that will enhance and expand the capacity of the U.S. health care workforce. Such partnerships leverage the expertise and reach of these organizations as well as support consistent practices for viral hepatitis prevention, care, and treatment. Federal partners will collaborate with health professional associations, medical, nursing and other health professional societies, and health professions schools to support graduate and postgraduate education that better equips a greater number and variety of providers to skillfully provide viral hepatitis prevention, care, and treatment services.

Educate Communities

Enhanced and expanded provider education efforts are vital to reaching the Action Plan's goals, but to successfully reduce viral-hepatitis-related health disparities in the United States, those activities must be complemented by active efforts designed to educate communities about the burden of viral hepatitis in the United States and the benefits of viral hepatitis prevention, screening, care, and treatment. Greater awareness about how to prevent, diagnose, and treat viral hepatitis is essential among the general public and especially among persons in priority populations (e.g., baby boomers, AAPIs, African Americans, PWID, persons attending substance use treatment programs, PLWHA, MSM, pregnant women). As evidenced by several studies, levels of knowledge and awareness are low among those populations most affected by hepatitis B and C, including various AAPI subpopulations and PWID. An education strategy that includes targeted outreach to populations at greatest risk can raise awareness of viral hepatitis as an important health concern, increase knowledge regarding the benefits of prevention and care, and encourage populations to seek and accept vaccination, testing, care, and treatment.

Conduct public education and awareness activities. Public education and testing campaigns and other awareness activities are key strategies for improving public understanding and influencing health behaviors among populations most impacted by viral hepatitis. During the first three years of the Action Plan, significant investments were made in researching and developing national educational campaigns for both hepatitis B and C with a variety of messages and tools to support them (see the CDC's *Know More Hepatitis* and *Know Hepatitis B* campaigns). From calendar years 2014 through 2016, the federal partners will collaborate to expand the reach of these campaigns through their networks as well as via partnerships with regional, state, local, and tribal organizations. Admittedly, some populations are harder to reach (e.g., young PWID in rural areas or immigrants) and remain uninformed about various facets of viral hepatitis, including associated adverse health effects, the need for testing and care, and the availability of effective treatments. To address this gap, federal partners will develop new educational materials and outreach efforts (e.g., social media) for specific at risk populations and networks that serve them.

Support communities in the prevention, care, and treatment of viral hepatitis. Given the scope of the silent epidemic of viral hepatitis and relatively low levels of awareness about it among the public and many of the populations most affected by viral hepatitis, community partners and allies are essential for successful efforts to reduce viral-hepatitis-related health disparities. During the 3-year implementation of the renewed Action Plan, federal partners will support existing community partners and seek to identify and engage new partners who can enhance and extend efforts to educate communities about the benefits of viral hepatitis prevention, screening, care, and treatment. This will include developing and disseminating tools and resources that can support partners in their activities.

Organize and promote observances. An important achievement of the initial Action Plan was the establishment of May 19 as the annual observance of Hepatitis Testing Day in the United States. This observance, the continued promotion of May as Hepatitis Awareness Month, and the recognition of July 28 as World Hepatitis Day represent important opportunities to generate significant public awareness via the media and online social networks as well as in targeted communities. Federal partners will continue to support these observances by encouraging participation among their networks and promoting key messages and tools developed for the observances, and these partners will strive to support other partner organizations to do the same.

Opportunities for Nonfederal Stakeholders

Medical, nursing, and other health professional societies; community groups; health departments; primary care associations; health professions schools and training programs; all drug users; patients; and other relevant stakeholder groups can contribute to these important activities to educate both providers and communities in many ways. Among these are

- Asking health care providers whether testing and/or vaccination is recommended;
- Sharing the CDC Viral Hepatitis Risk Assessment and fact sheets with family, friends, colleagues, and community members.
- Identifying significant gaps in provider training needs and materials;
- Advising in the development of provider training and tools or public education and awareness activities, including promoting cultural competency and recommending additional audiences, programs, or populations to seek to engage;
- Developing and supporting training opportunities for health care providers and others and encouraging participation;
- Helping to disseminate provider tools and public education messages and materials to relevant audiences to extend the reach of these efforts;
- Collaborating locally with stakeholders, partners, and communities disproportionately affected by viral hepatitis as well as other allies to support observances by organizing local events and awareness activities or seeking local media coverage; and
- Identifying and seeking to engage new partners in responding to viral hepatitis, particularly allies with the ability to reach populations most impacted by viral hepatitis.

Priority Area 1: Educating providers and communities to reduce health disparities

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

Training, Practice Guidelines, and Other Types of Support for Health Care Providers and Others

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
AHRQ	A. Develop products derived from the evidence-based practice centers' systematic reviews of hepatitis C. (2014) • Develop a Spanish translation of the consumer guide *Testing for the Hepatitis C Virus*. (2014) • Prepare a critique of methodology used to evaluate the effects of hepatitis C treatment on all-cause mortality and submit the manuscript to a peer-reviewed journal for publication. (2014)
CDC **CMS** **OHAIDP**	B. Educate providers regarding the Affordable Care Act and opportunities for reimbursement for viral hepatitis services including preventive care benefits such as testing and vaccination as well as patient access to comprehensive health care coverage that can include treatment for viral hepatitis. (2014, 2015, 2016)
CDC **FBOP** **HRSA** **IHS** **NIH** **OPA** **SAMHSA** **VA**	C. Assess and/or develop and disseminate educational curricula for viral hepatitis prevention, care, and treatment to be used by multiple disciplines of health professionals. (2014, 2015, 2016) • Conduct training/education on new direct-acting agents for chronic hepatitis C infection. (VA) • Develop a training program for opioid treatment centers and federally qualified health centers on improving HIV and hepatitis services to PWID. (SAMHSA) • Develop and disseminate educational programs, materials, and tools in collaboration with primary-care organizations and health professional associations (e.g., the American Academy of Family Practice; the American College of Physicians; the National Association of Social Workers; the American Psychological Association; the American Psychiatric Foundation, Association of Women's Health, Obstetrics, and Neonatal Nurses). (CDC, SAMHSA) • Develop and replicate professional education programs (e.g., telemedicine), materials, and tools addressing known gaps and needs concerning the prevention of viral hepatitis, identification of infected persons, and provision of care and treatment. (CDC, SAMHSA) • Provide viral hepatitis training opportunities for public health and direct care employees working on IHS programs. (IHS) • Support telemedicine and other professional education programs for screening, care, and treatment of viral hepatitis among HRSA safety net providers. (HRSA)

	• Encourage curriculum development for developing research in various areas of study. (NIH) • Train and maintain a viral hepatitis specialty care network of clinical pharmacists to monitor management of patients receiving hepatitis treatment. (FBOP, VA)
DOJ/FBOP	D. Update and publish hepatitis C Clinical Practice Guidelines to include new DAAs and expand medication use criteria for the management of treatment-associated anemias for people incarcerated in federal prisons. (2014)
OHAIDP	E. Collaborate with federal and nonfederal stakeholders to identify and disseminate promising and best practices for viral hepatitis prevention, care, and treatment. (2014, 2015, 2016)
SAMHSA	F. Circulate a letter to behavioral health providers that supports CDC's recommendations for hepatitis C screening and encourages behavioral health providers (mental health and substance abuse) to increase hepatitis C screening and testing. (2014, 2015, 2016)
VA	G. Construct a community of practice for nursing professionals involved in viral hepatitis treatment. (2014)
VA	H. Publish informational letter on hepatitis B for Veterans Health Administration providers. (2014)
VA	I. Support a postdoctoral fellowship for VA clinical psychologists on mental health issues specific to patients with viral hepatitis. (2014, 2015, 2016)

Collaboration with Professional Organizations

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **HRSA** **NIH** **OPA** **SAMHSA**	J. Collaborate with professional, medical, and other organizations to build a provider workforce skillful at providing viral hepatitis prevention, care, and treatment. (2016) • Create and promote collaborative partnerships that support the education of providers to screen, identify, and provide prophylaxis, care, and treatment for both adult and pediatric patients living with viral hepatitis. • Provide training for Title X clinical providers on recommendations for HCV testing as well as referral for appropriate care for HCV infection and related conditions. (OPA) • Work with specialty medical organizations to develop a certification program that will support a trained workforce in the medical evaluation, management, and treatment of viral hepatitis. (CDC)

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

Public Education and Awareness Activities

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Examine the potential of using social media to disseminate hepatitis C education messages to young persons. (2015)
CDC **FBOP** **HRSA** **HUD** **IHS** **NIH** **OHAIDP** **OMH** **OPA** **OSG** **OWH** **RHA** **SAMHSA** **VA**	B. Partner with regional, state, local, and tribal organizations to increase awareness about viral hepatitis and the Viral Hepatitis Action Plan; reduce stigma; educate patients and communities; and disseminate educational resources in communities disproportionately affected by viral hepatitis through speeches, webinars, grantee networks, agency websites, and social media. (2014, 2015, 2016)
CDC **HUD** **SAMHSA** **VA**	C. Increase the proportion of persons living with hepatitis B and C who know that they are infected and ensure that they are linked to timely care and treatment: (2015, 2016) • Continue implementing and supporting *Know More Hepatitis*, the national education campaign designed to increase awareness about hepatitis C and educate those born between 1945 and 1965 to get tested for hepatitis C. • Assess health education materials on viral hepatitis targeted for homeless individuals and homeless assistance providers, particularly in emergency shelter and street outreach settings. Develop plans to improve quality and distribution. (HUD) • Continue implementing and supporting the national education campaign (Know Hepatitis B) designed to increase awareness about hepatitis B among AAPIs and encourage testing of those at risk. (CDC) • Prepare educational materials for Veterans on viral hepatitis transmission, prevention, symptoms, treatment, and resources. (VA)

Supporting Communities in the Prevention, Care, and Treatment of Viral Hepatitis

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **OHAIDP** **RHA**	D. Identify opportunities to braid or blend activities in support of the Viral Hepatitis Action Plan and the National HIV/AIDS Strategy, in collaboration with the regional resource coordinators and other regional office staff (e.g., SAMHSA, HRSA). Identify viral hepatitis stakeholders in the region and (a) engage with them and actively participate in their meetings or (b) convene one or more meetings of stakeholders to review the 2014 Viral Hepatitis Action Plan and identify regional activities, priorities, gaps, and opportunities (e.g., to promote testing). (2014, 2015, 2016)
CDC	E. Seek new partnerships between faith-based and other nongovernmental organizations that have not traditionally been linked with hepatitis-related activities. At the same time, expand existing ones. (2015)
CDC **HRSA** **OHAIDP** **OMH**	F. Educate communities regarding the Affordable Care Act and opportunities for increased access to comprehensive health care coverage that include preventive care benefits such as viral hepatitis testing and vaccination, as well as other health care services for chronic viral hepatitis. (2014, 2015, 2016)
FDA	G. Provide physicians and community with information on new approvals of drugs and diagnostics, including new indications, for the management of viral hepatitis. (2014, 2015, 2016)
HRSA	H. Provide financial support through cooperative agreements to community-based organizations that educate communities about viral hepatitis. (2014, 2015, 2016)
NVPO	I. Launch, maintain, and update a comprehensive government website in English and Spanish on vaccines and immunization, including information about hepatitis A and B vaccines. (2015)
NVPO	J. Coordinate with relevant federal partners to discuss coordination and reporting of hepatitis vaccine-specific metrics in the Immunization Information System. (2015)
OHAIDP	K. Identify opportunities to work with the HHS Office of Refugee Resettlement and state and local providers of services for refugees to disseminate training, information, and best practices relating to viral hepatitis screening, education, counseling, and referral to care and treatment. (2015)
OMH **SAMHSA**	L. Share and promote promising approaches and best-practice model(s) with other high-risk communities for improving awareness, screening, vaccination, and linkage to care. (2015, 2016)

OMH	M. Collaborate with minority-serving institutions (MSI) to ensure that viral hepatitis and Affordable Care Act information are distributed to preconception peer educators via communication channels (to include e-mails and newsletters): (2016) • Add a viral hepatitis information component to the HIV curriculum. • Incorporate viral hepatitis prevention and screening into college health centers. • Emphasize ACA coverage for hepatitis screening and treatment (college students are eligible for coverage under their parent's health insurance until age 26). • Pilot in five MSIs in rural, urban, and tribal areas a viral hepatitis campaign targeted toward college students. • Share promising practices and lessons with other federal partners that collaborate with MSIs.
OSG	N. Publish an "executive perspective" in *Public Health Reports* by the ASH on a topic relevant to viral hepatitis. (2015, 2016)

Organization and Promotion of Observances

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **HRSA** **IHS** **NIH** **NVPO** **OHAIDP** **OMH** **OPA** **OSG** **OWH** **RHA** **SAMHSA** **FBOP** **HUD** **VA**	O. Coordinate, support, and promote national and global health events and partnerships to raise public awareness about viral hepatitis via participation in meetings, press conferences, social media, and other activities: (2014, 2015, 2016) • Collaborate with federal partners, private industry, and the media to observe Hepatitis Awareness Month in May in the United States and communicate timely viral hepatitis messages, particularly for those populations most affected. • Continue and expand observance of May 19 as Hepatitis Testing Day in the United States. • In partnership with the World Health Organization (WHO), support and promote July 28 as World Hepatitis Day and work with the media to convey the global and national significance of viral hepatitis.

Priority Area 2:

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

Take full advantage of existing tools.

Providers at every level in the health care system can play a critical role in meeting the needs of the millions of people at risk for and living with viral hepatitis. However, not all providers are prepared to address these needs and missed opportunities to prevent, diagnose, treat, and care for persons with viral hepatitis have resulted in preventable morbidity and mortality. In order to achieve the goals of the Viral Hepatitis Action Plan, we must fully utilize existing training, clinical care tools and policies, address unmet needs, and develop model programs to expand health care provider capacity to provide high-quality viral hepatitis prevention, care, and treatment in primary care and other settings.

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

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

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

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

Hepatitis B and C testing, referral to care, initiation of treatment, and achievement of viral suppression or cure represent a continuum of care that can be used to evaluate and improve efforts to comprehensively address these epidemics. Increasing the effectiveness of interventions logically begins with testing, which is needed to identify the many individuals who are unaware of their chronic viral hepatitis infections. Further research and analyses that describe the continuum of care in various settings can illuminate health disparities among priority populations and guide resource allocation, program planning, and implementation. Earlier diagnosis and improvements along the entire continuum of care can lead to reductions in the incidence of cirrhosis, liver cancer, and liver transplantation in the United States, not to mention improved health and productivity for persons who are infected.

Outlined next are the key activities that federal partners plan to take to improve testing, care, and treatment to prevent liver disease and cancer.

Expand Effective Testing Efforts to Support Early Identification of Viral Hepatitis Infection

Effective treatment of viral hepatitis requires timely diagnosis. According to the 2010 IOM report *Hepatitis and Liver Cancer*,[51] 65–75 percent of individuals chronically infected with hepatitis B and C were unaware of their infections. A 2012 CDC study examining viral hepatitis testing and infection prevalence among adults with access to health care conservatively estimated that 21.1 percent of HBV and 43.1 percent of HCV infections remained unidentified despite people being engaged in care.[52] Increasing the proportion of people who are aware of their viral hepatitis infection is a major goal of this Action Plan.

Improve testing policy. A significant advance in this arena during the first 3 years of the Action Plan was the alignment of the CDC and USPSTF recommendations regarding hepatitis C screening.[53, 54] This alignment of clear and specific screening recommendations reduces provider and payer confusion, providing an opportunity for adoption and promotion of viral hepatitis testing across a variety of health care settings, both public and private. Federal partners will continue developing and ensuring that there are updated guidelines and recommendations for hepatitis B and C testing.

