

FEDERAL IMPLEMENTATION PROGRESS REPORT FOR THE ACTION PLAN FOR THE PREVENTION, CARE, AND TREATMENT OF VIRAL HEPATITIS



2014



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

This report was prepared under the direction of the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), the Office of the Assistant Secretary for Health (OASH), and the U.S. Department of Health and Human Services (HHS). Information contained in the report was provided by the Viral Hepatitis Leads from various HHS agencies, the Department of Veterans Affairs, the Department of Justice Federal Bureau of Prisons (FBOP), and the Department of Housing and Urban Development (HUD). Corinna Dan, R.N., M.P.H., OHAIDP Viral Hepatitis Policy Advisor and Michelle Moses-Eisenstein, M.P.H., Public Health Analyst, coordinated development of this report. Jamie Weinstein, M.P.H., Jhilya Mayas, Ph.D., Kelly Wagner, and Barbara Draley of The MayaTech Corporation; and Steve Holman, M.B.A., all working under contract to OHAIDP, assisted OHAIDP staff in compiling and formatting the report.

Karen B. DeSalvo, M.D., M.P.H., M.Sc.....Acting Assistant Secretary for Health, HHS

Ronald O. Valdiserri, M.D., M.P.H Deputy Assistant Secretary for Health, Infectious Diseases, HHS

AN EXCERPT FROM THE
PRESIDENTIAL PROCLAMATION ON
WORLD HEPATITIS DAY 2014

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

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

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

— **President Barack Obama**
World Hepatitis Day Proclamation

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BACKGROUND

Updated in 2014, the *Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis* (Action Plan) builds on the foundation established in 2010 with the release of the Institute of Medicine (IOM) report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*. The IOM report identified viral hepatitis as an “underappreciated” health concern in the U.S., outlined barriers to prevention and control, and provided 22 recommendations to help improve the U.S. public health response to viral hepatitis. Spurred by the IOM report, HHS developed and released in 2011 *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis*, our nation’s first comprehensive viral hepatitis strategic plan.

The updated national Action Plan, released in April 2014, details more than 150 actions to be undertaken from 2014 through 2016 by agencies and offices across HHS and partners at the Department of Housing and Urban Development (HUD), the Department of Justice’s (DOJ) Federal Bureau of Prisons (FBOP), and the Department of Veterans Affairs (VA). Some actions outlined in the Action Plan can be accomplished using existing resources through improved coordination and integration, while others are subject to the availability of funds. All of the actions contribute to improving the prevention, diagnosis, and treatment of viral hepatitis in the United States.



Nonfederal stakeholders were strongly supportive of the renewal effort, providing input into the process. For the first time, the updated Action Plan included sample “Opportunities for Nonfederal Stakeholders” to further underscore the importance of contributions from all sectors of society and foster increased participation and collaboration in efforts toward attaining Action Plan goals.

In the U.S., as many as 5.3 million people are living with chronic hepatitis B virus (HBV) or hepatitis C virus (HCV) infection, and tens of thousands are at risk of infection. Beginning in 2011 and continuing through today, the development, updating, and implementation of the Action Plan has brought increased attention to both the previously silent epidemic of viral hepatitis and to the opportunities to halt its growing impact in communities across the nation. Prior to 2011, much of the work on viral hepatitis was conducted independently, sometimes in isolation from related efforts. The Action Plan has enabled further collaboration, resulting in advances in:

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

Since 2011, agencies and offices across HHS have been working to implement the actions described in the Action Plan. To support these efforts, OHAIDP/OASH convenes a Viral Hepatitis Implementation Group (VHIG) charged with coordinating, supporting, and monitoring activities related to the Action Plan. The VHIG comprises representatives from across HHS and other federal departments and is chaired by Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases and Director of the Office of HIV/AIDS and Infectious Disease Policy. Members of the VHIG have met repeatedly during the implementation of the Action Plan and have served as representatives within their respective agencies and offices on matters related to viral hepatitis. This progress report is an outcome of their collaborative efforts. Read more about the Action Plan, progress reports, and updates at <http://aids.gov/hepatitis>.

INTRODUCTION

This report marks the first opportunity to provide highlights of progress made after the release of the updated Action Plan. The HHS Office of HIV/AIDS and Infectious Disease Policy is charged with coordinating implementation of the Action Plan. As such, it has compiled several key accomplishments under each of the Action Plan's six priority areas. These highlights were reported by the federal partners engaged in implementing the Action Plan, but are only a sampling of the numerous activities that partners undertook during 2014.

This report features excellent examples of work by federal partners as well as many activities undertaken collaboratively with a variety of stakeholders, such as capacity-building among HBV coalition partners; viral hepatitis training and technical assistance for health centers and other healthcare providers; increasing participation in the annual observances of May as Hepatitis Awareness Month and July 28 as World Hepatitis Day; developing culturally and linguistically appropriate materials for communities experiencing high rates of chronic viral hepatitis (including African Americans, American Indians/Native Alaskans, and Asian Americans and Pacific Islanders); supporting the development of testing and linkage to care programs; and further exploring the use of new HCV therapies in special populations and HBV therapies to reduce perinatal transmission.

A recurrent theme across the field of viral hepatitis is the need for additional evidence to guide policy and practice at every level. Throughout 2014, federal partners made important contributions to addressing gaps in our understanding of the prevention, care, and treatment of viral hepatitis through articles published in peer-reviewed literature along with the development of reports and other technical documents. These publications help to advance efforts to develop and implement evidence-based programs, clinical services, and policies; they are compiled in Appendix A and described throughout this report. Many projects initiated in 2014 included products that were released in 2015 and so are included in this report.

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

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

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

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

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

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

- Office of Community Planning and Development (CPD)

U.S. DEPARTMENT OF JUSTICE (DOJ)

- Federal Bureau of Prisons (FBOP)

U.S. DEPARTMENT OF VETERANS AFFAIRS (VA)

- Patient Care Services, Veterans Health Administration (VHA)

WHITE HOUSE

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

VIRAL HEPATITIS IMPLEMENTATION GROUP (VHIG) MEMBERS

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Ronald Valdiserri, M.D., M.P.H. (Chair)
Deputy Assistant Secretary for Health, Infectious
Diseases
Director, Office of HIV/AIDS and Infectious
Disease Policy

Corinna Dan, R.N., M.P.H.
Viral Hepatitis Policy Advisor
Office of HIV/AIDS and Infectious Disease Policy

Michelle Moses-Eisenstein, M.P.H.
Public Health Analyst
Office of HIV/AIDS and Infectious Disease Policy

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

William B. Baine, M.D.
Senior Medical Advisor
Center for Outcomes and Evidence

CENTERS FOR DISEASE CONTROL AND PREVENTION

John Ward, M.D.
Director
Division of Viral Hepatitis
National Center for HIV/AIDS, Viral Hepatitis,
STD and TB Prevention

CENTERS FOR MEDICARE & MEDICAID SERVICES

Chisara N. Asomugha, M.D., M.S.P.H., F.A.A.P.
Medical Advisor
Quality Improvement Group
Center for Clinical Standards and Quality

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Marlisa Grogan, L.M.S.W.
Office of Special Needs Assistance Programs
Community Planning and Development

DEPARTMENT OF JUSTICE

Jeff Allen, M.D.
Chief of Health Programs
Federal Bureau of Prisons

Michelle Williams, Pharm.D.
LCDR, U.S. Public Health Service
HIV/Hepatitis C Program Manager
Health Services Division
Federal Bureau of Prisons

DEPARTMENT OF VETERANS AFFAIRS

Maggie Chartier, Psy.D., M.P.H.
Deputy Director
HIV, Hepatitis, and Public Health Pathogens
Programs
Patient Care Services

David Ross, M.D., Ph.D.
Director
HIV, Hepatitis, and Public Health Pathogens
Programs
Patient Care Services

FOOD AND DRUG ADMINISTRATION

Jonca Bull, M.D.
Assistant Commissioner for Minority Health

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Sarah R. Linde, M.D.
RADM U.S. Public Health Service
Chief Public Health Officer

Rupali Doshi, M.D., M.S.
Clinical Advisor
Office of the Associate Administrator
HIV/AIDS Bureau

INDIAN HEALTH SERVICE

Lisa Neel, M.P.H.
Program Analyst
National HIV/AIDS Program

NATIONAL INSTITUTES OF HEALTH

Jay Hoofnagle, M.D.
Director
Liver Disease Research Branch
National Institute of Diabetes and Digestive and
Kidney Diseases

Jag H. Khalsa, Ph.D., M.S.
Chief
Medical Consequences Branch
Division of Pharmacotherapies and Medical
Consequences of Drug Abuse
National Institute on Drug Abuse

Megan Singh, Ph.D.
Health Science Policy Analyst
Office of Scientific Program and Policy Analysis
National Institute of Diabetes and Digestive
and Kidney Diseases

NATIONAL VACCINE PROGRAM OFFICE

Karin Bok, Ph.D., M.S.
Public Health Analyst

OFFICE OF MINORITY HEALTH

Sonsiere Cobb-Souza
Director
Division of Program Operations

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

Michael A. Wittie, M.P.H.
Program Analyst
Office of Clinical Quality and Safety

OFFICE OF NATIONAL DRUG CONTROL POLICY

Christine Kourtides
Senior Policy Advisor

OFFICE OF POPULATION AFFAIRS

Sue Moskosky, M.S., R.N.C.
Deputy Director

OFFICE OF SURGEON GENERAL

LCDR Sarah Schillie, M.D., M.P.H., M.B.A.
Representing the Office of the Surgeon General
Medical Epidemiologist
Division of Viral Hepatitis
Centers for Disease Control and Prevention

OFFICE ON WOMEN'S HEALTH

Martha Bond, M.A.
Senior Public Health Advisor
Division of Program Innovation

REGIONAL HEALTH OFFICES

CAPT James Lando, M.D., M.P.H., F.A.C.P.M.
Regional Health Administrator, Region V
Representing Regional Health Offices

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Robert Lubran, M.P.A., M.S.
Director
Division of Pharmacologic Therapies
Center for Substance Abuse Treatment

WHITE HOUSE INITIATIVE ON ASIAN AMERICANS AND PACIFIC ISLANDERS

Francisco Sy, M.D., Dr.P.H.
HHS Liaison
Interagency Implementation Team

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

PRIORITY 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.

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

For too long, the epidemic of viral hepatitis has been fueled by silence and ignorance, resulting in significant health disparities. A two-pronged educational approach is critical to changing this situation by ensuring that providers are armed with the most current evidence-based tools and resources and that communities are empowered with the information needed to develop a culturally appropriate and effective response.

In 2014, the following were among the actions undertaken by federal partners to build a strong workforce of providers trained to diagnose and manage viral hepatitis and educate communities:

Building community capacity to address hepatitis B. CDC's Division of Viral Hepatitis (DVH) awarded a cooperative agreement to the Hepatitis B Foundation to provide capacity building, training, and technical assistance to more than 17 Hep B United coalition partners throughout the nation. Hep B United coalition partners aim to increase hepatitis B awareness, testing, vaccination, and treatment in Asian American and Pacific Islander (AAPI) communities — among individuals who may already be infected as well as their families and loved ones. Also, the Substance Abuse and Mental Health Services Administration has developed a variety of Minority AIDS Initiative (MAI) programs to build community capacity to address HIV and viral hepatitis.

Sharing updates on new therapies for viral hepatitis. FDA's Office of Health and Constituent Affairs hosts a viral hepatitis listserv that, together with the FDA Division of Antiviral Products, keeps healthcare providers, patients, and other interested parties abreast of information about: 1) new

therapeutic drugs for treating hepatitis; 2) important safety updates regarding the use of antiviral therapies for treating viral hepatitis; and 3) significant labeling changes that might impact the use of FDA-regulated products used in the diagnosis or treatment of viral hepatitis. The listserv currently has 52,275 subscribers. Information is also posted on the [FDA Viral Hepatitis Website](#), including the seven updates shared in 2014. FDA also maintains web links to [ClinicalTrials.gov](#), which helps patients with viral hepatitis find on-going clinical trials and provides information about approved and investigational therapeutics.

