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HHS Action Plan on Viral Hepatitis 2010

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Introduction

Developed by the Hepatitis Interagency Working Group Subcommittee, this action plan describes opportunities for HHS to respond to the recent Institute of Medicine (IOM) review of viral hepatitis prevention and build the capacity and internal and external collaborations essential for reducing the number of incident viral hepatitis infections and ameliorating the health and economic consequences of viral hepatitis among persons chronically infected. To adequately address topic areas specified by IOM, the Working Group convened separate HHS expert panels, each with two co-chairs, and tasked them with developing action plans. The inclusive plans, which reflect not only feedback from subject matter experts but input from the community, will help HHS improve its existing efforts to prevent viral hepatitis and related disease in at least three ways. First, the action plan will establish priorities for the specific actions that must be taken, and assign lead and partner agencies with responsibility for meeting these priorities. Secondly, the action plan will help HHS build prevention and care capacity and improve the efficiency of current efforts through improved coordination of viral hepatitis activities across HHS operating divisions. Finally, the action plan will serve as a guide for HHS to engage other governmental agencies and nongovernmental organizations in viral hepatitis prevention and care. The HHS viral hepatitis action plan is organized by the following six topic areas, which correspond to IOM recommendations: 1) increasing community awareness and provider education; 2) strengthening surveillance for viral hepatitis; 3) preventing viral hepatitis associated with injection-drug use; 4) preventing viral hepatitis transmission through vaccination; 5) preventing health-care associated viral hepatitis; and 6) improving screening, care, and treatment for viral hepatitis. Additionally, because other forms of viral hepatitis cause severe morbidity and mortality, the plan also

incorporates HHS activities directed to the prevention of these agents. Each topic area is comprised of a table outlining recommended initiatives, goals, and actions, along with a brief background section that provides context and rationale for these activities. Tables for each topic area also specify the HHS agencies that ideally will serve as lead or collaborating partners to carry out recommended actions in an immediate (2012) or long-term (2015) timeframe.

Background

Viral hepatitis is a silent epidemic in the United States. Although it is the 4th leading infectious cause of death, the disease is virtually unknown to health-care providers, the general public, at-risk populations, and policymakers (1-3). Americans with viral hepatitis are at increased risk for liver cancer and chronic liver disease -- viral hepatitis is a major cause of liver cirrhosis and liver cancer in the United States (1-4). Despite these statistics, an estimated 70% of persons with chronic viral hepatitis do not know that they are infected; without this information, these persons cannot receive the care and services needed to reduce the risk of exposing family members and other close contacts to the virus and to improve their own health outcomes (1). In the absence of appropriate treatment, 15-40% of infected persons will develop liver cirrhosis (5, 6 8). Viral hepatitis is the leading cause of liver transplantation in the United States Brown, 2005 (7).

Liver cancer and other liver disease caused by HBV and HCV infection affect some populations more than others, resulting in substantial health disparities. For example, liver cancer (which in its advanced stages has a 5-year survival rate of <5%) is twice as common in African Americans as in whites (4). In contrast to other types of cancer, liver cancer rates have tripled over the last several decades, magnifying the problem in those populations most affected. The most recent liver cancer surveillance data indicate that long-term liver cancer incidence is increasing in the U.S., with an average annual percentage change in incidence between 2001 and 2006 of 3.5% per year (4).

Because of the high costs of end-stage treatments (e.g., liver transplants), the lifetime health-care costs for a person with viral hepatitis can easily total hundreds of thousands of dollars (1). Computer models indicate that cases of life-threatening liver disease caused by viral hepatitis infections will increase as infected persons grow older and as their disease progresses (1, 2). Viral hepatitis causes 12,000-15,000 deaths per year (1, 2, and 8). In the next 10 years, more than 150,000 people in this country will die from liver cancer or end-stage liver disease associated with HBV and HCV (1). The costs, including those incurred from increased medical expenses and reduced productivity also will rise.

Viral hepatitis in the United States reflects large pandemics. Worldwide, 480 million to 540 million persons are living with chronic viral hepatitis, with 350 million to 370 million infected with HBV and 130 million to 170 million infected with HCV (9-11). All told, chronic viral hepatitis afflicts about 1 in every 12 persons worldwide. About 54,000 persons with chronic hepatitis B infections immigrate to the U.S. annually (CDC, unpublished data). Chronic hepatitis causes considerable morbidity. Globally, an estimated 78% of primary liver cancer and 57% of liver cirrhosis are caused by chronic viral hepatitis (10). One million deaths from viral hepatitis occur each year (9, 10). Liver cancer is the fourth -leading cause of death from cancer worldwide, the third -leading cause among men (4).

The changing epidemiology of viral hepatitis in the United States

The epidemiology of viral hepatitis in the United States continually evolves reflecting population changes and the impact of prevention measures. New populations at risk for viral hepatitis infections have emerged, along with new focus areas and opportunities for prevention. New HBV and HCV infections add to the burden of chronic viral hepatitis and liver disease. In 2007, there were an estimated 43,000 new cases of HBV infection (12). HBV is spread from mother to child at

the time of birth, among household contacts through incidental blood exposures in the home, through injection drug use, and through sexual contact (2, 13, 14). Viral hepatitis transmission should never occur as a result of health care delivery, but outbreaks have been documented in a variety of residential care and health care settings when providers have failed to follow basic infection control practices (15). Rates of HBV infection are highest among adults, reflecting low hepatitis B vaccination coverage among persons with risks such as injection drug use and multiple sexual partners (2,13,14). Prevention of mother-to-child transmission is critical, as 90% of HBV-infected newborns remain infected, and about 1 in 4 die from complications of chronic viral hepatitis in later life (17,18).

Surveillance data suggest nearly 20,000 persons are newly infected with HCV annually in the United States (12). A blood-borne infection, HCV is primarily spread through injection drug use (1,2,19,20). Transmission also occurs in health care settings as a result of unacceptable lapses in infection control, primarily related to the misuse of syringes and medication vials (15). Non-injecting drug users who snort cocaine and other drugs also have elevated risks for HCV, possibly from blood exposure associated with intranasal use (2, 19,20). Perhaps typically thought of as an urban disease, HCV transmission has been detected among young drug users in suburban and rural communities (21). In certain circumstances, HCV can be transmitted sexually and at the time of birth. After reports from Europe for several years, sexual transmission of HCV has been detected among U.S. cohorts of HIV-infected men who have sex with men (MSM) (2).

Although acute disease contributes to the health impact of hepatitis in the United States, most morbidity and mortality is the result of chronic viral hepatitis caused by HBV and HCV infection. The IOM estimates that 3.5-- 5.3 Americans are chronically infected with HCV (1). Baby boomers (i.e., persons 46--64 years of age), African Americans, and Asian Americans have substantially higher rates of viral hepatitis than the overall population; more than 1 in 33 baby boomers are

infected with viral hepatitis (22) Compared with white Americans, rates of HBV and HCV are even higher among most racial and ethnic minorities (1,2, 5-8, 14, 19, 20). For example, one in seven African American men in their 40s is living with HCV (22). Approximately 1 in 12 Asian Americans are living with HBV, and more than 50% of the people in the United States with HBV are Asian Americans (1, 2, 14). Cases of HIV and HBV or HCV co-infection reflect shared modes of transmission and infection with multiple viruses increases risks for cirrhosis or liver cancer. Approximately one third of persons with HIV infection are co-infected with HBV or HCV; HIV infection accelerates the progression of HCV infection to liver disease, placing co-infected persons at disproportionate risk for liver-related health problems (1-3, 6, 19, 20). HCV has emerged as one of the leading causes of death among persons with HIV (1, 2).

Although HBV and HCV are the major causes of viral-hepatitis-related mortality, at least three other forms of viral hepatitis can cause disease in the United States: hepatitis A virus (HAV), hepatitis D virus (HDV), and hepatitis E virus (HEV) (2). Spread by the fecal-oral route, HAV spread is largely associated with person-person contact and exposures to contaminated food and food products; disease severity is age dependent – older adults with hepatitis A have the highest risk of severe illness and death (24,25). Populations of adults with certain behavioral (e.g., MSM, IDU) and travel characteristics are at increased risk for hepatitis A (25). Fortunately, availability of hepatitis A vaccine and implementation of national recommendations to vaccinate all children against this virus have resulted in substantial declines in the incidence of hepatitis A (25). However, barriers (e.g. cost, provider awareness) to hepatitis A vaccination have resulted in low rates of vaccination coverage among high-risk adults (24). HEV, which also is spread by the fecal-oral route, is associated with large water-borne outbreaks, particularly those occurring in south and central Asia, sub-Saharan Africa, and the Middle East (26). The risk of mortality from hepatitis E is highest for pregnant women. Although clinical cases of HEV infection are rare in the United

States, serologic surveys suggest that a substantial number of persons have evidence of past exposures to HEV (27). Previously thought to cause only acute disease, chronic Hepatitis E was recently described among organ transplant recipients (26). Clinical trials have shown candidate hepatitis E vaccines to be safe and effective raising the possibility that will hepatitis E will become a vaccine preventable disease. HDV can only replicate in the presence of HBV, and therefore is only infectious among persons who have both types of infection (2, 28). Dual HBV-HDV infection occurs worldwide, including in the United States, and is associated with more severe and rapidly progressive hepatitis than HBV infection alone. Recent studies suggest that HBV-HDV infection continues to be a persistent but underappreciated cause of hepatitis among risk populations, particularly injection-drug users (IDUs) (2, 28).

Developing new science and tools for prevention, care, and treatment

Recent developments in many health-related areas can potentially contribute to lower rates of incident and chronic hepatitis virus in the United States and improve health outcomes for infected persons. For instance, the development of new medical technologies and therapies represents opportunities to improve the effectiveness of viral hepatitis prevention, care, and treatment; vaccine manufacturers currently are developing new and improved vaccines, and new, rapid point-of-care tests HCV can potentially increase access to HCV screening for hard-to-reach populations and foster integration with HIV prevention programs. The broader adoption of electronic medical records can be used to improve the quality of disease surveillance. In addition, progress is being made in the areas of information technology and communication, creating new options for reaching health-care providers and communities experiencing health disparities. Advances in treatment and care also are being made. Current treatments can halt or even reverse the liver damage caused by viral hepatitis. However, new treatments for Hepatitis C on the immediate

horizon hold even greater promise for a virologic cure. These advances can result in better health outcomes for patients and increase the importance of screening and testing as tools for identifying persons with chronic viral hepatitis and linking them to effective care and treatment services. Finally, policy changes will affect the incidence of hepatitis in the United States. For instance, recent changes in policies permitting federal support of syringe assistance programs are expected to have a positive effect on reducing the injecting-drug use behaviors associated with the transmission of HCV. Early diagnosis is beneficial in helping persons receive the care needed to protect their livers from further harm and learning how to avoid transmission to others.

Changing access to and delivery of health care

The Affordable Care Act (ACA) supports expanded access to health-care, requires certain prevention services to be covered by health insurance plans without co-payments, and provides funds to support community prevention programs. The ACA also increases resources for prevention research to develop recommendations for preventive services based on scientific evidence of effectiveness. New funding for comparative effectiveness research and public health investments in prevention holds great promise for implementing proven interventions (e.g., adult vaccination and screening) to prevent viral hepatitis and related liver disease and liver cancer. This HHS hepatitis action plan will leverage these new funding opportunities and define the synergy needed for HHS agencies to collaborate in setting recommendations for viral hepatitis prevention and care recommendations. Furthermore, the HHS action plan can be used to strengthen partnerships with federal, professional and patient organizations in efforts to set and implement those policies that guide public health and clinical practice (e.g., the Agency for Healthcare Research and Quality [AHRQ]), National Quality Forum [NQF], Advisory Committee for Immunization Practices, [ACIP], U.S. Preventive Services Task Force [USPSTF], American

Diabetes Association [ADA], American Cancer Society [ACS], and Centers for Medicaid and Medicare Services [CMS]).