Implement testing as a standard of care. In order to reduce the proportion of people with undiagnosed viral hepatitis, testing individuals according to current recommendations must become the standard of care provided in primary care and other settings where vulnerable populations can be reached such as substance abuse prevention and treatment and correctional health programs. One excellent opportunity lies in the broad implementation of the new recommendations for a one-time screening of all baby boomers. Health information technology (HIT) offers many opportunities to help promote routine testing for individuals by keying in on information contained in the electronic health record (EHR), such as year of birth, HIV, and pregnancy status. The Affordable Care Act, which is expanding access to health insurance for many people, offers opportunities to support hepatitis B and C testing as a standard of care. The USPSTF grade B recommendation for one-time HCV screening for persons at risk as well as baby boomers and periodic screening for persons with continued risk for HCV infection (e.g., PWID) supports broader implementation of testing as part of 'preventive health service benefits,' which most health plans must cover without charging insured persons a copayment or coinsurance. Hepatitis B testing for pregnant women is covered under the same preventive service benefits. At the time of this report, efforts are under way to review new and emerging evidence to determine whether hepatitis B testing recommendations should be expanded to include other populations.

Improve testing technology and use. The current testing technologies for hepatitis B and C do not always meet the needs of the providers who use them to identify patients and guide their care and treatment. At the time of this report, there is one rapid test approved in the United States for hepatitis C screening but no approved rapid test for hepatitis B; this hampers outreach and field work activities. Currently available technology makes identification of acute hepatitis C infection difficult due to a lack of adequate and reliable biomarkers and testing technology and diagnosis of chronic hepatitis C requires that at least two different blood tests be performed. Furthermore, testing technology such as genotyping is essential in guiding the treatment of individuals chronically infected with hepatitis C. Federal partners will continue to work with industry, providers, and community partners to explore improvements to existing technologies and the development of new tests.

Expand and Improve Linkage to Treatment and Care

The health care system is undergoing unprecedented change. Support for the development of effective models of care by federal partners and states as they implement health care reform holds promise as a way to improve health care for individuals with chronic viral hepatitis. One such model, patient-centered medical homes (PCMH), has been shown to be effective for vulnerable populations such as individuals with HIV. A PCMH provides comprehensive care that includes physical and mental health care, from prevention through chronic disease care. It is patient centered, addressing the whole patient, partnering with families, and respecting each patient's unique needs. Health care is coordinated across the health care system as well as within the PCMH health care team. Services are responsive and accessible in person, via e-mail, or by telephone. Another attribute of a PCMH is a commitment to quality and safety, including using evidence-based medicine and clinical decision support (CDS) tools. A number of federal programs are supporting PCMH and other models of care that hold promise for improving health outcomes for persons with viral hepatitis.

Improve linkage to care. After testing, the next step in improving the continuum of viral hepatitis care in the United States is linking patients into care. Historically, linkage to care has been hampered by a number of factors, including the lack of providers who are knowledgeable about viral hepatitis; difficulty accessing health insurance due to cost or preexisting conditions; program capacity for adequate follow-up with referral to a health care provider; and, until recently, no available rapid testing for hepatitis C. As we have learned from various HIV models, active and timely linkage to care following diagnosis is absolutely essential if we wish to improve health outcomes. We will identify and disseminate best practices for prompt linkage to treatment and care for hepatitis B and C.

Increase efforts to provide care and treatment to hepatitis B-infected mothers. Testing pregnant women for hepatitis B has been the recognized standard of care for more than 20 years because we can prevent HBV transmission from a pregnant woman to her infant at the time of birth. However, the focus of these efforts has primarily been on the infant: providing the hepatitis B vaccination and hepatitis B immune globulin at birth and ensuring completion of the series of three shots. There has been little support for efforts to address the health care needs of chronically infected mothers, many of whom were themselves infected at birth and have lived with the infection for decades. Without efforts to educate the mother and ensure that her chronic HBV is appropriately managed and treated, she is at high risk for developing liver disease and liver cancer. Federal partners will utilize many strategies to address these challenges, including using HIT tools such as CDS to ensure that hepatitis B-infected women are referred to care after giving birth (see priority area 4 for additional information on actions the federal partners will pursue to eliminate mother-to-child transmission of hepatitis B).

Improve Access to Quality Care and Treatment for Vulnerable Populations

Many of the individuals who are unaware of their viral hepatitis status are already being seen in primary care and other health care settings. However, due to low provider and public awareness about the risk factors for, prevalence of, and testing recommendations about hepatitis B and C, they have not been diagnosed. Others may be aware of their infection but unaware of the recommendations for the management of chronic viral hepatitis. Redoubling efforts to share information about new recommendations, therapeutic advances, training opportunities, best

practices, and culturally competent strategies with primary care providers and others caring for vulnerable populations (e.g., safety net hospitals, substance abuse treatment programs, correctional health programs, immigrant and refugee health programs) can improve the quality of viral hepatitis care in many settings and increase the number of individuals treated and cured.

Improve care and treatment in primary care. Improvements in care and treatment for viral hepatitis will require collaboration with health professional and patient advocacy organizations. Professional organizations can identify the most relevant training and tools for their members and offer guidance and leadership in the field. They often create or endorse condition-specific recommendations and can use their networks, annual meetings, and other outlets to share expertise and experiences and foster change and improvement in clinical practice. Patient advocacy groups can help all providers better understand health literacy and other concerns that are critical for effective bidirectional communication and ongoing engagement in care.

Clinical quality measures and CDS are tools that play a role in improving viral hepatitis care and treatment. Clinical quality measures help measure and track the quality of health care service provided across many aspects of patient care, including health outcomes, clinical processes, patient engagement, and care coordination. Clinical decision support tools enhance decision making in the clinical workflow, including computerized alerts and reminders for providers and patients, clinical guidelines, condition-specific order recommendations, specialized templates and reports, and other reference information. Federal partners are working to establish initial clinical quality measures and CDS for viral hepatitis, but more work in this area is needed.

Identification and replication of effective models of providing care and treatment is essential. A number of promising projects exist that can help inform other clinicians and health systems serving populations disproportionately burdened by viral hepatitis. Federal partners are supporting a number of demonstration projects and the replication of effective models such as the Extension for Community Healthcare Outcomes model, use of clinical quality measures, and expanded use of midlevel providers and clinical pharmacists in the provision of viral hepatitis care and treatment. More work is needed to describe these effective models and the elements that contribute to their effectiveness in order to facilitate replication.

Advance Research to Facilitate Prevention and Care for People Living with Hepatitis

Research is needed to improve viral hepatitis prevention and care. As we have seen in the field of HIV, describing the viral hepatitis care continuum will establish a baseline and provide a framework for understanding factors related to each step along the care continuum and how we can intervene with providers, consumers, and systems to improve health outcomes.

Research to improve quality of testing technology and activities. Starting with diagnosis, there is much to do to improve the continuum of care for viral hepatitis. Improved testing technology and enhanced use of existing tests will contribute to increasing the proportion of people who are aware of their viral hepatitis infection. Federal partners will conduct research to improve implementation of testing in clinical and other settings.

Promote research to improve prevention, care, and management. Prevention, care, and treatment of chronic viral hepatitis are areas where further research is needed. Currently, we lack an effective vaccine to prevent HCV infection. Studies have shown that relatively few of the millions of people

chronically infected have been effectively treated for hepatitis B or cured of hepatitis C. There is a need to develop and test models of prevention, screening, and care which can be scaled-up, particularly for specific populations, including HCV prevention, diagnosis, treatment, and care for young people at risk for or injecting drugs as well as culturally acceptable HBV diagnosis, treatment, and care for AAPIs. Alcohol abuse is associated with an accelerated progression of liver injury in patients with chronic viral hepatitis, leading to an earlier development of cirrhosis, higher incidence of hepatocellular carcinoma, and higher mortality. Counseling to achieve abstinence should be provided to patients with chronic HCV or HBV infections because of the strong negative influence on progression, response to treatment, and outcome of liver disease. Greater understanding of the barriers and facilitators, along with improved therapies and technologies, are needed at each step (diagnosis, referral to care, treatment, and cure) to successfully address viral hepatitis in the United States.

Evaluate the threat of emerging hepatitis E. Hepatitis E is not well understood in the United States but is known to cause illness and death, primarily in Asia and Africa. Research is needed to assess the impact of hepatitis E in the United States, understand the sources of infection, identify effective prevention strategies, and evaluate potential therapies.

Opportunities for Nonfederal Stakeholders

Organizations of medical, nursing, and other health professional societies; community and patient advocacy groups; health departments; primary care associations; health professions schools and training programs; clinicians; patients; private companies; people who inject drugs; and other relevant stakeholder groups can contribute to these important activities to improve viral hepatitis testing, care, and treatment in many ways. Among these are:

- Promoting the CDC Viral Hepatitis Risk Assessment and discussion of the resultant recommendations with providers;
- Sharing information about current antiviral therapies with chronically infected friends and family members;
- Identifying opportunities to increase provider awareness and utilization of existing training, tools, and model programs;
- Adopting viral hepatitis testing and care recommendations in clinical settings;
- Ensuring follow up and linkage to care when conducting viral hepatitis testing;
- Implementing electronic health record clinical reminders for hepatitis B and C screening;
- Developing culturally and linguistically relevant health literacy tools and materials for populations at risk for hepatitis B and C;
- Partnering with programs serving vulnerable populations to expand access to viral hepatitis prevention and care services;
- Promoting assessment of local and organizational baseline data on the viral hepatitis continuum of care;
- Mobilizing communities about the silent epidemic of viral hepatitis and the threats of an unaddressed epidemic; and
- Supporting the development of new technologies and therapies to improve hepatitis prevention, diagnosis, care, and treatment.

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

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

Policy

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
AHRQ	A. In 2014, AHRQ will continue to provide scientific, administrative, and dissemination support for the independent USPSTF, which is in the process of updating its recommendation statement on screening for hepatitis B. (2014)
OHAIDP	B. Coordinate across agencies to ensure that guidelines for hepatitis B testing and linkage to care are aligned (partial existing action; the hepatitis C segment has been completed), to the extent possible. (2015)
CDC	C. Build the capacity of state and local health departments to prevent viral hepatitis. (2014, 2015)
CDC	D. Conduct studies, gather evidence, and develop models to inform viral hepatitis testing policy development and guide resource allocation for viral hepatitis prevention, testing, care, and treatment. (2016)

Testing

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **CMS** **HRSA** **IHS** **OHAIDP** **ONC** **RHA** **SAMHSA** **VA**	E. Implement viral hepatitis testing as a standard of care in a reformed health system: (2014, 2015, 2016) • Adopt birth cohort testing for hepatitis C as VA policy. (VA) • Collaborate with health plans and seek to ensure that clinicians included in plan provider networks are skilled in viral hepatitis testing, care, and treatment. (CDC) • Conduct prevention research to study implementation of viral hepatitis testing in diverse clinical settings and identify and disseminate best practices. (CDC) • Develop a cross-HHS plan to guide implementation of CDC or USPSTF recommendations for hepatitis C testing in all appropriate settings. (CDC) • Develop explanatory materials specifying who is entitled to coverage (e.g., persons with traditional Medicaid and grandfathered private plans). (CDC) • Explore the Healthy Aging/Living Well section of the Affordable Care Act as an opportunity to extend viral hepatitis preventive services, care, and treatment to persons aged 55–64 years. (CDC) • Identify opportunities (e.g., those afforded by the Affordable Care Act) to improve the provision and coordination of comprehensive viral hepatitis services in public and private health plans. (CDC) • Implement HHS-recommended viral hepatitis testing as a standard of care in drug treatment programs and other settings serving at risk populations. (CDC)

	• Implement new strategies for viral hepatitis testing. (CDC) • Leverage the HHS "Healthy Aging, Living Well" program to improve rates of viral hepatitis screening among persons born during 1945–1965. (CDC) • Meet and form collaborations with stakeholders (i.e., agencies, organizations, payers, and providers) to facilitate implementation of hepatitis C testing in community, occupational, correctional, and public and private clinical settings. (CDC) • Monitor Affordable Care Act enrollment among persons at high-risk for viral hepatitis to determine rates of health insurance access. (CDC) • Monitor the Medicare national coverage determination process. (CDC)
HRSA	F. Promote viral hepatitis screening as recommended by national guidelines among safety net providers through agency newsletters and program letters. (2014, 2015, 2016)
IHS	G. Develop and launch a hepatitis C screening reminder module in the electronic health record. (2016)
VA	H. Intensify efforts to identify Veterans dually infected with HIV and hepatitis C. (2014)

Testing Development

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
FDA	I. The FDA Center for Devices and Radiological Health, collaborating with other FDA medical product centers, is working with manufacturers to explore consolidating the intended uses of existing diagnostic hepatitis C tests; develop visually read, rapid devices for diagnosing viral hepatitis (these devices would also obtain a claim for emergency screening of blood donors to prevent transmission of viral hepatitis); develop more sensitive and precise hepatitis C genotyping assays; and foster communication or partnership between manufacturers of hepatitis C diagnostics and manufacturers of hepatitis C drugs to enable a more expeditious pathway for the approval of new diagnostic devices. (2015)

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

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **HRSA** **HUD** **IHS** **NIH** **OHAIDP** **OMH** **SAMHSA** **VA**	A. Improve linkage to care and treatment among persons infected with viral hepatitis: (2014) • Develop and implement effective medical management models for use in priority populations. (CDC) • Identify and disseminate best practices for the prompt linkage of persons testing positive for viral hepatitis to needed care and treatment. • Support research related to developing and evaluating effective models to link and refer persons infected with viral hepatitis to care and treatment, as well as retaining people in care and treatment after referral. (NIH) • Increase linkages and referrals to care and treatment for behavioral health clients who screen positive for hepatitis B or C. (SAMHSA)

CDC **CMS** **ONC**	B. Use HIT to improve testing and enhance referral to viral hepatitis care in diverse clinical settings: (2014, 2015, 2016) • Develop performance measures for hepatitis testing, care, and treatment in collaboration with the American Medical Association's Physician Consortium for Performance Improvement (PCPI). (CDC) • Implement data elements (e.g., those concerning disease staging, HCC monitoring, and comorbidity management) in EMRs to monitor hepatitis testing, care, and treatment in health care settings. (CDC) • Use HIT to improve testing and enhance referral of children with perinatal hepatitis B infection. (CDC)
CDC **ONC**	C. Develop electronic specifications for three hepatitis C measures: (2015, 2016) • Annual hepatitis C screening for patients currently injecting drugs (PCPI 9b), • Referral to treatment for patients identified with hepatitis C infection (PCPI 9c), and • Screening for hepatitis C for patients at high risk (PCPI 9a). • Develop or translate CDS interventions related to these measures into Health eDecisions format and pilot sharing and the ability for EHRs to consume them via a web repository. This project will enable providers to use CDS and quality measures to improve their referral patterns for hepatitis C.
CDC **CMS** **HRSA** **IHS** **OHAIDP** **OMH**	D. Ensure that hepatitis B-infected pregnant women receive timely care and treatment: (2015) • Identify CMS options (e.g., Section 1115 waivers, health homes) to improve outreach and care coordination for hepatitis B-infected women and their household contacts. (CMS) • Identify strategies to enhance referral to care and treatment for hepatitis B-infected mothers.