Identifying opportunities to share new information, policies, and best practices and further leveraging resources to enhance the national response to viral hepatitis. OHAIDP coordinated efforts across federal partners for the observance of Hepatitis Awareness Month in May and the 2014 National Viral Hepatitis Testing Day (May 19th). Using blog posts, webinars, and national meetings, including the Hep B United Summit (May 21st-22nd) and the State Viral Hepatitis Prevention Coordinator Annual Meeting (October 20th-22nd; hosted by the National Alliance of State and Territorial AIDS Directors [NASTAD]), OHAIDP disseminated viral hepatitis guidelines and additional materials developed by CDC and other federal and community partners. To promote the dissemination of critical information, OHAIDP authored or contributed to the development of 56 viral hepatitis-related blogs on [blog.aids.gov](#) in 2014, maintained and updated the web presence at [www.AIDS.gov/hepatitis](#), and supported viral hepatitis Tweets from OASH as well as AIDS.gov social media activities. In collaboration with the VHIG, OHAIDP oversaw the development of the [2013 Viral Hepatitis Action Plan Progress Report](#) — an update highlighting key federal viral hepatitis activities undertaken during 2013.

Supporting health centers in addressing viral hepatitis. HRSA supports the provision of training, technical assistance, and information dissemination about a variety of topics including viral hepatitis to health centers through its [National Cooperative Agreement](#) partners.

- ◇ The National Health Care for the Homeless Council (NHCHC) regularly conducts regional and national trainings focusing on hepatitis C. In 2014, some of these trainings included: “Talking About Hepatitis C: How to Give Clear, Compassionate and Up to Date Information” and “Investigating Patient Attitudes Towards Hepatitis C to Guide Implementation of Primary Care Based HCV Treatment.”
- ◇ The National Association of Community Health Centers (NACHC) developed a [three-part blog series](#), “Focus on Hepatitis C: Health Centers Work to Address the Chronic Disease” spotlighting strategies used by three health centers to address hepatitis C, focusing on the importance of partnerships, the importance of patient and community relationships in providing care, and the role of telemedicine in increasing access to holistic, coordinated care for hepatitis C patients.

- ◇ The National LGBT (Lesbian, Gay, Bisexual, and Transgender) Health Education Center developed a brief entitled, “[Emerging Clinical Issue: Hepatitis C Infection in HIV-Infected Men Who Have Sex with Men](#),” released in June 2014. The brief details the epidemiology of HCV among HIV-infected men who have sex with men (MSM), as well as current screening, treatment and prevention recommendations for HCV.
- ◇ In 2014, the National LGBT Health Education Center and NACHC updated a toolkit, “[Taking Routine Histories of Sexual Health: A System-Wide Approach for Health Centers](#),” which includes strategies for identifying viral hepatitis risk. The toolkit was designed to help health centers develop and implement systems for routinely collecting sexual health histories as part of the primary care visit.
- ◇ The Association of Asian Pacific Community Health Organizations (AAPCHO) is funded by HRSA to support health centers in addressing the health care needs of Asian Americans, Native Hawaiians, and other Pacific Islanders. AAPCHO recognizes the disproportionate burden of hepatitis B in these communities; it provides hepatitis B-related direct training and technical assistance to health centers including: support to implement the 2014 U.S. Preventive Services Task Force (USPSTF) HBV screening recommendations; staff training to use electronic health record tools for HBV prevention, improvement of disease management, and the development of patient registry reports; and review and evaluation of existing HBV health education videos for use in clinical settings. Additionally, APPCHO provided technical assistance to community partners that submitted comments during the development of the USPSTF HBV screening recommendations.

Expanding access to expert clinical guidance. In April 2014, VA launched the first hepatitis C “Warmline” in collaboration with the University of California, San Francisco. This telephone consultation service, available to VA providers weekdays from 9:00 AM to 8:00 PM Eastern, offers expert clinical guidance based on federal HCV treatment guidelines, VHA guidelines, current medical literature, and clinical best practices. These resources aid frontline VA providers in making important decisions about the treatment of patients with hepatitis C.

Enhancing coordination of national viral hepatitis activities among federal and non-federal stakeholders. In spring 2014, OASH and the Office of the HHS Secretary released the updated [Action Plan](#). The Action Plan’s updating process engaged members of the federal VHIG (composed of 27 members from across the Departments of Health and Human Services, Housing and Urban Development, Justice, and Veterans Affairs) as well as a broad variety of non-federal stakeholders. Community input was solicited via both a Request for Information published on June 5, 2013 in the Federal Register and three community engagement webinars that garnered over 100 comments and specific recommendations—many of which were incorporated into the updated plan. To further increase engagement of all stakeholders in the updated Action Plan, OHAIDP hosted an Action Plan Launch Event on April 3, 2014, in the HHS headquarters auditorium in Washington, DC. It was webcast to an estimated 760 sites across the nation. Then-Secretary of Health and Human Services

Kathleen Sebelius and then-Assistant Secretary for Health Dr. Howard Koh participated in the launch along with federal and non-federal viral hepatitis leaders, experts, and community advocates.

Immediately following the launch of the Action Plan, OHAIDP convened a one-day stakeholder consultation on [Expanding Roles and Opportunities for Nonfederal Stakeholders to Implement the Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis \(2014-2016\)](#). A range of stakeholder groups were represented by the approximately 50 participants. They included professional organizations, national advocacy organizations, Perinatal Hepatitis B Prevention Coordinators, State Viral Hepatitis Prevention Coordinators, state health departments, health professionals, and others working to address HBV and HCV in the U.S.

Concurrent with the Action Plan update release, OHAIDP released a companion document — the *Stakeholder’s Workbook: Exploring Vital Roles and Opportunities to Break the Silence*. The workbook provides a questions-based tool that assists health departments, community organizations, and other stakeholders in identifying opportunities to advance and promote the goals of the updated Action Plan. The workbook contains easy-to-use worksheets to help prioritize activities, identify strategic partners and measures, and set target dates for completion. After its release, OHAIDP conducted outreach to key stakeholders including: the CDC-funded State Viral Hepatitis Prevention Coordinators, the Association of State and Territorial Health Officials (ASTHO), the National Association of City and County Health Officials (NACCHO), the National Alliance of State and Territorial AIDS Directors (NASTAD), HHS Regional Resource Coordinators, and coalitions such as Hep B United and the National Viral Hepatitis Roundtable. OHAIDP consulted with and provided technical assistance to organizations and groups that expressed interest in using the Stakeholder’s Workbook for the purpose of guiding viral hepatitis strategic planning activities such as the [Hep B United Strategic Plan](#) and Project Inform’s report, [Scaling up Risk-based Hepatitis C Screening in the United States](#).

Highlights of additional activities to educate healthcare providers conducted during 2014 are listed in the following tables.

FBOP

FBOP provided a live, instructor-led webcast training, *“Hepatitis C Treatment Update”* on newly available HCV medications to Health Services Division staff in February 2014. It also led in-person educational sessions on the *“Management of Chronic Hepatitis C Infection”* to health care providers and staff at the FBOP Clinical Director and Health Service Administrator Conference in June 2014 and the FBOP Pharmacy Residential Meeting in August 2014.

HRSA

HRSA's Bureau of Primary Health Care (BPHC) works closely with HHS operating and staff divisions, national partners, and key stakeholders to promote viral hepatitis training and technical assistance opportunities (webinars, publications, tools) for Health Center Program participants. The weekly Primary Health Care Digest has a distribution list of almost 13,000. It includes updates, announcements, and training opportunities relating to viral hepatitis. These have included notices of the 2014 CMS Medicare National Coverage Determination for HCV testing and Hepatitis Awareness Month resources.

In 2014, the Ryan White HIV/AIDS Program-funded AIDS Education and Training Centers (AETCs) funded more than 1000 training programs in hepatitis C across the 11 regional centers (with more than 100 local performance sites), and 3 national centers, and ongoing hepatitis C management support for healthcare providers in 9 telehealth centers.

IHS

In 2014, IHS continued its virtual viral hepatitis provider training program. Technical assistance was directly provided to 108 sites and included topics on HCV diagnosis, care and treatment. More broadly, the agency developed 12 national webinars on HCV screening, diagnosis and treatment, attended by over 200 professionals. Ongoing training opportunities were made available via collaborations with ECHO telehealth programs in Albuquerque, NM; Seattle, WA; and Phoenix, AZ. IHS also has a longstanding telehealth program that provides support for healthcare providers in remote locations to manage viral hepatitis along with other health conditions, hosted by the Alaska Native Tribal Health Consortium. In the fall of 2014, a new telehealth network was launched that includes support for HCV management and serves the Cherokee Nation with a hub in Tahlequah, OK.

RHA

Regional Resource Coordinators (RRC) and other regional staff collaborated with federal and nonfederal stakeholders to identify and disseminate promising and best practices for viral hepatitis prevention, care, and treatment. In Region II, the RRC partnered with Columbia University's New York/New Jersey AIDS Education and Training Center to host a hepatitis C webinar series titled: *“Hepatitis C in 2014.”* The three-part series, hosted on March 7th, March 31st, and May 5th 2014, targeted clinicians and focused on the updated AASLD and IDSA [Recommendations for Testing, Managing, and Treating Hepatitis C](#). Each webinar had over 200 participants from New York and New Jersey.

FBOP

FBOP released updated Clinical Practice Guidelines, *“Interim Guidance for the Management of Chronic Hepatitis C Infection-June 2014.”*

NIH

Staff from the intramural research program at the NIDDK continue to participate in the ongoing development and evolution of [clinical guidelines](#) for testing, managing, and treating hepatitis C under the auspices of the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). These guidelines are updated every three months.

OPA

In April 2014, OPA, in collaboration with CDC, released “Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.” Issued as a CDC MMWR Recommendations and Reports, this document targets Title X family planning clinics, primary care providers, and others providing family planning services. It includes recommendations for HCV screening and routine hepatitis B vaccination to all individuals under age 19 and all adults who are unvaccinated and do not have a documented history of hepatitis B infection.

VA

In November 2014, VA’s National Center for Health Promotion and Disease Prevention updated screening guidelines for hepatitis B infection to reflect current CDC guidelines and U.S. Preventive Task Force recommendations.

In December 2014, VA published an [Information Letter](#) on the care and treatment of hepatitis B infection, providing guidance to front-line clinical providers on the management of veterans.

VA’s internationally recognized “Chronic HCV Infection: Treatment Considerations” was launched in March 2014 and updated in May and December of the same year by a group of VA subject matter experts. The Treatment Considerations are continually updated to ensure that VA providers have the most current, objective, evidence-based information about HCV treatment regimens, drug interactions, and co-morbidity management to inform high-quality clinical decisions in caring for those living with chronic HCV. Paired with this document, VA’s Pharmacy Benefits Management has provided detailed “Criteria for Use” to support safe and clinically appropriate medication-prescribing practices for all HCV direct-acting antivirals on formulary.

Enhancing public educational materials for viral hepatitis. In 2014, CDC developed a new phase of the [Know More Hepatitis](#) national education campaign. It is designed to encourage people born from 1945 to 1965 to get tested for hepatitis C. This initiative supports CDC’s overall efforts to improve HCV testing, linkage to care, and treatment. New materials, released in early 2015, include a fact sheet for persons who inject drugs. CDC also developed [new public service announcements and educational and outreach materials](#) in several Asian languages for the Know Hepatitis B national campaign.

Increasing access to hepatitis B medication safety information. FDA coordinated the translation of several consumer resources, including medication safety education materials on hepatitis B, into Vietnamese, Korean, Chinese, and Thai for use in community clinics and hepatitis B screening events, and a document titled “[Sometimes Drugs and the Liver Don’t Mix](#)” into five Asian languages.

Expanding HCV outreach to American Indian and Alaska Native communities. In 2014, IHS Tribal partner, the [Northwest Portland Area Indian Health Board](#), recognized the high rate of chronic hepatitis C. It released a pamphlet and two Public Service Announcements in early 2015 to disseminate birth-cohort hepatitis C screening recommendations to American Indian/ Alaska Native (AI/AN) communities.

Since its inception in 2012, the Know More Hepatitis campaign — focused on educating baby boomers about hepatitis C — has garnered more than one billion audience impressions, worth an estimated \$1.4 million of donated media time and space.

Identifying opportunities to integrate viral hepatitis into HIV and related activities. Regional Health Administrators (RHAs) and their staff identified opportunities to integrate activities in support of the Action Plan and the National HIV/AIDS Strategy. Some of these activities educated providers and communities on issues relating to the Affordable Care Act and viral hepatitis. In partnership with regional, state, local, and tribal organizations, these efforts also increased awareness and education in communities disproportionately affected by viral hepatitis. Regional Resource Coordinators (RRCs) participated — and, in many cases, helped to coordinate — over 25 events across the nation to ensure inclusion of viral hepatitis in HIV and other regional prevention activities, including World AIDS Day events.