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Educating Providers and Transforming Communities to Reduce Health Disparities

Educating Providers and Transforming Communities

to Reduce Health Disparities

Every year, approximately 15,000 Americans die from liver disease associated with viral hepatitis, and another 85,000 become newly infected. In addition, an estimated 4.5 million people are living with chronic hepatitis B or hepatitis C in the United States (1 – 3). These data recently prompted the Institute of Medicine (IOM) to issue a report in January 2010 titled, "Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C," in which the Institute identified critical factors that contribute to this unnecessary burden of disease. Among the many startling findings associated with viral hepatitis, IOM found that viral-hepatitis-related knowledge is low among both health-care providers and members of the communities they serve (4).

Reducing the health disparities caused by both acute and chronic viral hepatitis in the United States will require providers at all levels of the health-care system to become more educated and aware of opportunities for prevention, screening, and treatment. Unfortunately, these opportunities are being missed on a daily basis: patients with risk factors for viral hepatitis fail to receive adequate risk factor assessment, screening, vaccination, clinical testing, and treatment despite seeking medical treatment from their providers (5 – 8). These missed opportunities lead to needlessly low vaccination coverage, avoidable viral hepatitis infections, and avoidable chronic liver disease and death. Since research has shown that the opinion of a medical provider is one of the strongest motivators for a patient to accept an intervention or change behaviors (9), increasing provider awareness of viral hepatitis will play a pivotal role in reducing health disparities. To be effective,

provider education should be initiated as early as possible, including as part of medical and other health- professional school curricula.

The state of provider knowledge was reviewed in the 2010 IOM report. IOM found that many providers remain uninformed about prevalence and incidence of viral hepatitis in the general U.S. population and in specific risk populations; risk factors for these infections (most notably the strong association between injection-drug use and hepatitis C virus infection and between Asian/Pacific Islander race and hepatitis B virus infection); prevention (including both vaccination and behavior modification to reduce risk for transmission in populations at risk); screening; the clinical course of chronic viral hepatitis; interpretation of test results; and treatment of chronic infection (4). In addition, as shown by continuing cases of health-care-acquired hepatitis infections, providers may need additional information regarding the infection-control practices that are integral to the prevention of hepatitis in health-care settings (10-16). Increased provider knowledge has been shown to improve delivery of preventive services, including those for viral hepatitis (17 - 19). The importance of provider knowledge will only increase in the coming era of improved therapies for chronic viral hepatitis, particularly hepatitis C. As therapy becomes more widely available and better tolerated, demand for screening and treatment services will increase, making the presence of a well-informed health-care provider workforce even more important.

HHS has many existing resources for education, including HRSA's AIDS Education and Training Centers (AETCs), CDC's National Network of STD/HIV Prevention Training Centers (NNPTCs), and SAMHSA's Addiction Technology Transfer Centers (AATCs). These resources can be employed to improve provider education regarding viral hepatitis. In addition, substantial

resources are offered by medical professional societies, which have a pre-existing infrastructure in place for continuing education, including credentialing and re-credentialing.

Increasing the quality of hepatitis care in the United States will require a strategy that recognizes the wide diversity of patients at risk for both acute and chronic viral hepatitis infections. These diverse patients are cared for by a wide range of clinical care providers, from community health representatives in remote Alaskan villages, to drug-treatment providers in inner cities, to primary care providers treating recent immigrants from Southeast Asia. To be effective, any plan to improve provider education must encompass all of these diverse health-care providers. (20)

Several studies have assessed awareness and knowledge about hepatitis B, particularly among various Asian/Pacific Islander (API) subpopulations (e.g.,Vietnamese, Cambodian, Korean, and Chinese Americans); these studies demonstrated similar results across these diverse groups (21-26). One study of Chinese Americans found that up to 61% were unaware that chronic hepatitis B is typically asymptomatic, and 46% believed that a curative treatment is available for this infection (26). Another study of Vietnamese Americans found that 70% were unaware that Asian Americans are at high risk for chronic hepatitis B (21), and most were uninformed about how the disease is spread (27-29). Several studies estimated that rates of testing among different sub-groups ranged from 10%--50% (30-31), and that up to two thirds of Asians are unaware of their infection status (32). Although these studies have helped elucidate the level of hepatitis B-related knowledge among several API groups, additional studies are needed to assess awareness and knowledge among other populations at risk (e.g., Saharan Africans).

An estimated 3.2 million Americans are infected with chronic hepatitis C in the United States, yet studies indicate that knowledge and awareness of this disease among the public is surprisingly low.

Most of the studies have focused on IDUs; however, the limited literature available for other populations (e.g., the general population, veterans, and physicians) also suggests that knowledge about this disease is poor. In a survey commissioned by the American Gastroenterological Association, 42% of participants were unaware how hepatitis C was transmitted; 34% were unaware of treatment options; 30% of believed hepatitis C to be a disease that only affects drug addicts and adults engaging in unhealthy lifestyles and behaviors; and 12% believed that "people like themselves" do not become infected with diseases like hepatitis C (33). High stigmatization of those infected has also been found among focus-group participants in CDC sponsored research (Jorgensen, unpublished data, 2010).

As noted by the IOM, hepatitis education programs have rarely been evaluated with the rigor needed to contribute to the evidence base about effective interventions. IOM found no research that demonstrated an improvement in knowledge about hepatitis B after the implementation of a targeted, evidence-based educational program. IOM also discovered that most of the programs involving risk reduction and hepatitis C were geared towards reducing risk behaviors in IDUs (4); as a result, IOM specifically recommends the development and implementation of national education campaigns to educate the general public and at-risk populations about hepatitis B and hepatitis C.

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Initiative 1. Through education, develop a health-care workforce in the United States that is better able to diagnose, prevent, and treat viral hepatitis.

Goals and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)

Goal: **1a.** Develop and disseminate materials for provider education after consultation from participating agencies and partners. ***Rationale:*** Provider education on viral hepatitis prevention, risk assessment, screening, and treatment needs to be standardized in the United States to reduce regional, racial, ethnic, and other health disparities.	***Lead Agency:*** CDC ***Participating Agencies:*** NIH, HRSA, SAMHSA, and IHS	-Lead the development of professional education materials addressing (at a minimum) 1) viral hepatitis prevalence and incidence; 2) risk factors for viral hepatitis infection (including foreign-born populations for hepatitis B and IDU and incarcerated persons for hepatitis C); 3) viral hepatitis prevention, including vaccination; 4) laboratory testing for viral hepatitis; 5) transmission of viral hepatitis in health-care settings; 6) reducing stigma associated with viral hepatitis infection; 7) health disparities associated with viral hepatitis infection; and 8) treatment of viral hepatitis. -Create funding opportunities to award grants to organizations involved in professional medical education with the goal of enhancing viral hepatitis prevention and control. -Disseminate developed materials.	2012 (modify thereafter as needed)
Goal: **1b.** Expand the viral hepatitis education components of the AIDS Education and Training Centers (AETCs).	***Lead Agency:*** HRSA ***Participating Agencies:*** CDC and SAMHSA	-Use the materials developed for the overall provider education program as the basis for development of the expanded AETC program.	2012 (ongoing)

Rationale: HIV and viral hepatitis share risk factors, and providers seeing patients at risk for or infected with HIV are seeing patients at risk for or infected with viral hepatitis. Increased knowledge of viral hepatitis among HIV- and primary-care providers will decrease health disparities.			
Goal: **1c.** Expand the viral hepatitis education components of the National Network of STD/HIV Prevention Training Centers (NNPTCs). ***Rationale:*** HIV and STD infection share risk factors with viral hepatitis. Therefore, prevention activities for HIV and STDs overlap with viral hepatitis prevention activities. These educational components will be more effective at reducing health disparities if they are integrated.	***Lead Agency:*** CDC ***Participating Agency:*** HRSA	-Use the materials developed for the overall provider education program as the basis for development of the expanded NNPTC program.	2012 (ongoing)
Goal: **1d.** Expand the viral hepatitis education components of SAMHSA's Addiction Technology Transfer Centers (AATCs). ***Rationale:*** The AATCs are in a unique position to increase the capacity of providers in behavioral health (including those working with substance abuse prevention and	***Lead Agency:*** SAMHSA ***Participating Agencies:*** CDC and HRSA	-Use the materials developed for the overall provider education program as the basis for development of the expanded AATC program.	2012 (ongoing)

treatment programs) to perform viral hepatitis prevention, risk assessment, and screening.			

Initiative 2. Develop partnerships with professional and medical organizations and other key stakeholders to incorporate content and training related to chronic viral hepatitis into initial and continuing health education.

Goals and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)

Goal: **2a**. Work with primary-care provider organizations to develop training programs to improve primary providers' ability to perform viral hepatitis prevention, risk assessment, screening, and treatment. ***Rationale:*** The capacity of specialty physicians in the United States (chiefly gastroenterologists) to treat viral hepatitis is inadequate, based on the estimated number of patients and the number and geographic distribution of providers. As more and more viral hepatitis infections are identified, more and more of the burden of viral hepatitis care will fall upon primary-care physicians. Working with provider organizations (e.g., the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, and the American College of Obstetrics and Gynecology) will ensure that the members of these groups are capable of providing appropriate care.	***Lead Agency:*** CDC ***Participating Agencies*:** CDC, IHS, HRSA, ACF, and AOA	-Use the materials developed for the overall provider education program as the basis for primary-care provider training programs. -In collaboration with primary-care provider organizations, explore the use of new electronic media in increasing capacity of primary-care providers to deliver viral hepatitis care. -In collaboration with primary-care provider organizations, explore the use of techniques such as automated vaccination and other reminders in electronic health record (EHR) systems to improve delivery of viral hepatitis care. -State and local health departments to participate in local provider education, in particular in areas with large Asian populations, in order to tailor messaging to local conditions.	2012 (1 - 2 years)
Goal: **2b.** Work with providers of behavioral health, substance abuse prevention and treatment services, addiction medicine, mental health, and	***Lead Agency:*** SAMHSA ***Participating Agencies:*** CDC and HRSA	-Use the materials developed for the overall provider education program as the basis for training programs for providers of behavioral health,	2012 (ongoing)

alternative care to develop training programs to improve these providers' ability to perform viral hepatitis prevention, risk assessment, and screening. ***Rationale:*** Because viral hepatitis is associated with behavioral risk factors and because hepatitis C in particular is so strongly associated with IDU, reducing health disparities associated with viral hepatitis will require the full and enthusiastic participation of providers of behavioral-health and substance-abuse care.		substance abuse prevention and treatment services, addiction medicine, mental health, and alternative care.	
Goal: **2c**. Work with social-service providers, especially immigrant services to Asian populations, to increase their ability to refer patients to appropriate medical care settings for hepatitis B prevention, screening, and treatment services. ***Rationale:*** Because of the continued disparate impact of hepatitis B in Asian immigrant communities, reducing health disparities will require educating providers of immigrant services, who may be the first to interact with new Asian immigrants who may be unaware that they are infected with hepatitis B.	***Lead Agency***: CDC ***Participating Agencies***: ACF, AOA, and HRSA	-Use the materials developed for the overall provider education program as the basis for training programs for social-service providers, especially those providing immigrant services to Asian populations.	2012 (ongoing)
Goal: **2d.**Work with specialty	***Lead Agency:*** NIH	-Use the materials developed for the overall provider	2012 (1 year)

organizations to develop and promulgate standardized guidelines for viral hepatitis treatment. ***Rationale:*** Both primary- and specialty-care providers face challenges in making viral hepatitis treatment decisions because of the diversity of treatment guidelines available. With new treatments for both hepatitis B and hepatitis C expected in the near future, standardizing guidelines will become even more important. To reduce health disparities in access to and quality of hepatitis B and C treatment, treatment recommendations will need to be standardized in the United States. Collaboration involving public health agencies and professional organizations (e.g., the American Association for the Study of Liver Diseases, the American College of Gastroenterology, and the American Gastroenterological Association) will help ensure that their members are able to deliver consistent and effective care to all Americans.	***Participating Agencies***: CDC, HRSA, IHS, and CMS	education program, along with active communication with specialty organizations, as the basis for development and promulgation of standardized guidelines for viral hepatitis treatment.	
Goal: **2e.** Work with educational organizations to develop and promulgate standardized viral hepatitis curricula for students in medical, dental, nursing, physician's assistant, alternative medicine, and other allied health schools.	***Lead Agency:*** CDC ***Participating Agencies****:* NIH and HRSA	-Use the materials developed for the overall provider education program as the basis for developing, with educational organizations, standardized viral hepatitis curricula.	2012 (modify thereafter as needed)

Rationale: The current evidence suggests that providers in the United States are insufficiently informed regarding viral hepatitis prevention, risk assessment, screening, and treatment. In addition to the measures intended to increase the viral hepatitis knowledge base of providers already practicing, efforts are needed to increase providers' knowledge of viral hepatitis earlier in their careers.			

