Status Report on the Implementation of the Viral Hepatitis Action Plan

Compiled by the Viral Hepatitis Implementation Group (VHIG)

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BACKGROUND

On May 12, 2011, the U.S. Department of Health and Human Services (HHS) issued *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis* (Viral Hepatitis Action Plan), which outlines actions that will improve the prevention, diagnosis, and treatment of viral hepatitis in the United States. The action plan was a direct response to the January 2010 report from the Institute of Medicine (IOM), "Hepatitis and Liver Cancer." This plan was created by a federal interagency workgroup, convened by Dr. Howard Koh, Assistant Secretary for Health, which was comprised of subject matter experts from various HHS agencies. Critical input into the action plan was also provided by stakeholders from other federal agencies; professional societies; and state, local, and community partners. The actions presented in the Viral Hepatitis Action Plan represent efforts to be undertaken in calendar years 2011, 2012, or 2013. Some of the actions outlined in the Plan can be accomplished by using existing resources through improved coordination and integration, while others are subject to the availability of funds.

Following the Viral Hepatitis Action Plan's release, a Viral Hepatitis Implementation Group (VHIG) was convened and charged to coordinate, support, and oversee activities related to the Action Plan. The VHIG is comprised of representatives from across the HHS and other federal agencies (see Appendix A for the membership list) and is chaired by Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases.

VHIG members compiled the current report in late September 2011 to document the status of recommended actions from the Viral Hepatitis Action Plan, prioritized by their respective agencies for calendar year 2011. The actions listed are either already underway or will be initiated before the end of calendar year 2011. This report is organized by federal agency and the six topic areas outlined in the Viral Hepatitis Action Plan: (1) Educating Providers and Communities to Reduce Health Disparities; (2) Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer; (3) Strengthening Surveillance to Detect Viral Hepatitis Transmission and Disease; (4) Eliminating Transmission of Vaccine-Preventable Viral Hepatitis; (5) Reducing Viral Hepatitis Caused by Drug-Use Behaviors; and (6) Protecting Patients and Workers from Health-Care-Associated Viral Hepatitis. **Please note that the information contained herein was provided by the technical experts who serve on the VHIG and has not gone through official agency clearance. Further, this report is meant to provide a brief summary of current actions rather than a detailed description of each activity.** The VHIG plans to provide periodic status reports on progress.

Top Priorities by Viral Hepatitis Action Plan Topic Area and Agency	
1. EDUCATING PROVIDERS AND COMMUNITIES TO REDUCE HEALTH DISPARITIES	
Agency	**Top Priorities: Examples of Activities Planned or Underway**
Centers for Disease Control and Prevention (CDC)	• Assess medical and health education materials and programs on viral hepatitis and draft plans to improve quality and distribution (1.1.1) (co-led by the Health Resources and Services Administration (HRSA)). – **CDC's Division of Viral Hepatitis (DVH) is expanding provider education through a supplemental cooperative agreement focused on the development of a medical school curriculum and a distance-based learning program for practitioners.** • Leverage Affordable Care Act resources for workforce development to support creation of a viral hepatitis curriculum (1.1.1) (co-led by HRSA). – **Planned for 2012.** • Implement the educational curriculum for viral hepatitis in CDC training programs to educate providers serving priority populations (1.1.2). – **CDC/DVH is participating on the Federal Training Centers Collaboration interagency workgroup with agencies that administer federally funded training center programs**. • Fully integrate the HHS viral hepatitis curriculum within HHS provider training programs and begin to evaluate this activity (1.1.2) (co-led by HRSA). – **CDC/DVH is beginning integration with the development of curriculum and distance based learning tools.** • Work with academic institutions and educational organizations to develop and promulgate standardized viral hepatitis curricula for students in postgraduate medical, dental, nursing, physician's assistant, alternative medicine, and other allied health schools (1.1.3) (co-led by HRSA and the National Institutes of Health (NIH)). – **In June 2010, DVH hosted a meeting at CDC to discuss the priorities for provider education. Participants included representatives from academic societies and other HHS agencies. The discussion will inform the development of the curriculum mentioned above.** • Conduct formative research with populations at risk for hepatitis B virus (HBV) and hepatitis C virus (HCV) infection to understand knowledge, attitudes, and behaviors related to testing, care, and treatment of chronic viral hepatitis (1.2.1). – **CDC/DVH has conducted formative research with populations at risk and is planning additional research of this type.** • Develop a national education campaign and pre-test campaign materials with members of the target audience (1.2.1). – **A national campaign, "Know More Hepatitis," is in development by CDC/DVH.** • Continue to promote May as Hepatitis Awareness Month, including a National Hepatitis Testing Day in the United States, and work with the media to