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

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **CMS** **FBOP** **HRSA** **IHS** **NIH** **OHAIDP** **OMH** **SAMHSA** **VA**	A. Improve viral hepatitis care and treatment in primary care and other settings: (2014, 2015, 2016) • Collaborate with professional organizations and other partners to identify or develop and disseminate timely care and treatment guidelines. (CDC) • Develop and streamline simple algorithms for HCV treatment of special populations. (NIH) • Establish a viral hepatitis commission to implement guidelines; identify best practices; and develop policy recommendations to improve screening, care, and treatment for patients with viral hepatitis and develop strategic initiatives to increase access to treatment for hepatitis C infection. (IHS) • Establish clinical quality measures to monitor performance. (CDC) • Identify, describe, replicate, and disseminate effective models and methods to expand capacity for the provision of hepatitis care and treatment. (OHAIDP) • Improve patient outcomes by improving hepatitis lab testing procedures. (FBOP) • In accordance with clinical quality measures, develop clinical decision schema and other tools to ensure high-quality care for patients living with viral hepatitis. (CDC)

	• Support safety net providers to become treatment providers for hepatitis C. (HRSA) • Support training of primary care providers to become buprenorphine or naloxone opioid dependence treatment providers. (SAMHSA)
CMS	B. Cover treatment for viral hepatitis under several Medicaid coverage categories, including physician services, laboratory services, and pharmacy, depending on an individual's particular needs. C. For adults enrolled in Alternative Benefit Plans (Medicaid expansion plans), preventive services are an essential health benefit and must be provided at no cost sharing, including hepatitis A and B vaccines, hepatitis B testing for pregnant women, and hepatitis C testing for individuals at risk and those born in 1945–1965. D. For adults enrolled in Medicaid, state Medicaid programs have the option to cover preventive services, which includes vaccines and screening, such as hepatitis B vaccines and hepatitis C screening for at risk beneficiaries. Because of this flexibility, coverage of these services varies from state to state. In states that have chosen to cover all USPSTF grade A and B recommended preventive services and ACIP-recommended vaccines and their administration with no cost sharing, coverage of these preventive hepatitis services will be required. (2014, 2015, 2016)
VA	E. Expand access to evaluation and treatment for Veterans with viral hepatitis in rural and highly rural areas. (2014, 2015, 2016)
FDA	F. Collaborate on the use of companion diagnostics to determine the appropriate patient individualized therapy regimen for new viral hepatitis drugs.
CDC **CMS** **HRSA** **IHS** **OHAIDP** **OMH** **VA**	G. Promote access to care, and monitor care and treatment for chronic hepatitis B and C in a reformed health care system. (2014, 2015, 2016)

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

Hepatitis Testing

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **FDA** **NIH**	A. Promote development of and assess new laboratory tests and laboratory testing procedures to more accurately identify persons infected with viral hepatitis, and develop methods for effectively providing testing to a wide range of populations: (2016) • Determine acceptable and feasible alternative hepatitis B markers for screening and identifying pregnant women with hepatitis B infection (including hepatitis B extracellular antigen (HBeAg) and hepatitis B viral load), and develop and validate assays for their detection and measurement. (CDC) • Develop and validate new tests, including those capable of distinguishing between acute and chronic hepatitis C (i.e., viral and host-derived markers of hepatitis C infection) without need for serial testing. (CDC, NIH) • Develop and validate new tests for detecting fibrosis noninvasively to allow for monitoring progression of liver disease. (CDC, NIH)

	• Develop laboratory technology and create virus detection systems to identify strains that are resistant to vaccination, diagnosis, or therapy; identify strains that exhibit unusual transmissibility and virulence properties; and monitor the emergence of occult, rare, or previously unrecognized causes of viral hepatitis. (CDC) • Improve interpretation of discrepant and indeterminate hepatitis B surface antigen (HBsAg)-screening test results from pregnant women to decrease unnecessary testing, focus post-exposure prophylaxis (PEP), and relieve anxiety that might result from false positive hepatitis B test results. (CDC) • Improve the quality of diagnosis for hepatitis D. (CDC) • Support development of point-of-care assays (e.g., HBsAg and hepatitis C core antigen) to detect serologic evidence of both exposure to viral hepatitis and active viral hepatitis infection. (CDC) • Understand barriers to possible implementation (e.g., hepatitis B reporting statutes). (CDC)
NIH **CDC**	B. Encourage studies of the efficacy, risks, and costs of approaches to screening for hepatitis C in the U.S. population, including the addition of birth cohort-based to standard risk-based screening. (2016)
CDC **NIH**	C. Develop algorithms to increase use of anti-HDV testing among persons identified with HBsAg in serum. (2016)

Hepatitis Prevention, Care, and Treatment

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
NIH	D. Develop and test novel viral hepatitis prevention interventions (2015, 2016)
CDC **FDA** **HRSA** **NIH** **VA**	E. Develop care models to optimize management of the diverse populations living with viral hepatitis: (2014, 2015, 2016) • Construct and evaluate a real-world observational cohort of patients initiating therapy for hepatitis C. Look for new safety signal or other issues in populations less represented in clinical trials. (FDA) • Coordinate development of a research agenda to better understand and address the multiple barriers for patients with co-occurring conditions. (CDC) • Evaluate promising models of care to address the unique issues faced by priority populations affected by viral hepatitis. (CDC) • Report on findings of HCV Treatment Expansion Initiative. (HRSA) • Support studies of approaches to preventing or reversing fibrosis of the liver in persons with chronic viral hepatitis, including those who have been successfully treated. (NIH)
NIH	F. Promote identification and validation of biomarkers for early detection of hepatocellular carcinoma in persons with viral chronic hepatitis. (2016)
FBOP	G. Publish outcomes of hepatitis C treatment with dual therapy (peginterferon and ribavirin) and new therapies approved in 2011 for hepatitis C genotype 1 infection utilized within the FBOP. (2014)
FDA	H. Build and analyze a pooled clinical trial database from pharmaceutical sponsors for regulatory research. (2015).

CDC **FDA** **NIH**	I. Develop a guidance for the development of drugs to treat chronic hepatitis B and promote basic research on novel targets for therapy in hepatitis B and clinical studies of their efficacy and safety. (2016)
CDC **FDA** **NIH**	J. Finalize the FDA Guidance for the Development of Direct Acting Antivirals for the Treatment of Chronic Hepatitis C to facilitate the development of new treatments and encourage conduct of studies of efficacy and safety of new oral (interferon-free) regimens for hepatitis C in "difficult-to-treat" populations such as children; PWID; liver and renal transplant recipients; and persons with acute hepatitis C, HIV co-infection, chronic alcoholism, or chronic end-stage renal or liver disease. (2016)
NIH	K. Using a community-based participatory research approach, conduct pilot testing of the effectiveness of a culturally proficient intervention in improving HBV vaccination, screening rates, and linkages to care among underserved Asian Americans attending a community clinic. (2016)
NIH	L. Promote research on determinants of and potential interventions to prevent perinatal transmission of hepatitis C. (2016)
NIH	M. Encourage development of targeted antiviral agents with activity against HDV. (2016)
VA	N. Present research priorities of Veterans with viral hepatitis to QUERI-HIV/HCV and to the Veterans Health Administration (VHA) Research Committee. (2014)

Emerging Forms of Viral Hepatitis: E

AGENCY(IES)	**ACTION** *(Dates indicate the year the action(s) will be completed.)*
CDC **NIH**	O. Assess the prevalence and burden of hepatitis E infection and optimal means of screening and diagnosis in specific U.S. cohorts, such as patients with chronic liver disease, acute liver failure, solid organ transplant, HIV infection, or neurologic diseases or patients on long-term immunosuppressive therapy. Encourage studies aimed at identifying sources of locally acquired hepatitis E infection in the United States to understand how to prevent infection. (2016)
NIH	P. Promote studies on the efficacy, safety, and optimal use of peginterferon or oral ribavirin in patients with chronic hepatitis E infection. Identify new oral antiviral agents with activity against hepatitis E. (2016)
CDC	Q. Improve the quality of diagnosis for hepatitis E.

Priority Area 3:

Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease

Collect accurate and timely information to get the job done.

Surveillance and other health data are necessary to shape and direct effective viral hepatitis prevention, care, and treatment efforts. Data can also play an important role in making decisions on how resources can best be allocated to meet the needs of populations at risk for or infected with HBV or HCV. In order to achieve the goals of the Viral Hepatitis Action Plan, federal and nonfederal partners must build new relationships, identify opportunities to utilize HIT, and maximize our use of available data for informed decision- making.

GOAL 3.1 Monitor viral hepatitis-associated health disparities, transmission, and disease.

GOAL 3.2 Monitor provision and impact of viral hepatitis prevention, care, and treatment services.

GOAL 3.3 Develop and implement new technologies and laboratory procedures to improve viral hepatitis surveillance.

Viral hepatitis has not received attention commensurate with the impact of the epidemic, in part because the impact has not been well quantified or understood. New hepatitis B and C infections are reportable conditions, but fewer than half of individuals newly infected experience symptoms which leads to low rates of testing, diagnosis, and reporting. Chronic HBV and HCV are usually slowly progressing diseases with few specific symptoms to alert those infected, further hindering opportunities for diagnosis and reporting. Low levels of health care provider and public awareness contribute to missed diagnoses and continued ignorance about the impacts of viral hepatitis at the individual level as well as at the population level. Accurate blood tests for HBV that enable the diagnosis and reporting of acute and chronic disease are available. However, a rapid HBV test, which could facilitate testing in outreach and other non-clinical venues serving vulnerable individuals, is not available in the United States. Rapid test development has been slow for HCV with the first such test approved for use in 2010.[55] Additional testing technologies such as a single test to diagnose acute HCV and low-cost tests to confirm chronic infection are not available, which affects our ability to diagnose and report acute and chronic HCV.

Existing surveillance systems often lack the capacity to capture and analyze the data needed to accurately describe the scope of the problem, both for the chronically infected as well as for populations experiencing emerging or reemerging outbreaks. Recent changes in HIT are revolutionizing how and which data are collected, providing many potential opportunities to

strengthen our understanding of the epidemics of hepatitis B and C and inform our response to viral hepatitis, nationally and locally.

Outlined next are the key activities that federal partners plan to take to strengthen surveillance to detect viral hepatitis transmission and disease.

Monitor Viral Hepatitis Health Disparities, Transmission, and Disease

Surveillance data are important to help decision-makers understand, prioritize, and act upon public health threats. Historically, viral hepatitis surveillance has been hampered by a number of factors: low levels of health care provider awareness leading to missed opportunities to test and failure to adequately report positive test results; complex testing and diagnosis algorithms leading to incomplete testing and reporting; large numbers of cases reported to health departments with limited capacity to assess, analyze, and collate these data; and, not least, the slowly progressing nature of chronic viral hepatitis infections that fails to instill a sense of urgency to better understand and address the epidemics. Some notable actions taken to address these issues in response to the first Action Plan were for the CDC to expand local flexibility to establish performance metrics for viral hepatitis activities through the Adult Viral Hepatitis Prevention Coordinators' program and enhanced surveillance activities to help identify the number of infected persons who need linkage to counseling and medical follow-up and characterize infected persons who receive treatment.

Leverage HIT advances. The Affordable Care Act and the Health Information Technology for Economic and Clinical Health Act offer many opportunities to improve HIT, incentivizing the use of electronic health records and stimulating further advances in the field. More data are being generated and captured than ever before, and our ability to use data effectively is also expanding. HIT advances can improve the provision and documentation of services in clinical settings and the reporting of communicable diseases to public health authorities due to increased connectivity between clinical settings and public health. It is imperative that federal partners engaged in viral hepatitis activities seize the opportunities offered by these advances such as automated case detection, enhanced connectivity and reporting, and increased capacity to monitor services provided and performance measures.

Identify and respond to outbreaks. When called upon, federal partners respond to outbreaks of viral hepatitis in collaboration with state and local public health authorities. But as explained above, outbreaks can be difficult to detect because acute viral hepatitis infections are often asymptomatic, and populations most at risk can be difficult to access. In the case of hepatitis C, the lack of a specific test to identify acute HCV further complicates matters. The recent identification of new infections of HCV among young PWID is a potent example of the importance of surveillance activities in guiding prevention activities. If we are unsuccessful in characterizing and confronting this reemergence of HCV, a whole new generation of individuals will be exposed to and infected with HCV. However, with an accurate assessment of the scope and breadth of the epidemic, federal partners, along with state and local public health authorities and community stakeholders, can implement prevention efforts and mount effective responses to this emerging health threat.

Develop new partnerships. A key part of expanding surveillance efforts is the development of new partnerships. Stakeholders such as commercial laboratories, health care systems, third-party payers, health researchers, and others collect health data that can be used to improve and

supplement existing viral hepatitis surveillance information. This enhanced information will help to ensure a more targeted response to emerging epidemics of viral hepatitis and direct our efforts to reach those populations who are infected and not yet diagnosed.

Monitor the Provision and Impact of Viral Hepatitis Prevention, Treatment, and Care, Highlighting Population-Specific Health Disparities

There are many health disparities in viral hepatitis. Minority communities are disproportionately burdened. AAPIs constitute at least 50 percent of chronic hepatitis B infections in the United States despite being only 6 percent of the population and experience the highest rates of liver cancer. African Americans have rates of chronic HCV approximately double that of whites and the highest rates of new HBV infections. American Indian and Alaska Natives have the highest death rates due to HCV and viral hepatitis overall. Hispanics experience rapid chronic HCV disease progression and significant barriers to accessing testing and care. Fifteen to 25 percent of all new HBV infections occur among MSM, and more recent evidence indicates high rates of new HCV infection in HIV-positive MSM.[56] People who inject drugs account for 50 percent of new HCV cases.[57] There are many more disparities in viral hepatitis prevention, care, and treatment; and in order to address the epidemic, federal partners must understand and work to eliminate them.

Monitor prevention and testing services and their impact. Few studies have been conducted to evaluate population-specific viral hepatitis testing rates; existing research on priority populations does shed some light on these issues but is often limited by small sample sizes and a lack of representativeness of the populations included. Prevention measures such as vaccination are known to be effective, but little information is available about vaccination rates in vulnerable populations, especially adults. Testing is critical to identifying individuals who are chronically infected, but research has shown that there are disparities in access to and receipt of viral hepatitis testing. We must work to establish a baseline understanding of the disparities in prevention and testing in order to focus on those populations and geographic areas with the greatest need.

Support the development of standardized definitions and data collection. As we collectively work toward improving how we collect data and what we know about viral hepatitis, it is important that various stakeholders use the same definitions and measures to facilitate analyses and comparisons of data collected from different organizations, populations, and regions. One example of standardization efforts is the development of core indicators in the field of HIV. These core indicators will facilitate federal efforts to monitor and report on progress toward achieving the National HIV/AIDS Strategy's goals and inform data standardization across diverse, federally funded HIV programs. As an important component of this Action Plan, federal and other key partners will assess current viral hepatitis data collection activities and develop a plan to standardize definitions and data collection processes.

Develop and Implement New Surveillance Technologies and Tools

Innovations in viral hepatitis surveillance are needed to improve our understanding of and response to viral hepatitis. New laboratory tools and techniques can help us better understand and identify transmission among networks of individuals at risk, improve algorithms to screen and identify individuals with hepatitis B infection, and promote the development of improved viral hepatitis testing technologies. Federal partners will work toward developing standardized laboratory techniques, update practical and reliable algorithms for screening in high-risk

populations, and develop more quantitative tests for use in diagnosis and monitoring viral hepatitis.