Initiative 3. Decrease health disparities of those infected, but unaware that they have chronic hepatitis B infection by increasing early identification, referral, and treatment

Goals and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **3a**. Develop and implement a national education campaign designed to increase awareness about hepatitis B, educate the public about risk factors, and encourage testing of those at risk. ***Rationale:*** Most persons living with chronic hepatitis B are not aware they are infected. A national campaign will help raise awareness of the disease and encourage	***Lead Agency****:* CDC ***Participating Agencies****:* OMH, HRSA, and IHS	-Develop a communications plan and award a communication contract to implement the plan. -Coordinate consultation from participating agencies and partners in the planning and implementation of the national campaign.	2013 (2--4 years)

testing of those at risk.			
Goal: **3b.** Provide funding to state, local, and tribal health departments and other organizations to develop targeted outreach programs. ***Rationale:*** Organizations at the state and local level are best suited to provide outreach and support to complement a national campaign.	***Lead Agency:*** CDC ***Participating Agencies:*** OMH, IHS, and HRSA	-Create funding opportunities to award community grants designed to reach specific at-risk populations with culturally sensitive and linguistically appropriate evidence-based interventions.	2012 (5 years)

Initiative 4. Decease health disparities of those infected, but unaware that they have chronic hepatitis C infection by increasing early identification, referral, and treatment.

Goals and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **4a**. Develop and implement a national education campaign designed to increase awareness about hepatitis C, educate the public about risk factors, and encourage testing of those at risk. ***Rationale:*** An estimated three fourths of those living with chronic hepatitis C are not aware they are infected. A national	***Lead Agency:*** CDC ***Participating Agencies:*** OMH, HRSA, and IHS	-Develop a communications plan and award a communication contract to implement the plan. -Coordinate consultation from participating agencies and partners in the planning and implementation of the national campaign.	2013 (2-4 years)

campaign will help raise awareness of the disease and encourage testing of those at risk.			
Goal: **4b.** Provide funding to national, regional, and local organizations able reach specific populations at risk for HCV infection. ***Rationale:*** Specialized organizations at all levels may provide a complimentary piece to a national campaign and be best able to reach specific audience segments at risk for hepatitis C. This could include organizations serving ethnic minorities or organizations with specific missions (e.g., those serving HIV-infected persons, baby boomers, or others at risk).	***Lead Agency:*** CDC ***Participating Agencies:*** OMH and IHS	-Create funding opportunities to award community grants designed to reach specific populations at risk with culturally sensitive, evidence-based interventions.	2012 (5 years)

Initiative 5. Research needs for provider education and community education

Goals and Rationale	**Lead/Participating Agencies**	**Recommended Actions**	**Timeframe** **Year of Initiation (duration)**
Goal: **5a**. Identify specific gaps	***Lead Agency:*** CDC	Conduct qualitative and quantitative research designed to understand the	2012 (3 years)

in professional knowledge, skills, and abilities, as well as structural and attitudinal barriers that affect risk assessment, counseling, and testing of those at risk. ***Rationale:*** Although screening for viral hepatitis has been determined to be inadequate in the United States, the reasons for providers' failure to perform risk assessment, counseling, and testing are largely unknown. Understanding these provider attitudes will allow tailoring of educational programs to meet providers' needs.	***Participating Agencies:*** HRSA, CDC, CMS, and AHRQ	knowledge, skills, abilities, and attitudes of providers with regards to risk assessment, counseling, and testing of those at risk.	
Goal: **5b.** Identify the most effective approaches to increasing provider knowledge, improving skills, and initiating appropriate testing of patients. ***Rationale:*** Although many potential venues for provider education exist, including federally funded training centers, publications, and professional societies, the most effective means to increase providers' knowledge base remain largely unknown.	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, AHRQ, and IHS	Conduct research to determine the most effective way to increase providers' knowledge and practice.	2012 (2 years)

Goal: **5c**. Identify specific training needs unique to settings at risk. ***Rationale:*** To be effective, viral hepatitis prevention, screening, and treatment need to occur in unique settings, such as behavioral health (including substance abuse prevention and treatment programs). These settings are likely to require unique provider training.	***Lead Agency:*** SAMHSA ***Participating Agencies***: CDC and HRSA	Conduct research to determine the most effective way to increase providers' knowledge and practice in specific setting serving populations at risk. Partner with provider organizations working in setting serving populations at risk.	2012 (4 years)
Goal: **5d.** Conduct formative research of specific populations at risk, particularly API. ***Rationale:*** Understanding the needs among the various API populations, their linguistic preferences, cultural backgrounds, and practices is critical to the success of community education efforts.	***Lead Agency:*** CDC ***Participating Agencies:*** OMH, HRSA, and IHS	-Conduct focus groups, surveys, and key informant interviews in communities/regions with high rates of chronic hepatitis B and/or API populations to determine attitudes, behaviors, and media channel preferences. -Assess existing data from various sources (i.e., census, market segmentation profiles) to determine population characteristics and media preferences.	2012 1 year
Goal: **5e**. Conduct formative research of specific populations at risk, (particularly ethnic	***Lead Agency:*** CDC ***Participating Agencies:*** OMH, HRSA, and	- Conduct focus groups, surveys, and key informant interviews in communities with high rates of chronic hepatitis C and/or populations at risk to determine knowledge,	2012 1 year

minorities) ***Rationale:*** Understanding the needs specific to the various populations at risk for HCV, including their perceptions of risk and how best to reach them, is critical to the success of community education efforts.	IHS	attitudes, behaviors, and media habits and how these may affect perceptions of stigmatization, access to health care, and acceptability of HCV testing. -Assess existing data from various sources (i.e., census, market segmentation profiles) to determine population characteristics and media preferences.	

Strengthening Viral Hepatitis Surveillance

Strengthening Viral Hepatitis Surveillance

The framework used by the Centers for Disease Control and Prevention for preventing and controlling diseases, including viral hepatitis, is supported by public health surveillance (1, 2). Data disseminated by a public health surveillance system are used by national, state, and local public health professionals and decision makers to:

- measure and monitor trends in the burden of a disease (or other health-related events), including detection of epidemics and pandemics, and changes in related factors;
- identify of new or emerging health concerns;
- identify of populations at high risk;
- guide the planning, implementation, and evaluation of public health programs and policies;
- detect changes in health practices and the effects of these changes;
- prioritize the allocation of health resources;
- describe the clinical course of disease; and
- provide a basis for epidemiologic research.

Despite the useful data that can be obtained through public health surveillance, the existing surveillance system for viral hepatitis in the United States is poorly funded and consequently fragmented, resulting in incomplete coverage and inconsistent reporting of cases by jurisdictions (3).

Three data systems are currently used to conduct the surveillance activities that yield data regarding the burden of viral hepatitis disease in the United States: 1) the National Notifiable Disease Surveillance System (NNDSS), 2) the sentinel surveillance project established in 2004, which operates via the CDC's Emerging Infections Program (EIP), and 3) the National Health and Nutrition Examination Survey (NHANES).

NNDSS, the backbone of viral hepatitis surveillance, is a passive case-reporting system used by state health departments to report cases of nationally notifiable diseases, including viral hepatitis, to CDC (1). Hepatitis A and acute hepatitis B are reportable conditions in all states. Thus, all states notify CDC about cases of hepatitis A and acute hepatitis B. Chronic hepatitis B and acute and chronic hepatitis C are not reportable in all states. Therefore, not all states notify CDC of cases of these conditions. For both acute and chronic hepatitis states rely on the receipt of positive laboratory reports to identify cases. Unfortunately, the case-report forms currently in use do not

capture all information relevant to identifying cases of viral hepatitis surveillance. For example, the form does not collect results of testing for acute and chronic hepatitis C infection. NNDSS has historically had several additional limitations that are specific to conducting viral hepatitis surveillance. For instance, through this system,

- asymptomatic cases are not identified and reported;
- confirmed cases are under-reported;
- case ascertainment is incomplete;
- CDC/CSTE approved case definitions are applied inconsistently; and
- information about clinical characteristics, demographic characteristics, risk behaviors, and potential exposures are incomplete.

Additionally, data generated through NNDSS for chronic hepatitis B and C cases are limited. For most states it is not always possible to determine if multiple laboratory reports generated for one individual with chronic infection are in fact all associated with that one individual.

The EIP hepatitis surveillance demonstration project is also a passive system. Ten states (i.e., Connecticut, Colorado, Georgia, Minnesota, New Mexico, New York State, New York City, Oregon, San Francisco, and Tennessee) currently are funded by the Division of Viral Hepatitis (DVH) within CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) to work on hepatitis surveillance activities (4). These funds are used to support follow-up of cases to obtain information about risk behaviors and exposures; conduct special studies to develop and test protocols, procedures, and materials; identify at-risk contacts; and refer case-patients and their contacts for appropriate counseling and care. As part of this project, remnant serum specimens from patients with acute cases of hepatitis A and B are collected and sent to the DVH laboratory for additional testing, including genetic sequencing.

NHANES provides useful information regarding viral hepatitis, although this national survey has its own unique limitations. This survey collects data regarding some risk factors and potential exposures, vaccination against hepatitis A and B, and knowledge of hepatitis C disease status (5). Additionally, serum specimens are collected to allow testing to determine viral hepatitis status. Data from NHANES are used to estimate the prevalence of chronic hepatitis B and C and to determine patient awareness of viral hepatitis C disease status at the national level. These data,

however, are not useful for designing and evaluating prevention and intervention programs at the state and local levels.

A sustained level of technical assistance and resources are required to develop, implement, and maintain a hepatitis surveillance system that provides high-quality data. To accurately quantify and describe the number of HCV- and HBV-infected persons identified by state health departments, efficient and reliable systems for receiving and managing reports of positive laboratory results must be in place, along with adequate personnel and infrastructure to enable the confirmation and investigation of those reports.