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

- ◇ CDC regularly updates material posted on its website and develops and shares digital tools and resources such as an online hepatitis risk assessment, web buttons, badges, and widgets and more. CDC has an active Twitter presence via @cdchep with over 28,000 followers. In 2014, CDC also worked with the National Prevention Information Network to feature a Hepatitis Event Page during May's observance of Hepatitis Awareness Month; organizations posted information about their viral hepatitis testing events and individuals were able to search for testing locations on this page.
- ◇ HUD distributed a Hepatitis Awareness Month message via its listserv to grantee and staff networks (over 30,000 individuals), reinforcing the association between homelessness and increased risk for viral hepatitis and providing information about resources and how to get more involved in raising awareness.
- ◇ In July 2014, OHAIDP and CDC collaborated with the Office of National AIDS Policy (ONAP) and ONDCP to plan and conduct a World Hepatitis Day event in the White House South Court Auditorium and via webcast. The event included remarks by then-Assistant Secretary for Health Dr. Howard Koh, Ambassador Deborah Birx who leads the President's Emergency Plan for AIDS Relief (PEPFAR), and Dr. Paul Farmer, founder of Partners in Health and Harvard Professor of Global Health and Social Medicine. Twelve leaders in the field of viral hepatitis were recognized for their contributions toward achieving the goals of the Action Plan.
- ◇ OPA supported hepatitis awareness efforts via email and Twitter messages in 2014. OPA regularly disseminates family planning and related preventive health information to more than 5,500 stakeholders, including its Title X-funded grantees, service site providers, and the public. In 2014, OPA shared 35 messages regarding hepatitis webinars for providers, materials for at-risk populations, and other prevention, care and treatment updates — including information about the updated Action Plan, viral hepatitis funding opportunities, and the CDC's Viral Hepatitis Risk Assessment.
- ◇ OMH launched a targeted communications and awareness campaign for the annual observances of National Hepatitis Testing Day, Hepatitis Awareness Month, and World Hepatitis Day including a Director's blog post on viral hepatitis in African-American communities. The campaign included traditional media placement, social media, materials, a toolkit for testing events and health fairs, and webinars. The campaign reached more than 25,000 through OMH newsletters. The Twitter campaign potentially reached 4.8 million consumers and professionals, and included tweets in Spanish.
- ◇ OWH promoted viral hepatitis information to the public and to health care providers via its website including cross-posting blogs. During the month of May, OWH prepared hepatitis-related messages for callers waiting on hold to be connected to the OWH hotline, developed and sent hepatitis-themed tweets in English and Spanish, and re-tweeted messages throughout calendar year 2014.

THE HCV CARE CONTINUUM: MEASURE THE PROGRESS TO CURING HCV

By Corinna Dan, R.N., M.P.H., Viral Hepatitis Policy Advisor, Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Health and Human Services

Chronic HCV infection affects an estimated 3.5 million individuals in the United States; over 50% of them are unaware that they are infected.¹ Chronic HCV has been termed a “silent epidemic”, due to the largely asymptomatic nature of the disease. HCV infection can persist for decades without causing symptoms. During this time however, liver disease may continue to progress. HCV infection can cause significant liver disease, cirrhosis, hepatocellular carcinoma (HCC), and death. Persons born between 1945 and 1965 (often referred to as the “baby boomers”) represent approximately 75% of those infected. Many of these individuals were infected many years, or even decades, ago. As the baby boomer population ages and the duration of their HCV infection increases, the serious clinical consequences associated with chronic infection are also expected to increase. Thus, the clinical burden of HCV will continue to increase, particularly in this group,² if we do not redouble our efforts to identify individuals currently living with HCV and link them to lifesaving care and curative therapies.

The coordinated federal response to combat viral hepatitis is only 4 years old, and yet, we have made progress both in raising awareness and in understanding gaps in our response to the silent epidemic of chronic HCV infection. As we continually work to evaluate progress in efforts toward achieving the goals of the Action Plan, it is important to have a consistent set of indicators that we can track over time. The HCV continuum of care provides a set of indicators that can be used this way by federal partners, state and local health departments, health systems, and advocates. In 2013, CDC developed and published the first U.S. HCV continuum of care, based on the Chronic Hepatitis Cohort Study (CHeCS) data to help inform our national response³. Philadelphia provides an example of a jurisdiction that has evaluated its continuum of care indicators and used the findings to identify gaps and strategies to improve their work on HCV⁴. The authors identified a lack of HCV testing due to low provider awareness and lack of patient perception of risk as well as limited access to healthcare

¹ Centers for Disease Control and Prevention. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945 — 1965. *Morbidity and Mortality Weekly Review*. 2012;61(RR04):1-18.

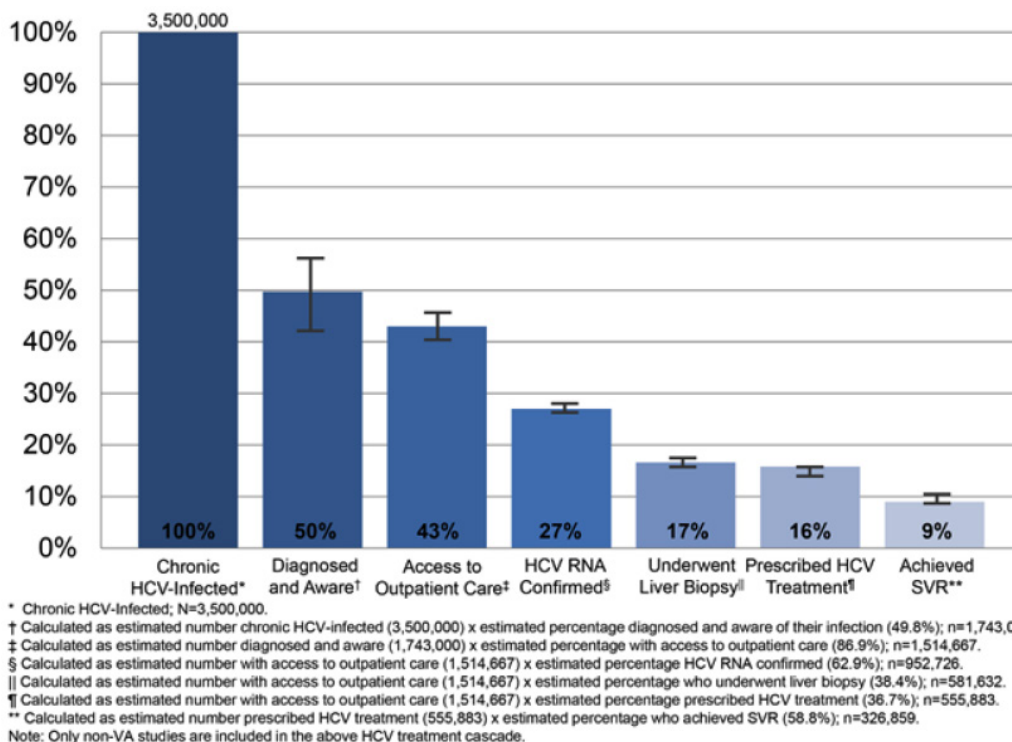
² Davis GL, Alter MJ, El-Serag H, et al. Aging of hepatitis C virus (HCV)-infected persons in the United States: multiple cohort model of HCV prevalence and disease progression. *Gastroenterology*. February 2010;138(2):513-521.

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

⁴ Viner K, Kuncio D, Newbern EC, and Johnson CC. The continuum of hepatitis C testing and care. *Hepatology*. March 2015;61(3):783-789.

services. Strategies implemented include a change to reporting all HCV confirmatory test results (not just those that are positive) coupled with provider training regarding the implementation of routine confirmatory testing, and increasing communication and collaboration among HCV surveillance, prevention, and clinical personnel. The continuum graph is a visual representation of where we must focus efforts and resources to close gaps and increase the proportion of people ultimately cured of HCV.

HCV CONTINUUM OF CARE



Yehia B, Schranz A, Umscheid, C, et al. The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and meta-analysis. PLoS One. 2014;9(7): e1011554

Yehia, et al., conducted a systematic review and meta-analysis to provide more comprehensive, updated estimates of the proportion of individuals who successfully complete each step of a proposed HCV management cascade⁵. With only 50% of those infected with HCV diagnosed, the continuum of care indicates that efforts at the initial stages are required in order to increase awareness of the disease and improve screening rates among persons at risk. We have seen new opportunities and resources to improve screening rates in recent years, including: USPSTF/CDC recommendations that all persons born between 1945 and 1965 receive a one-time HCV antibody test,^{1,6,7} availability of point-of-care antibody screening⁸, and numerous federal, private, and community-led efforts to increase awareness of HCV and its clinical consequences. While over 80% of people who have an

initial antibody test are linked to care, just over half have their infections confirmed based on CDC HCV testing recommendations.⁵ The continuum of care further shows that, of all people who have confirmed chronic HCV infection, less than 60% are prescribed HCV treatment and only one-third have achieved a cure.

Given the limited funding dedicated to HCV prevention, awareness, and care, continued creativity and innovation will be key to increasing all the indicators along the HCV continuum of care. Opportunities in this area include:

- ◇ **Leveraging and expanding upon existing resources** by identifying best practices and building on existing programs.
- ◇ **Harnessing the power of technology** by using electronic medical record tools, engaging social media, and developing web-based education and tools.
- ◇ **Highlighting successes and wins** by describing the HCV continuum of care within a jurisdiction, e.g., Philadelphia, or health system and advances such as the USPSTF/CDC aligned screening recommendations and new curative therapies.
- ◇ **Referring to the national roadmap** by using both the 2011 Action Plan which laid a foundation for advancing efforts to address HCV and the updated Action Plan which provides a framework for identifying national goals and actions for all stakeholders invested in ending the HCV epidemic.

Efforts to improve outcomes along the continuum are progressing in states, counties, and cities across the nation, through effective partnerships, innovative resource utilization, and strong leadership. Expanding these efforts will help the U.S. reach the ultimate goal of achieving an HCV continuum of care with high levels of diagnosis, access to care, and cure for Americans with HCV.

⁵ Yehia B, Schranz A, Umscheid, C, et al. The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and meta-analysis. PLoS One. 2014;9(7):e101554.

⁶ Chou R, Cottrell E, Wasson N, et al. Screening for hepatitis C virus infection in adults: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2013;158(2):101-108.

⁷ U.S. Preventive Services Task Force. Hepatitis C Screening Recommendation. June 2013.
<http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/hepatitis-c-screening>.

⁸ US Food and Drug Administration. FDA approves rapid test for antibodies to hepatitis C virus. 2010.
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm217318.htm>

PRIORITY 2: IMPROVING TESTING, CARE, AND TREATMENT TO PREVENT LIVER DISEASE AND CANCER

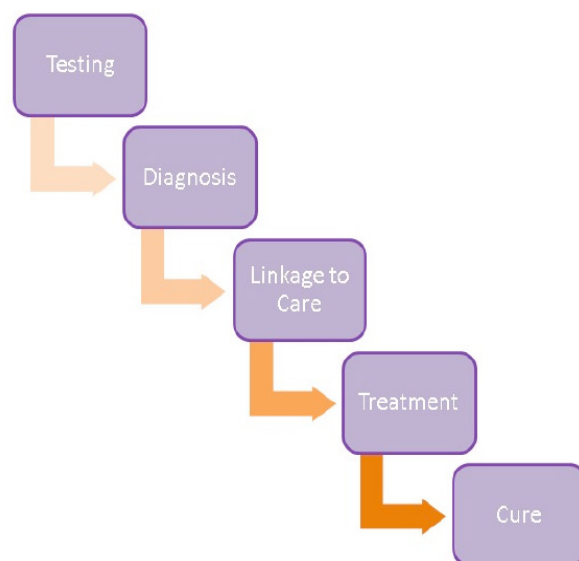
GOAL 2.1 — Identify persons infected with viral hepatitis early in the course of their disease.

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.

Providers at every level in the health care system play a critical role in meeting the needs of the millions of people at risk for or living with viral hepatitis. However, not all providers and systems are prepared to address these needs; missed opportunities to prevent, diagnose, treat, and care for persons with viral hepatitis result in preventable morbidity and mortality. These missed opportunities highlight the need for taking full advantage of existing tools, and developing additional innovative strategies. By identifying targets for improvement throughout the healthcare system, we can close the gaps that prevent individuals from receiving the care needed to improve hepatitis-related health outcomes.