	communicate timely viral hepatitis messages (1.2.2). – **In 2011, CDC/DVH implemented a Hepatitis Awareness Month plan designed to raise awareness about viral hepatitis. In July, CDC/DVH initiated discussions with partners about the development of a National Hepatitis Testing Day.** • In partnership with the World Health Organization, support and promote July 28 as World Hepatitis Day and work with the media to convey the global and national significance of viral hepatitis (1.2.2). – **CDC implemented World Hepatitis Day activities and events designed to raise awareness about the global burden of viral hepatitis and CDC's global role in combating the disease.**
Federal Bureau of Prisons (BOP)	• Educating providers to reduce health disparities (1). – **Revised hepatitis B & C Clinical Practice Guidelines and are providing educational presentations (CENTRAS) regarding Hepatitis to Health Care Providers, including our Regional Hepatitis Clinical Consultant Pharmacists.** – **Will provide clinical training opportunities to our Regional Hepatitis Clinical Consultant Pharmacists to enhance their knowledgebase and keep current with new medications available on the market to treat hepatitis.** – **Will collaborate with the Department of Veterans Affairs (VA) with regard to appropriate utilization and guidance for the new hepatitis therapies and partnering with their training programs.**
Health Resources and Services Administration (HRSA)	• Assess medical and health education materials and programs on viral hepatitis and draft plans to improve quality and distribution (1.1.1) (co-led by CDC). – **Currently assessing materials and programs. HRSA is committed to sharing medical and health education materials (whether HRSA generated or other) throughout our various programs, grantees, listservs, and more.** – **HRSA's HIV/AIDS Bureau (HAB) has developed a HCV treatment guide for managing co-infected patients and posted it on their website.** • Leverage Affordable Care Act resources for workforce development to support creation of a viral hepatitis curriculum (1.1.1) (co-led by CDC). – **Will participate in curriculum development; contribute content; and/or, most importantly, share the curriculum through our programs, grantees, and listservs.** • Train all health care providers in HHS-sponsored clinical programs to deliver viral hepatitis vaccination, early detection, testing management of alcohol and other cofactors, and treatment (1.1.2). – **AIDS Education Training Centers will continue to provide training to Ryan White CARE providers on hepatitis prevention, care, and treatment.** – **HRSA/HAB is funding 29 sites and an evaluation center in the integration of HCV treatment in to HIV primary care. This includes significant amounts of**

	multidisciplinary team training on HCV treatment. – **Bureau of Primary Health Care (BPHC)/HRSA plans for hepatitis education and training for health centers:** ○ **Distribution of HCV treatment guidelines via all grantees, the Primary Care Association, and the National Cooperative Agreement listserv.** ○ **Placing guidelines on the BPHC technical assistance (TA) Web site.** ○ **A national Webinar on substance abuse (by Center for Integrated Health Solutions (CIHS)).** ○ **A national Webinar on viral hepatitis and behavioral health (by CIHS).** ○ **A cooperative agreement with the Association of Asian Pacific Community Health Organizations (AAPCHO) to address HBV.** • Fully integrate the HHS viral hepatitis curriculum within HHS provider training programs and begin to evaluate this activity (1.1.2) (co-led by CDC). – **HRSA can explore integration opportunities; however, evaluation will be difficult without funding tied to this activity.** • Work with academic institutions and educational organizations to develop and promulgate standardized viral hepatitis curricula for students in postgraduate medical, dental, nursing, physician's assistant, alternative medicine, and other allied health schools (1.1.3) (co-led by CDC and NIH). – **HRSA can disseminate content as previously mentioned through our various programs, grantees, and listservs.**
Indian Health Service (IHS)	• Delivery of effective, culturally fluent hepatitis transmission education for the IHS provider and the American Indian or Alaska Native (AI/AN) service population (1.1.1). – **For the provider audience, IHS has partnered with the Office of Minority Health Resource Center and the Seattle Indian Health Board to develop a training series on integrating HIV and hepatitis services in IHS, Tribal organization, and urban Indian organization (I/T/U) settings.** – **For the AI/AN population audience, IHS is in the process of developing two youth-centered health education programs inclusive of hepatitis prevention messages.**
National Institutes of Health (NIH)	• Work with academic institutions and educational organizations to develop and promulgate standardized viral hepatitis curricula for students in postgraduate medical, dental, nursing, physician's assistant, alternative medicine, and other allied health schools (1.1.3) (co-led by CDC and HRSA). – **To aid in implementing the HHS Viral Hepatitis Action Plan, the NIH convened the Trans-NIH Committee on Viral Hepatitis with representation from all of the relevant Institutes and Centers (ICs). In describing the implementation actions on this and other goals, relevant ICs are cited. Relevant ICs on this goal include the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute on Drug Abuse (NIDA), the National Cancer Institute (NCI), and the National Institute of Allergy and Infectious Diseases (NIAID), with the National Institute on Minority Health and Health Disparities and the**

	Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) in secondary roles. Current activities are educational Web sites and research training grants. – **Future activities may include providing expert advice to inform educational materials related to issues such as viral hepatitis and injecting drug users (IDUs), pregnancy and transmission to infants, and awareness in high school-age youth through such collaborations as NIAID and NIDDK staff working with CDC and HRSA. Additionally, a future workshop may be held by the National Institute on Alcohol Abuse and Alcoholism on determining the interactions of low-moderate alcohol intake levels with HCV and HBV.** – **NIH also has several representatives on the Viral Hepatitis Education Workgroup to coordinate efforts on this and other education-related goals.**
Office of Women's Health (OWH)	• Increase the proportion of persons living with hepatitis B and hepatitis C who know that they are infected and are linked to timely care and treatment (1.2.1). – **Most persons living with HBV and HCV are not aware that they are infected. A national campaign will help raise awareness of these diseases and encourage testing of those at risk.** o **OWH will integrate HBV and HCV prevention education to all OWH HIV/STDs programs and activities.** o **OWH will collaborate with CDC in the promotion of their national Hepatitis awareness campaign.** • Establish and coordinate national and global health events and partnerships to raise public awareness about viral hepatitis (1.2.2). – **Many hard-to-reach communities and populations remain uninformed about various facets of viral hepatitis, including associated adverse health effects, the need for testing and care, and the availability of treatment. Creating viral hepatitis media events and developing targeted, local campaigns to promote these events will raise awareness among those populations most affected by these infections and help attract sources of funding for viral-hepatitis–related initiatives.** o **Since May is also Hepatitis Awareness Month, OWH will integrate hepatitis prevention to National Women's Health Week activities.** o **Display prominently on the OWH Web page awareness and education information on hepatitis during May.** o **Include hepatitis messages to pregnant women in Text4Baby.**
Substance Abuse and Mental Health Services Administration (SAMHSA)	• Integrate a viral hepatitis component into the curricula of all HHS health care provider training programs. Begin implementation of the viral hepatitis educational curriculum in drug treatment centers (e.g., Addiction Technology Transfer Centers) to educate providers serving priority populations (1.1.2). – **The ATTC Network has at least a decade of experience in dealing with viral hepatitis education, training, and workforce development. Continuing education and training efforts are underway to update the viral hepatitis curricula and intensify dissemination and implementation of evidence-based practices among service providers. The Central East and Mountain West ATTCs**