Opportunities for Nonfederal Stakeholders

Health departments are traditional partners in surveillance activities but collaboration can be extended to involve health care organizations, community stakeholders, health researchers, manufacturers, modelers, 3rd party payers, and others who can contribute to our understanding of the spread and impact of viral hepatitis and how we can intervene. Suggested activities include:

- Reporting viral hepatitis in accordance with public health and communicable disease requirements;
- Collaborating with public health authorities to improve surveillance data completeness and quality;
- Assisting with outbreak investigations;
- Using electronic health record technology to assess and evaluate the impact of viral hepatitis and related services;
- Developing more detailed information about population-specific health disparities in viral hepatitis prevention, diagnosis, care, and treatment;
- Promoting research on determining the prevalence of hepatitis among homeless individuals and families;
- Working with public health and commercial laboratories to improve viral hepatitis reports and surveillance processes;
- Establishing patient registries to evaluate and improve patient management and clinical processes;
- Contributing to research and the development of improved testing procedures and technologies; and
- Supporting state surveillance projects and epidemiological investigations to help understand the characteristics and needs of the emerging hepatitis C epidemic among young people who inject drugs.

Priority Area 3: Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease

GOAL 3.1 Monitor viral hepatitis health disparities, transmission, and disease.

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **ONC**	A. Expand viral hepatitis surveillance through accessing EHRs: (2016) • Automate case detection of viral hepatitis using electronic records (i.e., electronic laboratory data and electronic health records). • Collaborate with commercial laboratories and other systems to improve the efficiency and effectiveness of viral hepatitis surveillance. • Pilot the use of EHRs with data mining tools in collaboration with health care systems to improve surveillance. • Use aggregated EHRs to monitor performance measures of hepatitis testing, care, and treatment and associated health outcomes.
CDC **HRSA**	B. Strengthen the capacity of state and local health departments and promote reporting to state health authorities by primary care providers to collect viral hepatitis surveillance data: (2014, 2015, 2016) • Evaluate the quality of viral hepatitis surveillance. (CDC) • Help state and local health departments gather data from a variety of sources (e.g., surveillance, law enforcement, health care, U.S. Census) to develop epidemiologic profiles for guiding viral hepatitis prevention within their communities. (CDC) • Improve the quality of surveillance for perinatal hepatitis B transmission. (CDC) • Revise and implement standard reporting criteria for tracking current hepatitis C infection in collaboration with the Council of State and Territorial Epidemiologists and state and local partners. (CDC) • Upgrade surveillance information technology to improve exchange of surveillance data among reporting sites (e.g., laboratories), state and local health departments, and the CDC. (CDC)
CDC	C. Provide epidemiologic and laboratory consultation and assistance for outbreaks of viral hepatitis: (2014, 2015, 2016) • Develop and strengthen collaborations between those health agencies responsible for outbreak response in health care and other settings. • Identify current gaps in laboratory and epidemiologic capacity and identify strategies to address them.
CDC	D. Conduct enhanced surveillance for viral hepatitis: (2014, 2015, 2016) • Conduct epidemiologic studies of viral hepatitis infections among PWID. • Conduct studies of viral hepatitis infections among U.S.-bound refugees. • Conduct surveys and special studies to investigate emerging patterns and modes of transmission, identify new or rare forms of viral hepatitis, and evaluate access to care for persons living with viral hepatitis. • Improve the reporting of acute hepatitis B and C infections detected at blood banks.

	• Link viral hepatitis surveillance data to those obtained through other surveillance systems (e.g., HIV, cancer) and to electronic laboratory reports and medical records.
CDC	E. Survey populations to monitor viral hepatitis health disparities: (2014, 2015, 2016) • Gather data from nontraditional sources (e.g., U.S. Census data, clinical datasets, counseling and testing databases, health records from correctional settings). • Revise federal surveys (e.g., NHIS) to expand monitoring of health disparities among target populations.
CDC	F. Use aggregated health data (e.g., National Hospital Discharge Survey, Multiple Components in One Database) to describe viral-hepatitis-associated disease and mortality and the impact of prevention, care, and treatment services.
CDC **ONC**	G. Facilitate the adoption of ICD-10 codes in viral hepatitis surveillance. Ensure that viral hepatitis diagnostic codes (ICD-9 through 2013 and ICD-9, ICD-10, or SNOMED-CT for 2014 and thereafter) are required for EHR certification under proposed regulations for 2014 EHR certification. (2014, 2015, 2016)

GOAL 3.2 Monitor provision and impact of viral hepatitis prevention, care, and treatment services.

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **NVPO** **SAMHSA**	A. Monitor provision and impact of preventive services for viral hepatitis: (2016) • Identify effective methods for monitoring the impact of perinatal prevention programs. (CDC) • Monitor and report the effect of ACIP-recommended hepatitis B vaccination for persons with diagnosed diabetes mellitus (the impact on disease cases should be monitored and reported). (CDC) • Monitor trends in hepatitis vaccination coverage in populations recommended for vaccination by the ACIP. (CDC)
CDC **HRSA** **SAMHSA** **VA**	B. Monitor testing rates for hepatitis B and C to assess trends in testing, including among individuals in behavioral health settings and those who are HIV-infected. (2014, 2015)
FBOP	C. Improve viral hepatitis surveillance in federal prisons through the integration of a Lab Information System with BOP Electronic Medical Record to better track hepatitis screening of inmates and identify inmates who have not been screened. (2014, 2015)
CDC **IHS** **NIH** **VA**	D. Monitor the provision and impact of viral hepatitis care and treatment services and its impact on health care utilization: (2015, 2016) • Continue to conduct observational cohort studies (e.g., the Chronic Hepatitis Cohort Study) and other evaluations of persons in care for viral hepatitis. (CDC) • Develop core indicators to monitor prevention, screening, care, and treatment of viral hepatitis. (IHS) • Promote health services research to monitor and evaluate the quality of prevention, care, and treatment services. (NIH) • Expand the use of electronic registries for viral hepatitis care. (VA)

	• Facilitate collection and timely analysis of viral hepatitis immunization, testing, and other types of prevention information (e.g., datasets Medicaid, VA, FBOP, and the WHO). (CDC) • Promote the development of systems to monitor where persons are tested for viral hepatitis and the quality of prevention and care services that they receive. (CDC)
CDC **FBOP** **HRSA** **IHS** **OHAIDP** **SAMHSA** **VA**	E. Assess existing data collection activities across federal agencies and along the viral hepatitis treatment cascade. Identify and develop a plan to implement standardized definitions and data collection. (2015)
VA	F. Improve rates of confirmatory testing for active hepatitis C infection. (2014)

GOAL 3.3 Develop and implement new technologies and laboratory procedures to improve viral hepatitis surveillance.

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Develop cross-platform annotations for viral or host factors. (2015)
CDC	B. Develop and standardize laboratory techniques to monitor (1) viral and host genetic factors associated with viral hepatitis transmission, intra-host evolution, and population dynamics and (2) transmission networks and disease progression. (2015, 2016)
NIH **CDC**	C. Develop practical and reliable algorithms for screening high-risk populations for chronic hepatitis B to identify, appropriately diagnose, and manage persons with hepatitis B infection. (2015)
NIH **CDC**	D. Promote development and assessment of quantitative tests for HBsAg, HBeAg, hepatitis B core antibody, and hepatitis B surface antibody for their clinical utility, reliability, and accuracy. (2016)
NIH **CDC**	E. Promote development of quantitative assays for HDV RNA that could be used in diagnosis and in monitoring therapy. (2016)
NIH **CDC**	F. Promote development and assessment of reliable commercial assays for immunoglobulin M and G anti-hepatitis E as well as for hepatitis E RNA and hepatitis E RNA genotyping to allow for accurate diagnosis of acute hepatitis E and identification of chronic infection including viral strain. (2016)

Priority Area 4:

Eliminating Transmission of Vaccine-Preventable Viral Hepatitis

Take full advantage of vaccines that can prevent hepatitis A and B.

Focused efforts to increase the number of persons who receive hepatitis A and B vaccination will lead to further reductions in the burden of hepatitis A and B in the United States and to the elimination of mother-to-child transmission of hepatitis B.

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

GOAL 4.2 Achieve universal hepatitis A and B vaccination for vulnerable adults and youth.

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

Two of the three types of viral hepatitis that contribute most substantially to disease burden in the United States are vaccine preventable. Vaccines to prevent infection with HBV and HAV became available in the United States in 1981 and 1995, respectively. Since then, ACIP has issued several sets of recommendations regarding their use; these recommendations have progressively targeted more and more of the U.S. population as vaccine recipients.

Hepatitis A vaccination is currently recommended for all children at age 1, for persons who are at increased risk for infection (e.g., travelers, MSM, PWID, persons who have occupational risk of exposure), persons at increased risk for complications from hepatitis A (e.g., persons with chronic liver disease), persons 12 months to 40 years of age taking post exposure prophylaxis, and any person wishing to obtain immunity.[58] As a result of implementing these recommendations, rates of hepatitis A infection in the United States have declined by 95 percent since the hepatitis A vaccine first became available in 1995.[59] As efforts continue to reduce hepatitis A through vaccination and other prevention activities, *Healthy People 2020* has set a goal for 0.3 cases of hepatitis A virus per 100,000 population,[60] moving the nation closer to the possibility of elimination of indigenous transmission of hepatitis A virus.

Comprehensive hepatitis B vaccination recommendations, which include all children aged 18 years or younger,[61] have resulted in similar reductions in acute hepatitis B infections. Vaccination contributed to an 82 percent national decline in hepatitis B incidence between 1990 and 2010.[62] Rates of hepatitis B vaccination coverage in infants and adolescents are high (93 percent in infants aged 19–35 months and 88 percent in adolescents aged 13–17 years). However, non-U.S.-born children who were not vaccinated at birth and have parents born in countries with high background rates of hepatitis B are at risk for perinatal transmission and transmission through infected household contacts. As many as 1 million persons with chronic hepatitis B infection remain a potential source for transmission in the United States.

In its 2010 report, the IOM highlights that the goal of eliminating perinatal HBV transmission has not been achieved largely because of incomplete coverage of newborns with a birth dose of hepatitis B vaccine.[63] Vaccination coverage rates for newborns are suboptimal (69 percent by the third day of life), and an estimated 750 new cases of perinatally acquired hepatitis B occur in the United States each year (estimate provided by CDC).[64] Perinatal transmission of HBV is especially serious, because approximately 90 percent of HBV-infected newborns develop chronic infection; up to 25 percent of these children will die prematurely from cirrhosis, liver failure, or liver cancer later in life.

Hepatitis B vaccination programs for adults have been less successful than those targeting children. ACIP has recommended the vaccination of health care workers and persons in other priority populations (i.e., those at high risk for hepatitis B infection, including persons with multiple sexual partners, MSM, and PWID) since 1982. The 2006 ACIP recommendation stressed the need for universal vaccination in health care settings that serve adults in priority populations, including patients attending sexually transmitted disease (STD) clinics, clients of substance-abuse treatment facilities, and incarcerated persons.[65] Despite these recommendations, vaccination coverage among adults in priority populations remains low (45 percent in adults with high-risk behaviors).[66]

Development of new, more effective vaccines that provide long-term protection and reduce the number of doses required for protective immunity could improve existing hepatitis A and B vaccination coverage levels in the United States. The development of vaccines that induce protective immunity in those with reduced immune response rates, such as persons in older age groups and adults with comorbidities, is equally important. Researchers continue to work on the development of effective vaccines for hepatitis C and E infection. While rare in the United States, HEV is a leading cause of hepatitis in developing countries, particularly southern Asia and Sub-Saharan Africa. For pregnant women infected with HEV, case fatality approaches 20 percent. As such, development of an HEV vaccine is of global health importance, and promising clinical trials have shown hepatitis E vaccine candidates to be safe and effective.

Outlined next are the key activities that federal partners plan to take to eliminate vaccine-preventable viral hepatitis.

Eliminate Mother-to-Child Transmission of Hepatitis B

Perinatal HBV transmission can be prevented by identifying HBV-infected (i.e., HBsAg-positive) pregnant women and providing hepatitis B immune globulin and hepatitis B vaccine to their infants within 12 hours of birth. Preventing perinatal HBV transmission is an integral part of the national strategy to eliminate hepatitis B in the United States. National guidelines call for the following:

- Universal screening of pregnant women for HBsAg during each pregnancy;
- Report HBsAg-positive pregnant women to the state or local Perinatal Hepatitis B Prevention Program;
- Provision of immunoprophylaxis for infants born to infected mothers, including hepatitis B vaccine and hepatitis B immune globulin;
- Case management of HBsAg-positive mothers and their infants;
- Post-vaccination testing to determine infant outcomes; and

- Routine vaccination of all infants with the hepatitis B vaccine series, with the first dose administered at birth.[67]

To support implementation of these guidelines and pursue elimination of mother-to-child transmission of hepatitis B, the following activities will be undertaken:

Identify and protect mothers. Federal partners and other key stakeholders will work to ensure that all HBV-infected expectant mothers are identified and linked to care, by promoting hepatitis B screening during prenatal care, enhancing culturally appropriate care coordination to ensure that both the women and their infants receive necessary services, and increasing the rates of hepatitis B vaccination among women.

Identify and protect infants. Administration of a dose of hepatitis B vaccine to all newborns before discharge from hospitals or birthing centers provides a safety net for preventing perinatal and household transmission of hepatitis B. Yet despite expert consensus on the importance of a hepatitis B vaccine birth dose, nearly one in three U.S. newborns leave the hospital unprotected. Other factors, such as high maternal viral load may also put infants at risk of infection. From calendar years 2014 through 2016, federal partners and other key stakeholders will work to ensure that all neonates receive a birth dose of hepatitis B vaccine as the standard of care in hospitals and birthing centers.

Conduct provider education and public outreach. Both provider and public education are needed to advance the nation toward the goal of eliminating perinatal transmission of HBV. Federal partners will work with appropriate professional organizations and maternal and child health champions to pursue improvements in specific practices that can aid in better identifying hepatitis B-infected pregnant women in need of services. In addition, federal partners and other stakeholders will work to expand awareness among women of reproductive age about the importance of hepatitis B screening as well as of the importance of the birth dose of hepatitis B vaccine for newborns.

Advance research and enhance monitoring. To support these efforts, researchers must pursue studies that evaluate and inform ongoing strategies to further reduce mother-to-child transmission of hepatitis B. Promoting implementation of the birth dose coverage of hepatitis B vaccine as a national quality measure and the adoption of facility-based reporting will greatly enhance our ability to monitor progress toward the goal of elimination.

Vaccinate All Vulnerable Youth and Adults

Federal partners and other stakeholders will develop and implement strategies to increase hepatitis A and B vaccination rates among vulnerable populations, working directly with these populations as well as within their respective networks of providers, grantees who serve them, and other allies. Studies that improve our understanding of age-specific responses to hepatitis A and B vaccines, explore issues such as duration of the vaccine's long-term protection, and consider the possible use of vaccines for PEP are necessary to support efforts to expand vaccination among vulnerable adults.

Advance Hepatitis Vaccine Research

Safe and effective hepatitis A and B vaccines are currently available. However, research continues to develop improved hepatitis A and B vaccines and move us closer toward new vaccines to prevent hepatitis C and E infections. Between calendar years 2014 and 2016, the federal partners will

develop approaches to improve the protection afforded by existing vaccines as well as identify new and innovative vaccine delivery systems. Development of a vaccine that prevents new HCV infections remains a high-priority task, and federal partners will support basic research and collaborate in efforts to develop vaccine candidates and support studies on the safety and efficacy of such candidate vaccines. HEV, a major cause of viral hepatitis infection in Asia and Africa, may likely be preventable in the near future, as research continues on promising candidate vaccines. Additional research is needed to bring these candidate vaccines into production to benefit vulnerable populations. Federal agencies will continue to collaborate with nonfederal stakeholders to evaluate hepatitis E vaccine candidates, develop capacity and tools to support studies of such candidates, and study vaccine implementation in endemic countries.