Limitations in the reporting and notification system are largely due to lack of adequate funding of hepatitis surveillance at the national, state, and local levels. This limitation has especially affected efforts to characterize chronic hepatitis B and chronic hepatitis C infections because follow-up of the large volume of case reports is labor intensive and the public health benefit is not as well documented as it is for acute disease. With the exception of the EIP sites, no specific funding is provided to states participating in NNDSS for activities pertaining to viral hepatitis surveillance. Most states have limited if any staff dedicated to hepatitis surveillance activities.

The recent Institute of Medicine (IOM) report on Hepatitis and Liver Cancer recognized the limitations of the current status of viral hepatitis surveillance and made recommendations for developing a viral hepatitis surveillance system that provides accurate and reliable data/information for public health action (2). The first recommendation was to evaluate the current viral hepatitis surveillance system and to use the information from the evaluation to guide the development of technical guidance and standards for viral hepatitis surveillance. The second recommendation was to develop a specific cooperative agreement so support core surveillance for viral hepatitis. Additional recommendations included funding to support core viral hepatitis surveillance, including electronic laboratory reporting, electronic medical record extraction systems, and web-based, PHIN-compliant reporting systems. Active targeted surveillance, including seroprevalence surveys of special populations was recommended to improve estimation of the magnitude of the problem among racial/ethnic groups, the homeless, at-risk groups, and immigrant populations. The report also discussed the need to collaborate and/or integrate with

existing surveillance systems to maximize the utility of those systems to provide information about viral hepatitis that is useful for public health planning and practice.

To be effective, any plan to improve viral hepatitis surveillance must focus on ways to ensure generation of the data needed to support prevention and intervention programs and policies. The following table outlines specific initiatives, goals, and recommended actions that can be used to inform decisions on policy and prevention and intervention programs at local, state, and national levels, and ultimately, to determine and reduce the burden of viral hepatitis in the United States.

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Strengthening Viral Hepatitis Surveillance

<u>Surveillance Initiative #1</u>: Build a network of state-based surveillance systems with the capacity to identify and investigate cases of acute and chronic hepatitis.

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Objective: To document and understand the current status and resources needed at the national, state, and local levels to develop, improve and standardize the viral hepatitis surveillance system at the state level. ***Rational*:** With the exception of 10 demonstration sites, the federal government has not provided funding, guidance, or oversight for viral hepatitis surveillance at the state level. As a result, there is little information about the status and capacities of state-based viral hepatitis surveillance programs. The first step in building a state-based surveillance system for viral hepatitis surveillance is to understand the current status capacities and needs of each state/site.	*Lead Agency*: CDC/ *Participating Agencies*: NA *External participants: CSTE, APHL,*	Conduct comprehensive evaluations of existing state and federal viral hepatitis surveillance system. Determine capacity and ability to conduct surveillance of acute and chronic hepatitis in each state and the ability to send case reports to CDC. Document current status and needs for staff, training, and IT capacity Address additional staffing needs: Hire data manager to develop databases for and manage data from the evaluation activities. The data manager will also assist with data analyses.	2010-2011 (1 year, ongoing annual updates
Objective: To determine states' ability to correctly apply case definitions. ***Rational**:* Active viral hepatitis case definitions include clinical and laboratory criteria. The clinical characteristics of acute viral hepatitis infection are the same for all types of hepatitis.	*Lead Agency*: CDC/ *Participating Agencies*: NA	Analyze existing data and conduct studies to identify and quantify misclassification and causes of misclassification. Review testing algorithms applied by laboratories and ascertainment and application of clinical criteria by health departments.	2010-2013 (2-3 years)

Therefore, laboratory criteria are necessary to distinguish between types of hepatitis infection. Correct identification of cases by type is essential for determining prognosis/treatment and appropriate vaccination against hepatitis A and/or B.			
***Objective**:* Implement and support state-based viral hepatitis surveillance systems. ***Rationale**:* State-based surveillance of viral hepatitis requires funding, standardized criteria and procedures for identifying cases, uniform data collection, data reporting and notification systems.	*Lead Agency*: CDC/ *Participating Agencies*: CDC/OSELS	Conduct comprehensive review to identify hepatitis surveillance systems with best practices and findings. Develop and test surveillance protocols for each type of viral hepatitis based on best practices and findings from the comprehensive evaluation. The protocols will include procedures for conducting quality control and ongoing evaluation activities. Evaluate current case report forms, revise forms to collect clinical, laboratory, and demographic data, as well as information about risk behaviors/exposures, and co-morbidities. Test forms and clear final versions through OMB. Develop a Funding Opportunity Announcement to provide funding to all states and territories to support viral hepatitis surveillance. Identify cases of acute and chronic hepatitis to support prevention efforts, including disease transmission and progression of disease and, referral of infected persons to care, treatment, and	2011-2012 (2 years)

		counseling for persons affected by the disease. Address additional staffing needs: Hire a project officer to assist in the development of and oversee the cooperative agreement. Hire an epidemiologist to assist with protocol development and dissemination, revise case report forms and clear through OMB.	

Surveillance initiative 2: Supplement information from case reporting with existing sources of health data from across HHS agencies, other federal departments, and public and private health care systems.

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Objective: To improve tracking hepatitis events in special populations: a. Health disparities among racial and ethnic minorities b. Persons in behavioral high risk groups ***Rational:*** Surveillance data are needed to measure burden of disease, detect outbreaks, and characterize the distribution and transmission of infectious agents for prevention and control. However, traditional case-reported data are often missing information on race/ethnicity and risk behaviors; for example, in 2007, 50-52% of hepatitis A, B, and C cases had no risk factor data available. Supplementing case reports with data that can provide risk and race/ethnicity is warranted.	*Lead Agency*: CDC *Participating Agencies*: CMS, HRSA, SAMHSA *External participants*: CSTE, APHL	Identify and evaluate data from each source to determine attributes and quality and to understand limitations. Appendix A list a number of surveys and data reporting systems that either currently includes information about viral hepatitis or have the potential to collect information about viral hepatitis. These are the data sources that may be used to support viral hepatitis surveillance. Identify opportunities to integrate newly identified data sources into existing systems. Address additional staffing needs: Hire data manager to manage large data sets. Hire programmer to write programs to analyze data and generate templates and reports.	2011-2014 (3-4 years)
Objective: To expand hepatitis-related outcomes under surveillance to include measures of receipt of preventive services and treatment among infected person.	*Lead Agency*: CMS, *Participating Agencies*: HRSA, NIH	Collaborate with other federal agencies to identify, access, and analyze data from various sources. Evaluate and analyze claims data, hospital discharge data, and data	2011-2013 (3 years)

***Rational**:* Comprehensive surveillance should monitor not only new infections, but the consequences of infection including healthcare utilization, complications of infection (e.g., chronic liver disease, hepatocellular carcinoma, liver transplants) and deaths. Treatment and prevention are intended to prevent complications of disease, so monitoring these events will help evaluate prevention effectiveness.		from ambulatory healthcare settings to document usefulness for understanding the spectrum of viral hepatitis disease.	
***Objective**:* To inventory potential sources of hepatitis- related events across agencies ***Rational**:* The current viral hepatitis surveillance system does not provide information necessary to meet all data needs. Data from other sources will be used to improve the ability to provide data to support public health programs and policies.	*Lead Agency*: CMS CDC *Participating Agencies*: CMS	Use working group participants to identify datasets List outcomes/metrics available by dataset	*Inventory:* 2010 (6 months)
Goal**:* Establish baselines for prevention activities and for monitoring the impact of prevention efforts. ***Rational: Currently new cases of acute and chronic infections are systematically reported. However, comprehensive surveillance would ideally include reporting of severity, utilization of clinical care and counseling services, subsequent	*Lead Agency*: CMS CDC *Participating Agenc* CMS, HRSA, SAMI	Conduct studies to establish baselines and follow-up from new data sources.	2011-2012 (2 years)

behaviors (example, alcohol use), and complications.			

<u>Initiative #3:</u> Develop and implement new technologies and laboratory procedures to improve hepatitis surveillance.

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Objective: Develop a system that includes both clinical and public health laboratories to monitor hepatitis screening tests. ***Rational:*** State health departments require clinical laboratories to report positive test results for markers of hepatitis A, B, and C. Prevention of hepatitis currently requires screening; achieving this goal will allow surveillance data to be used to evaluate the impact and implementation of screening.	*Lead Agency*: CDC *Participating Agencies*: CMS *External Participants; APHL*	Determine existing network of clinical laboratories that conduct testing for viral hepatitis. Assess the sources and flow of screening test results, and consolidate in a database accessible by state health departments for monitoring and evaluation. Test and revise the consolidate database prior to implementation and on a routine basis.	2011-2012 (2 years)
Objective: Assess new laboratory testing procedures to improve distinction between types of hepatitis disease reported to surveillance. ***Rational:*** Currently, several states do not include hepatitis C in the viral hepatitis surveillance program. Other states do not distinguish between acute and chronic cases. To improve accuracy of case reporting, treatment, and care, states need less complicated and cheaper testing algorithms for distinguishing types of viral hepatitis cases.	*Lead Agency*: CDC/ *Participating Agencies*: FDA, NIH	Review availability and evaluate new straightforward highly sensitive diagnostic assays that can determine active viral hepatitis events (specific type of hepatitis) and be used directly in referral for care and treatment management without intermediary confirmatory steps. Develop, evaluate, and implement test capable of distinguishing between vaccine induce immunity and infection-induced immunity to hepatitis A and B.	2011-2012 (2 years)

***Objective**:* Build the capacity for state public health laboratories to provide support in outbreak investigations ***Rational**:* A recent APHL survey indicated most of the public health laboratories (PHL) conduct only screening tests. Testing for markers of acute hepatitis and molecular diagnostic capacity is lacking in most of the participating PHL, affecting capability for early response in outbreak investigations.	*Lead Agency:* CDC/DVH *Participating Agencies:* CMS *External Participants:* APHL	Assess capacity of public health laboratories (PHL) and recommend capacity requirements for effective diagnostic of viral hepatitis during an outbreak investigation. Provide technical assistance to public health laboratories by conduct viral hepatitis workshops and hands-on training for state PHL staff at the CDC/DVH Laboratory. Engage PHL in proficiency testing for viral hepatitis markers not available through CAP PT or other commercial sources.	2011 (1 year)
***Objective**:* Develop electronic infrastructure with the ability to capture results of existing and future laboratory markers of viral hepatitis infection. ***Rational**:* Due in part to the passive nature of the current reporting system, there is limited efficiency and accuracy in laboratory reporting of cases of viral hepatitis to health departments. Electronic monitoring, laboratory reporting through a centralized database, and application of standard laboratory-based case definitions can deliver accurate reports ready for review, verification and analysis.	*Lead Agency*: CDC/OSELS *Participating Agencies*: CMS	Evaluate the capability of the NNDSS and other surveillance systems to capture and consolidate viral hepatitis test results from various sources, including public health and commercial laboratories. Develop in implement program algorithms, capable of capturing cases of acute and chronic hepatitis using laboratory-based case definitions.	2011 -2013 (3 years)

<u>Initiative #4:</u> Assess the utility of electronic health records for conducting viral hepatitis surveillance activities.