In 2014, the following were among the actions undertaken by federal partners to improve testing, care, and treatment to prevent liver disease and cancer:

Supporting development and dissemination of updated U.S. Preventive Services Task Force (USPSTF) HBV screening recommendations. In May 2014, USPSTF issued an updated recommendation for screening for hepatitis B infection in persons at high risk for infection in non-pregnant adolescents and adults. AHRQ provides administrative, research, technical, and communication support to the Task Force, which is an independent group of national experts that works to improve the health of all Americans by making evidence-based recommendations on clinical preventive services such as screenings, counseling services, or preventive medicines. The new [USPSTF recommendation statement on HBV screening](#), which was given a “B” grade, supports the need to identify chronically-infected individuals who may benefit from treatment and reduce HBV transmission. Among those considered at high risk for HBV in the United States are persons born in countries with a high prevalence ($\geq 2\%$) of HBV, HIV-positive persons, persons who inject drugs (PWID), and men who have sex with men (MSM).

Increasing HBV testing capacity. In 2014, CDC provided \$900,000 of grant funding to improve the capacity of health care providers and other stakeholders to provide HBV testing and care in cities with large populations of persons born in countries with intermediate-to-high HBV prevalence. In three areas, funding was awarded to coalitions of key stakeholders (i.e. community-based organizations, health departments, specialists in HBV care, and primary-care providers) to support efforts to screen and diagnose people with chronic HBV and provide linkage to high-quality HBV care. Funded organizations included Saint Barnabas Medical Center (NJ) in partnership with Charles B. Wang Community Health Center (NY), Asian Health Coalition (IL), and Regents of the University of California at Davis (CA). The funded coalitions collaborated to implement screening and case-finding activities; conduct community outreach, patient navigation, case management, and other support services; implement training of primary-care staff to enhance screening, monitoring, management and referral practices; and implement activities to increase community and health professional awareness of hepatitis B.

Developing guidance for effective HCV outreach testing. In 2014, CDC developed a Guide to Comprehensive Hepatitis C Counseling and Testing — a manual to enhance counseling and testing for individuals at risk for, or potentially infected with, hepatitis C. Released in April 2015, the manual is available for [use in public health settings](#) and for [use in primary care practices](#). It was developed in part by CDC-funded State Viral Hepatitis Prevention Coordinators and field-tested by primary care providers. The manual includes a sample risk assessment, testing algorithms, sample HCV test counseling conversations, and recommended alcohol education for individuals whose HCV test results are positive.

Expanding coverage for HCV testing for Medicare recipients. In June 2014, CMS expanded Medicare coverage to include screening for HCV infection, consistent with the 2013 grade B recommendation by the USPSTF. The tests must be ordered by the beneficiary’s primary care

physician or practitioner within the context of a primary care setting, performed by an eligible Medicare provider for beneficiaries who are at high risk for HCV infection, and use the appropriate FDA-approved laboratory tests. A single screening test is covered for Medicare beneficiaries who do not meet the high-risk definition, but who were born from 1945 through 1965. “High risk” is defined as persons with a current or past history of illicit injection drug use and persons who have a history of receiving a blood transfusion prior to 1992. Repeat screening for high-risk persons is covered annually only for persons who have had continued illicit injection drug use.

Providing quality viral hepatitis testing and linkage to care for federal inmates. FBOP continues risk-based hepatitis screening of inmates and additional screening as clinically indicated. FBOP offers prenatal hepatitis B screening for pregnant females in FBOP custody to prevent mother-to-child transmission and provides hepatitis A and hepatitis B vaccination to appropriately-indicated adult inmates according to the FBOP National Preventative Health Care Clinical Practice Guidelines. FBOP inmates identified as HCV- or HBV-positive are enrolled in Chronic Care Clinics for appropriate care and management of their disease. Inmates receiving HCV treatment are monitored by a network of regional hepatitis clinical pharmacist consultants, in addition to receiving care management from their local health services team.

Supporting viral hepatitis prevention and testing in public health. In 2014, CDC provided \$5.2M in funding to support health department jurisdictions that conduct core viral hepatitis prevention activities including integration of testing into public health clinical settings. These funds provided support to State Viral Hepatitis Prevention Coordinators (VHPCs) in over 50 jurisdictions around the country, including 48 states and several major cities. VHPCs evaluate local data to tailor prevention activities for their jurisdictions and then seek local partnerships and resources to implement these activities where they are most needed. These activities include integrating viral hepatitis prevention vaccination, testing, and linkage to care within existing public health, clinical care, and community settings.

Enhancing the integration of viral hepatitis screening in primary care. HRSA’s BPHC, in collaboration with CDC, and in support of both HIV and viral hepatitis services, funded [Partnerships for Care \(P4C\)](#). The three-year contract was awarded in FY2104 utilizing Secretary’s Minority AIDS Initiative Funds to support the integration of high-quality HIV services into primary care through innovative partnerships between health centers and state health departments in four states. Given the high levels of hepatitis co-infection among people living with HIV, this project also includes support for hepatitis B and C screening and referrals to care.

Developing and disseminating electronic tools to improve hepatitis C testing and management. IHS continued dissemination of the HCV Screening Reminder for people born from

1945 to 1965. IHS also developed and released a Microsoft Excel-based registry tool that assists clinicians in assessing patients and setting priorities for treatment. IHS conducted training on the registry at 10 sites in 2014.

Expanding screening and vaccination in family planning settings. In 2013, OPA provided Title X funds to 95 grantees that delivered family planning and related preventive health services through more than 4,000 service sites to more than 4.5 million individuals. Released in 2014, “Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs” includes recommending screening for HCV in males and females and offering routine hepatitis B vaccination to all individuals under age 19 as well as all adults who are unvaccinated and do not have a documented history of hepatitis B infection.

By December of 2014, IHS had screened 33% of patients born during 1945 — 1965 for HCV, an increase of 44% over 2013 screening levels among individuals seen at federally supported IHS sites.

Developing improved diagnostics for viral hepatitis. FDA is working with manufacturers to develop visually readable, rapid devices for diagnosing viral hepatitis that may be used to prevent transmission, such as in emergency screening of blood donors (e.g., in combat zones). FDA is also working with manufacturers to develop more sensitive and precise hepatitis C genotype testing, and to consolidate the intended uses of existing hepatitis C tests such that a single test could be used both to diagnose HCV and assess treatment response (i.e., determine genotype).

Expanding the use of health information technology (HIT) to improve viral hepatitis services. In 2014, the following federal partners developed tools and evaluated HIT strategies to address viral hepatitis:

- ◇ Using a community-based participatory approach, the National Institute on Minority Health and Health Disparities supports ongoing needs assessments and focus groups. It is developing pilot testing of culturally proficient HIT intervention strategies to improve HBV vaccination, screening rates, and linkages to care among underserved Asian Americans visiting a community clinic. This study was initiated in January 2013 with a planned completion date of December 2016.

- ◇ Under an inter-agency agreement with CDC, the Office of the National Coordinator for Health Information Technology (ONC) worked to develop electronic specifications of three American Medical Association — Physician Consortium for Performance Improvement (AMA-PCPI) measures:

AMA-PCPI measure 9a: Screening for HCV patients at high risk.

AMA-PCPI measure 9b: Annual HCV screening for patients who are active injection-drug users.

AMA-PCPI measure 9c: Referral to treatment for patients identified with HCV infection.

In addition to developing these electronic Clinical Quality Measures (eCQMs), ONC is developing electronic clinical decision support (CDS) tools designed to help healthcare providers better screen and care for HCV patients. To support more widespread dissemination and use, the CDS tools are included in the HL7 balloted Knowledge Artifact Sharing draft standard. The eCQMs and CDS tools have been developed, and publication is expected by mid-to-late 2015.

Increasing viral hepatitis testing among homeless veterans. Collaborating with the VA's Healthcare for the Homeless Program, the Office of Public Health (OPH) funded 25 small grants in 2014 to increase HIV and HCV testing for veterans through multiple homeless outreach programs. More than 400 homeless veterans were tested for HCV through this program.

TREATMENT AND CURE

Enabling access to new HCV therapies. In 2014, FDA approved three new regimens for the treatment of chronic hepatitis C.

- ◇ Harvoni® (ledipasvir and sofosbuvir), the first combination pill, was approved in October 2014. Harvoni® was the first approved regimen to treat chronic HCV genotype 1 infection that does not require administration with interferon or ribavirin. Harvoni® was a new drug that received the FDA's breakthrough therapy designation, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. It was reviewed under the FDA's priority review program.
- ◇ Olysio® (simeprevir) in combination with Sovaldi® (sofosbuvir) was approved for treatment of chronic HCV genotype 1 infection in November 2014. Each component drug was initially approved in 2013. This regimen was reviewed under the FDA's priority review program.
- ◇ Viekira Pak™ (ombitasvir, paritaprevir and ritonavir tablets co-packaged with dasabuvir tablets), another treatment option for patients with chronic HCV genotype 1 infection, was approved in December 2014. Viekira Pak™ was also a new drug with breakthrough therapy designation and was reviewed under the FDA's priority review program; it is the only once-daily oral regimen available.

Innovating to improve the HCV continuum of care. Federal partners conducted the following activities to improve the HCV continuum of care for targeted populations:

- ◇ CDC provided funding (\$4.3M) to increase capacity of primary-care providers to diagnose and cure HCV among disproportionately affected populations in three communities. In each community, a coalition of key stakeholders (i.e., health departments, specialists in HCV care, and primary-care providers) was funded to develop and implement these services. Funds were awarded to the University of Chicago, the Maryland Department of Health and Mental Hygiene, and Public Health—Seattle & King County. Project activities include expanding the use of electronic health records to enhance HCV testing and care; assessing community impact of services; and increasing health department capacity to gather and follow-up on reports of current HCV cases in target populations.
- ◇ Through OMH’s HIV/AIDS Health Improvement for Re-entering Ex-offenders Initiative (HIRE) program, clients are linked to care within 30 days of testing positive for HIV, and are also screened for hepatitis C and linked to medical treatment as necessary. Grantees have established partnerships with organizations providing comprehensive healthcare services, substance use and mental disorder treatment programs, family services, education/GED programs, job placement/training programs, housing assistance and public assistance programs. Additionally, through the Health and Social Service Resource (HSSR) Network, Linkage to Life (L2L) grantees utilized a systems navigation approach to link clients with and retain them in comprehensive primary care, HIV/AIDS treatment, and social and supportive services including viral hepatitis screening and follow-up through each HSSR Network.

From September 2013- August 2014, a total of 1,095 HIRE participants were screened and tested for viral hepatitis; 116 individuals tested positive and 90 clients attended a routine viral hepatitis medical care visit within three months of HIV diagnosis. L2L grantees screened and tested 1,888 participants during the same period; 205 clients tested positive and 143 clients attended a routine viral hepatitis medical care within three months of HIV diagnosis. The Linkage to Life Program ended August 31, 2014.

Integrating viral hepatitis into HIV demonstration projects for at-risk individuals. Through SAMHSA’s Minority AIDS Initiative Continuum of Care (MAI-CoC) pilot program, grantees are required to use 5 percent of funding for viral hepatitis activities and report those activities to SAMHSA. To capture testing rates, positivity, vaccination, and referral to care, SAMHSA has updated its Rapid HIV and Hepatitis Testing Form.