Opportunities for Nonfederal Stakeholders

Success in eliminating transmission of vaccine-preventable viral hepatitis will require the involvement of the many parts of the public health, medical, and research communities, including health departments, health care providers, laboratory workers, patients, hospitals and birthing centers, pharmaceutical companies and others in the vaccine industry, partners in the National Vaccine Plan, related professional associations, and community and advocacy groups representing vulnerable populations. Among the opportunities for their engagement in these actions are:

- Asking health care providers if vaccination for HAV and/or HBV is recommended;
- Requesting a test for HBV if recommended by the CDC Viral Hepatitis Risk Assessment;
- Conducting health care provider and consumer education on HBV screening for pregnant women and ensuring neonates receive a birth dose of hepatitis B vaccine;
- Ensuring that institutional policies include HBV screening for expectant women and prompt administration of the birth dose of hepatitis B vaccine to infants;
- Completing the three-dose series and receiving post-vaccination testing for infants born to HBsAg-positive women;
- Disseminating federally developed recommendations, guidelines, and campaign materials to professional, institutional, consumer, and community networks;
- Educating the public and health care providers about the preventive benefits coverage provisions of the Affordable Care Act and their implications for improved hepatitis A and B vaccine coverage;
- Collaborating with public health and community stakeholders to educate, screen, and vaccinate priority populations;
- Initiating or enhancing vaccination in clinical settings serving priority populations; and
- Investing in research on new or improved vaccines.

Priority Area 4: Eliminating Transmission of Vaccine-Preventable Viral Hepatitis

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

Identification and Protection of Mothers and Infants

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **CMS** **FBOP** **HRSA**	A. Promote testing to identify all hepatitis B-infected pregnant women by increasing laboratory reporting of pregnancy status on reports of HBsAg-positive tests and determine appropriate referral for care: (2014, 2015, 2016) • Eliminate mother-to-child transmission of hepatitis B by offering prenatal screening for pregnant females in FBOP custody. (FBOP) • Increase identification of HBV-infected pregnant women and their newborns through comparison of prenatal lab results with other sources of information. (CDC) • Promote inclusion of pregnancy status on all electronic and paper reports of positive HBsAg test results sent by laboratories to clinicians. (CDC) • Promote testing of pregnant women for viral hepatitis during prenatal care in community health centers and other care settings. (HRSA) • Promote reporting and referral of HBsAg-positive pregnant women to the Perinatal Hepatitis B Prevention Program. (CDC)
CDC **HRSA**	B. Identify pregnant women with hepatitis B infection early in pregnancy and determine appropriate referral for evaluation, care, and treatment or vaccination during pregnancy. (2014, 2015, 2016)
CDC	C. Identify barriers and implement effective strategies to ensure that all infants are protected against hepatitis B transmission: (2014, 2015, 2016) • Promote the birth dose of HBV vaccine as the standard of care in hospitals and birthing centers for all infants (regardless of maternal HBsAg status). • Promote timely PEP for infants born to HBsAg-positive women. • Ensure that all infants born to HBsAg-positive women receive post-vaccination serologic testing. • Reduce unnecessary revaccination from delayed post-vaccination testing of infants born to hepatitis B-infected pregnant women. (2016) • Increase completion of a four-dose HBV vaccine series for low-birthweight infants (weighing less than 2,000 grams) born to HBsAg-positive women. (2016)
CDC	D. Support development of WHO strategies to vaccinate all infants at birth (birth dose), and help regions and countries set and achieve goals for reducing hepatitis B infection among vaccinated cohorts.

Provider Education and Public Outreach

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	E. In collaboration with professional organizations (e.g., Association of Public Health Laboratories), promote inclusion of pregnancy status on all electronic and paper reports of positive HBsAg test results sent by laboratories to clinicians. (2015, 2016)
CDC	F. Educate clinical providers to screen for hepatitis B in children considered to be at increased risk because they were not vaccinated at birth and their parents were born in countries highly endemic for hepatitis B. (2015)
OMH **OWH**	G. Expand hepatitis B awareness and education to women of reproductive age: (2015) • Conduct webinars for women, federal and nonfederal partners, and others about viral hepatitis and its impact on pregnant women. (OWH) • Disseminate information about prevention, vaccination, screening, testing, care, and treatment using the OMH network. (OMH)

Research and Monitoring

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **NIH**	H. Demonstrate safety and efficacy of antiviral therapy as a means of prevention of maternal-infant spread of hepatitis B in pregnant women with serum HBsAg and high levels of hepatitis B DNA, including the optimal timing of initiation of therapy, levels of hepatitis B DNA that warrant treatment, and safety of therapy for both the newborn and the mother. (2016)
CDC	I. Assess the feasibility of screening pregnant women with hepatitis B infection for hepatitis B DNA or HBeAg. (2016)
CDC	J. Revise and create a new model for estimating of the number of births to hepatitis B infected pregnant women. (2016)
CDC	K. Evaluate FDA-approved commercial assays for HBeAg. (2016)
CDC **CMS** **ONC**	L. Adopt facility-based reporting of annual hepatitis B birth dose coverage as a National Quality Measure and perform reliability testing: (2015, 2016) • Convert the National Quality Forum 0475 measure, "Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge," into an electronic clinical quality measure format (e-specification). (CMS) • Review measure for potential use in the Medicaid EHR Incentive Program. (CMS)
NIH	M. Encourage studies on the safety and efficacy of continuing antiviral therapy for hepatitis B during pregnancy and breastfeeding. (2016)

GOAL 4.2 Achieve universal hepatitis A and hepatitis B vaccination for vulnerable adults and youth.

Vaccine Availability and Utilization

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Obtain expert opinion on setting a goal for elimination of indigenous transmission of hepatitis A virus in the United States. (2016)
CMS	B. Cover hepatitis A and B vaccine administration for children and adolescents under the Medicaid program: • Children and adolescents under the age of 19 must be provided all vaccines recommended by the ACIP, including hepatitis B vaccines covered by the Vaccines for Children program. • For children and adolescents enrolled in CHIP under the age of 19, the state must ensure access to all ACIP-recommended vaccines, including hepatitis B. • Individuals 19 and 20 years of age who are eligible for Early and Periodic Screening, Diagnostic, and Treatment services are also required to be provided all ACIP-recommended vaccines.
CDC **CMS** **FBOP** **HRSA** **IHS** **NVPO** **OHAIDP** **SAMHSA** **VA**	C. Develop strategies to increase hepatitis A and B vaccination rates among vulnerable adults and youth in alignment with ACIP recommendations and *Healthy People 2020* goals: (2014, 2015, 2016) • Identify strategies to expand access to and use of viral hepatitis vaccines in primary care settings. (IHS) • Increase hepatitis A vaccine coverage among children less than 19 years of age. (CDC) • Increase rates of immunization against hepatitis A and B among vulnerable Veterans. (VA) • Integrate hepatitis A and hepatitis B vaccination into primary care programs. (HRSA) • Promote hepatitis A and hepatitis B vaccination in behavioral health settings. (SAMHSA) • Reduce transmission of vaccine-preventable viral hepatitis by utilizing FBOP Preventative Health Care Guideline, which describes appropriate indications for hepatitis A and B vaccination of inmates. (FBOP) • Promote the Standards for Adult Immunization Practice (http://www.hhs.gov/nvpo/nvac/reports/nvacstandards.pdf). (NVPO)

Research and Monitoring

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	D. Seek opportunities to study the immunogenicity of hepatitis A vaccine for PEP among adults less than 40 years of age. If effective, vaccine has the advantage over immunoglobulin of inducing continuing protection. (2015)
CDC	E. Increase understanding of hepatitis A and B vaccine-induced immunity to guide prevention efforts: (2014, 2015) • Assess long-term vaccine-induced and infection-induced immunity for HAV. • Determine markers of long-term vaccine-induced protection against chronic HBV. • Monitor long-term protection among adults vaccinated for hepatitis A and B to determine whether a booster is needed.
CDC	F. Address the health disparity in protection against HAV infection for older adults who sustain the highest morbidity and mortality from acute infection. Studies to assess changes in vaccination protection among older adults can be considered. (2015)
NIH	G. Encourage development and evaluation of HBV vaccination interventions in drug treatment settings and venues that serve PLWHA and PWID. (2015)

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

Vaccine Research and Development

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Develop dynamic modeling approaches to generate vaccines and antiviral drugs. (2014, 2015)
CDC	B. Improve prophylaxis for hepatitis A virus infection: (2016) • Develop computational capacity and tools for delivery of improved prophylactic antibody preparations against hepatitis A. • Support production of improved antibody-containing formulations for passive prophylaxis against hepatitis A virus.
CDC	C. Evaluate novel delivery system for hepatitis B vaccine (in rhesus macaques). (2016)
CDC FDA NIH	D. Advance HCV vaccine development: (2014, 2015, 2016) • Develop hepatitis C vaccine candidates. (FDA) • Develop potency assays. (FDA) • Promote basic research on the immune pathogenesis of hepatitis C to help progress in developing a hepatitis C vaccine and support early phase studies on the safety and efficacy of candidate hepatitis C vaccines. (NIH)

CDC	E. Advance hepatitis E vaccine research. (2015, 2016) • Collaborate with partners to evaluate hepatitis E vaccine candidates and vaccine implementation in endemic countries. • Develop computational capacity and tools to support efficacy studies of candidate hepatitis E vaccines.

Policy

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	F. Develop national policy for new vaccines (e.g., for hepatitis A, B, or C) and new indications for vaccination. (2014, 2015, 2016)
NVPO	G. Support the production of a catalogue of priority vaccine targets of domestic and international importance through a contract with the IOM. (2014)

Priority Area 5:

Reducing Viral Hepatitis Caused by Drug Use Behaviors

Stop the spread of viral hepatitis associated with drug use.

A broad cross-section of public- and private-sector partners is increasingly alarmed by the emergence of an epidemic of hepatitis C infection among young people who inject drugs, both male and female, primarily in rural and suburban settings, who started prescription opioid use before transitioning to heroin injection. There is an urgent need for research, surveillance, and prevention strategies that interrupt viral hepatitis transmission in order to curb rising incidence rates in young people and others who use and/or inject drugs.

GOAL 5.1 Ensure that persons who inject drugs have access to viral hepatitis prevention, care, and treatment services.

GOAL 5.2 Develop and mobilize community resources to prevent viral hepatitis caused by injection drug use.

GOAL 5.3 Expand access to and delivery of hepatitis prevention, care, and treatment services in correctional settings.

GOAL 5.4 Advance research to improve prevention of viral hepatitis among persons who use drugs.

Of new cases of hepatitis C infection reported to the CDC, injection drug use is the most commonly identified risk factor. An estimated 64 percent of PWID are chronically infected with HCV, and 2.7–11 percent are chronically infected with HBV.[68] PWID are not only disproportionately affected by HCV and HBV[69] but also more likely to have adverse hepatitis-related health outcomes compared to other infected populations, primarily because of comorbidities and inadequate access to and receipt of health services. Several additional factors contribute to the adverse health outcomes experienced by many PWID infected with viral hepatitis, including lack of awareness of infection status and late diagnosis.

Among PWID, HCV is transmitted more easily than HIV. Present in high concentrations in the blood of infected persons, HCV is readily transmitted after exposure to blood-contaminated needles, syringes, and drug preparation equipment. Consequently, the incidence of HCV infection is high among people who recently began injecting drugs. After a marked decline in the number of reported cases of acute HCV in the past 2 decades, reported cases of acute infection remained steady between 2003 and 2011. Of concern, the CDC reports that for 2011, there was a 45 percent increase in reported cases of acute hepatitis C.[70] While PWID are a group at great risk for hepatitis, those who face alcohol and drug addictions but do not report current injection drug use also face

health risks if diagnosed with viral hepatitis, because ongoing drug and alcohol use can exacerbate liver damage.

Despite these challenges, a decline in overall prevalence of HCV infection has been observed among some cohorts of PWID associated with the provision of comprehensive health services and efforts that promote awareness of infection status.[71] Recovery from substance abuse through effective addiction treatment and recovery supports can also reduce risk for HCV infection.[72]

Strategies to address the needs of people who use drugs must have a foundation in state of the art interventions that are culturally relevant, include input from PWID, and be responsive to the needs of the individual. Outlined next are the key activities that federal partners plan to take to reduce viral hepatitis associated with drug use behaviors.

Ensure Access to Hepatitis Prevention, Care, and Treatment

The prevalence of viral hepatitis is high among PWID, including those entering substance abuse treatment programs. Integrating evidence-based medical and behavioral drug treatment and recovery services with viral hepatitis prevention, care, and treatment services can help to improve health outcomes and reduce the further transmission of these infections. An important accomplishment from the 2011 Viral Hepatitis Action Plan was SAMHSA's development and release of Treatment Improvement Protocol (TIP) 53: *Addressing Viral Hepatitis in People with Substance Use Disorders* in February 2012.[73] The TIP was written to improve knowledge of HBV and HCV risk, testing, treatment, and care among providers of substance abuse treatment. SAMHSA promoted the release through multiple online outlets and sent a "Dear Colleague" letter to all SAMHSA substance abuse treatment grantees.

Provide training and education for recovery and treatment providers. Though efforts have been made to promote education, many substance abuse treatment providers remain unaware of the high rates of viral hepatitis among those facing addictions and what role they may be able to play in helping to prevent or diagnose these infections. To address this gap, federal partners will work to incorporate HCV education into training materials for providers working with priority populations, including PWID and others seeking medical treatment for opioid addiction, by developing and disseminating an HCV treatment curriculum for this population. In addition, federal partners will work with agencies on integrating new viral hepatitis protocols into existing practices that support people as they reenter communities from recent incarceration.

Integrate behavioral health and hepatitis services. A key approach to addressing viral hepatitis among people who use drugs is to cross-train and integrate addictions and mental health services with viral hepatitis prevention, screening, and referral to care for PWID and others who engage in drug use. In response to this need, federal partners will work toward the integration of viral hepatitis prevention, screening, and care services where opportunities exist. Integrating viral hepatitis services (screening, vaccination, confirmatory testing, and referral to care and treatment) into existing behavioral health services, such as medication-assisted treatment (MAT; e.g., methadone or buprenorphine), where appropriate, will leverage existing federal systems that are already working with PWID but may not typically focus on infectious diseases.

Conduct research and evaluation activities. In order to develop and utilize the most effective strategies and interventions for preventing, diagnosing, and treating viral hepatitis in PWID, continued research on new approaches and evaluation of existing approaches are needed. Additional

information and evaluation studies are needed to better characterize barriers to HCV care and treatment for PWID; assess specific models of care for PWID, especially for adolescents and young adults; and develop strategies that enable substance abuse providers to learn about viral hepatitis and how it affects their clients.

Develop and Mobilize Community Resources for Prevention

Despite the challenges previously discussed, public health efforts on the community level have successfully prevented viral hepatitis among PWID. Hepatitis B vaccination programs and other large-scale hepatitis vaccination initiatives targeting PWID are both feasible and effective, particularly in substance abuse treatment settings.[74, 75] Additionally, PWID have been shown to accept vaccination when offered,[76, 77, 78] and outbreaks of HBV infection among PWID have been successfully quelled by public health and community collaborative vaccination programs. Creating viral hepatitis prevention partnerships with community-based providers of hepatitis care and other medical and social services targeted to substance users can help to synergize efforts; improve the delivery of hepatitis prevention services; and reduce stigma and discrimination against people who inject drugs in need of medical, behavioral, and public health services.