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
***Objective**:* Use electronic medical records to identify cases of acute and chronic viral hepatitis. ***Rationale**:* Clinical information and laboratory results are essential for identifying cases of viral hepatitis. Currently, viral hepatitis surveillance is based primarily on laboratory reports that do not include symptoms, detailed demographic information, vaccination status, or dates of vaccinations. Medical records will include both clinical and laboratory results, improving the ability to accurately identify and classify cases.	*Lead Agency*: CMS *Participating Agencies*: CDC, NIH, IHS	Investigate existing and new algorithms for identifying acute and chronic viral hepatitis cases from electronic medical records. Collaborate with health care systems to pilot the use of electronic medical records to improve surveillance.	2011-2014 (3-4 years)
***Objective**:* Use electronic medical records to estimate rates of anicteric infection and under reporting ***Rational**:* Most cases of viral hepatitis do not have symptoms, resulting incomplete ascertainment of cases. Additionally, viral hepatitis is under-reported to both the state health department and to CDC because of the need for clinical information to supplement laboratory reports. To determine the overall burden of viral	*Lead Agency*: CMS *Participating Agencies*: CDC/DVH	Design and conduct studies to provide estimates of rates of anicteric infection and under-reporting, using electronic medical records.	2011-2012 (2 years)

hepatitis, estimates of asymptomatic (anicteric) cases and of under-reporting is required.			

National Notifiable Disease Surveillance System

HHS Agency CDC

Period Covered 1990 – 2010 = summary and case-specific electronic data available

< 1990 = only summary electronic data available

Type of System All 50 states, New York City, District of Columbia, and 5 U.S. territories

Sample Design All cases, no sampling

Location of Data & Documentation Branch share drive

Population Covered Total U.S.

Frequency of Data Release Cases are notified to CDC on a weekly basis

Total N or N/Reporting Period

Response Rate (if survey) N/A

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Status

Collect Information on HBV Status Status

Collect Information on HCV Status Status

Relevant Data Elements IDU, MSM, HET, travel for HAV

National Health and Nutrition Examination Survey

HHS Agency CDC

Period Covered NHANES II (1976 – 1980), NHANES III (1988 – 1994), NHANES 1999 – 2010

Type of System 15 counties in the U.S. each year

Sample Design Representative sample of the U.S.

Location of Data & Documentation NHANES website: http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm

Population Covered Total U.S.

Frequency of Data Release Every two years

Total N or N/Reporting Period ~3,000 – 5,000 persons/year

Response Rate (if survey) ~80%

Collect Information on Unspecified Hepatitis Status No

Collect Information on HAV Status Status and Vaccination

Collect Information on HBV Status Status and Vaccination

Collect Information on HCV Status Status

Relevant Data Elements IDU, MSM, sexual behavior, vaccination history, HIV and other STDs

Multiple-Cause-of-Death Records

HHS Agency CDC

Period Covered 1980s – 2007

Type of System All 50 states, District of Columbia, and U.S. territories

Sample Design All deaths, no sampling

Location of Data & Documentation NCHS/NVSS/MCOD website: http://www.cdc.gov/nchs/data_access/Vitalstatsonline.htm

Population Covered Total U.S.

Frequency of Data Release Annually

Total N or N/Reporting Period 2000 – 2007 = ~2.4 million per year

Response Rate (if survey) N/A

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Status

Collect Information on HBV Status Status

Collect Information on HCV Status Status

Relevant Data Elements Underlying cause of death, contributing causes of death using ICD codes

National Ambulatory Medical Care Survey

HHS Agency CDC

Period Covered 1980s – 2007

Type of System All 50 states, District of Columbia

Sample Design National probability sample

Location of Data & Documentation NCHS/Ambulatory Health Care Data website: http://www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm

Population Covered Total U.S.

Frequency of Data Release Annually

Total N or N/Reporting Period 112 geographic PSUs •~ 3,000 physicians •~ 25,000 visits •1 week reporting period

Response Rate (if survey) 2004 = 66%

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Status and Vaccination

Collect Information on HBV Status Status and Vaccination

Collect Information on HCV Status Status

Relevant Data Elements Major diagnosis and other diagnoses, drugs prescribed, vaccination

National Hospital Ambulatory Health Care Survey

HHS Agency CDC

Period Covered 1980s – 2007

Type of System All 50 states, District of Columbia

Sample Design National probability sample

Location of Data & Documentation NCHS/Ambulatory Health Care Data website: http://www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm

Population Covered Total U.S. • ~ 400 EDs and ~ 250 OPDs • ~ 37,000 ED and ~ 35,000 OPD visits • 4-week reporting period

Frequency of Data Release Annually

Total N or N/Reporting Period	112 geographic PSUs • ~ 500 hospitals • ~ 400 EDs and ~ 250 OPDs • ~ 37,000 ED and ~ 35,000 OPD visits • 4-week reporting period
Response Rate (if survey)	ED 2004 = 92% • OPD 2004 = 87%
Collect Information on Unspecified Hepatitis Status	Status
Collect Information on HAV Status	Status and Vaccination
Collect Information on HBV Status	Status and Vaccination
Collect Information on HCV Status	Status
Relevant Data Elements	Major diagnosis and other diagnoses, drugs prescribed, vaccination

United States Cancer Statistics (NPCR+SEER program)

HHS Agency	CDC
Period Covered	1999 – 2006
Type of System	All 50 states, District of Columbia
Sample Design	All cases, no sampling
Location of Data & Documentation	United States Cancer Statistics website: http://www.cdc.gov/cancer/npcr/uscs/2006/download_data.htm
Population Covered	Total U.S.
Frequency of Data Release	Annually
Total N or N/Reporting Period	1999 – 2006 = 10,983,517
Response Rate (if survey)	N/A
Collect Information on Unspecified Hepatitis Status	No
Collect Information on HAV Status	No
Collect Information on HBV Status	No
Collect Information on HCV Status	No
Relevant Data Elements	Liver cancer

Enhanced Perinatal Surveillance

HHS Agency	CDC
Period Covered	1999 – 2003; 2005 – 2010
Type of System	Population-based or facility-based
Sample Design	Population-based or facility-based
Location of Data & Documentation	HICSB servers
Population Covered	Children <18 yrs of age in selected areas in US and DC • 24 areas for 1999-2003 • 15 areas for 2005-2010
Frequency of Data Release	Twice annually
Total N or N/Reporting Period	2005 – 2010 = ~12,000
Response Rate (if survey)	N/A
Collect Information on Unspecified Hepatitis Status	No
Collect Information on HAV Status	No
Collect Information on HBV Status	Status
Collect Information on HCV Status	Status

Relevant Data Elements	Was mother screened for HBsAg during pregnancy? Was mother diagnosed with hepatitis B (HBsAg+) or C during pregnancy or at L&D?

HIV Incidence Surveillance System

HHS Agency	CDC
Period Covered	
Type of System	Population-based
Sample Design	Convenience sample of all new HIV diagnoses
Location of Data & Documentation	HICSB servers
Population Covered	U.S. and D.C.
Frequency of Data Release	Periodically
Total N or N/Reporting Period	Total U.S.
Response Rate (if survey)	N/A
Collect Information on Unspecified Hepatitis Status	No
Collect Information on HAV Status	No
Collect Information on HBV Status	No
Collect Information on HCV Status	No
Relevant Data Elements	

National HIV/AIDS Reporting System

HHS Agency	CDC
Period Covered	2009 – 2011
Type of System	Population-based
Sample Design	Population-based
Location of Data & Documentation	HICSB servers
Population Covered	U.S., D.C., and territories (HIV data from 37 states)
Frequency of Data Release	At a minimum annually
Total N or N/Reporting Period	Total U.S.
Response Rate (if survey)	N/A
Collect Information on Unspecified Hepatitis Status	No
Collect Information on HAV Status	No
Collect Information on HBV Status	No
Collect Information on HCV Status	No
Relevant Data Elements	

The National HIV Behavioral Surveillance System

HHS Agency	CDC
Period Covered	NHBS Round 1 (2003 – 2008); NHBS Round 2 (2009 – 2010); NHBS Round 3 (anticipated to be 2011 – 2015)
Type of System	25 MSAs chosen from 50 U.S. states and Puerto Rico by sampling in areas where prevalence of HIV is high

Sample Design Two sampling methodologies used depending on the cycle; these are considered hidden populations, so methods reflect this reality (time-space sampling and respondent-driven sampling)

Location of Data & Documentation Not publically available (surveillance data)

Population Covered High risk men who have sex with men (MSM), injection drug users (IDU), and heterosexuals at risk (HET); aged >18 years, a current resident of an MSA, not a previous participant in NHBS during the current cycle, and able to provide informed consent

Frequency of Data Release N/A, data are released in tables every year though MMWRs and Surveillance summaries

Total N or N/Reporting Period ~10,500/year (but varies by year)

Response Rate (if survey) N/A

Collect Information on Unspecified Hepatitis Status No

Collect Information on HAV Status Status and Vaccination

Collect Information on HBV Status Status and Vaccination

Collect Information on HCV Status Status

Relevant Data Elements IDU, MSM, sexual behavior, vaccination history, HIV and other STDs

Medical Monitoring Project

HHS Agency CDC

Period Covered 2007 – 2010

Type of System Locally and nationally representative, population-based samples of adults receiving HIV/AIDS care in the U.S

Sample Design 3-stage probability proportional to size (states, HIV care facilities, HIV+ adult patients)

Location of Data & Documentation http://www.cdc.gov/hiv/topics/treatment/mmp/index.htm

Population Covered 20 states in 2007 and 2008, 17 states from 2009 onward; patients at least 18 years of age, diagnosed with HIV, and receiving care from participating health care facilities

Frequency of Data Release Annually

Total N or N/Reporting Period ~5,000 persons/year

Response Rate (if survey) 2009 = 100% for states, ~80% for facilities, ~50% for interview, ~60% for medical record abstraction

Collect Information on Unspecified Hepatitis Status Vaccination (interview)

Collect Information on HAV Status Status and Vaccination (abstraction)

Collect Information on HBV Status Status and Vaccination (abstraction)

Collect Information on HCV Status Status (abstraction)

Relevant Data Elements IDU, MSM, sexual behavior, vaccination history, HIV and other STDs

Transgender HIV Behavioral Survey

HHS Agency CDC

Period Covered Have not collected data yet

Type of System Pending

Sample Design Respondent Driven Sampling

Location of Data & Documentation Pending funding of sites

Population Covered Up to 6 metropolitan areas in the US; Areas to be determined by funding

Frequency of Data Release Pending

Total N or N/Reporting Period 200 per a metro area

Response Rate (if survey) Unknown

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Status and Vaccination

Collect Information on HBV Status Status and Vaccination

Collect Information on HCV Status Status

Relevant Data Elements Transgender women (people born male, but who identify or live as a woman)

National Health Interview Survey

HHS Agency CDC

Period Covered 2000 – 2010; 2008 added hepatitis A vaccine questions

Type of System Population based: U.S. civilian non-institutionalized

Sample Design Stratified, multistage sample

Location of Data & Documentation NHIS website: http://www.cdc.gov/nchs/nhis/quest_data_related_1997_forward.htm

Population Covered Adults (18 years and older)

Frequency of Data Release Annually

Total N or N/Reporting Period 2000 = 32,374 • 2001 = 33,326 • 2002 = 31,044 • 2003 = 30,852 • 2004 = 31,326 • 2005 = 31,428 • 2006 = 24,275 • 2007 = 23,393 • 2008 = 21,781 • 2009 = 27,731

Response Rate (if survey) Varies from year to year; 65.4% in 2009

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Vaccination beginning in 2008

Collect Information on HBV Status Vaccination

Collect Information on HCV Status No

Relevant Data Elements Ever had hepatitis (no type) and ever lived with someone with hepatitis; combined risky behavior

and another on ever spent more than 24 hours living on the streets, in a shelter, or in a jail or prison

Behavioral Risk Factor Surveillance System

HHS Agency CDC

Period Covered 2006, 2007

Type of System All 50 states, New York City, District of Columbia, and 5 U.S. territories

Sample Design Stratified sample

Location of Data & Documentation BRFSS website: http://www.cdc.gov/BRFSS/technical_infodata/surveydata.htm

Population Covered Adults (18 years and older)