	have taken the leadership role in this regard through provision of an annual conference, outreach competencies, Web-based information, an academic course lecture, and a training manual (see attached listing). • Collaborate with professional, medical, and other organizations to build a workforce capable of providing viral hepatitis prevention, care, and treatment. In collaboration with behavioral, mental health, and social service provider organizations, networks, and groups, develop and disseminate training materials and programs on viral hepatitis prevention, care, and treatment (1.1.3). – **SAMHSA is working to place a greater emphasis on viral hepatitis prevention, intervention, and treatment through the mechanism of TA provided to Block Grant and Discretionary grantees. The Center for Substance Abuse Treatment (CSAT) Division of Pharmacologic Therapies (DPT) will develop a Webinar to inform various stakeholder organizations regarding the necessity of addressing the viral hepatitis epidemic.**
2. IMPROVING TESTING, CARE, AND TREATMENT TO PREVENT LIVER DISEASE AND CANCER	
Agency	**Top Priorities: Examples of Activities Planned or Underway**
Agency for Healthcare Research and Quality (AHRQ)	• Support U.S. Preventive Services Task Force (USPSTF) efforts to update guidelines for hepatitis C testing and treatment (2.1.1). – **An update of the 2004 USPSTF recommendation on screening for infection with HCV is currently underway and will be completed in 2012.** • Develop and implement performance measures for hepatitis testing in HHS-sponsored health programs (e.g., community health centers, IHS clinics, HIV test sites) (2.1.3). – **The AHRQ Effective Health Care Program has undertaken a comparative effectiveness review of *Screening for Hepatitis C Virus Infection in Adults.* Draft key questions were available for public comment from February 14 through March 14, 2011. The protocol is currently under development.** • Evaluate promising models of care to address the unique issues faced by priority populations affected by viral hepatitis (2.4.2). – **The AHRQ Effective Health Care Program has undertaken a comparative effectiveness review of *Adherence to Hepatitis C Treatment Interventions.* Draft key questions were available for public comment from June 27 through July 25, 2011. The protocol is currently under development.** • Support investments in basic, translational, comparative, and effectiveness research to facilitate the discovery and development of effective and well-tolerated treatments for viral hepatitis and related disease resulting from chronic viral hepatitis infection (e.g., hepatocellular carcinoma (HCC)) (2.4.3). – **The AHRQ Effective Health Care Program has undertaken a review of *Comparative Effectiveness of Treatment for Hepatitis C in Adults.* Draft key questions were available for public comment from February 14 through March 14, 2011. The protocol is currently under development.**

CDC	• Revise guidelines for hepatitis C testing and linkage to care and treatment (2.1.1). – **CDC/DVH constituted internal and external workgroups; began a systematic review of prevalence literature; and held a consultation in August 2011 with subject matter experts, community advocates, and other stakeholders.** • Identify strategies to enhance referral to care and treatment for HBV-infected mothers (2.2.2). – **The Perinatal Hepatitis B Prevention Program (PHBPP) coordinators are charged with facilitating the referral of HBV-infected pregnant women for care and treatment. Proposed CDC National Center for Immunization and Respiratory Diseases (NCIRD) Immunization Funding Opportunity Announcement (FOA) requirements for the PHBPP include this "charge" and are pending approval by CDC's Association of Immunization Managers (AIM). CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) is exploring with specialty partners (e.g., the American Association for the Study of Liver Diseases (AASLD), the American Congress of Obstetricians and Gynecologists (ACOG)) the development of guidelines for referral, working to identify providers to accept such referrals and mechanisms to pay for medical services, and increasing efforts to train and educate providers.** • Conduct demonstration projects to guide integration of point-of-care testing for HCV and HIV (2.4.1). – **CDC/DVH has completed lab and field performance evaluations of HCV point-of-care tests and submitted the results for publication, and is prepared to start a demonstration study in HIV testing settings if a Clinical Laboratory Improvement Amendments (CLIA) waiver for the Food and Drug Administration (FDA)-approved point-of-care HCV test is granted.**
HRSA	• Hepatitis C Treatment Expansion Initiative Demonstration Sites (2). – **HRSA/HAB is funding 29 demonstration sites and one TA and evaluation center to develop models of HCV treatment integrated into HIV primary care. Lessons learned will be documented and disseminated at the end of the project and should have applicability to integration of HCV care into primary care for mono-infected patients.** – **HRSA/HAB has developed a guide to models of hepatitis C integration into HIV primary care that exist within currently funded Ryan White CARE programs and have posted this to the HRSA/HAB Web site.** – **HRSA/BPHC primary care infrastructure activities:** ○ **Will continue to promote the Patient-Centered Medical Home to enhance the capacity for effective care coordination and treatment for all chronic diseases, including hepatitis.** ○ **In discussions with CDC and University of New Mexico on ways to use telemedicine and expand Project ECHO (Extension for Community Healthcare Outcomes).**