Launch and strengthen partnerships. Partnerships across the public and private sectors are needed to improve viral hepatitis prevention, care, and treatment for all drug users. It is critical, especially in rural and underserved areas, that these partnerships include an array of organizations, including local health departments, pharmacies, law enforcement, social service agencies, community organizations, health care providers, and other stakeholders. Federal agencies will work to strengthen nonfederal partnerships to increase awareness, support community mobilization, and extend the reach of the Viral Hepatitis Action Plan.

Coordinate resources to expand and enhance access to comprehensive prevention services for PWID. State, local, and community partners play an essential role in helping to develop and support comprehensive viral hepatitis prevention programs for PWID. These programs should include the provision of information and education about viral hepatitis transmission through contaminated needles, syringes, and injection equipment; ready access to viral hepatitis testing; MAT for opioid dependence; and, where supported with state, local, or private funds, access to sterile injection equipment for PWID who cannot or will not stop injecting drugs.

Take prevention and research opportunities to address hepatitis C transmission in young PWID. In 2013, OHAIDP, in partnership with the NIH, the CDC, SAMHSA, and other federal agencies, convened a consultation to address the emerging epidemic of hepatitis C infection among young PWID. The resultant meeting report[79] outlined many of the challenges, gaps, and possible strategies to address the new cases of HCV that have been detected in adolescents and young adults who have recently initiated injection drug use. The rapid detection and provision of care and treatment can prevent further transmission of HCV among this vulnerable population. Federal partners will work to develop age-appropriate HCV prevention interventions, including those that can reach young persons before they transition to injecting. A number of research approaches are needed and will be pursued, such as conducting incidence and prevalence research on HCV among young PWID and emphasizing research studies on implementation science. Additional research into the risk factors for hepatitis transmission in young persons is needed to inform prevention interventions for this population.

Expand Access and Services in Correctional Settings

The prevalence of viral hepatitis is high among persons who are incarcerated, many of whom have a history of injection drug use. Identifying persons infected with viral hepatitis in correctional settings provides an important opportunity to intervene with needed prevention and care services.

Increase availability of viral hepatitis testing and services in federal, state, and local correctional facilities. Due to the high prevalence of viral hepatitis among people who are incarcerated, there is a pressing need to increase the availability of prevention, care, and treatment services for this population. Federal partners will work with partners in correctional health to increase the availability of viral hepatitis education, counseling and testing, care, and treatment services by incorporating viral hepatitis activities and services into existing systems such as HIV testing and care initiatives and corrections admissions processes.

Increase the availability and uptake of training. Health care providers and other support staff (e.g., social workers, case managers) working in correctional facilities need continued education and training in viral hepatitis prevention, care, and treatment. To support expansion of access to quality viral hepatitis services in correctional settings, federal agencies will work with federal and nonfederal partners at the federal, state, and local levels to increase the availability and implementation of training activities.

Advance Research Activities to Improve Prevention of Viral Hepatitis Among PWID

There are research questions that remain unanswered regarding viral hepatitis risk, transmission, testing, care, treatment, and reinfection among PWID and other drug users. Additional studies are needed to assess the population-level benefits of preventing the acquisition and transmission of HCV among PWID including studies that specifically address the benefit of curative HCV treatment as an HCV prevention strategy among people who inject drugs.

Investigate research questions related to hepatitis and PWID. Federal researchers will collaborate with other partners to design and conduct studies to enhance our understanding of drug use patterns and practices and how these may affect HCV transmission. Examples of possible research priorities are examining social networks of PWID and their association with HCV transmission; evaluating the effectiveness of various prevention strategies, including substitution therapy to reduce HCV infection; understanding the most effective practical procedures for screening, evaluation, and management of PWID and other high-risk groups; and increasing our understanding of the effects of anti-HCV therapy on reducing the spread of the virus among PWID.

Opportunities for Nonfederal Stakeholders

Community groups, peer educators, health departments, opioid treatment programs, substance abuse treatment facilities, people who inject drugs or are in recovery, HIV prevention and care providers, patients and their families, organizations providing recovery support services such as peer support, and many others can contribute to our collective efforts to reduce viral hepatitis associated with drug use. Among these are

- Learning the risks of viral hepatitis associated with injection drug use and strategies to prevent transmission;

- Sharing accurate facts about viral hepatitis with friends, peers, and family members;
- Identifying significant gaps in services, social supports and other needs of PWID at the community level;
- Advising in the development of training tools and curricula for working with PWID and other drug users;
- Addressing the needs of young people infected with and affected by HCV (since young PWID may not prioritize hepatitis C prevention, interventions will need to holistically address their other priorities, focusing on basic needs and age-appropriate health care and drug treatment, integrating HCV prevention interventions into these points of contact);
- Developing culturally and age-appropriate risk reduction messages for young people who are at risk of transitioning to injecting or are currently injecting;
- Promoting the availability of training opportunities for providers and others who work closely with those at risk for initiating injection drug use, PWID, and people in correctional facilities;
- Helping to disseminate educational tools and public education messages and materials to relevant audiences to extend the reach of these efforts;
- Collaborating locally with partners from the addictions and recovery communities, researchers, public health authorities, syringe service programs, opioid substitution providers, and other allies to support increased viral hepatitis education and services for people who inject drugs; and
- Educating law enforcement about the burgeoning problem of HCV among PWID through partnerships developed by key stakeholders with law enforcement entities.

Priority Area 5: Reducing Viral Hepatitis Caused By Drug Use Behaviors

GOAL 5.1 **Ensure that persons who inject drugs have access to viral hepatitis prevention, care, and treatment services.**

Integrate Behavioral Health and Hepatitis Services

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC HRSA SAMHSA	A. Integrate viral hepatitis prevention, screening, and care services as standard components of behavioral health programs and primary care. (2014, 2015, 2016)
CDC HRSA NIH SAMHSA	B. Provide persons who inject drugs with access to care and drug treatment to prevent transmission and progression of disease: (2014, 2015, 2016) • Promote integrated care and treatment approaches for the management of viral hepatitis and co-morbid health conditions. (CDC) • Support screening, care, and treatment of viral hepatitis among opioid treatment and syringe services programs. (HRSA, SAMHSA)
VA	C. Increase capacity for mental health services among individuals with viral hepatitis. (2015)

Training and Education

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	D. Examine the feasibility of incorporating hepatitis C education into the training materials for doctors newly licensed to prescribe buprenorphine. (2015)
OMH	E. Provide training to outreach programs serving the reentry population on how to integrate Screening, Brief Interventions, and Referral to Treatment into existing protocols and practices. (2015)
SAMHSA	F. Develop and disseminate a hepatitis treatment curriculum to improve hepatitis services for persons who inject drugs. (2014)

SAMHSA	G. Provide training to physicians in behavioral health and primary care programs on office-based treatment of opioid dependence using buprenorphine or naloxone products. Assist physicians receiving appropriate training to obtain the Drug Enforcement Administration waiver needed to prescribe buprenorphine products for treatment of opioid dependence. Include hepatitis and HIV disease training as part of this training. (2015)

Research and Evaluation

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	H. Examine and assess barriers to hepatitis C care and treatment for PWID. (2015)
CDC	I. Analyze data from demonstration projects in settings that serve PWID to identify the best strategies for providing hepatitis C testing and linkage to care and treatment. (2015)
CDC	J. Evaluate and identify models of care that help PWID access and complete recommended hepatitis C therapy. (2015, 2016)
CDC	K. Conduct qualitative research to investigate views of prospective prescribers of opioid treatment therapies to measure hepatitis C knowledge and willingness to learn about hepatitis C. (2015)
IHS	L. Assess ongoing and planned activities to reduce viral hepatitis related to drug-use for effectiveness. (2014)
NIH	M. Encourage studies that demonstrate how HCV prevention programs can be integrated into settings that reach substance users who are not engaged in substance abuse treatment. (2015)

GOAL 5.2 Develop and mobilize community resources to prevent viral hepatitis caused by injection drug use.

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Launch and strengthen community partnerships with local health departments, law enforcement, other government agencies, community-based organizations, and health care providers to prevent viral hepatitis in PWID. (2014, 2015, 2016)
CDC	B. Coordinate federal, state, and local resources to expand and enhance hepatitis prevention interventions for PWID. Where state, local, or private resources are available, these comprehensive services should include access to sterile injection equipment. (2015)

CDC **IHS** **NIH** **SAMHSA**	C. Prevent hepatitis C transmission among young persons who inject drugs and those new to injection drug use by rapidly detecting hepatitis C and facilitating provision of care and treatment: (2016) • Develop a cross-HHS action plan to respond to the recent increase in hepatitis C infections among persons who inject drugs, particularly young persons (less than 30 years of age). (CDC) • Develop approaches to detect and treat acute hepatitis C infection among young PWID. (CDC) • Develop hepatitis C prevention interventions that can reach young persons before they transition to injecting or when they have recently initiated injecting. (CDC, NIH)
OHAIDP	D. Partner with the Office of National Drug Control Policy to increase awareness and community mobilization to prevent viral hepatitis infections caused by injection drug use. (2014)

GOAL 5.3 Expand access to and delivery of hepatitis prevention, care, and treatment services in correctional settings.

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **FBOP** **HRSA** **NIH** **OHAIDP** **OMH**	A. Increase the availability of viral hepatitis testing and counseling in federal, state, and local correctional facilities by working with federal and nonfederal partners: (2014, 2015, 2016) • Enhance drug treatment and viral hepatitis prevention, care, and treatment in correctional programs. (CDC) • Incorporate hepatitis C testing and care into existing HIV testing and care initiatives in correctional settings. (CDC) • Increase hepatitis prevention education provided to inmates at intake during the admissions process and through drug education programs offered to people incarcerated in federal prisons. (FBOP) • Promote linkages with correctional settings to provide continuity of viral hepatitis prevention, care, and treatment for individuals recently released and reentering the community. (HRSA, OMH) • Develop and evaluate programs to increase the reach, quality, and effectiveness of hepatitis prevention, care, and treatment services in correction settings, particularly integrated services that address substance use, HIV, and other infectious diseases. (NIH)
OHAIDP	B. Increase the availability and uptake of viral hepatitis training on prevention, care, and treatment for health and nonhealth staff in federal, state, and local correctional facilities in collaboration with federal and nonfederal partners. (2015)

GOAL 5.4 Advance research to improve prevention of viral hepatitis among persons who use drugs.

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Determine the effectiveness of opioid agonist therapy in combination with other prevention strategies to reduce HCV infections. (2016)
CDC	B. Investigate hepatitis C transmission networks among the social networks of PWID. (2016)
CDC NIH	C. Encourage studies of patterns of drug use and their association with hepatitis C transmission to provide scientific support for innovative behavioral and social preventive interventions based upon anti-addiction therapy, modification of methods of drug use combined with hepatitis C testing, education, care, and treatment: (2016) • Examine the techniques used by young PWID to prepare and inject prescription opioids, specifically abuse-deterrent and extended-release formulas. (CDC)
NIH	D. Develop practical algorithms for screening, evaluation, and management of PWID and other groups at high risk for hepatitis C infection. (2015)
NIH	E. Encourage studies on coordination of services for HCV and co-occurring conditions including other infectious diseases and drug injection. (2016)
CDC NIH	F. Demonstrate whether antiviral therapy of patients with acute or chronic hepatitis C infection is effective in reducing the spread of infection in high-risk situations, such as injection drug use. (2016)

Priority Area 6:

Protecting Patients and Workers from Health Care-Associated Viral Hepatitis

Quality health care is safe health care.

Neither patients nor providers should be at risk for acquiring HBV, HCV, or other bloodborne infections during health care encounters. Stakeholders in the Action Plan recognize that such health care-associated infections are an important public health and patient safety issue and are committed to better understanding the causes and further reducing the risk of their occurrence.

GOAL 6.1 Reduce transmission of viral hepatitis to patients resulting from misuse of medical devices and drugs.

GOAL 6.2 Reduce transmission of viral hepatitis associated with blood, organs, and tissues.

GOAL 6.3 Reduce occupational transmission of viral hepatitis.

GOAL 6.4 Enhance understanding of the preventable causes of viral hepatitis transmission in health care settings.

When errors occur during the delivery of health care, the potential exists for transmission of viral hepatitis to both health care workers and patients. A wide variety of health care settings have been implicated in the transmission of HBV and HCV, both of which are transmitted more easily than HIV.[80] Fortunately, significant advances have been made in preventing such transmission, including reducing the risk of acquiring viral hepatitis from transfused blood products, widespread adoption of standard infection control procedures and safe injection practices, and increased rates of hepatitis B vaccination among health care providers. However, health care-associated outbreaks of HBV and HCV infection persist in hospitals as well as nonhospital care settings, including outpatient settings, hemodialysis units, and long-term care facilities. Health care-associated viral hepatitis infections are most frequently due to breaches in infection control; unsafe injection practices; reuse of needles, fingerstick devices, and syringes; and other unsafe health care practices that put both patients and providers at risk. Federal partners will work with key stakeholders to pursue the following activities so as to further reduce the risk of health care-associated transmission of viral hepatitis.

Use Medical Devices Correctly for Every Patient

Investigations into health care-associated viral hepatitis transmission events, often in long-term care settings, have repeatedly demonstrated that diagnostic devices designed for individual use can transmit disease when used, improperly, for multiple patients. For example, finger-stick devices, or lancets, have been a major source of HBV transmission when used on multiple patients. Failure to clean and disinfect multiuse blood glucose monitors between patients and

misuse of single-patient monitors also have been identified as sources of viral transmission. Syringes can transmit viral hepatitis if used for more than one patient or when a medication vial is contaminated with a used syringe and then the same vial is used for subsequent patients. To continue to reduce transmission of HBV, HCV, and other bloodborne pathogens in health care settings, the federal partners will collaborate with one another and nonfederal partners to improve device design and medication labeling; develop guidance and provide training on health care safety and infection control standards; enhance professional and institutional accountability; support relevant research; and, where appropriate, provide oversight. Especially important are opportunities to collaborate with and leverage existing federal and public-private initiatives already underway to reduce health care-associated infections in acute care hospitals, ambulatory surgical centers, end-stage renal disease facilities, and long-term care facilities. These include both the National Action Plan to Prevent Health Care-Associated Infections and the One and Only Campaign.

Enhance and promote medical device safety. Federal partners will collaborate with partners from industry and other sectors on efforts to reduce transmission of viral hepatitis due to the improper use of syringes, contamination of medication vials, improper handling of point-of-care devices, and improper reprocessing of reusable medical devices. These activities will address improved syringe design and medication label content as well as improved oversight for infection control procedures, guidance or regulatory action, and research on where and when such actions are indicated.

Boost provider education on and awareness of infection control and injection safety. Important steps toward this goal are also needed at the provider level, so federal partners will engage in a variety of provider education activities regarding basic infection control across all variety of health care settings. This includes providing training and examining opportunities for reinforcing infection control and injection safety in continuing education and related competency certifications for health care providers. In addition, the federal partners will collaborate with, leverage, and help extend existing related initiatives including the One and Only Campaign and the National Action Plan to Prevent Healthcare-Associated Infections.

Ensure the Safety of Blood, Organs, and Tissues

Efforts to ensure the safety of blood in the United States using viral nucleic acid testing (NAT) and serologic testing have dramatically reduced the number of viral hepatitis infections attributable to blood transfusions and tissue transplants. However, additional improvements in testing could bring the risk for transmission of viral hepatitis to recipients of blood and tissue closer to zero.