Frequency of Data Release Annually

Total N or N/Reporting Period 2006 = 355,710 • 2007 = 430,912

Response Rate (if survey) Median Overall Response Rate: 2006: 35.4% (20.5-58.4) • 2007: 33.5% (13.8-58.9)

Interview Completion Rate: 2006: 66.9% (40.4-83.0) • 2007: 75.2% (51.6-87.7)

Collect Information on Unspecified Hepatitis Status No

Collect Information on HAV Status No

Collect Information on HBV Status Vaccination

Collect Information on HCV Status No

Relevant Data Elements Blood transfusion, MSM, drug use, HIV, HET

REACH 2010 & REACH U.S. Risk Factor Survey

HHS Agency CDC

Period Covered REACH 2010: 2006; REACH U.S.: 2009, 2010

Type of System 28 communities in U.S. that have community health interventions

Sample Design Stratified sample

Location of Data & Documentation Branch data repository

Population Covered Minority adults age > 18 years - blacks, Hispanics, Asians/Pacific Islanders, and American Indians

Frequency of Data Release Annually

Total N or N/Reporting Period REACH 2010 for year 2006: 21,723; REACH U.S. for year 2009: 24,169

Response Rate (if survey) Median Response Rate: 2006: 40.0% (25 – 87%) • 2009: not published

Collect Information on Unspecified Hepatitis Status No

Collect Information on HAV Status No

Collect Information on HBV Status Status and Vaccination

Collect Information on HCV Status Status

Relevant Data Elements Hepatitis B vaccination history, ever tested, test results, reasons for testing, ever treated,

currently seeing a doctor for hepatitis

National Data Warehouse

HHS Agency IHS

Period Covered 2001 – 2010

Type of System Population-based on IHS internal facilities and about 30% of tribal facilities that report to national data warehouse

Sample Design Originates as clinical data - all cases included, so no sampling. Recorded as ICD-9 codes for clinical visits and as CVX codes for vaccination

Location of Data & Documentation Data stored in servers with IHS OIT and accessible by IHS DEDP

Not routinely on web

In FY 2011, will become SAS-BI accessible by epidemiologists

Population Covered AI/AN population served by IHS (approximately 1.3 million)

Frequency of Data Release At will

Total N or N/Reporting Period Not routinely extracted for hepatitis (see below for NPIRS data)

Response Rate (if survey) All IHS internal; 30% tribal facilities

Collect Information on Unspecified Hepatitis Status Status (hepatitis, unspecified ICD-9 codes)

Collect Information on HAV Status Status (HAV ICD-9 codes)

Collect Information on HBV Status Status (HBV ICD-9 codes)

Collect Information on HCV Status Status (HCV ICD-9 codes)

Relevant Data Elements

National Patient Information Reporting System

HHS Agency IHS

Period Covered 1995 – 2010

Type of System Population-based (All IHS and tribal facilities)

Sample Design Originates as clinical data: all cases included, so no sampling

Recorded as ICD-9 codes for clinical visits

Location of Data & Documentation Data kept centrally in Rockville, MD

Analysis occurs at CDC and IHS DEDP by Interagency Agreement, but not routinely (only by request of IHS DEDP)

Population Covered AI/AN population served by IHS

Frequency of Data Release At will

Total N or N/Reporting Period As an example, for hepatitis-related hospitalizations from 2005 – 2007 (NOT outpatient visits): hepatitis A = 31; hepatitis B = 164; hepatitis C = 2,065. Data in publication

Response Rate (if survey) 100%

Collect Information on Unspecified Hepatitis Status Status (hepatitis, unspecified ICD-9 codes)

Collect Information on HAV Status Status (HAV ICD-9 codes)

Collect Information on HBV Status Status (HBV ICD-9 codes)

Collect Information on HCV Status Status (HCV ICD-9 codes)

Relevant Data Elements

Resource and Patient Management System (EHR)

HHS Agency IHS

Period Covered Current

Type of System Clinical medical record

Sample Design Originates as clinical data: all cases included, so no sampling

Recorded as ICD-9 codes for clinical visits and as CVX codes for vaccination

Location of Data & Documentation Data are recorded at ~432 sites; kept locally by HIS

Population Covered AI/AN population served

Frequency of Data Release At will

Total N or N/Reporting Period Unknown

Response Rate (if survey) all IHS internal; 95% tribal facilities

Collect Information on Unspecified Hepatitis Status Status (hepatitis, unspecified ICD-9 codes)

Collect Information on HAV Status Status (HAV ICD-9 codes) & Vaccination (hep A vaccine CVX codes)

Collect Information on HBV Status Status (HBV ICD-9 codes) & Vaccination (hep B vaccine CVX codes)

Collect Information on HCV Status Status (HCV ICD-9 codes)

Relevant Data Elements Potential surveillance system only, because data are kept locally and not used for routine public health surveillance purposes. No national aggregate reporting outside of OMB-mandated quality measures (which do not include hepatitis at this point)

Drug Abuse Warning Network (Emergency Department)

HHS Agency SAMHSA

Period Covered 2004 – 2008 (ongoing)

Type of System National and metropolitan

area facility-based active surveillance system (emergency departments) representing the 50 United States and the District of Columbia

Sample Design Stratified sample

Location of Data & Documentation SAMHSA

Population Covered Any ED visit or death related to recent drug use with no restrictions on age

Frequency of Data Release Annually

Total N or N/Reporting Period Number of reporting facilities whose data contributed to estimates: 2004 = 220 • 2005 = 224 • 2006 = 205 • 2007 = 207 • 2008 = 231

Estimated 4.4 million drug-related ED visits/year • n = ~375,000

Response Rate (if survey) Overall weighted response rates: 2005 = 28.9% • 2006 = 26.1% • 2007=29.6% • 2008=32.9%

Collect Information on Unspecified Hepatitis Status No

Collect Information on HAV Status No

Collect Information on HBV Status No

Collect Information on HCV Status No

Relevant Data Elements Drug abuse/misuse, injection drug use, associated health conditions (diagnoses)

Drug Abuse Warning Network (Mortality)

HHS Agency SAMHSA

Period Covered 2003 – 2008 (ongoing)

Type of System Active surveillance of selected metropolitan and State medical examiner/coroner jurisdictions

Census of drug-related deaths at participating facilities

Not national in scope

Sample Design No

Location of Data & Documentation SAMHSA

Population Covered Any death related to recent drug use with no restrictions on age

Frequency of Data Release Annually

Total N or N/Reporting Period State medical examiners: 2003 = 6 • 2004 = 6 • 2005 = 8 • 2006 = 8 • 2007 = 10 • 2008 = 12

All other areas: varies

Response Rate (if survey) State medical examiners: 100% RR each year

All other areas: response rate varies

Collect Information on Unspecified Hepatitis Status No

Collect Information on HAV Status No

Collect Information on HBV Status No

Collect Information on HCV Status No

Relevant Data Elements Drug abuse/misuse, injection drug use, cause of death (text field), including related health conditions

National Survey of Substance Abuse Treatment Services

HHS Agency SAMHSA

Period Covered 2000 – 2009

Type of System Substance abuse treatment facility census across 50 States, the District of Columbia, and other U.S. jurisdictions

Sample Design All substance abuse treatment facilities in the 50 States, the District of Columbia, and other US jurisdictions that are known to SAMHSA

Location of Data & Documentation SAMHSA, SAMHDA public use file: http://www.oas.samhsa.gov/systems.htm

Population Covered Public and private substance abuse treatment facilities

Frequency of Data Release Annually

Total N or N/Reporting Period Number of reporting facitilites: 2000 = 13,428 • 2005 = 13,371 • 2009 = 13,513 •

Number of clients in treatment on survey reference date: 2000 = 1,000,896 • 2005 = 1,081,049 •

2009 = 1,182,077

Response Rate (if survey) 2000 = 94.0% • 2005 = 95.3% • 2009 = 93.4%

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status No

Collect Information on HBV Status Status

Collect Information on HCV Status Status

Relevant Data Elements Services are provided at facility including screening for hepatitis B and hepatitis C –

no client specific data collected; measures scope and use of drug abuse treatment services

National Survey on Drug Use and Health

HHS Agency SAMHSA

Period Covered 2005 – 2009

Type of System National and State, in-person household survey representing the civilian non-institutionalized population in the 50 U.S.

States and District of Columbia

Sample Design	Stratified multistage area probability sample: stage 1: census tracts • stage 2: segments • stage 3: dwelling units • stage 4: persons
Location of Data & Documentation	SAMHSA, SAMHDA public use file: http://www.oas.samhsa.gov/systems.htm
Population Covered	Civilian non-institutional population aged 12 or older
Frequency of Data Release	Annually
Total N or N/Reporting Period	~68,000 per year
Response Rate (if survey)	Overall weighted response rates: 2005 = 69.6% • 2006 = 67.2% • 2007 = 66.1% • 2008 = 66.3% • 2009 = 67.2%
Collect Information on Unspecified Hepatitis Status	Status
Collect Information on HAV Status	No
Collect Information on HBV Status	No
Collect Information on HCV Status	No
Relevant Data Elements	Drug abuse/misuse, injection drug use, alcohol use, health status, Beginning in 2005, added questions on ever told by doctor had hepatitis (no type) and told by doctor had hepatitis (no type) in the past 12 months

Treatment Episode Data Set

HHS Agency	SAMHSA
Period Covered	Admissions data: 1992 – 2008; discharge data: 2006 – 2007
Type of System	Substance abuse treatment facilities across 50 States, the District of Columbia, and Puerto Rico
Sample Design	Admission-based system; Includes admissions (and discharges) to facilities that are licensed or certified by the State substance abuse agency to provide substance abuse treatment (or are administratively tracked for other reasons).
Location of Data & Documentation	SAMHSA, SAMHDA public-use file: http://www.oas.samhsa.gov/systems.htm
Population Covered	Clients at substance abuse treatment facilities receiving public funding (and some privately-funded)
Frequency of Data Release	Annually
Total N or N/Reporting Period	~1.9 million records/year
Response Rate (if survey)	N/A
Collect Information on Unspecified Hepatitis Status	No
Collect Information on HAV Status	No
Collect Information on HBV Status	No
Collect Information on HCV Status	No
Relevant Data Elements	Drug history information about individuals admitted to treatment

Healthcare Cost and Utilization Project

HHS Agency AHRQ

Period Covered 1988 – 2010

Type of System Collection of information from national, state, and all-payer health care systems

Sample Design Collection of healthcare databases

Location of Data & Documentation AHRQ; databases and tools: http://www.ahrq.gov/data/hcup/datahcup.htm; HCUPnet: http://www.hcup-us.ahrq.gov/overview.jsp; databases; Available for purchase: http://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp

Population Covered Total U.S. for national databases, or state-specific for state-level databases

Frequency of Data Release Varies

Total N or N/Reporting Period Varies

Response Rate (if survey) Varies

Collect Information on Unspecified Hepatitis Status

Collect Information on HAV Status

Collect Information on HBV Status

Collect Information on HCV Status

Relevant Data Elements Cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, State, and local market levels

HCUP-Nationwide Inpatient Sample

HHS Agency AHRQ

Period Covered 1988 – 2008

Type of System Largest all-payer inpatient hospital care database in the United States

Sample Design A stratified sample of hospitals that comprises approximately 90% of all hospital discharges in the United States Can be weighted to produce national estimates

Location of Data & Documentation Available for purchase through AHRQ: http://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp

Population Covered Hospital inpatient stays in U.S. (in 2008, covered 42 states)

Frequency of Data Release Annually

Total N or N/Reporting Period > 7million hospital stays from ~ 1,000 hospitals

Response Rate (if survey)