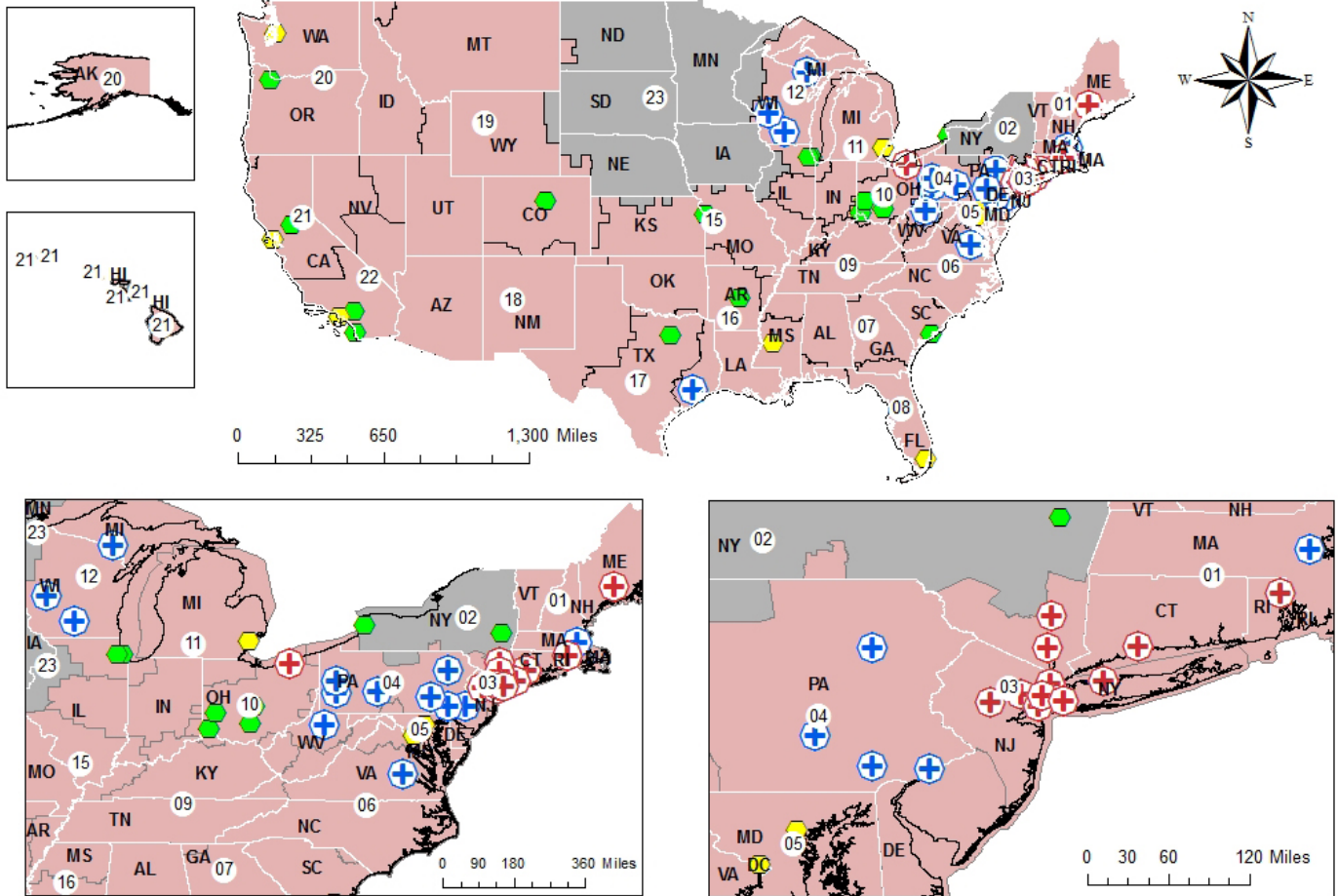
Redesigning the HCV system of care for veterans. In September 2014, VA hosted a conference to address the system redesign of HCV care across the system. This meeting was attended by representatives from each of the 21 Veterans Integrated Service Networks (VISNs). Out of this meeting, VISN Hepatitis C Innovation Teams (HITs) were formed in 19 out of 21 VISNs. HITs were tasked with creating broad based regional teams with a focus on system redesign. Their goals are to assess current HCV clinical care and variability in facility treatment capacity and practice across their regions, identify gaps in care, and implement broad-based, redesigned strategies to align with future state goals for HCV testing and treatment.

VA has several field-based quality improvement initiatives including:

- 1) The use of a “Hepatocellular Carcinoma (HCC) Tracker”, a web-based tool to identify and follow patients with HCC. This tracker augments care coordination and case management to create a Cancer Care Tracking System for HCC to detect and treat liver cancer earlier.
- 2) A model for VISN-wide multidisciplinary and multi-facility liver cancer teams and tumor boards which have been shown to improve both access to and the quality of liver cancer care that has expanded to three VISNs.
- 3) The HCV Dashboard Collaborative Project, which brings together VISN and facility teams who have developed HCV dashboards to share best practices and mentor other teams to use this technology to improve HCV clinical care.

The figures below depict the geographic distribution of these and other important quality improvement initiatives, which include the Liver Disease and HIV psychology fellowship sites and HIV and HCV testing initiatives in VA homeless and outreach and care programs.

Facility-Based QI Initiatives Supported by HHPHP



Updated 3/20/2015



- + HCC Tracker Locations
- + Tumor Board Locations
- ⬡ HIV/Liver Disease Psychology Fellowship Locations
- ⬡ HIV/HCV Testing in Homeless Programs
- Funded VISN HIT Teams
- No VISN HIT funding

Responding to public concern about access to hepatitis C treatment. In December 2014, OHAIDP convened an HHS listening session with clinical and community leaders on the important issue of improving access to curative HCV treatment. The advent of more effective, second-generation, direct-acting HCV antiviral drugs represents a tremendous scientific accomplishment with huge potential for public health benefits. During the session, which was attended by senior HHS staff (Acting Assistant Secretary for Health Karen DeSalvo, Principal Deputy Assistant Secretary for Health Wanda Jones, and Deputy Assistant Secretary for Health, Infectious Diseases, Ronald Valdiserri), community leaders and other stakeholders raised concerns about barriers to treatment access as described in a letter sent to Secretary Burwell in September 2014. It had been signed by more than 700 organizations, healthcare providers, and individuals. The meeting provided an opportunity for stakeholders to share concerns about restrictions to treatment access that, in their opinion, do not appear to be medically justified. These include restrictions based on degree of liver fibrosis, alcohol and drug use/abuse, and prescriber qualifications. In this rapidly evolving arena, HHS continues to collaborate with stakeholders to implement the Action Plan and improve the diagnosis, treatment, and prevention of viral hepatitis.

Understanding viral hepatitis progression and liver cancer markers. NIH worked in 2014 to support and conduct research focusing on the progression of HBV and HCV and detection measures for liver disease and cancer.

- ◇ The availability of a small-animal model would provide an enormous benefit to research the pathogenesis, prevention and treatment of hepatitis B and C. Several such models have been developed by investigators funded by the National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and are being used in studies of both viral infections. Mice with humanized livers can be infected with HBV or HCV, which allows the study of the early events that occur in the liver during infection that lead to cell injury, recovery, or chronic infection.
- ◇ Intramural investigators from NCI are supporting ongoing studies of the mechanisms of cancer stem cells and viral hepatitis-mediated hepatocarcinogenesis in liver cancer. Molecular profiling and gene expression array studies that compare signatures of chronic liver diseases with hepatocellular carcinoma revealed a molecular signature that separates patients for their risk of developing advanced disease.
- ◇ NCI is also currently supporting a project for the serial collection of serum and plasma from patients with cirrhosis who are predominantly HCV-positive and progress to liver cancer. A biorepository containing serum and plasma samples from cirrhotic patients who developed liver cancer will provide an important resource for the prospective validation of biomarkers for the early detection of liver cancer.
- ◇ Intramural researchers at NIAID, NIDDK, NCI and the NIH Clinical Center are conducting ongoing translational research studies on the molecular mechanisms of pathogenesis of

acute and chronic liver disease (with a focus on viral hepatitis, cirrhosis and hepatocellular carcinoma) aimed at investigating the role of hepatitis viruses in liver carcinogenesis. Other ongoing studies include elucidating the role of host and viral factors in hepatitis virus infections, identifying new diagnostic and prognostic biomarkers for HCC, and using large patient cohorts to validate previously-discovered predictive markers for the progression of hepatitis C to cirrhosis.

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

- ◇ NIDDK supports ongoing studies through the Hepatitis B Research Network, which has the goal to advance understanding of disease processes and natural history of chronic hepatitis B, as well as to identify effective approaches to treatment with currently available therapies. The Network brings together clinical centers from throughout the U.S. and Canada. Through partnerships with industry and CDC, this multi-center Network has initiated two prospective cohort studies (with over 1700 patients enrolled) and three [clinical trials](#) with several supportive ancillary studies. A study, ancillary to the Hepatitis B Research Network, has recently been initiated to follow a cohort of adult patients with HBV and HIV co-infection that will allow for analysis of the separate contribution of HIV infection to the course and outcome of chronic hepatitis B, and help define the optimal means of managing hepatitis B in patients with HIV infections. A [recent publication](#) summarized baseline clinical characteristics of adults enrolled in the Hepatitis B Research Network. Funding will continue for the Network through 2020.
- ◇ NIMHD supports a community-based participatory study in a Korean church that examines the effectiveness of two dissemination strategies for implementing the evidence-based hepatitis B intervention in-person training and technical assistance (IPT/TA) and e-training and technical assistance of community health workers to increase hepatitis B screening and vaccination rates among Korean-American workers. This study was initiated in July 2013, with a planned completion date of February 2016.

Expanding HCV therapy research. In 2014, NIH continued efforts to expand options for hepatitis C treatment.

- ◇ NIH researchers at NIAID and NIDDK have initiated several clinical research studies of oral regimens of therapy for acute and chronic hepatitis C. These studies are focused on high-risk patients in vulnerable populations who are usually not included in industry-supported studies that lead to drug licensure. These populations include the uninsured, recent emigrants from Africa and Asia, racial/ethnic minority populations, persons with advanced liver disease and cirrhosis, and persons co-infected with HIV. Special groups include patients with genotypes 2,

3 and 4, patients with drug-resistant HCV mutations, and patients who are co-infected with HIV ([SWIFT-C](#), A5327).

- ◇ NIH researchers in the NIDDK's Intramural Research Program have an ongoing collaboration with National Center for Advancing Translational Sciences (NCATS) performing high-throughput screening to identify novel targets and molecules for HCV therapy. One of the identified molecules is undergoing a [phase 1 study](#) in NIDDK's intramural Liver Diseases Branch, with results expected in 2015.

Examining perinatal HCV transmission & infection. A multi-center [observational study](#) by the Maternal-Fetal Medicine Units Network, supported by the NIH's NICHD, is examining risk factors for HCV transmission from mother to baby and risk factors associated with HCV infection in pregnant women. The study will also describe the outcomes of pregnant women with HCV as well as the outcomes of their infants up to 18 months of age. To date, the study has enrolled 309 of the planned 1800 pregnant women with HCV infection and 370 of the planned 1800 uninfected pregnant women control group. This study was initiated in October 2012, with a planned completion date of April 2019.

Identifying effective hepatitis D therapy. The hepatitis delta virus (HDV) is a rare but important cause of severe liver disease and cirrhosis in individuals co-infected with HBV, for which there is currently no effective treatment. NIH researchers in NIDDK's Intramural Research Program have completed a [pilot trial](#) of a farnesyl transferase inhibitor (lonafarnib) that showed its efficacy in reducing levels of HDV RNA in the blood, and improving liver tests with minimal side effects when given for 28 days (NCT01495585). A more ambitious, multicenter, multinational randomized controlled trial of 6 months of therapy is being designed; it is due to start enrollment in 2015.

PRIORITY 3: STRENGTHENING SURVEILLANCE TO DETECT VIRAL HEPATITIS TRANSMISSION AND DISEASE

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.

We must identify and collect accurate and timely information to improve and evaluate our efforts to address viral hepatitis. Surveillance and other health data can 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, viral hepatitis. 2014 saw further expansion and innovation among federal efforts on surveillance through collaborations with new partners, exploration of new data collection strategies, and the development of new tools. This new data can help guide future efforts to ensure maximum impact on the prevention, care, and treatment of viral hepatitis across the health care spectrum.

In 2014, the following were among the actions undertaken by federal partners to strengthen surveillance to detect viral hepatitis transmission and monitor disease:

Supporting enhanced HCV surveillance. CDC continued to support seven state and local health departments (San Francisco, Florida, Massachusetts, Michigan, New York State, Philadelphia, and Washington State) in conducting more active surveillance for hepatitis A, B, and C. In Philadelphia, CDC supported a project to measure “matching” of cases of HCV infection documented in electronic health records with the state registry of HCV cases. CDC also established a collaborative relationship with New York State Public Health Laboratories to develop web-based processing of HCV sequences for transmission linkage analyses, and a collaborative relationship with Indiana Public Health Laboratory to conduct research and surveillance of early HCV infection in incarceration centers.

Responding to viral hepatitis outbreaks. In 2014, CDC supported outbreak or cluster investigations of six food-handler-related hepatitis A consultations, one nursing home hepatitis B investigation, and ongoing efforts around hepatitis C related to inadequate syringe hygiene in a medical clinic.