IHS	• Monitoring and delivering Hepatitis C treatment successfully within I/T/U sites (2). – **IHS is monitoring and delivering Hepatitis C treatment in the I/T/U system through several mechanisms. Outstanding examples include:** ○ **About 20 IHS and tribal sites throughout Alaska are currently utilizing telemedicine networks out of the University of New Mexico (ECHO) and Alaska Native Tribal Health Consortium (ANTHC), LiverConnect, to improve care and treatment of persons living with Hepatitis. The network of telemedicine doctors, nurses and pharmacists builds a strong foundation for care and treatment in I/T/U sites.** ○ **From 10/1/2010 to 10/1/2011, 21 IHS sites in areas outside of Alaska have participated in the ECHO HCV Community Clinic program.** ○ **Patient follow-up procedures, including computerized patient management registries, are in use in Anchorage, Alaska by the local Liver Disease and Hepatitis program. This program, including monitoring chronic Hepatitis B and C patients, is offered in most of the Alaska Tribal Health System service units.** ○ **The ANTHC Liver Disease Hepatitis Program is currently developing and testing performance measures for hepatitis testing relevant to IHS sites.** • Increased hepatitis B screening in the I/T/U system (2). – **There is currently a small pilot program in development to increase hepatitis B screening in remote sites and develop performance measures relevant to the IHS system. This effort is being led by the ANTHC Liver Disease Hepatitis Program located in Anchorage, Alaska.**
NIH	• Support development of point-of-care assays to detect serologic evidence of both exposure to viral hepatitis and active viral hepatitis infection (2.4.1). – **Relevant ICs on the Trans-NIH Committee on Viral Hepatitis include NIDDK and NIAID.** – **Although a rapid-antibody, point-of-care, serologic test for HCV is available (OraQuick®), tests to diagnose acute HCV and distinguish it from chronic disease, as well as rapid screening assays for hepatitis A virus (HAV), HBV, and hepatitis E virus (HEV), would be valuable. The Committee discussed means of encouraging applications in these areas.** • Support investments in basic, translational, comparative, and effectiveness research to facilitate the discovery and development of effective and well-tolerated treatments for viral hepatitis and related disease resulting from chronic viral hepatitis infection (2.4.3). – **Relevant ICs on the Trans-NIH Committee on Viral Hepatitis include NIAID, NIDDK, the National Institute of General Medical Sciences (NIGMS), NCI, and the National Center for Complementary and Alternative Medicines (NCCAM). Several NIH ICs have strong research efforts already in place for viral hepatitis, including both intramural and extramural research programs of NIAID and**

	NIDDK. – **Current activities include basic research supported by NIAID on HBV and HCV and contract resources for *in vitro* and *in vivo* drug screening for HBV and HCV. NIDDK sponsors the Hepatitis B Research Network, which supports clinical research on pathophysiology and treatment strategies, including comparative effectiveness research, as well as strong portfolios in HBV and HCV research and intramural research on therapy for HBV, HCV, and hepatitis D virus (HDV). NIGMS supports basic research on viral infections through a program on biophysics, structural biology, and HIV, which currently includes several grants on developing HCV drugs, targets, and therapeutics. NCI supports basic research on mechanisms of HCC development resulting from HBV and HCV, as well as Specialized Programs of Research Excellence supporting multiproject, interdisciplinary, translational research in Gastrointestinal Cancer including liver cancer. NCI also supports collaborative supplements between HCC and AIDS investigators. NCCAM supports rigorous clinical trials of complementary and alternative medicines, including herbals such as milk thistle, for chronic HCV and other liver diseases.** – **Future activities include plans to support research on alternate targets for HBV treatment, HDV testing and treatment (e.g., IDUs), and HCV vaccine development (e.g., focusing on protective immunity). The NIH is also planning interactive workshops on several topics related to viral hepatitis research. Committee representatives from NIAID, NIDA, NCI, and NIDDK are also developing means of further encouraging applications in these areas.**
SAMHSA	• Implement routine viral hepatitis testing as part of the standard of care in a reformed health care system. Implement HHS-recommended viral hepatitis testing as a standard of care in drug treatment programs (2.1.2). – **SAMHSA is providing guidance to the field and especially to federally funded drug treatment centers regarding the public health imperative represented by the viral hepatitis epidemic. The importance of infusing viral hepatitis testing as a standard of care is also being infused into the SAMHSA's primary care and behavioral health initiatives. SAMHSA will compile data from an inventory of the Opioid Treatment Programs (OTPs) and a representative sample of grantee programs from its discretionary portfolio, to assess and address adherence to the recommendation. DPT is also updating the accreditation guidelines for OTPs that will include a hepatitis testing standard.** • Improve viral hepatitis care and treatment in primary care settings. Develop "brief interventions for alcohol" training and disseminate via federally funded training centers and other partner organizations (2.3.1). – **SAMHSA has developed a major Screening, Brief Intervention, and Referral to Treatment (SBIRT) program over the past 8 years, involving 15 grantees. The program has recently been expanded from a service program to include a medical residency training program involving 17 medical universities. SBIRT principles and guidelines are also actively disseminated by the ATTC Network.**

Department of Veterans Affairs (VA)	• Ensuring access to and proper use of the new FDA-approved HCV direct acting antiviral drugs (DAA) (2). – **Twenty-one percent of Veterans with HCV currently in VA care have previously been treated with antiviral therapy. To ensure the availability of DAAs to patients who have not been treated or who have failed previous treatment, VA has used various models to project demand for DAAs. These models were combined with data from VA's National HCV Clinical Case Registry (CCR), which tracks all Veterans with HCV in VA care (see below), to predict the numbers of patients who will be treated with these new agents. This has allowed VA to project costs and needed capacity to care for these patients. Results from these projections have been used to brief Veterans Health Administration (VHA) leadership. To ensure that our workforce is prepared to properly use these therapies, a large training meeting was held in early September to educate VA HCV providers on prescribing these new agents and managing their side effects.** – **VA is developing national treatment guidelines and criteria for use for DAAs to ensure high quality care is being provided to Veterans with HCV. VA's National Hepatitis C Program Office provides leadership and oversight of VA's HCV care and supports quality improvement initiatives to assure access to high-quality HCV care across the entire VA health care system.** • VA's National Hepatitis C Program Office has established and maintained four Hepatitis C Resource Centers (HCRC) over the last decade (2). – **The VA HCRCs develop patient education materials, provider training products, and effective models of care for dissemination across the VA system. The HCRCs will play a key role in 2012 in educating VA providers about new HCV treatments. Currently, the HCRCs, along with other key program offices in VHA, are deploying telehealth programs, using video teleconferencing in rural areas to improve patient access to HCV care, and deliver training on HCV to primary care providers and to mid-level practitioners in specialty clinics. Using telehealth technology to educate and mentor providers is consistent with the work of Project ECHO in New Mexico.**
3. STRENGTHENING SURVEILLANCE TO DETECT VIRAL HEPATITIS TRANSMISSION AND DISEASE	
Agency	**Top Priorities: Examples of Activities Planned or Underway**
CDC	• Monitor the misclassification of viral hepatitis cases as a quality assurance measure (3.1.1). – **Efforts are ongoing by CDC/DVH to estimate underreporting of viral hepatitis, promote the submission of lab test data with cases reported from states, and revise case report forms.** • Assure state and local health authorities receive timely epidemiologic and laboratory assistance in viral hepatitis outbreak investigation (3.1.1). – **CDC/DVH and CDC's Division of Healthcare Quality Promotion (DHQP) continue to support state outbreak investigations, with numerous "consults" each month. CDC/DVH funded seven state health departments in July 2011 to**