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Status

Collect Information on HBV Status Status

Collect Information on HCV Status Status

Relevant Data Elements Primary and secondary diagnoses; primary and secondary procedures

HCUP-Kids' Inpatient Database

HHS Agency AHRQ

Period Covered 1997 – 2006

Type of System Only all-payer inpatient hospital care database for children in the United States

Sample Design Sample drawn from State Inpatient Databases, can be weighted to produce national estimates

Location of Data & Documentation Available for purchase through AHRQ: http://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp

Population Covered Persons age < 20 years in State Inpatient Databases

Frequency of Data Release Every 3 years

Total N or N/Reporting Period ~2-3 million hospital discharges for children;

2006 includes 3,739 hospitals from 38 states;

2003 includes 3,438 hospitals from 36 states;

2000 includes 2,784 hospitals from 27 states;

1997 includes 2,521 hospitals from 22 states

Response Rate (if survey)

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Status

Collect Information on HBV Status Status

Collect Information on HCV Status Status

Relevant Data Elements Primary and secondary diagnoses; Primary and secondary procedures

HCUP-State Inpatient Databases

HHS Agency AHRQ

Period Covered 1995 – 2009

Type of System Set of hospital databases from data organizations in participating States that capture discharge information on patients initially seen in the emergency room and then admitted to the same hospital

Sample Design Inpatient discharge abstracts in participating States, translated into a uniform format that share a common structure and data elements across states

Location of Data & Documentation Available for purchase through AHRQ: http://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp

Population Covered ~90% of all U.S. community hospital discharges; some states include discharges from specialty

facilities, such as acute psychiatric hospitals

Frequency of Data Release Annually

Total N or N/Reporting Period 90% of all U.S. hospital discharges

Response Rate (if survey)

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Status

Collect Information on HBV Status Status

Collect Information on HCV Status Status

Relevant Data Elements Primary and secondary diagnoses; primary and secondary procedures

HCUP-Nationwide Emergency Department Sample

HHS Agency AHRQ

Period Covered 2006 – 2007

Type of System Largest all-payer database of emergency department visits in the United States

Sample Design 20% stratified sample of U.S. hospital-based EDs constructed using records from both the HCUP State Emergency Department Databases (SEDD) and the State Inpatient Databases (SID); can be weighted to produce national estimates

Location of Data & Documentation Available for purchase through AHRQ: http://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp

Population Covered SEDD captures information on ED visits that do not result in an admission (i.e., treat-and-release visits and transfers to another hospital); SID contains information on patients initially seen in the emergency room and then admitted to the same hospital

Frequency of Data Release Annually

Total N or N/Reporting Period 2007 NEDS: ~27 million ED visits from almost 970 hospital-based EDs in 27 states; 2006 NEDS: ~26 million ED visits from over 950 hospital-based EDs in 24 states

Response Rate (if survey)

Collect Information on Unspecified Hepatitis Status Status

Collect Information on HAV Status Status

Collect Information on HBV Status Status

Collect Information on HCV Status Status

Relevant Data Elements Primary and secondary ICD-9-CM diagnoses; primary and secondary procedures ICD-9-CM and CPT-4

HCUP-State Emergency Department Databases

HHS Agency	AHRQ
Period Covered	1999 – 2009
Type of System	Set of databases, from data organizations in participating States, that capture discharge information on all emergency department visits that do not result in an admission
Sample Design	Emergency department encounter abstracts in participating States, translated into a uniform format that share a common structure and data elements across states
Location of Data & Documentation	Available for purchase through AHRQ: http://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp
Population Covered	ED visits in 28 states
Frequency of Data Release	Annually
Total N or N/Reporting Period	
Response Rate (if survey)	Composition and completeness of data files may vary from State to State
Collect Information on Unspecified Hepatitis Status	Status
Collect Information on HAV Status	Status
Collect Information on HBV Status	Status
Collect Information on HCV Status	Status
Relevant Data Elements	All-listed diagnoses; all-listed procedures

Improving screening, care, and treatment for Viral Hepatitis

Battling Liver Disease and Cancer by Improving Clinical Care and Treatment for Persons with Chronic HBV and HCV Infection

Most cases of chronic viral hepatitis in the United States are caused by HBV and HCV. Chronic infection by either of these viruses can damage the liver and lead to cirrhosis, which predisposes infected persons to liver failure and liver cancer. Therefore, successful treatment and clinical management of chronic viral hepatitis can reduce the burden of cirrhosis, liver cancer, and the need for liver transplantation in the United States. Approximately 20 years ago, therapies for chronic HBV and HCV were nonexistent, and only clinical monitoring and patient education could be offered. However, intensive research on HBV and HCV over the last few decades has led to the development of effective therapies. One such therapy, interferon treatment, has improved hepatitis B e-antigen positive chronic hepatitis B in about 30% of patients and chronic hepatitis C in about 15% of patients. In addition, the U.S. Food and Drug Administration (FDA) has approved several treatments for chronic hepatitis, seven of which are available for HBV and another three for HCV. These and other investments in research and therapeutic development have dramatically improved the health of persons with chronic hepatitis B and hepatitis C infections: nearly 90% of patients with HBV achieve viral suppression with treatment, and approximately 50% of patients with HCV achieve eradication.

Even with these impressive advances, considerable challenges remain. Many infected persons are never offered appropriate care, which includes appropriate medical monitoring, health education, and clinical preventive services (e.g., vaccination). Even fewer patients receive treatment, which not only encompasses elements of care, but the provision of a licensed antiviral drug. Substantial treatment challenges persist, even among patients who are provided with antivirals. For instance, though the current oral therapies for chronic HBV are generally well-tolerated and effective while the patient is taking the regimen, important unanswered questions remain, including whether the antiviral being used could potentially become resistant, whether and when treatment can be started or discontinued, and whether it is safe to use these drugs long-term. Issues in treatment of patients with chronic hepatitis C include the need to improve treatment response rates (particularly for

those infected with genotypes 1 and 4) and to develop treatment regimens that are better tolerated (i.e., associated with fewer significant side effects). The high costs of many of the agents used to treat both types of chronic hepatitis also pose a significant barrier to treatment. Furthermore, these infections commonly persist for decades and progressively damage the liver without causing noticeable symptoms. As a result, many people remain unaware of their illness and do not seek care. Thus, enhancing systems that provide screening for persons at risk and that link infected persons to appropriate medical care remains a significant challenge. Finally, successful treatment depends on patient adherence to treatment regimens, necessitating the development of systems and models for delivering care specific for these conditions.

The goal of the U.S. Department of Health and Human Services is to improve prevention, clinical management, and treatment of patients with chronic viral hepatitis. Achieving this objective will require a trans-departmental effort to 1) enhance identification and screening of at-risk populations, 2) improve linkage of newly diagnosed patients to care facilities, and 3) improve care and treatment outcomes, which includes developing new therapeutic agents. Integrating services and programs into a unified set of initiatives focused on the clinical, preventive, and treatment aspects of viral hepatitis will synergize existing efforts towards reducing the disease burden in the United States.

Clinical and Preventive Care and Treatment Services Panel

Priority: Improving Prevention, Care and Treatment in Clinical Settings

Initiative 1: Improve the capacity of the health-care system to support screening

Goals and Rationale	**Lead, Participating Agencies**	**Recommended Actions**	**Year of Initiation (Duration)**
Goal: **1a.** Create a single set of federal guidelines and recommendations for hepatitis B and C screening. ***Rationale:*** The guidelines for screening for hepatitis B and C are not aligned across HHS operating divisions, potentially causing confusion for clinicians. A first step in improving rates of screening is to create a consistent set of HHS recommendations. Then, HHS can work across operating divisions to improve rates of screening in both clinical and public health settings.	***Lead Agency:*** CDC ***Participating Agencies:*** AHRQ, HRSA, HIS, and SAMHSA ***Lead Agency:*** ASHID ***Participating Agencies:*** CDC, HRSA, SAMHSA, CMS, IHS, and AHRQ	-Coordinate guidelines and align for hepatitis B and C screening and care referral across HHS operating divisions. -Coordinate across DHHS operating divisions to improve rates of recommended screening for hepatitis B and C in clinical and public health settings.	2011 (2 years) 2012 (3 years)

Goal: **1b.** Support providers to increase screening though the development of technical-assistance documents, training, performance measures, and electronic medical record (EMR) functionality. ***Rationale:*** Low levels of screening the United States are due in part to lack of understanding by providers regarding the current recommendations and importance of diagnosis. A multi-tiered approach is needed to change provider behavior and improve provider performance in this area.	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, SAMHSA, VA, and IHS ***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, SAMHSA, VA, and IHS ***Lead Agency:*** AHRQ ***Participating Agencies:*** HRSA, CMS, and IHS ***Lead Agency:*** ONC ***Participating Agencies:*** CDC, IHS, HRSA, VA, and AHRQ	-Develop training and technical assistance curricula for training on hepatitis B and C screening recommendations. -Increase training of clinicians on screening recommendations through federally funded training centers. -Develop and implement performance measures for hepatitis screening. -Support hepatitis screening and treatment in EMRs.	2013 (2 years) 2013 (ongoing) 2011 (2 years) 2011 (2 years)
Goal: **1c.** Improve financial incentives to expand screening. ***Rationale:*** Lack of reimbursement is a significant contributor to lack of screening for uninsured and underinsured populations. The Affordable	***Lead Agency:*** CMS ***Participating Agencies:*** CDC, HRSA, IHS, and SAMHSA	-Assess barriers to payment for screening in federally funded clinical and public health settings, and develop strategies to address the barriers.	2012 (2 years)

Care Act might offer some relief for vulnerable populations.			

Initiative 2: Improve screening rates in targeted clinical settings and populations

Goals and Rationale	Lead/ Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **2a.** Improve screening rates in community health centers (CHC) ***Rationale:*** CHC are a primary source of care for vulnerable populations and will expand their reach under ACA.	***Lead Agency:*** HRSA ***Participating Agency:*** CDC	-Promote screening based on risk behavior in CHCs.	2011 (3 years)
Goal: **2b.** Improve screening for hepatitis B among immigrant communities. ***Rationale:*** Many hepatitis B cases occur among foreign-born Americans particularly from certain regions of the world. These populations canabe reached through organizations that serve these communities.	***Lead Agency:*** CDC ***Participating Agencies:*** SAMHSA and HRSA	-Partner with key stakeholders in immigrant communities to integrate screening into immigrant, refugee health, state and local health departments, and community-based organizations through development of pilot projects to reach persons recommended to receive hepatitis B screening.	2011 (3 years)
Goal: **2c.** Improve screening rates in incarcerated populations. ***Rationale:*** Incarcerated populations have high rates of chronic viral hepatitis and limited access to prevention	***Lead Agency:*** ASHID ***Participating Agencies:*** CDC and FBOP ***Lead Agency:*** CDC	-Work with Federal Bureau of Prisons to assess and improve screening in FBOP facilities. -Promote screening based on risk behavior in jails and prisons.	2012 (2 years) 2013 (3 years)

services and medical care.	***Participating Agency:*** DOJ		
Goal: **2d.** Develop comprehensive viral hepatitis intervention programs in state and local health departments ***Rationale:*** **State and local health departments directly provide viral hepatitis education and preventive services, and can work to integrate and coordinate these services in appropriate community-based and care settings**	Lead agency: CDC **Participating Agencies: HRSA, HHS/OMH,**	Sustain CDC support for viral hepatitis prevention coordinators for 49 states and a few large cities. In six project areas, demonstrate ways to integrate viral hepatitis vaccination and screening with HIV, STD, and TB prevention services and document best practices. Develop cooperative agreement to fund development of comprehensive viral hepatitis intervention programs to support epidemiologic assessment, community outreach, vaccination, screening, and referral for care services for persons at risk for viral hepatitis	2015