Understanding viral hepatitis health disparities. Beginning in late 2014, CDC examined several public-use or large CDC databases to assess viral hepatitis-related health disparities. Using data from the National Health and Nutrition Examination Survey (NHANES), the Chronic Hepatitis Cohort Study (CHeCS), and the National Health Interview Survey (NHIS) CDC documented health care disparities among Asians/Asian-Americans and Africans/African Americans among hepatitis B and for African Americans and uninsured persons with hepatitis C.

Monitoring testing and care for HCV. CDC established a “care continuum” for HCV — screening, confirmatory lab work, referral to specialty care, work-up for treatment, provision of antiviral therapy, and cure — and has measured progress along this continuum of HCV-infected persons in the Chronic Hepatitis Cohort Study. In findings published in 2014, less than two-thirds of patients who had positive HCV antibody tests had subsequently undergone an RNA test to confirm current infection. The authors recommended the implementation of rapid-reflex RNA testing to improve the identification of individuals who could benefit from HCV therapy.¹ In addition, CDC developed and expanded a collaboration with Quest Diagnostics, the largest single provider of laboratory testing in the U.S., to analyze anonymous data from its national lab test results database. CDC’s analysis revealed modest increases in HCV screening following CDC and USPSTF recommendations for universal one-time screening of the 1945 to 1965 birth cohort. CDC also started a similar collaboration with LabCorp.

In an effort to improve health care quality and delivery by identifying and addressing clinical performance gaps in testing and care, CMS implemented quality measures in the Physician Quality Reporting System. They are related to screening of at-risk patients, HCV initial testing and RNA confirmatory testing, testing after initial treatment, and vaccination against HAV and HBV.

In 2014, VA continued to maintain a robust surveillance program for hepatitis C, which includes:

- ◇ Tracking the number of veterans in the 1945 to 1965 birth cohort tested for hepatitis C,
- ◇ Tracking compliance with the standard of routine reflex confirmatory testing to determine which patients with positive antibody results have chronic hepatitis C,

¹ Spradling PR, Tong X, Rupp LB, Moorman AC, Lu M, Teshale EH, Gordon SC, Vijayadeva V, Boscarino JA, Schmidt MA, Holmberg SD; Chronic Hepatitis Cohort Study (CHeCS) Investigators. Trends in HCV RNA testing among HCV antibody-positive persons in care, 2003-2010. *Clin Infect Dis.* 2014;59(7):976-981.

- ◇ Maintenance of facility-level and national electronic hepatitis C Clinical Case Registries (CCR), which supports preparation of an annual report generated from the CCR on the population of patients with hepatitis C in VA care, including demographics, clinical comorbidities, and antiviral treatment metrics. CCR data are also used to generate weekly, monthly, and ad hoc reports for operational purposes.

Additionally, the [State of Care for Veterans with Hepatitis C, 2014](#), the summative multi-year analysis of hepatitis C care within VA, was completed. This report presents data from 2002-2013 and describes the population of veterans with HCV infection in VHA care, assesses trends in complications of HCV infection, and examines access and quality of care metrics.

Monitoring viral hepatitis testing & diagnoses in health centers. HRSA collects data related to hepatitis from all HRSA-supported health centers.

Health Center Service Reports on Hepatitis B and C	
Hepatitis B	Hepatitis C
<p>In 2012, health centers reported providing services to:</p> <ul style="list-style-type: none"> a. 21,890 patients with a diagnosis of hepatitis B with 48,080 patient visits (averaging 2.20 visits per patient), and b. 294,400 patients screened for hepatitis B. 	<p>In 2012, health centers reported providing services to:</p> <ul style="list-style-type: none"> a. 132,078 patients with a diagnosis of hepatitis C with 303,713 patient visits (averaging 2.30 visits per patient), and b. 255,775 patients screened for hepatitis C.
<p>In 2013, health centers reported providing services to:</p> <ul style="list-style-type: none"> a. 23,759 patients with a diagnosis of hepatitis B with 50,295 patient visits (averaging 2.12 visits per patient), and b. 317,647 patients screened for hepatitis B. 	<p>In 2013, health centers reported providing services to:</p> <ul style="list-style-type: none"> a. 145,309 patients with a diagnosis of hepatitis C with 321,011 patient visits (averaging 2.21 visits per patient), and b. 296,349 patients screened for hepatitis C.

Exploring improved HCV diagnostics. CDC validated the performance of an HCV antigen assay using panels comprising blood samples from U.S. patients. HCV antigen assays are more sensitive than currently available tests. They could be used to improve detection of acute HCV infection and to reduce the costs of confirmatory testing following an initial HCV antibody test. Findings were published in the *Journal of Clinical Virology*.² FDA is encouraging the development of tests for HCV antibodies/antigens similar to those developed for HIV. This would benefit STD clinics and providers working with people who inject drugs by improving diagnostic capability.

Analyzing HBV genotypes. CDC completed an analysis of HBV-genotype distribution among U.S. residents with acute and chronic HBV infection. Based on the analysis, HBV vaccination efforts in the U.S. should be scaled up for persons at risk.³ CDC also identified U.S. blood donors with incubation-phase HBV infections and characterized them according to if they are infected with strains of HBV that are not prevented by vaccines due to mutations of the virus.

Improving understanding of tools to detect HCV transmission. To improve our understanding of HCV transmission and inform future epidemiologic activities, CDC conducted a comparative evaluation of protocols to detect the HCV genome in dried blood spots⁴ and established protocols based on deep sequencing of the HCV genome to infer transmission linkages.

²Mixson-Hayden T, Dawson GJ, Teshale E, Le T, Cheng K, Drobeniuc J, Ward J, Kamili S. Performance of ARCHITECT HCV core antigen test with specimens from US plasma donors and injecting drug users. *J Clin Virol*. 2015;66:15-18.

³Ramachandran S, Purdy MA, Xia GL, Campo DS, Dimitrova ZE, Teshale EH, Teo CG, Khudyakov YE. Recent population expansions of hepatitis B virus in the United States. *J Virol*. 2014;88(24):13971-13980.

⁴Tejada-Strop A, Drobeniuc J, Mixson-Hayden T, Forbi JC, Le NT, Li L, Mei J, Terrault N, Kamili S. Disparate detection outcomes for anti-HCV IgG and HCV RNA in dried blood spots. *J Virol Methods*. 2015;212:66-70.

PRIORITY 4: ELIMINATING TRANSMISSION OF VACCINE-PREVENTABLE VIRAL HEPATITIS

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 indication for their optimal use.

Elimination of mother-to-child transmission of hepatitis B is possible with the tools available to us. Federal partners can further reduce the burden of hepatitis A and B in the U.S. by focusing on efforts to increase the number of persons who receive hepatitis A and B vaccination. Increased awareness among healthcare providers, communities, and those at risk, coupled with the availability of more efficacious therapies, can move us closer to the goals outlined in the Viral Hepatitis Action Plan.

In 2014, the following were among the actions undertaken by federal partners to eliminate the transmission of vaccine-preventable viral hepatitis:

Improving identification of pregnant women with chronic HBV. [CDC Special Laboratory Reports](#) for identification of hepatitis B-infected pregnant women were implemented by four major commercial laboratories: ARUP Laboratories, LabCorp, Mayo Medical Laboratories, and Quest Diagnostics. The reports aid in the identification of hepatitis B-infected pregnant women and timely post-exposure prophylaxis for their infants. The reports have helped CDC-supported Perinatal Hepatitis B Prevention Programs in most states identify an increased number of hepatitis B-infected pregnant women, and support the provision of care for the mothers and their infants.

CDC's DVH [analyzed discrepant hepatitis B surface antigen \(HBsAg\) results for pregnant women screened for hepatitis B virus](#), and determined that the majority of results were false positives. However, true positives did occur, and testing for total hepatitis B core antibody was useful for resolving discrepancies.¹

Preventing perinatal HBV transmission. Perinatal hepatitis B prevention programs in Michigan and New York City collaborated with CDC to close the gap between the expected and identified number of births to hepatitis B-infected mothers. They compared outcomes of infants born to infected mothers, and examined the reliability of a facility-based National Quality Forum measure regarding hepatitis B vaccine coverage among newborn infants.

CDC DVH [analyzed data from the Enhanced Perinatal Hepatitis B Prevention Program from 2008-2013](#) and determined that 95% of uninfected infants born to Hepatitis B-infected mothers responded to the primary Hepatitis B vaccine series. The proportion of responding infants decreased as the interval between the final dose of vaccine and post vaccination testing increased.²

CDC DVH [analyzed the cost-effectiveness of the U.S. Perinatal Hepatitis B Prevention Program](#) and concluded that it increased quality-adjusted life years and led to reductions in the number of perinatal and childhood infections, thereby representing a cost-effective use of resources.³

CDC's DVH [developed models to estimate the annual number of perinatal Hepatitis B virus infections](#). An estimated 952 infections occurred in 2009, suggesting that a substantial number of infections are not identified by the Perinatal Hepatitis B Prevention Program.⁴

Understanding and expanding the use of HBV therapies to prevent perinatal transmission.

NIH's NICHD, in collaboration with the CDC, has funded a research group to conduct a randomized, placebo-controlled trial of maternal tenofovir (in addition to standard infant HBV immune globulin and vaccine) for prevention of transmission of hepatitis B from HBeAg-positive women to their infants in Thailand since 2012. HBeAg is a serologic marker and an indicator of infectivity. HBeAg-positive women are at highest risk for transmission of HBV to their infants at the time of birth, even with the standard prophylaxis of HBV immunoglobulin and vaccine. Between January 2013 and August 2015, the study completed its target enrollment of 328 women. Results are expected in late 2016. This study is funded by NICHD in collaboration with the CDC in a cooperative agreement. More information about this study is available [here](#).

CDC DVH [analyzed MarketScan® data to describe antiviral treatment during pregnancy for women infected with hepatitis B](#). MarketScan® databases include data on over 200 million patients (since 1995)

¹ Veselsky SL, Walker TY, Fenlon N, Teo CG, Murphy TV. Discrepant hepatitis B surface antigen results in pregnant women screened to identify hepatitis B virus infection. *J Pediatr*. 2014;165(4):773-778.

² Ko SC, Schillie SF, Walker T, Veselsky SL, Nelson NP, Lazaroff J, Crowley S, Dusek C, Loggins K, Onye K, Fenlon N, Murphy TV. Hepatitis B vaccine response among infants born to hepatitis B surface antigen-positive women. *Vaccine*. 2014;32(18):2127-2133.

³ Barbosa C, Smith EA, Hoerger TJ, Fenlon N, Schillie SF, Bradley C, Murphy TV. Cost-effectiveness analysis of the national Perinatal Hepatitis B Prevention Program. *Pediatrics*. 2014;133(2):243-253.

⁴ Ko SC, Fan L, Smith EA, Fenlon N, Koneru AK, Murphy TV. Estimated annual perinatal hepatitis B virus infections in the United States, 2000 — 2009. *J Ped Infect Dis*. 2014; doi:10.1093/jpids/piu115.

including publicly- and privately-insured individuals. The data captures patient level data, treatment patterns, and costs. Antiviral treatment was prescribed for fewer pregnant women than non-pregnant women (12.6 percent and 20.0 percent, respectively). Tenofovir was the most commonly prescribed agent.⁵

Understanding the cost of perinatal HBV prevention. CDC's DVH [analyzed the cost-effectiveness of testing hepatitis B-infected pregnant women for hepatitis B e antigen or viral load](#) and concluded that testing, followed by maternal antiviral prophylaxis for mothers who are hepatitis B e antigen positive or have high viral loads, is cost-effective.⁶

Planning optimal use of HBV vaccine. In 2014, and following 2011 recommendations from the National Vaccine Advisory Committee (NVAC), NVPO began development of the National Adult Immunization Plan (NAIP). Created with input from hundreds of stakeholders across every sector of the adult immunization landscape, the NAIP will be a 5-year national plan channeling the collective efforts of federal and nonfederal stakeholders. NVPO's ultimate vision for the NAIP is to protect public health and achieve optimal prevention of infectious diseases (including HAV and HBV) and their consequences through vaccination of all adults.

Developing an HCV vaccine. [FDA published findings](#) on T-cell memory phenotypes induced by vaccination against HCV. This is important in establishing biomarkers for predicting success for experimental vaccines during clinical trials. HCV clearance correlates with HLA-DR expression on proliferating CD8+ T-cells in immune-primed chimpanzees.⁷

NIAID is conducting a [double-blinded, randomized, Phase I/II trial](#) to evaluate the safety, immunogenicity, and initial efficacy of a vaccine to prevent acute and chronic hepatitis C infection in high-risk people. The Phase I component of the trial has been completed, and Phase II is currently enrolling participants. The study is expected to enroll approximately 450 participants and is slated for completion in October 2016.