Improvements also are needed to better protect patients receiving solid organ transplants. Because of the high demand for and limited supply of organs, persons with risk factors for hepatitis are accepted as donors. In addition, although NAT can detect viral hepatitis infection earlier compared to other testing platforms, this type of screening currently is not mandatory; consequently, not all organ procurement organizations are using NAT to screen donors. Requiring universal testing of donors by NAT could reduce the risk of HBV and HCV transmission to transplant recipients. To further protect transplant patients from viral hepatitis, revisions to

federal recommendations concerning organ donor screening (both laboratory and risk factor) have been published.[81] Moreover, sharing information through a national biovigilance program could assist in further understanding the potential risks associated with donated blood, organs, and tissues.

From calendar years 2014 through 2016, the federal partners will work to improve both tests and testing practices used to detect viral hepatitis as part of the blood, organ, and tissue donation processes, revising policies and issuing new guidance as appropriate. The federal partners also will support and work to improve existing surveillance systems that provide vital information on viral hepatitis infection among blood donors and explore opportunities for public-private efforts that could aid national surveillance programs with the analysis of adverse events associated with the transfusion and transplantation processes.

Reduce Occupational Transmission of Viral Hepatitis

Health care workers are at high risk for exposure to and transmission of hepatitis B and C as a result of contact with blood or other contaminated fluids from infected patients. Given the risk of exposure, the Occupational Safety and Health Administration requires that hepatitis B vaccine be offered to health care personnel who have a reasonable expectation of being exposed to blood and body fluids on the job. However, vaccination coverage among health care workers remains below *Healthy People 2020* targets of 90 percent (68 percent among health care providers aged 18–49 years, according to the 2009 NHIS).[82] Needle sticks and sharps injuries remain a source of bloodborne pathogen exposure among health care workers. During the first 3 years of the Action Plan, steps to reduce this risk included publication of a safety alert and advisory recommending the use of blunt-tip surgical needles for some high-risk procedures[83] and updated guidelines on the management of HBV-infected health care workers.[84] From calendar years 2014 through 2016, federal partners will work with professional organizations and other stakeholders to further reduce this risk and manage possible exposure to HBV and HCV among health care providers by working to increase hepatitis B vaccination coverage for health care workers, updating and disseminating guidelines on the management of HCV-infected health care workers and on the management of occupational viral hepatitis exposures, and providing training and education activities to providers in their respective networks. In addition, these partners will support research to identify best practices for preventing viral hepatitis transmission in priority settings.

Understanding the Causes of Health Care-Associated Viral Hepatitis

When outbreaks of health care-associated viral hepatitis occur, it is important to investigate them and gather insights and lessons learned to inform improved practices and policies. Federal partners will seek to support health departments and health care providers to investigate outbreaks and share findings and recommendations to guide improved training and practices to avoid similar instances in the future. Partners will commission studies and conduct site visits to explore the barriers to compliance with safe use of medical devices, make recommendations for improved practices, and conduct research to identify next-generation technologies that can help further reduce health care-associated transmission of viral hepatitis.

Opportunities for Nonfederal Stakeholders

Success in better understanding the causes of and further reducing incidents of health care-associated transmission of viral hepatitis will require the involvement of the entire public health and medical community, including hospital, ambulatory care, and long-term care industries, as well as those charged with quality and oversight along with health departments; health care and patient advocates; patients; device manufacturers; and public health, medical, and other professional associations. Among the opportunities for their engagement in these actions are

- Asking health care providers if a new needle, new syringe, and a new vial will be used for procedures or injections;
- Asking health care providers how they prevent the spread of infections in their facilities;
- Ensuring institutional infection control and prevention policies are updated, clearly communicated, and enforced;
- Updating and conducting provider trainings in infection control;
- Investing in new technologies that reduce transmission of blood borne pathogens;
- Disseminating federally developed recommendations, guidelines, and campaign materials to professional and institutional networks;
- Vaccinating all health care workers for hepatitis B;
- Implementing measures to prevent opioid diversion;
- Reporting suspected health care-associated outbreaks and collaborating with public health investigation and research efforts;
- Developing new resources, tools, and technologies that reduce the likelihood of health care-associated disease transmission; and
- Conducting research to identify transmission risks and guide the development of improved procedures, policies, and practices.

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

GOAL 6.1 Reduce transmission of viral hepatitis to patients resulting from misuse of medical devices and drugs.

Medical Device Safety

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Reduce transmission associated with the improper use of syringes and the contamination of medication vials: (2014, 2015, 2016) • Encourage the industry to incorporate tamper-evident or tamper-resistant designs into syringes and other injection equipment. • Expand educational campaigns (including injection-safety checklists) and infection control or regulatory guidance, and use campaigns and materials to promote safe use of syringes and injectable medications. • In collaboration with U.S. Pharmacopeia, revise label content for medication vials.
CDC	B. Improve oversight of health care facilities and providers to ensure compliance with proper infection control procedures: (2014, 2015, 2016) • Assist oversight authorities in ensuring the appropriate use of medical devices and the provision of associated training within health care settings. • Identify and disseminate model legislation or regulations at state and local levels to promote optimal infection control in health care facilities. • Incorporate evidence-based infection control components into applicable health and safety standards.
CDC **CMS** **FDA**	C. Reduce risk of transmission resulting from improper handling of point-of-care devices (e.g., blood glucose monitors) and other medical equipment: (2014, 2015, 2016) • Develop an educational campaign for device manufacturers, user facilities, and clinicians to address cleaning, disinfection, and sterilization of reusable devices. (CDC) • Develop innovative approaches to effective device cleaning. (CDC) • Issue draft guidance for industry on development of technology to reduce opportunities for human error during use of automated endoscope reprocessors (e.g., selection of appropriate settings, connectors, disinfectants). (CDC) • Issue draft guidance for industry on the reprocessing of reusable medical devices in health care settings that addresses the validation of device cleaning, disinfection, and sterilization. (CDC) • Review and take necessary action on the regulatory status of blood lancets. (CDC) • Support research to determine risk of viral hepatitis transmission via internal components of hemodialysis machines. (CDC)

Provider Education and Awareness

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	D. Improve provider education regarding basic infection control across all health care settings: (2015) • Engage the affected industries to raise awareness of infection control standards, guidelines, and training needs. • Enhance provider and purchaser education regarding limiting use of single-dose vials to only one patient to encourage increased uptake of prefilled syringes and "right-sized" medication vials. • Identify opportunities to improve infection-control education, and expand requirements for continuing education and related competency certifications for health care providers.
HRSA	E. Promote adherence to national guidelines for prevention of health care-associated viral hepatitis among safety net providers. (2016)
OHAIDP	F. In collaboration with the initiative to prevent health care-associated infections and other public health partners, increase awareness and improve coordination of injection safety and infection control in health care settings. (2014, 2015)

GOAL 6.2 Reduce iatrogenic transmission of viral hepatitis associated with blood, organs, and tissues.

Testing

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC **CMS** **HRSA**	A. Revise existing policies to implement nucleic acid testing for hepatitis C among organ donors. Publish new PHS guidelines. (2015)
CDC **FDA**	B. Improve sensitivity testing for hepatitis B and C in blood, and explore the use of pathogen reduction technology: (2014, 2015, 2016) • Encourage the development of viral inactivation technologies in platelets and other blood products for transfusion. (FDA) • Engage manufacturers to promote development of rapid, high-sensitivity nucleic acid testing systems for hepatitis B and C. (CDC) • Explore the development of new pathogen reduction technology by examining current regulatory approach. (CDC)
FDA	C. Engage test kit manufacturers to increase the sensitivity of NATs used to detect hepatitis B in donors. (2016)
FDA	D. Explore the need for donor screening for hepatitis E and possibly hepatitis A. (2016)
NIH	E. Support research on development of more sensitive tests and improved algorithms for HBV in blood donor screening. (2016)

NIH	F. Develop algorithms for screening and prophylaxis against hepatitis B reactivation in patients receiving immunosuppressive therapies or undergoing transplantation. (2014)

Surveillance

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	G. Designate blood donors as sentinels of health care-associated hepatitis B and C infections. (2016)
CDC **OHAIDP**	H. Improve existing biovigilance systems for blood, organs, and tissues: (2016) • Explore opportunities and undertake a coordinated cross-agency and public-private collaborative effort to set up a national surveillance system to collect, analyze, and share data on circumstances, risk behaviors, modes of transmission, and adverse events associated with the donation, processing, distribution, and transfusion or transplantation process. (CDC)
OHAIDP	I. Support the National Blood Collection & Utilization Survey, which provides data on viral hepatitis infection among blood donors to begin identifying hepatitis-related adverse events. (2014, 2015)

GOAL 6.3 Reduce occupational transmission of viral hepatitis.

Policy

AGENCY(IES)	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Update guidelines for the management of hepatitis B and C exposures among health care personnel and guidelines of the management of hepatitis C-infected health care personnel: (2015) • Evaluate the evidence for updating hepatitis C PEP among health care personnel, including the use of safer and more tolerable agents for PEP. • Update and publish revised guidelines on the management of hepatitis C-infected health care personnel. • Update and publish revised guidelines on the management of occupational hepatitis B exposures.
IHS	B. Update guidance for viral hepatitis immunization, screening, and prophylaxis for health care workers in IHS facilities. (2014)
CDC **FBOP** **FDA** **HRSA**	C. Develop guidance to ensure hepatitis B protection and increase hepatitis B vaccination coverage among health care personnel. (2015, 2016)

Provider Education

AGENCY	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	D. Support research on best practices for preventing viral hepatitis transmission associated with the misuse of prescription opioids and other anesthetic drugs by health care personnel: (2016) • Engage stakeholders to improve current practices related to narcotics security. • Generate a best-practices document outlining recommended steps for investigation and management when diversion is suspected.
FBOP	E. Issue and conduct education on the viral hepatitis PEP guidance for FBOP staff. (2014)
VA	F. Update national bloodborne pathogens exposure training for VHA health care providers. (2014)

GOAL 6.4 Enhance understanding of the preventable causes of viral hepatitis transmission in health care settings.

AGENCY	ACTION *(Dates indicate the year the action(s) will be completed.)*
CDC	A. Expand support for health departments to thoroughly investigate possible í of health care-associated viral hepatitis: (2014) • Develop and disseminate best practices for the investigation of potential cases of health care-associated viral hepatitis. • Enhance identification of potential cases of health care-associated viral hepatitis infections by partnering with blood centers, which periodically identify new hepatitis B and C infections in repeat blood donors. • Maintain communication and strengthen ties between state health care-associated infection programs and viral hepatitis surveillance programs. • Support training of health department staff to perform infection control assessments using CDC checklists and guidelines (e.g., outpatient checklist) during onsite investigations related to suspected health care-associated hepatitis transmission.
CDC	B. Evaluate strategies to help providers adhere to recommended practices for the safe use of medical devices: (2015) • Commission a study to evaluate purchasing practices of health care facilities to understand the patterns of use that contribute to poor compliance. • Conduct site visits or focus groups to identify barriers to use of safety devices and single-patient medication vials.
CDC	C. Support research to identify the next generation of pathogen reduction technologies for red blood cells: (2015) • Support clinical trials to explore the safety and efficacy of technologies currently being used in other parts of the world. • Support grants to promote the development of new processing technologies.

Measuring Progress on Implementing the Viral Hepatitis Action Plan

The renewed plan introduces several measures selected to support accountability and transparency as well as aid in monitoring and measuring the results of implementing the Action Plan. These include core measures of progress toward the Action Plan's four overarching goals as well as several additional measures to be used in assessing progress. These are summarized in table 1 on page 75.

Core Measures

The core measures are aligned with the renewed Action Plan's four overarching goals, which were set forth in the original Action Plan released in 2011. By 2020:

- Increase the proportion of persons who are aware of their HBV infection from 33 percent to 66 percent,
- Increase the proportion of persons who are aware of their HCV infection from 45 percent to 66 percent,
- Reduce the number of new cases of HCV infection by 25 percent, and
- Eliminate mother-to-child transmission of HBV.

Through discussion with members of the VHIG, including experts from the CDC, NIH, the VA, and others, the following were chosen as the best currently available measures and data sources for each of these overarching goals:

Goal 1: Increase the proportion of individuals who are aware of their chronic HBV infection from 33 percent to 66 percent.

Based on data from the CDC's 2009 *Racial and Ethnic Approaches to Community Health (REACH) Across the U.S. Risk Factor Survey*, the original Action Plan established the baseline of 33 percent of persons living with chronic HBV infection being aware of their infection status. Since that survey is no longer conducted, the best available national data source for use in monitoring change in the proportion of persons who are aware of their chronic HBV infection is data from the National Health and Nutrition Examination Survey (NHANES). NHANES is designed to assess the health and nutritional status of adults and children in the United States and is unique in that it combines health interviews and physical examinations. Each year, approximately 5,000 people from a nationally representative sample are interviewed for the NHANES. The survey uses oversampling of persons older than 60 and racial or ethnic minorities, and interviewers visit 15 U.S. counties each year. The NHANES interviews now routinely ask interviewees whether they have ever been told (by a healthcare professional) that they had HBV and, if yes, if they were treated. These data are compared with the results of serum testing from all interviewees. Thus, the NHANES will be used from calendar years 2014 through 2016 to monitor change in the proportion of persons who are aware of their chronic HBV infections.

Goal 2: Increase the proportion of individuals who are aware of their chronic HCV infection from 45 percent to 66 percent.

The original Action Plan established the baseline for this goal using data from the 2007 National Health and Nutrition Examination Survey (NHANES), which included specific HCV-related health interview questions that year. The NHANES, described above, now routinely ask interviewees whether they have ever been told (by a healthcare professional) that they had HCV and, if yes, if they were treated. These data are compared with the results of serum testing from all interviewees. The NHANES will be used from calendar years 2014 through 2016 to monitor change in the proportion of persons who are aware of their chronic HCV infections.

Goal 3: Reduce the number of new cases of HCV infection by 25 percent.

The original Action Plan did not specify a baseline for this third overarching goal. After conferring with VHIG members and surveillance experts at the CDC, it was determined that the CDC's National Notifiable Diseases Surveillance System (NNDSS) was the best available source of data for establishing the baseline and monitoring progress toward the goal of a 25 percent reduction in new cases of acute HCV infection. The NNDSS is the primary source of viral hepatitis surveillance data in the United States. In 2011, the year in which the Action Plan was launched, 1,229 new HCV cases were reported to the NNDSS; because of underreporting and other factors, the actual number of new HCV infections in the United States is actually much larger. Thus, this figure (i.e., 1,229 newly reported HCV cases) will be used as the baseline for this goal. Over the 3 years of the renewed plan, progress toward this goal will be measured by continued use of the annual NNDSS data. Though NNDSS is the best currently available data source for monitoring progress toward this goal, as with the measures described above, these data have limitations. Currently available levels of federal funding limit the robustness of national HCV surveillance. Furthermore, state-level differences in HCV surveillance persist. Not all states report HCV data to the CDC, since reporting is governed by public health statutes at the state level and not currently required in every state. This results in variable, inconsistent reporting across the country.

Goal 4: Eliminate mother-to-child transmission of HBV.

Two measures have been identified to help monitor progress toward this fourth and final overarching goal of the Action Plan. The first is the annual number of infants perinatally infected with HBV. These data are available from the CDC's National Vital Statistics System (NVSS), which collects data from birth and death certificates at the state and local levels. The NVSS data is used to derive estimates of the annual number of infants perinatally infected with HBV. The baseline estimate established for this measure is 747 infants perinatally infected with HBV, based on 2009 NVSS data. Between calendar years 2014 and 2016, NVSS data will continue to be used to monitor progress toward this goal.