	improve the investigation of recent HCV infections. CDC/DVH has published the outcomes of outbreak investigations in its annual surveillance report. • In collaboration with the Council of State and Territorial Epidemiologists (CSTE) and state and local partners, revise and implement standard reporting criteria for viral hepatitis (3.1.1). – **In June 2011, CDC/DVH and CSTE revised the national case definitions for HBV and HCV.** • Use aggregated EMRs to monitor performance measures of hepatitis testing, care, and treatment and associated health outcomes (3.1.3). – **CDC/DVH has funded five state health departments to begin the integration of electronic laboratory reporting as a component of viral hepatitis case surveillance.** • Create public-private partnerships to establish observational cohort st**u**dies and other evaluations of persons in care for viral hepatitis (3.3.2). – **The CHeCS observational cohort study by CDC/DVH is following 2,500 HBV patients and more than 10,000 HCV patients in four health care organizations with 1,250,000 patients (Hawaii, Oregon, Michigan, and Pennsylvania). Initial papers have been submitted describing rates of testing, identification of HBV and HCV patients, and entry to care.**
HRSA	• Strengthening surveillance to detect viral hepatitis transmission and disease (3). – **HRSA/BPHC activities related to data and surveillance:** ○ **All grantees are reporting on HBV and HCV prevalence among health center patients.** ○ **All grantees are reporting on testing for HBV and HCV among health center patients.**
VA	• In November 2009, VA established an official written policy requiring reflex nucleic acid confirmatory testing for HCV infection on patient specimens that are positive for initial screening for HCV antibodies (3). • The VA Center for Quality Management in Public Health maintains a CCR for all Veterans in VA care with confirmed chronic HCV (3). – **The CCR software is deployed throughout the VA, providing a population health registry at every VHA facility to support local care delivery and a national clinical database. National and local reports are available describing basic demographics, mortality, treatment rates and outcomes, other conditions commonly seen in patients with HCV, and essential quality measures of HCV clinical care, allowing design of targeted interventions to improve care. As an example, VA monitors vaccination against HAV and HBV in HCV-infected Veterans. In fiscal year (FY) 2010, at least 68 percent of chronic HCV patients had been either vaccinated against or immune to HAV and 76 percent for HBV. The National VA HCV CCR has been used to produce a summary report, *The State of Care for Veterans with Hepatitis C,* available on the Internet at http://www.hepatitis.va.gov/provider/policy/HCV-state-of-care-2010.asp.**

	• VA is committed to improving hepatitis B testing and surveillance (3). – **HBV screening guidelines are currently in development and will be promoted to front-line clinicians once finalized. Surveillance efforts for HBV are underway via population-based seroprevalence studies and future access to a new clinical data warehouse that is in development.**
4. ELIMINATING TRANSMISSION OF VACCINE-PREVENTABLE VIRAL HEPATITIS	
Agency	**Top Priorities: Examples of Activities Planned or Underway**
BOP	• Eliminating transmission of vaccine-preventable viral hepatitis (4). – **Will conduct an HAV and HBV vaccine drug use evaluation to be released in December 2011.** – **Will include HBV prevention, testing, and immunization information as part of our drug education program.**
CDC	• Estimate the US and global burden of hepatitis E (4.3.3). – **CDC/DVH and World Health Organization staff have completed the evidence review and have begun data analysis.**
IHS	• Development and delivery of effective vaccination programs (4.3). – **LiverConnect is an educational resource for providers.** – **The *LDHP Patient Newsletter* provides the latest research, latest treatment options, and information on biannual testing drives (liver function tests and viral load).** – **The IHS electronic health record provides clinical decision support for vaccines, including provider reminders for HAV and HBV vaccination for all children and for adults who received a dose prior to 18 years of age. Work is underway to explore the feasibility of developing provider reminders for HAV and HBV vaccination for unvaccinated patients diagnosed with HCV infection and chronic liver disease.**
NIH	• Facilitate development of candidate hepatitis C vaccines designed to induce protective immune responses (4.3.2). – **Relevant ICs on the Trans-NIH Committee on Viral Hepatitis include NIAID, NIDDK, and NIDA. These ICs support a large portfolio in HCV vaccine research relevant to this goal. Future activities include the initiation of a Phase II HCV vaccine trial by NIAID.**
HHS National Vaccine Program Office (NVPO)	• Work with the Institute of Medicine (IOM) to assess the priority for the development of hepatitis C vaccines (4.3.2). – **In response to a request from the NVPO, IOM has convened an ad hoc committee to develop an evidence-based approach and methodology for identifying and prioritizing new preventive vaccines of domestic and global importance. A pre-publication report is expected in March 2012.**
Office of Minority Health (OMH)	• Integrate hepatitis A and B vaccination as a standard of care in comprehensive prevention programs that serve priority populations (4.2.1).