Ensuring vaccine safety. In response to concerns about vaccine safety, NVPO and AHRQ released a review of vaccine safety: [Safety of Vaccines used for Routine Immunization in the United States](#) on July 1, 2014 in the journal Pediatrics. A [summary of the evidence review](#) is also available. The report found scientific evidence that addresses several common concerns about a variety of vaccines. For example, the report found strong scientific evidence that there is not a link between hepatitis B vaccines and childhood leukemia.

⁵ Fan L, Owusu-Edusei K Jr, Schillie SF, Murphy TV. Antiviral treatment among pregnant women with chronic hepatitis B. *Infect Dis Obstet Gynecol.* 2014;546165.

⁶ Fan L, Owusu-Edusei K Jr, Schillie SF, Murphy TV. Cost-effectiveness of testing hepatitis B-positive pregnant women for hepatitis B e antigen or viral load. *Obstet Gynecol.* 2014;123(5):929-937.

⁷ Zubkova I, Duan H, Wells F, Mostowski H, Chang E, Pirolo K, Krawczynski K, Lanford R, Major M. Hepatitis C virus clearance correlates with HLA-DR expression on proliferating CD8+ T cells in immune-primed chimpanzees. *Hepatology.* 2014;59(3):803-813.

PRIORITY 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.

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.

A growing cross-section of public and private sector partners are alarmed by the emergence of an epidemic of hepatitis C infection among young persons who inject drugs (PWID). This trend is being seen among both males and females, primarily in rural and suburban settings, who begin using prescription opioids before transitioning to injecting prescription opioids and/or heroin. There is an urgent need for research, surveillance, and prevention strategies to stop the spread of viral hepatitis associated with drug use. These strategies must address a diverse set of challenges, including successfully engaging vulnerable populations who often face significant barriers in access to health care.

In 2014, the following were among the actions undertaken by federal partners to reduce viral hepatitis associated with drug using behaviors:

Promoting viral hepatitis prevention and screening in behavioral health care settings.

Through the Center for Substance Abuse Treatment's (CSAT) Targeted Capacity Expansion-HIV grant program, SAMHSA provided an estimated \$850,000 to 34 grantees to assist in the attenuation of the transmission of vaccine-preventable viral hepatitis by achieving universal hepatitis A and B vaccination for vulnerable adults. In 2014, for the first time, a SAMHSA grant required — rather than offering — use of grant funds for viral hepatitis activities (e.g., screening, testing, education, linkage

to care). Through the new Minority AIDS Initiative-Continuum of Care (MAI-CoC) Pilot program, five percent of the awarded funds must be used for viral hepatitis activities, including hepatitis A and B vaccination for vulnerable adults. SAMHSA awarded \$16.8 million to 34 grantees through the MAI-CoC Pilot program, which fosters integration of HIV services, behavioral health services, and primary care. On July 25, 2014, SAMHSA's Chief Medical Officer released an annual [Dear Colleague Letter](#) that discussed the need for HCV screening and testing among persons with substance use and mental health disorders. This letter was delivered to over 53,000 individuals including state Mental Health Commissioners, state Alcohol and Drug Abuse Directors, SAMHSA grantees, etc. It described the rationale for HCV testing in behavioral health populations, discussed the recent USPSTF endorsement of hepatitis C screening, and provided contact information for State Viral Hepatitis Prevention Coordinators who can assist with implementation of screening and testing programs.

SAMHSA CSAT administers and manages the HCV Screening Grants with resources from the Secretary's Minority AIDS Initiative Fund. Under this pilot initiative, 9 SAMHSA Opioid Treatment Program (OTP) grantees received HCV screening grants to implement HCV screening/testing in their facilities from July 2013 through June 2014. During that one-year period, a total of 2,101 HCV screening tests were administered. Four grantees received a no-cost extension in order to reach the proposed testing target. Overall, 19% of clients tested positive for HCV. Fifty-two percent of all individuals tested were PWID; among them, 28% tested positive for hepatitis C. Only 10% of individuals who were not PWID tested positive for HCV. Most of the clients screened for HCV received referrals for counseling and other health services. The vast majority of individuals who tested positive for HCV antibodies were provided with referrals for confirmatory testing, education and counseling services. Several grantees reported that, during the grant period, providing HCV training to local facility staff proved instrumental in making the OTP clients more receptive to testing. As a result of implementing this grant project, some grantees are making efforts to provide routine HCV screening to all clients with substance use disorders.

Expanding workforce capacity to address HCV in behavioral health care settings.

The SAMHSA-funded Addiction Technology Transfer Center (ATTC) Network's charge is to respond to the emerging needs of the addictions' professional workforce; consequently, it was critical to develop a curriculum specifically designed to educate providers that work with PWID. Recognizing the urgency of educating staff, the 10 ATTC regional centers developed a new website, [HCV Current Initiative](#); a face-to-face training curriculum, "Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers"; an online HCV course and a training calendar for HCV-specific ATTC Network trainings. The nationwide network of trainers will be available to provide hepatitis C training for health center staff, and others who work with PWID.

Expanding HCV treatment access in corrections. NIH's National Institute on Drug Abuse (NIDA) is examining ways to adapt the "Seek, Test, and Treat" paradigm to those infected with HCV who are in the criminal justice system — a setting with numerous opportunities to identify individuals with HCV infection and provide linkage to treatment, given the high prevalence of HCV among the incarcerated.

Originally developed to address HIV, the seek, test, treat, and retain (STTR) model of care involves reaching out to high-risk, hard-to-reach drug-abusing groups who have not been recently tested for HIV (seeking); engaging them in HIV testing (testing); initiating, monitoring, and maintaining HIV treatment for those testing positive (treating); and retaining patients in care (retaining). This model of care is based on previous research demonstrating that expanding HIV testing and reducing viral load among HIV-positive individuals through highly active antiretroviral therapy can be effective in reducing the HIV transmission at a population level.

Providing access to treatment for substance use disorders and HCV in corrections. Since a substantial proportion of people in jails and prisons are there because of crimes related to substance abuse, the inmate population includes many persons living with chronic HCV infection. The DOJ/FBOP provides inmates who have acquired HCV as a result of prior injection drug use with access to substance abuse treatment as well as HCV care to prevent transmission and progression of disease. FBOP provides these services through a robust drug education program provided at intake during the admissions and orientation process and through various subsequent drug abuse programs. In 2014, FBOP expanded access to HCV medications available for treatment of inmates to include newly approved sofosbuvir- and simeprevir-based regimens.

OMH promoted continuity of viral hepatitis care and substance use disorder treatment of inmates who were released from incarceration and are reentering the mainstream population through two grant programs, HIRE and Linkage to Life. Both programs support community-based efforts to ensure that people living with HIV, as well as those who are co-infected with HIV and HCV, successfully transition from state or federal incarceration back into communities.

Efforts to reduce HCV transmission associated with injection drug use are also aided by preventing drug use initiation and treating substance use disorders. During 2014, the Federal Government continued to implement the Prescription Drug Abuse Prevention Plan, to help prevent and reduce misuse of prescription medications. The plan focuses actions in four major areas: education of the public and healthcare providers, expansion of prescription drug monitoring programs, proper disposal of unused prescription medication, and enforcement. Efforts also include evidence-based strategies, such as the provision of medication-assisted treatment for individuals with opioid use disorders, implementation of syringe services programs (SSPs) to reduce disease transmission among people who inject drugs and help them access treatment, promotion of access to naloxone to prevent overdose deaths, and integration of screening and treatment services to address the intersection of substance use disorders and viral hepatitis infections.

Advancing research on HCV to better serve PWID. CDC launched a treatment-as-prevention modeling study to assess whether targeted treatment to PWID can have an effect on reducing HCV incidence when combined with evidence-based prevention interventions. The overarching goal of the three-year effort is to collect and use epidemiologic data on risk behaviors, drug use patterns, and injection networks. The data are meant to support the development and implementation of an integrated approach to supporting people through the HCV continuum of care from prevention and screening to treatment among young, non-urban, PWID. CDC awarded a total of \$600,000 in FY2014 to two organizations: University of New Mexico Health Sciences Center (NM) and University of Cincinnati (OH).

In addition to providing hepatitis C virus testing, awardees will provide testing for the presence of HBV and HIV. This research will guide and improve the understanding of patterns of HCV, HBV and HIV in non-urban PWID. This project will develop and provide linkages to appropriate prevention services; care and treatment including access to clinical interventions; harm reduction strategies; drug treatment interventions; and treatment of hepatitis C, hepatitis B, and HIV infection, when warranted. Awardees will assess access to recommended hepatitis C treatment regimens, record the basis for decisions to defer or begin all-oral therapy, and assess hepatitis C infection status at least once during the 12 months following enrollment or completion of all-oral hepatitis C therapy. Rates of hepatitis C infection or re-infection will be evaluated through follow-up assessment.

In 2014, Region VIII's Federal Regional National HIV/AIDS Strategy workgroup — comprised of active members from OMH, OWH, OPA, HRSA, Administration for Community Living (ACL), SAMHSA, Office for Civil Rights (OCR), and outside of HHS with HUD, USDA, and the Social Service Administration — spearheaded an effort with the State Viral Hepatitis Prevention Coordinators from each of the six states in the region, to further explore how to integrate viral hepatitis into regional collaboration. In April 2014, 68 stakeholders from four of the six states met at a day-long meeting in Denver to closely examine the Action Plan's six priority areas and to assess what the region's work in each area has been, the resources available, and the recommendations for future collaboration. From discussions at the forum, participants created a toolkit that was disseminated to approximately 400 contacts throughout the region. Increases in new HCV infections among PWID in specific geographic pockets were identified as an area of concern for many stakeholders. In response, a series of webinars on the alignment of HCV prevention, substance use disorder treatment resources, and harm reduction efforts were developed and launched in early 2015.

NIH undertook a series of activities in 2014 to contribute to the research of substance use and hepatitis.

- ◇ PWID are at high risk of acquiring HIV and/or HCV infection through exposure to blood and other bodily fluids during unsafe injection practices. They also have limited access to HCV care. Engaging PWID in substance use disorder treatment programs reduces viral hepatitis transmission. A recent study showed that providing opioid agonist therapy to young adult injection drug users significantly reduced the incidence of new HCV infections compared to those who received non-opioid forms of treatment.¹
- ◇ NIH's NIDA funds laboratory research on developing improved rapid HCV screening tests. This type of test is useful in outreach settings and when working with PWID, because rates of infection are high and many face barriers to healthcare. Providing rapid testing has been shown to be one strategy to engage PWID in healthcare.²
- ◇ Recent studies have shown that on-site testing, vaccination, and coordinated linkage to care within methadone maintenance treatment programs are feasible and efficacious for identifying, treating, and preventing viral hepatitis transmission; however, widespread implementation of this care model is dependent upon sustainable funding streams.^{3,4}

Using modeling to estimate impact of HCV interventions. FDA Office of Vaccines Research Review researchers have established collaborations with members in academia to develop mathematical models of HCV transmission in PWID. The model uses empirical data from Chicago and can be adapted for populations in other cities. NIH's NIDA research using mathematical modeling of HIV/HCV co-infection is being used to generate evidence to support optimal screening and treatment guidelines.

¹Larney S, G Beckwith C, D Zaller N, T Montague B, Rich J. "Seek, test, treat and retain" for hepatitis C in the United States criminal justice system. *Int J Prison Health*. 2014;10(3):164-171.

²Assoumou SA, Huang W, Horsburgh CR Jr, Drainoni ML, Linas BP. Relationship between hepatitis C clinical testing site and linkage to care. *Open Forum Infect Dis*. 2014;1(1):ofu009.

³Tsui JI, Evans JL, Lum PJ, Hahn JA, Page K. Association of opioid agonist therapy with lower incidence of hepatitis C virus infection in young adult injection drug users. *JAMA Intern Med*. 2014;174(12):1974-1981.

⁴Perlman DC, Jordan AE, McKnight C, Young C, Delucchi KL, Sorensen JL, Des Jarlais DC, Masson CL. Viral hepatitis among drug users in methadone maintenance: associated factors, vaccination outcomes, and interventions. *J Addict Dis*. 2014;33(4):322-331.

PRIORITY 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.

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.