The second measure that will be adopted to monitor progress toward the overarching goal of eliminating mother-to-child HBV transmission is hepatitis B vaccine birth dose coverage. The birth dose of hepatitis B vaccine is a safe and effective way to prevent perinatal transmission and is a logical measure of prevention progress. Data to establish the baseline for this measure and monitor progress comes from the CDC's National Immunization Survey (NIS). The NIS is an ongoing survey sponsored by the agency's National Center for Immunization and Respiratory Diseases in collaboration with its National Center for Health Statistics. Data from the NIS are used

to produce timely estimates of vaccination coverage rates for all childhood vaccinations recommended by ACIP among children between the ages of 19 and 35 months living in the United States. List-assisted random digit dialing is used to conduct a telephone survey of a nationally representative sample of parents and guardians. After the telephone survey, children's immunization providers are surveyed by mail to verify each child's vaccination status. Based on NIS data from 2010, the baseline estimate for this measure is 64.1 percent of infants having received the first dose of hepatitis B vaccine within 3 days of birth. Consistent with the *Healthy People 2020* target for this objective, the Action Plan also adopts the target of 85 percent of the annual birth cohort reporting receipt of the first dose of hepatitis B vaccine within three days of birth. During the 3-year period of implementing the renewed Action Plan, the NIS will be used to monitor birth dose HBV vaccination rates.

Additional Measures of Progress to Aid in Monitoring the Action Plan

In addition to the core measures described above, discussion among the VHIG identified several measures from currently available data sources that could be used to assess progress on key dimensions of the renewed Action Plan. During the 3-year period of implementing the renewed Action Plan, federal and nonfederal stakeholders will further explore these and other possible measures that may be used to monitor significant trends that can inform ongoing implementation of the plan. These measures include the following:

Measures 1 & 2: Mortality Related to Hepatitis B and C Infection

Mortality due to chronic hepatitis B has remained stable over the past decade, despite the availability of treatments that can reduce the likelihood of severe disease and death. Mortality due to chronic hepatitis C has been increasing but new therapies and those expected to be approved over the next 3–5 years have been shown to be more effective in curing patients of their HCV and greatly reducing the chance of developing severe end-stage liver disease. Increased efforts to prevent new infections and to diagnose individuals early in the course of their disease articulated in the Action Plan should ultimately reduce deaths due to HBV and HCV. Mortality data from the National Multiple Cause of Death Data component of the NVSS will be used to monitor trends in deaths associated with hepatitis B and C infections; specifically, the number and age-adjusted mortality rate of hepatitis B and C listed as the underlying or a contributing cause of death in the United States. These data are derived from death certificates that include a single underlying cause of death, a maximum of 20 additional multiple causes recorded with international classification of diseases codes, and demographic data. The baselines for both measures (see table 1) are derived from CDC analysis of 2010 NVSS data.

Measure 3: HBV Vaccination Coverage Among Health Care Workers

An important measure to aid in monitoring progress in priority area 6, "Protecting Patients and Workers from Health Care-Associated Viral Hepatitis," will be the proportion of health care workers who have received at least three doses of hepatitis B vaccine. This measure parallels a similar *Healthy People 2020* developmental objective, which seeks to increase hepatitis B vaccine coverage among health care personnel. For that developmental objective, HHS used 2008 NHIS data to establish a baseline of 64.3 percent of health care personnel who had received at least three doses

of hepatitis B vaccine. *Healthy People 2020* set a target of 90 percent coverage by 2020. Over the 3 years of implementing the renewed Action Plan, NHIS data will be used to continue to monitor hepatitis B vaccine coverage among health care workers.

Limitations

While there are obvious benefits to using existing national surveillance systems and surveys to monitor the ongoing implementation of the Viral Hepatitis Action Plan, there are also acknowledged limitations. Serologic data are clearly preferable to self-report, especially since many individuals who are chronically infected are unaware of their current status, but current resource limitations preclude the use of the former to monitor prevalence of HBV and HCV infection. Other surveys are limited by insufficient reporting capacity, lack of outreach to institutionalized and other disproportionately affected populations, and small sample sizes.

To compensate for some of these limitations and to augment the information being used by all stakeholders to track progress during the 3 years of implementation of the renewed Action Plan, the federal partners will work with other stakeholders to identify and explore possible additional measures from available data sources that could also be used to monitor relevant trends or progress in particular areas and/or for specific populations. One example is monitoring trends in data from the Organ Procurement and Transplantation Network regarding the number of persons with chronic HBV or HCV added to the liver transplant waitlist and the number of liver transplants performed for persons with HBV or HCV. Another example is making use of sentinel surveillance data. In the absence of comprehensive national surveillance data, sentinel surveillance can be an indicator of progress within a jurisdiction or health system and provide insight into progress being made nationally, especially when these data are collected and analyzed regularly over time. However, there appear to be local and regional differences in prevalence of viral hepatitis and also in the provision of health care services, so sentinel surveillance data must be extrapolated with caution. These differences are likely to become more pronounced as the health care system changes over time. Finally, given the disproportionate impact of viral hepatitis on some racial and ethnic minority populations, VHIG members will explore whether there may be opportunities for supplemental data analysis or studies to better understand and inform efforts aimed at addressing the health disparities of specific racial or ethnic and other minority populations (e.g., PWID, MSM).

The introduction of these core measures will aid all stakeholders in monitoring progress toward the Action Plan's overarching goals. Our shared commitment to the further exploration of other possible metrics to aid in monitoring progress and relevant trends will enhance accountability, provide new insights, and facilitate necessary adjustments or midcourse revisions when warranted.

Table 1. Goals and Related Measures to Monitor Progress of the Viral Hepatitis Action Plan

Baseline Estimate (Source)	Year of Baseline Estimate	Measure	Future Source of Data	2020 Goal
Goal 1: **Increase the proportion of persons who are aware of their chronic HBV infection from 33% to 66%.**				
33% (REACH Survey)	2009	Proportion of persons with HBV infections who know that they are infected	NHANES	66%
Goal 2: **Increase the proportion of persons who are aware of their chronic HCV infection from 45% to 66%.**				
45% (NHANES)	2010	Proportion of persons with HCV infections who know that they are infected	NHANES	66%
Goal 3: **Reduce the number of new cases of HCV infection by 25%.**				
1,229 (NNDSS)	2011	Number of reported and estimated acute hepatitis cases in the United States	NNDSS	922
Goal 4: **Eliminate mother-to-child transmission of HBV.**				
747 (NVSS)	2009	Number of infants perinatally infected with HBV	NVSS	No cases*
64.1% (NIS)	2010	Hepatitis B vaccine "birth dose" coverage	NIS	85%
Measure 1: **Reduce mortality related to hepatitis B infection.**				
0.5 per 100,000 people; 1,844 (Ly et al., 2013)	2010	Number and age-adjusted mortality rate of hepatitis B listed as the underlying or a contributing cause of death in the United States	NVSS	To be developed
Measure 2: **Reduce mortality related to hepatitis C infection.**				
4.6 per 100,000 people; 16,627 (Ly et al., 2013)	2010	Number and age-adjusted mortality rate of hepatitis C listed as the underlying or a contributing cause of death in the United States	NVSS	To be developed
Measure 3: **Reduce occupational transmission of viral hepatitis.**				
64.3% (NHIS)	2008	HBV vaccination among health care workers	NHIS	90% (*Healthy People 2020*)

*The *Healthy People 2020* goal is 400 cases.

Appendices

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Appendix B: Other Contributing Federal Staff

In addition to the members of the VHIG, many other federal staff contributed to the development of this renewed Action Plan and the specific actions and measures it contains.

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Appendix C: 2010 IOM Recommendations for Improving Viral Hepatitis Prevention, Care, and Treatment in the United States

SURVEILLANCE

- The Centers for Disease Control and Prevention should conduct a comprehensive evaluation of the national hepatitis B and hepatitis C public health surveillance system.
- The Centers for Disease Control and Prevention should develop specific cooperative viral-hepatitis agreements with all state and territorial health departments to support core surveillance for acute and chronic hepatitis B and hepatitis C.
- The Centers for Disease Control and Prevention should support and conduct targeted active surveillance, including serologic testing, to monitor incidence and prevalence of hepatitis B virus and hepatitis C virus infections in populations not fully captured by core surveillance.

KNOWLEDGE AND AWARENESS ABOUT CHRONIC HEPATITIS B AND HEPATITIS C

- The Centers for Disease Control and Prevention should work with key stakeholders (other federal agencies, state and local governments, professional organizations, health care organizations, and educational institutions) to develop hepatitis B and hepatitis C educational programs for healthcare and social-service providers.
- The Centers for Disease Control and Prevention should work with key stakeholders to develop, coordinate, and evaluate innovative and effective outreach and education programs to target at risk populations and to increase awareness in the general population about hepatitis B and hepatitis C.

IMMUNIZATION

- All infants weighing at least 2,000 grams and born to hepatitis B surface antigen-positive women should receive single-antigen hepatitis B vaccine and hepatitis B immune globulin in the delivery room as soon as they are stable and washed. The recommendations of the Advisory Committee on Immunization Practices should remain in effect for all other infants.
- All states should mandate that the hepatitis B vaccine series be completed or in progress as a requirement for school attendance.
- Additional federal and state resources should be devoted to increasing hepatitis B vaccination of at risk adults.
- States should be encouraged to expand immunization-information systems to include adolescents and adults.
- Private and public insurance coverage for hepatitis B vaccination should be expanded.
- The federal government should work to ensure an adequate, accessible, and sustainable hepatitis B vaccine supply.
- Studies to develop a vaccine to prevent chronic hepatitis C virus infection should continue.

VIRAL HEPATITIS SERVICES

- Federally funded health-insurance programs, such as Medicare, Medicaid, and the Federal Employees Health Benefits Program, should incorporate guidelines for risk-factor screening for hepatitis B and hepatitis C as a required core component of preventive care so that at risk people receive serologic testing for hepatitis B virus and hepatitis C virus and chronically infected patients receive appropriate medical management.
- The Centers for Disease Control and Prevention, in conjunction with other federal agencies and state agencies, should provide resources for the expansion of community-based programs that provide hepatitis B screening, testing, and vaccination services that target foreign-born populations.
- Federal, state, and local agencies should expand programs to reduce the risk of hepatitis C virus infection through injection-drug use by providing comprehensive hepatitis C virus prevention programs. At a minimum, the programs should include access to sterile needle syringes and drug-preparation equipment because the shared use of these materials has been shown to lead to transmission of hepatitis C virus.
- Federal and state governments should expand services to reduce the harm caused by chronic hepatitis B and hepatitis C. The services should include testing to detect infection, counseling to reduce alcohol use and secondary transmission, hepatitis B vaccination, and referral for or provision of medical management.
- Innovative, effective, multi-component hepatitis C virus prevention strategies for PWID and other drug users should be developed and evaluated to achieve greater control of hepatitis C virus transmission.
- The Centers for Disease Control and Prevention should provide additional resources and guidance to perinatal hepatitis B prevention program coordinators to expand and enhance the capacity to identify chronically infected pregnant women and provide care coordination services, including referral for appropriate medical management.
- The National Institutes of Health should support a study of the effectiveness and safety of peripartum antiviral therapy to reduce and possibly eliminate perinatal hepatitis B virus transmission from women at high risk for perinatal transmission.
- The Centers for Disease Control and Prevention and the Department of Justice should create an initiative to foster partnerships between health departments and corrections systems to ensure the availability of comprehensive viral hepatitis services for incarcerated people.
- The Health Resources and Services Administration should provide adequate resources to federally funded community health facilities for provision of comprehensive viral-hepatitis services.
- The Health Resources and Services Administration and the Centers for Disease Control and

Prevention should provide resources and guidance to integrate comprehensive viral hepatitis services into settings that serve high-risk populations such as STD clinics, sites for HIV services and care, homeless shelters, and mobile health units.

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Appendix D: Agency Abbreviations and Acronyms

AAPI	Asian American and Pacific Islander
ACIP	Advisory Committee on Immunization Practices
AHRQ	Agency for Healthcare Research and Quality (HHS)
AI/AN	American Indian/Alaska Native
CBHSQ	Center for Behavioral Health Statistics and Quality (SAMHSA)
CDC	Centers for Disease Control and Prevention (HHS)
CDS	clinical decision support
CMS	Centers for Medicare & Medicaid Services (HHS)
DAA	direct-acting antiviral agent
EHR	electronic health record
FBOP	Federal Bureau of Prisons (U.S. Department of Justice)
FDA	U.S. Food and Drug Administration (HHS)
HAV	hepatitis A virus
HBeAg	hepatitis B extracellular antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
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
IHS	Indian Health Service (HHS)
IOM	Institute of Medicine
MAT	medication-assisted treatment
MSI	minority-serving institution
MSM	men who have sex with men
NAT	nucleic acid testing
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NIH	National Institutes of Health (HHS)
NIS	National Immunization Survey
NNDSS	National Notifiable Disease Surveillance System
NVPO	National Vaccine Program Office (HHS)
NVSS	National Vital Statistics System
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)
OWH	Office on Women's Health (HHS)
PCMH	patient-centered medical home
PCPI	Physician Consortium for Performance Improvement
PEP	post-exposure prophylaxis
PLWHA	person living with HIV/AIDS
PWID	person who injects drugs
REACH	Racial and Ethnic Approaches to Community Health
RHA	Regional Health Administrators (HHS)
SAMHSA	Substance Abuse and Mental Health Services Administration (HHS)
STD	sexually transmitted disease
TIP	Treatment Improvement Protocol
USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
VHA	Veterans Health Administration (VA)
VHIG	Viral Hepatitis Implementation Group
WHO	World Health Organization

Appendix E: References

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Federal Viral Hepatitis Resources

Agency for Healthcare Research and Quality

http://www.ahrq.gov/research/findings/evidence-based-reports/er174-abstract.html#Report
http://www.ahrq.gov/health-care-information/topics/topic-hepatitis-c.html

Centers for Disease Control and Prevention

http://www.cdc.gov/hepatitis/
http://www.cdc.gov/knowmorehepatitis/

Centers for Medicare and Medicaid

http://www.medicare.gov/coverage/hepatitis-b-shots.html

Food and Drug Administration

http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/ucm151488.htm

Indian Health Service

https://www.ihs.gov/Epi/index.cfm?module=epi_hepatitis_resources

National Institutes of Health

http://www.niaid.nih.gov/topics/hepatitis/Pages/default.aspx
http://health.nih.gov/search_results.aspx?terms=Hepatitis

National Vaccine Program Office

http://www.vaccines.gov/diseases/hepatitis_a/
http://www.vaccines.gov/diseases/hepatitis_b/

Office of Minority Health

http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlid=185

Office of Population Affairs

http://www.hhs.gov/opa/reproductive-health/stis/hepatitis-b/
http://www.hhs.gov/opa/reproductive-health/stis/hepatitis-c/

Office on Women's Health

http://www.womenshealth.gov/hiv-aids/opportunistic-infections-and-other-conditions/hepatitis-c-virus-and-hiv-aids.html

Substance Abuse and Mental Health Services Administration

http://www.dpt.samhsa.gov/comor/hepatitis.aspx

Department of Health and Human Resources

http://aids.gov/hiv-aids-basics/staying-healthy-with-hiv-aids/potential-related-health-problems/hepatitis/

Department of Justice

http://searchjustice.usdoj.gov/search?output=xml_no_dtd&proxystylesheet=bop_test&as_sitesearch=www.bop.gov&q=viral+hepatitis

Department of Veteran Affairs

http://www.hepatitis.va.gov/
http://www.publichealth.va.gov/infectiondontpassiton/womens-health-guide/hepatitis/hepatitis-a.asp
http://www.publichealth.va.gov/infectiondontpassiton/womens-health-guide/hepatitis/hepatitis-b.asp
http://www.publichealth.va.gov/infectiondontpassiton/womens-health-guide/hepatitis/hepatitis-c.asp

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