	– **OMH is implementing two HIV/AIDS demonstration programs that serve priority populations. The HIV/AIDS Health Improvement for Re-entering Ex-offenders (HIRE) Initiative serves federal and state reentrants that are living with or at high risk for HIV/AIDS. Current grantees coordinate HIV and Viral Hepatitis Prevention, Counseling, Testing, and Treatment Services. The Linkage to Life (L2L) Health and Social Service Resource Network demonstration program serves families living with HIV/AIDS that are in transition from incarceration and substance abuse treatment. L2L will expand HIV testing and treatment services to include viral hepatitis.**
VA	• VA's National Hepatitis C Program Office supports a Liver Health Initiative through VA's Hepatitis C Resource Centers, with the goal of decreasing transmission of vaccine-preventable viral hepatitis and promoting liver health in Veterans with substance use disorders. – **The Liver Health Initiative is a focused clinician training program aimed at changing clinician behavior in Substance Use Disorder (SUD) Clinics throughout the VA system This program is designed to educate SUD providers about the risk of viral hepatitis in the population whom they serve and to promote liver health and a comprehensive hepatitis prevention program in the Veteran SUD population. In addition, SUD programs are encouraged to provide appropriate vaccination against HAV and HBV and provide appropriate linkage to medical care for HIV and/or hepatitis.** • VA' s National HIV and HCV Programs, Office of Mental Health Services, and Office of Academic Affiliations are developing a HIV/HCV Psychology Postdoctoral Fellowship Program, designed to train clinical psychologists to manage the unique mental health and substance use comorbidities frequently found in patients infected with HIV and/or HCV.
5. REDUCING VIRAL HEPATITIS CAUSED BY DRUG-USE BEHAVIORS	
Agency	**Top Priorities: Examples of Activities Planned or Underway**
BOP	• Reducing viral hepatitis caused by drug-use behaviors (5). – **Collaborated with OMH to provide hepatitis prevention services in community reentry programs.** – **Visited Hope Village Residential Reentry Center (RRC) on May, 31, 2011, in Washington, DC and discussed their partnership with Unity Health. A follow-up meeting with Unity Health took place on June 29, 2011, to discuss access to medical records and continuity of care for inmates transitioning from institution to an RRC and/or community.** – **Added *Viral Hepatitis Prevention, Care, and Treatment*, a one-page educational document, to the Drug Education Program provided to BOP inmates.**

CDC	• Examine patterns of HCV transmission among young IDUs infected with HCV (5.5.2) (co-led by NIH). – **DVH has conducted onsite outbreak investigations in Massachusetts and Wisconsin, and has awarded funds to seven state health departments to improve HCV surveillance and enhance investigation of persons with recent HCV infection.**
NIH	• Examine patterns of HCV transmission among young IDUs infected with HCV (5.5.2) (co-led by CDC). – **Relevant ICs on the Trans-NIH Committee on Viral Hepatitis include NIDA and NICHD. These ICs support research relevant to this goal.**
OMH	• Integrate viral hepatitis prevention services with HIV prevention programs (5.1.2). – **OMH will integrate viral hepatitis prevention services with HIV demonstration prevention programs to include Curbing HIV/AIDS Among High-Risk Minority Youth and Adolescents, Minority Community Partnerships Preventing Risky Behaviors Among College Students, HIRE, and L2L.** • Promote continuity of viral hepatitis care and drug treatment for inmates who are released from incarceration and are reentering the community (5.4.2). – **OMH is implementing the HIRE demonstration program that coordinates HIV and viral hepatitis prevention, counseling, testing, and treatment services.**
OWH	• Promote continuity of viral hepatitis care and drug treatment for inmates who are released from incarceration and are reentering the community (5.4.2). – **Providing viral hepatitis and drug treatment services as a component of community-based correctional reentry programs would promote continuity of care for infected persons and reduce the transmission of viral hepatitis. Include education about hepatitis prevention in the OWH program for incarcerated women reentering their communities.**
SAMHSA	• Integrate viral hepatitis prevention and care services as standard components of substance abuse and treatment programs. Disseminate evidence-based best practices through a new SAMSHA Treatment Improvement Protocol (TIP) to guide integration of drug treatment and hepatitis prevention, care, and treatment (5.1.1). – **TIP 53 on hepatitis and substance abuse treatment has been cleared by SAMHSA for publication. It is scheduled for release in late 2011 or early 2012. Curriculum development based on TIP 53 will follow. A presentation on the evidence base for responding to the viral hepatitis epidemic will be delivered at the 2011 "Keeping It Real" Conference, Central East ATTC and Danya Institute (Silver Spring, October 17, 2011).** – **SAMHSA is in the process of updating OTP national accreditation guidelines to include a hepatitis testing standard. The Administration presently has an active educational project focused at OTP staff.** • Strengthen TA to drug treatment providers to facilitate the integration and effective delivery of viral hepatitis prevention, care, and treatment services (5.1.1).