Quality health care is safe health care. Neither patients nor providers should be at risk for acquiring HBV, HCV, or other blood-borne infections during health care encounters. Healthcare interventions, by their very nature, carry a risk of exposure to blood or other contaminated materials. To combat these risks, ongoing efforts to reduce health care-associated transmission of viral hepatitis and ensure safety are critical.

In 2014, the following were among the actions taken by federal partners to protect patients and health workers from health care-associated viral hepatitis:

Expanding our understanding of health care associated HCV risks. CDC completed modeling studies of per-exposure and cumulative risks of HCV transmission by health care providers who tamper with injectable anesthetic opioids. The results of these analyses suggested that many cases of HCV infection from nosocomial outbreaks were attributable to providers tampering with anesthetic opioids; that transmission risk from tampering is substantially higher than from surgery. These findings suggest that existing care and management recommendations and guidelines for providers infected by blood-borne viruses should consider the findings of this model. To reduce the risk of harm to patients from providers who tamper with anaesthetic opioids, the following prevention activities are suggested:

- ◇ Periodic opioid screening of providers,
- ◇ Raising greater awareness among healthcare staff about provider substance abuse and provider diversion of controlled drugs,
- ◇ Educating healthcare staff on how colleagues abusing narcotics might be identified,
- ◇ Adopting computerized dispensing and charting systems to monitor controlled drug access, and
- ◇ Enabling staff recruitment agencies and bodies that credential and license healthcare professionals to verify past criminal history and reports of adverse actions taken by regulatory authorities and employers.¹

Ensuring the safety of the blood supply. NIH conducted a series of research-based activities to support the protection of the blood supply in the U.S. and guard against transfusion-related transmission of viral hepatitis, including the following:

- ◇ Scientists in the NIH Clinical Center’s Department of Transfusion Medicine (DTM) continue to prospectively monitor blood recipients for evidence of post-transfusion hepatitis. This study, designated TRIPS, has now prospectively followed approximately 1,600 blood recipients and has detected zero transmissions of either HBV or HCV. This indicates that current donor screening measures, which include both antibody and nucleic acid testing (NAT) for these agents, are highly effective. Additionally, NIH recently determined that donor prevalence for antibodies to HEV is approximately 16%. Despite this high donor exposure rate, no donors have been found to be HEV RNA positive, and no evidence has been found of HEV transmission to the more than 400 recipients prospectively followed. Thus, HEV blood transmission is a theoretical problem in the U.S., but does not yet reach a threshold that would require routine donor screening.
- ◇ There are at least 15 clinically relevant pathogens that can be transmitted by blood, and in 2014, scientists in the NIH Clinical Center’s DTM worked to develop technology to detect all of them from a single small-volume sample. They explored both Next-Gen Sequencing and micro-array analyses, and the detection of HBV, HCV, and HEV; HAV also possibly will be included in this multi-pathogen approach.
- ◇ In addition to supporting investigator-initiated research on issues related to hepatitis and blood safety, the NIH’s National Heart Lung and Blood Institute (NHLBI) supported the Retrovirus Epidemiology Donor Study — II (REDS-II) and the Recipient Epidemiology and Donor Evaluation Study — III (REDS-III), which continue to find new ways to enhance transfusion safety and the practice of blood banking domestically and internationally. For example, the REDS-II Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors Study

¹Hatia, R. I., Dimitrova, Z., Skums, P., Teo, E. Y.-L. and Teo, C.-G. Nosocomial hepatitis C virus transmission from tampering with injectable anesthetic opioids. *Hepatology*. 2015;62:101-110.

provided updated data for incidence, prevalence, and donor risk factors for known transfusion-transmissible infections (TTI) and demonstrated the feasibility of establishing a nationally-coordinated, representative donor surveillance effort. The REDS-III Blood Donation Rules Opinion Study (BloodDROPS) provided insight into non-compliance with certain current donor deferral policies, the motivations of at-risk individuals who donate, and attitudes and behaviors toward the donation screening process.

Promoting safe organ transplantation. In order to promote transplant patient safety, as of February 1, 2014, HRSA's Organ Procurement and Transplantation Network requires an Organ Procurement Organization (OPO) to use a new [guideline](#) for medical-social evaluation questions to determine if a potential deceased donor is at increased risk for HIV, HBV, or HCV transmission. OPOs must screen all deceased organ donors with Nucleic Acid Testing (NAT) methodology for HCV effective August 10, 2015. Living Donor Recovery Hospitals must also use the new guideline for medical-social evaluation questions to determine if a potential living donor is at increased risk for HIV, HBV, or HCV transmission.

Protecting health care providers from vaccine-preventable viral hepatitis. CDC [analyzed the cost-effectiveness of pre- and post-exposure approaches for ensuring previously vaccinated healthcare personnel are protected from HBV infection](#). Incremental cost-effectiveness ratios may inform healthcare institutions as they determine which approach will be utilized for protecting healthcare personnel. Also in 2014, IHS revised the [Indian Health Manual](#) to provide updated guidance for employee hepatitis B immunization, screening, and prophylaxis.

THE END OF THE BEGINNING

By Ronald Valdiserri, M.D., M.P.H., Deputy Assistant Secretary for Health, Infectious Diseases, and Director, Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Health and Human Services

As reflected in the project highlights described in this report, much was accomplished during 2014 by federal partners to improve our national response to viral hepatitis.

Among those many accomplishments was the updating and release of the Viral Hepatitis Action Plan for 2014—2016. We worked with federal and community partners to develop and broadly disseminate the update of the nation's first comprehensive cross-governmental action plan to combat chronic viral hepatitis in April 2014. Since then, the plan has served as a roadmap for our federal response, as reflected in this progress report.

We also encouraged nonfederal stakeholders to consider using the updated Action Plan as a blueprint for their own activities. Indeed, the updated Action Plan emphasizes that achieving our nation's life-saving viral hepatitis goals will require contributions from partners across all sectors of society. This includes people living with HBV and HCV; clinicians; members of the scientific community; industry representatives; public health and community leaders; colleagues from state, local and federal government; and many, many others. Together, we are helping to break the silence around a public health problem that has too long been neglected.

The potential for progress toward these goals is greater than ever before, as these activities are unfolding during a truly remarkable time in our response to both hepatitis B and hepatitis C. We know more than ever before about how to prevent, diagnose, and treat these diseases—and, in the case of HCV, even how to cure it! So while it is appropriate to acknowledge and celebrate our successes, we must acknowledge that there is a great deal more to be done.

There's a famous quote from Winston Churchill, delivered during the years of the Second World War that, to my mind, describes where we are today with our efforts to confront and respond to viral hepatitis. Prime Minister Churchill reminded the citizens of England, "(Now) this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning."

Truly we are at the "end of the beginning" of our response to viral hepatitis, but important challenges remain:

- ◇ Although we have a highly effective intervention to prevent the perinatal transmission of hepatitis B, there are still close to 1,000 babies born every year in the U.S. who are infected with hepatitis B.
- ◇ Many of us are alarmed by the resurgence of hepatitis C associated with injection drug use arising from America's epidemic of prescription opioid drug abuse.
- ◇ And sadly, far too many people who are chronically infected with hepatitis B or hepatitis C have not yet been diagnosed.

So yes, there is much more work left to do. While we recognize and appreciate the progress achieved in 2014 and the foundation it has laid for our continued work, we won't stop now. I hope readers will join my colleagues and I from across the federal government in re-dedicating themselves to the vision of becoming a nation resolved to combat the silent epidemic of viral hepatitis and achieving the goals of the Viral Hepatitis Action Plan.

APPENDIX A – REFERENCES

PRIORITY AREA 1 - EDUCATING PROVIDERS AND COMMUNITIES TO REDUCE HEALTH DISPARITIES

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PRIORITY AREA 3 – STRENGTHENING SURVEILLANCE TO DETECT VIRAL HEPATITIS TRANSMISSION AND DISEASE

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APPENDIX B – ABBREVIATIONS

AAPCHO	Association of Asian Pacific Community Health Organizations
AAPI	Asian-American and Pacific Islander
AASLD	American Association for the Study of Liver Diseases
ACL	Administration for Community Living (HHS)
Action Plan	Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis
AETC	AIDS Education and Training Center (HRSA)
AHRQ	Agency for Healthcare Research and Quality (HHS)
AI/AN	American Indian/Alaska Native
AMA-PCPI	American Medical Association — Physician Consortium for Performance Improvement
ASTHO	Association of State and Territorial Health Officials
ATTC	Addiction Technology Transfer Center (SAMHSA)
BloodDROPS	REDS-III Blood Donation Rules Opinion Study
BPHC	Bureau of Primary Health Care (HRSA)
CCR	Clinical Case Registries
CDC	Centers for Disease Control and Prevention (HHS)
CDS	clinical decision support
CHeCS	Chronic Hepatitis Cohort Study
CMS	Centers for Medicare & Medicaid Services (HHS)
CSAP	Center for Substance Abuse Prevention (SAMHSA)
CSAT	Center for Substance Abuse Treatment (SAMHSA)
CPD	Office of Community Planning and Development (HUD)
DOJ	U.S. Department of Justice
DTM	Department of Transfusion Medicine (NIH)
DVH	Division of Viral Hepatitis (CDC)
ECQM	electronic Clinical Quality Measures
FBOP	Federal Bureau of Prisons (DOJ)
FDA	Food and Drug Administration (HHS)

HAV	hepatitis A virus
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HDV	hepatitis delta virus
HEV	hepatitis E virus
HHS	U.S. Department of Health and Human Services
HIRE	Health Improvement for Re-entering Ex-offenders Initiative
HIT	health information technology
HRSA	Health Resources and Services Administration (HHS)
HSSR	Health and Social Service Resource
HUD	U.S. Department of Housing and Urban Development
IDSA	Infectious Diseases Society of America
IHS	Indian Health Service (HHS)
IOM	Institute of Medicine
IPT/TA	intervention in-person training and technical assistance
L2L	Linkage to Life
LGBT	Lesbian, Gay, Bisexual and Transgender
MAI-CoC	Minority AIDS Initiative Continuum of Care
MMWR	Morbidity and Mortality Weekly Report
MSM	men who have sex with men
NACCHO	National Association of City and County Health Officials
NACHC	National Association of Community Health Centers
NAIP	National Adult Immunization Plan
NASTAD	National Alliance of State and Territorial AIDS Directors
NAT	Nucleic Acid Testing
NCATS	National Center for Advancing Translational Sciences (NIH)
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NCI	National Cancer Institute (NIH)
NHANES	National Health and Nutrition Examination Survey

NHCHC	National Health Care for the Homeless Council
NHIS	National Health Interview Survey
NHLBI	National Heart Lung and Blood Institute (NIH)
NIAID	National Institute of Allergy and Infectious Diseases (NIH)
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NIH)
NIDA	National Institute on Drug Abuse (NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
NIMHD	National Institute on Minority Health and Health Disparities (NIH)
NIH	National Institutes of Health (HHS)
NVAC	National Vaccine Advisory Committee
NVPO	National Vaccine Program Office (HHS)
OASH	Office of Assistant Secretary for Health (HHS)
OCR	Office for Civil Rights (HHS)
OHAIDP	Office of HIV/AIDS and Infectious Disease Policy (HHS)
OMH	Office of Minority Health (HHS)
ONAP	Office of National AIDS Policy
ONC	Office of the National Coordinator for Health Information Technology
ONDCP	White House Office of National Drug Control Policy
OPA	Office of Population Affairs
OPH	Office of Public Health (VHA)
OPO	Organ Procurement Organization
OSG	Office of the Surgeon General
OTP	Opioid Treatment Program (SAMHSA)
OWH	Office on Women's Health (HHS)
P4C	Partnerships for Care (HRSA)
PEPFAR	President's Emergency Plan for AIDS Relief
PHS	U.S. Public Health Service
PWID	persons who inject drugs
REDS-II	Retrovirus Epidemiology Donor Study-II

REDS-III	Recipient Epidemiology and Donor Evaluation Study – III
RHA	Regional Health Administrator
RRC	Regional Resource Coordinator
SAMHSA	Substance Abuse and Mental Health Services Administration
TTI	transfusion-transmissible infections
USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
VHA	Veterans Health Administration (VA)
VHAC	Viral Hepatitis Action Coalition
VHIG	Viral Hepatitis Implementation Group
VHPC	State Viral Hepatitis Prevent Coordinator
VISN	Veterans Integrated Service Network
VISN HIT	VISN Hepatitis C Innovation Team
WHIAAPI	White House Initiative on Asian Americans and Pacific Islanders