	– **Division of Pharmacologic Therapies (DPT) will disseminate the HHS Viral Hepatitis Plan, emphasizing SAMHSA's multiple roles, to state Project Officers and Grant Project Officers. DPT will also provide face-to-face and Web-based training to SAMHSA employees and SAMHSA-based contractors during FY 2012.** • Integrate viral hepatitis prevention services with HIV prevention programs. Identify and implement feasible options for integrating viral hepatitis prevention services with HIV prevention activities targeting IDUs and other populations at risk for both viral hepatitis and HIV (e.g., men who have sex with men (MSM)) (5.1.2). – **DPT has entered into discussions with Center for Substance Abuse Prevention (CSAP) representatives regarding inclusion and prioritization of viral hepatitis issues into the Strategic Prevention Framework.** • Strengthen technical assistance and training to help prevention programs integrate viral hepatitis and HIV prevention strategies (5.1.2). – **SAMHSA will conduct a Viral Hepatitis Prevention workshop at the 2012 National Prevention Network conference cosponsored by CSAP and the National Association of State Alcohol and Drug Abuse Directors.** • Coordinating federal, state, and local resources to expand and enhance IDU access to sterile syringes and hepatitis prevention interventions. Increase support for comprehensive and targeted disease-prevention partnerships involving syringe service programs, state and local health departments, other government agencies (e.g., law enforcement), and community representatives (5.2.2). – **Nine Targeted Capacity Expansion and HIV Grantee programs are participating in SSPs:** ○ **Brandywine Counseling, Wilmington, DE** ○ **Illinois Department of Alcohol and Substance Abuse, El Rincon, Chicago, IL** ○ **GBAPP, Bridgeport, CT** ○ **Initiativa Comunitaria, San Juan, PR** ○ **Long Island Association for AIDS Care, Nassau County, NY** ○ **New Jersey AIDS Alliance, Newark, NJ** ○ **Philadelphia Health Management, Philadelphia, PA** ○ **Tapestry Health, Northampton, MA** ○ **University of Illinois at Chicago, Chicago, IL** • Promote integrated care and treatment approaches for the management of viral hepatitis and comorbid health care conditions. Implement SBIRT trainings in community outreach programs to reduce alcohol consumption and decrease the likelihood that former IDUs will resume drug use (5.3.1). – **SAMHSA is connecting SBIRT protocols and practices with Outreach Programs through training and dissemination of curricula such as *Hepatitis C: A Guide for Counselors and Outreach Workers*, an online course.** • Pilot different approaches to preventing persons from returning to injection drug use after successful clearance of HCV infections following antiviral therapy (5.3.1). – **DPT will focus on relapse prevention among IDUs utilizing resources available through its Medical Education and Supporting Services for OTPs TA contract.**

	Activities in FY 2012 will include national and regional training seminars and Webinars. • Enhance drug treatment and viral hepatitis prevention, care, and treatment in correctional programs. Identify best practices to help correctional facilities improve drug treatment programs offering viral hepatitis care and treatment to incarcerated populations (5.4.1). – **Hepatitis best-practice guidelines and protocols appropriate for criminal justice settings, with an emphasis on reentry populations, will be disseminated to CSAT's criminal justice discretionary grantees during FY 2012.** • Develop and implement joint HHS and Department of Justice (DOJ) policies to stimulate and guide development of viral hepatitis prevention, care, and treatment services and those that provide drug treatment in correctional settings (5.4.1). – **DPT will ensure that joint HHS and DOJ policies related to viral hepatitis prevention, care, and treatment are disseminated via the CSAT criminal justice grant portfolio.**
6. PROTECTING PATIENTS AND WORKERS FROM HEALTH-CARE-ASSOCIATED VIRAL HEPATITIS	
Agency	**Top Priorities: Examples of Activities Planned or Underway**
CDC	• Encourage industry to develop reuse prevention equipment and/or devices that indicate prior use of injection equipment (6.1.2). – **CDC, FDA, and the Centers for Medicare & Medicaid Services (CMS) helped organize and participated in an industry meeting on this topic, sponsored by Premier Safety Institute and titled *Safer Designs for Safer Injections: Innovations in Process, Products, and Practices*, (May 24 , 2011, Atlanta, GA). DHQP is engaged in ongoing dialogue with industry partners on this topic in the context of the CDC-led Safe Injections Practices Coalition.** • Expand educational campaigns and infection control and/or regulatory guidance, and use campaigns and materials to promote safe use of syringes and injectable medications (6.1.2). – **The CDC-led Safe Injection Practices Coalition continues to expand implementation of the One and Only Campaign. Examples of new partners promoting safe use messages include the U.S. Air Force, HRSA, and the Institute for Safe Medication Practices. In July 2011, the Safe Injection Practices Coalition also launched a free continuing-education activity for health care providers titled *Unsafe Injection Practices: Outbreaks, Incidents, and Root Causes* on Medscape.** • Enhance provider and purchaser education regarding limiting use of single-dose vials to only one patient to encourage increased uptake of prefilled syringes and "right-sized" medication vials (6.1.3). – **This was promoted among manufacturers, providers and purchasers as part of the Safer Designs for Safer Injections industry partner meeting (see 6.1.2) and as part of ongoing activities relating to the One and Only Campaign.**

	• Identify opportunities to improve infection-control education, and expand requirements for continuing education and related competency certifications for health care providers (6.1.3). – **Policy options relating to infection control education and certification were outlined in a new *CDC and Association of State and Territorial Health Officials Policy Toolkit for Healthcare-Associated Infection Prevention*, (April 1 ,2011 http://www.cdc.gov/HAI/prevent/astho-policy-toolkit.html). DHQP is also inventorying related state-level activities (e.g., recent Nevada law requiring that healthcare providers attest to awareness of and training in CDC safe injection guidelines).** • Engage the affected industries to raise awareness of infection control standards, guidelines, and training needs (6.1.3). – **CDC published the *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*, (2011, http://www.cdc.gov/HAI/pdfs/guidelines/Ambulatory-Care-04-2011.pdf) which specifies infection control standards and training needs. CDC, the Safe Injections Practices Coalition, and other partners have promoted the Guide and accompanying checklist to affected professional groups, health care organizations, and governmental partners.** • Update policies to facilitate implementation of nucleic acid testing for HCV among organ donors (6.2.3) (co-led by CMS). – **The Office of Blood, Tissue and Organ Safety (CDC/DHQP) has drafted PHS Guidelines for Reducing Transmission of HIV, HBV, and HCV Through Solid Organ Transplantation, which are now being submitted for public comment in the Federal Register. The draft guidelines include recommendations for NAT screening of deceased and living donors.** • Identify barriers and develop strategies to address barriers to hepatitis B vaccination among health care workers and trainees (6.3.1). – **CDC/DVH has updated guidelines for HBV vaccination of health care workers (scheduled for publication October 2011) and has initiated policy development to guide the medical management of HBsAg+ health care workers.** • Improve surveillance and prevention of sharps injuries (6.3.2) (co-led by FDA). – **CDC/DHQP published the *Summary Report for Blood and Body Fluid Exposure Data Collected from Participating Healthcare Facilities* (June 1995 through December 2007, http://www.cdc.gov/nhsn/PDFs/NaSH/NaSH-Report-6-2011.pdf) which describes findings from the National Surveillance System for Healthcare Workers. CDC/DHQP is currently supporting and promoting a new Web-based voluntary surveillance system, the National Healthcare Safety Network's Healthcare Personnel Safety Component, to collect information important to the prevention of occupational exposures and infections among health care personnel.** • Release a joint Safety Alert/Advisory recommending the use of blunt surgical deedless for the suturing of fascia (6.3.2) (co-lead by FDA).

	– **Statement under development.** • Link state health-care-associated infection programs to viral hepatitis surveillance programs (6.4.1). – **CDC/DHQP and CDC/DVH have had ongoing discussions to identify opportunities and strategies for linking these programs. Plans are underway to promote interaction between these programs among health-associated infection (HAI) program coordinators during the October 2011 HAI Grantee Meeting.** • Develop and disseminate best practices for the investigation of potential cases of health care-associated viral hepatitis (6.4.1). – **CDC/DVH and CDC/DHQP have drafted a best practices case investigation guide which incorporates feedback from selected health department partners. Next steps include the development of a communications plan for dissemination.** • Commission a study to evaluate purchasing practices of health care facilities to understand the patterns of use that contribute to poor compliance (6.4.2). – **While funding for this specific study has not been identified, CDC has given technical input on a FDA-sponsored study on injectable medication vial labeling that is being conducted by the U.S. Pharmacopeia. In addition, focus groups conducted under auspices of the New York State Department of Health and DHQP have included a hypothesis-generating exploration of purchasing practices among clinicians and clinic managers.** • Conduct site visits and/or focus groups to identify barriers to use of safety devices and single-patient medication vials (6.4.2). – **Focus groups studies funded by CDC/DHQP were conducted in April 2011 and included a hypothesis-generating exploration of barriers to use of safety devices and single-patient medication vials among clinicians and clinic managers. Report from contractor is currently under review.** • Engage stakeholders to improve current practices related to narcotics security (6.4.3). – **The problem of narcotics diversion leading to medication contamination has been identified and the public has been informed. Stakeholder engagement is planned.** • Generate a "best-practices" document outlining recommended steps for investigation and management when diversion is suspected (6.4.3). – **This activity is projected for 2012, subject to resource availability.**
Food and Drug Administration (FDA)	• Issue a Draft Guidance for Industry on the reprocessing of reusable medical devices in health care settings that addresses the validation of device cleaning, disinfection, and sterilization (6.1.1). – **Issued draft guidance on May 2, 2011.** – **Created a reprocessing Web site.**

	– **Held a public workshop on June 8–9, 2011.** – **A joint Association for the Advancement of Medical Instrumentation and FDA summit, *Medical Device Reprocessing: Reducing Hospital-Related Infections and Readmissions*, will be held at the White Oak campus in Silver Spring, MD, on October 11–12, 2011.** • Review and take necessary action on the regulatory status of blood lancets (6.1.1). – **Issued a guidance on blood lancet labeling on November 29, 2010.** – **Additional review in progress; hope for completion by the end of 2011.** • In collaboration with U.S. Pharmacopeia, revise label content for medication vials (6.1.2). – **FDA is reviewing product labeling for safety with respect to risks of hepatitis transmission for additional products such as pharmacy bulk packs.**
NIH	• Support clinical trials to explore the safety and efficacy of technologies currently being used in other parts of the world (6.4.4). – **Relevant ICs on the Trans-NIH Committee on Viral Hepatitis include NIDA, NHLBI, and the NIH Clinical Center. NIDA and NHLBI currently support research in this area, including a NIDA-sponsored study in Australia and NHLBI-supported studies for prevention of transfusion-transmissible infections including viral hepatitis. The REDS III program and its predecessor REDS II will continue to support research to evaluate and prevent transfusion-transmissible infections including viral hepatitis.** • Support grants to promote the development of new processing technologies (6.4.4). – **Relevant ICs on the Trans-NIH Committee on Viral Hepatitis include NHLBI and the NIH Clinical Center. The NHLBI supports the development of tests for improved or broad detection of transfusion-transmissible infections including viral hepatitis.** – **In the future, NHLBI is interested in supporting R01s targeting pathogen inactivation. Continuing research support is also provided through SBIR and STTR grants to test development for transfusion-transmissible infections including viral hepatitis. The Committee discussed other means of encouraging applications in these areas.**
ACTIONS IN RESPONSE TO THE OVERALL MISSION OF THE VIRAL HEPATITIS ACTION PLAN	
Agency	**Top Priorities: Examples of Activities Planned or Underway**
HHS Office of the Surgeon General (OSG)	• OSG can act as a platform for Action Plan activities, particularly those that overlap with other national plans such as the National Prevention Strategy. Perhaps the implementation workgroup could discuss what issues or projects from the Action Plan we would like OSG to promote.
White House Initiative on Asian Americans and Pacific Islanders (AAPI)	• Prevention and control of HBV is one of the four priority goals in the HHS agency plan for AAPI. The HHS agency plan was submitted to the White House initiative on AAPI.

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