Initiative 3: Improve linkage to Hepatitis B and C care and treatment after diagnosis

Goals and Rationale	Lead , Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **3a.** Improve patient education. ***Rationale:*** For patients to be empowered to seek appropriate care and treatment and prevent transmitting the virus to others, they need to understand their diagnosis, prognosis, treatment options, and risks for transmission.	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, IHS, SAMHSA, and AHRQ ***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, IHS, and SAMHSA	-Develop recommendations for patient education at the time of viral hepatitis diagnosis that address prevention, prognosis, care, and treatment. -Develop a toolkit of patient education information for clinicians that includes materials on preventing transmission and information on healthy lifestyle, natural history, prognosis, care, and treatment options.	2011 (2 years) 2012 (2 years)
Goal: **3b.** Improve case management services for chronic viral hepatitis. ***Rationale:*** Case management is a critical component of chronic disease management. The development of models and recommendations will assist the community in expanding these services.	***Lead Agency:*** CDC ***Participating Agencies:*** CMS, HRSA, IHS, and SAMHSA ***Lead Agency:*** CDC ***Participating Agencies:*** CMS, HRSA, IHS, and SAMHSA	-Identify existing models and best practices for chronic viral hepatitis case management. -Develop case-management service recommendations for patients diagnosed with chronic viral hepatitis to improve referral, linkage, and retention in hepatitis care.	2012 (1 year) 2013 (2 years)
Goal:	***Lead Agency:*** CDC	-Improve linkage to care among women diagnosed	2011 (3 years)

3c. Assure women diagnosed with hepatitis in pregnancy receive ongoing care and treatment. ***Rationale:*** Although pregnant women should be screened for hepatitis, it is unclear how well women identified in pregnancy are linked to on-going care and treatment after delivery.	***Participating Agencies:*** HRSA and HIS	in pregnancy.	

Initiative 4: Improve access to and quality of care for Hepatitis B and C

Goals and Rationale	Lead , Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: 4a. Improve chronic viral hepatitis care in primary care settings. ***Rationale:*** Patients with chronic viral hepatitis benefit from appropriate care, including hepatitis vaccination and counseling regarding alcohol use, acetaminophen use, and transmission risk. However, a lack of a defined package of services for chronically infected patients is a barrier to improving care.	***Lead Agency:*** CMS ***Participating Agencies:*** NIH, HRSA, CDC, IHS, and SAMHSA ***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, SAMHSA, and IHS ***Lead Agency:*** HRSA ***Participating Agencies:*** CDC and CMS	-Develop a "package of service" for persons chronically infected with hepatitis B or C virus that includes performance measures, and disseminate the recommendations. -Provide training and technical assistance on the package of service. -Promote provision of package of hepatitis-care services among diagnosed patients in CHCs	2011 (2 years) 2013 (3 years) 2013 (3 years)
Goal: **4b.** Improve financing of chronic hepatitis care. ***Rationale:*** Lack of access to care and insurance is a major barrier to the provision of chronic viral hepatitis care. The ACA will provide opportunities to expand coverage of care services for chronic viral hepatitis.	***Lead Agency:*** CMS ***Participating Agencies:*** CDC, HRSA, SAMHSA, and IHS	-Assess and address barriers to financing recommended services identified in the package of service.	2012 (2 years)
Goal:	***Lead Agency:***	-Develop "brief interventions	2010

4c. Improve prognosis of chronic viral hepatitis through reduction of alcohol use. ***Rationale:*** Alcohol use hastens progression of chronic viral hepatitis and reduces response rates to HCV treatment.	SAMHSA ***Participating Agencies:*** IHS, HRSA, CDC, and VA	for alcohol" training modules and disseminate via federally funded training centers.	
Goal: **4d**. Improve the care and treatment of patients with end- stage liver disease. ***Ratonale:*** Given the trajectory of the epidemic, increasing numbers of patients will be presenting with end stage liver disease. Improving the capacity of the health-care system to provide this type of care will ensure better health outcomes.	***Lead Agency:*** HRSA ***Participating Agencies:*** IHS ***Lead Agency:*** HRSA ***Participating Agencies:*** CMS and HIS	-Develop instructional documents for primary-care providers on the management of consequences of chronic viral hepatitis (e.g., end-stage liver disease, portal hypertension, and hepatocellular carcinoma). -Promote high quality care for patients with chronic liver disease in CHCs, including hepatocellular carcinoma screening for patients with cirrhosis.	2011 (2 years) 2013 (3 years)
Goal: **4e.** Promote the concept taken from HIV of targeted prevention for HBV and HCV positives in the care and treatment of patients with chronic viral hepatitis. ***Rationale:*** Patient centered counseling around reducing risk of transmission has been	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, SAMHSA, and IHS	-Increase the training offered by federally funded training centers to ensure that clinicians learn how to counsel patients with chronic viral hepatitis about ways to decrease transmission (i.e., prevention with positives for hepatitis)	2013 (3 years)

shown to be effective in HIV programs. A similar strategy should be effective for chronic viral hepatitis.			

Initiative 5: Improve access to and quality of treatment for Hepatitis B and C

Goals and Rationale	Lead , Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **5.1** Increase rates of HCV treatment by integrating HCV treatment into primary care. ***Rationale:*** Primary-care providers will need to be employed to significantly expand HCV treatment in the United States, particularly if screening programs are successful in identifying those infected.	***Lead Agency:*** HRSA ***Participating Agency:*** NIH ***Lead Agency:*** HRSA ***Participating Agencies:*** NIH ***Lead Agency:*** HRSA ***Participating Agencies:*** CMS, VA, IHS, and CDC ***Lead Agency:*** HRSA ***Participating Agencies:*** CMS, VA, IHS, and CDC	-Develop a standard protocol for Hepatitis C treatment of HIV-infected patients, and test the protocol in a demonstration program. Adapt for mono-infection and disseminate. -Develop technical assistance documents to assist HIV primary-care providers in the management of hepatitis C treatment. Adapt for mono-infection and disseminate. -Glean "lessons learned" from Ryan White Special Projects of National Significance examining the integration of HCV care and treatment in HIV primary care settings.	2010 (4 years) 2011 (4 years) 2013 (1 year) 2013 (3 years)

		-Replicate models (e.g., telemedicine, mentoring, centers of excellence, and models for developing funding opportunities) to expand capacity for the provision of hepatitis care and treatment in primary-care settings including CHCs.	
Goal: **5.2** Expand HCV treatment to a larger proportion of persons identified as potential treatment candidates. ***Rationale:*** Only a minority of those currently identified as being HCV-infected are currently offered treatment. A major barrier to treatment is co-occuring substance abuse and/or untreated mental illness. Better management of these comorbidities likely will improve treatment rates.	***Lead Agency:*** AHRQ ***Participating Agencies:*** SAMHSA, HRSA, CDC, and IHS	-Identify models of treatment of chronic viral hepatitis that promote access to mental-health and substance-abuse services to enhance treatment of patients with dual and triple diagnoses and disseminate best practices.	2012 (2 years)

Initiative 6: Support research focused on improving clinical care and improving treatment for persons at-risk for and those diagnosed with chronic viral hepatitis.

Goals and Rationale	Lead , Participating Agencies	Recommended actions	Year of Initiation (duration)
Goal: **6a.** Improve current treatments for chronic hepatitis B and C. ***Rationale:*** Current therapy for chronic hepatitis C involves two medications, a long-acting interferon given by injection and ribavirin, an oral medication. The combination of these two medications, though effective, is associated with numerous side effects that either preclude patients from starting treatment or completing therapy. An ideal treatment for chronic hepatitis B would result in sustained clearance of HBV, restoration of the immunological milieu to control recurrence, have an acceptable safety profile, be easy to administer, be devoid of resistance, and require a finite duration for achieving optimal treatment response.	***Lead Agency:*** NIH ***Participating Agencies:*** FDA	-Support basic, translational, and comparative and effectiveness research to facilitate the discovery and development of more effective and better tolerated chronic viral hepatitis treatment approaches and to improve the monitoring of liver complications arising from chronic viral hepatitis.	2010 Ongoing
Goal: **6b.** Enhance the public health methodologies and operations used to screen for chronic viral hepatitis.	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, CMS, IHS,	-Support comparative and effectiveness studies on approaches to and operations associated with viral hepatitis screening.	2012 (3-5 years)

Rationale: Sequestered subpopulations at high risk for acquiring or with high prevalence of chronic viral hepatitis present unique challenges to identify cases. Optimizing screening efficiency and effectiveness through investigation of methodologies and operations would serve to improve case ascertainment, thereby improving public health in high-risk subpopulations.	SAMHSA		
Goal: **6c.** Increase of the number of chronic viral hepatitis patients accessing the health-care system. ***Rationale:*** Given the subpopulations associated with chronic viral hepatitis and the complexity of systems, significant attrition occurs between the time of diagnosis to presentation to a health-care facility. Identifying barriers to facilitate the transitioning from the time to diagnosis to the delivery of health care would improve delivery of care and patient understanding of their condition.	***Lead Agency:*** AHRQ ***Participating Agencies:*** NIH and HRSA	-Support evaluations of health-care systems focused on the optimal delivery of care for patients with viral hepatitis.	2012 (3-5 years)
Goal: **6d.** Improve health-care delivery to patients with	***Lead Agency:*** AHRQ ***Participating***	-Support comparative and effectiveness studies on models of treatment support for chronic viral	2012 (3-5 years)

chronic viral hepatitis. ***Rationale:*** Once treatment is initiated, compliance with the therapeutic regimen is essential to prevent the development of resistance and to optimize the opportunity to achieve a successful therapeutic outcome. Understanding systems of support during therapy in the diverse patient populations would improve treatment outcomes.	***Agencies:*** NIH and HRSA	hepatitis patients.	

Preventing Injection-Drug Use as a Cause of Viral Hepatitis

Preventing Injection-Drug Use as a Cause of Viral Hepatitis

Injection-drug use is a primary risk factor for the transmission and acquisition of HCV and HBV infection, and injection-drug users (IDUs) have high rates of both types of hepatitis virus. Although the prevalence of HCV infection among IDUs varies based on availability of and access to hepatitis prevention services within a community (e.g., syringe service programs [SSPs]), it remains exceedingly high compared with other risk groups. IDUs are not only disproportionately affected by these viruses, but more likely to have adverse hepatitis-related health outcomes, primarily because of the inadequate access to and provision of health services (e.g., hepatitis prevention, care, and treatment programs). Several additional factors contribute to the suboptimal health outcomes experienced by many HBV- and HCV-infected IDUs, including late diagnosis, lack of medical care and treatment, lack of awareness of infection status, and lack of knowledge concerning viral hepatitis and liver health.

Surveillance data indicate that incident cases of acute viral HAV and HBV infections have been dramatically reduced in the general population as a result of routine childhood hepatitis A vaccination and universal hepatitis B vaccination (1). Unfortunately, similar reductions have not occurred for IDUs. Most new infections are occurring in this population, and IDUs constitute the largest group of persons with chronic HCV infection in the United States. As determined by numerous cohort studies, chronic HBV infection has been identified in 2.7%-11% of IDUs (2). IDUs contribute disproportionately to the burden of HBV infection in the United States, with chronic HBV registries reporting 4%-12% of chronically infected persons having a history of injection-drug use (3). CDC estimates that 2.0% of those incarcerated are infected with HBV and 15% are infected with HCV (4 MMWR 2003); thus, collaborations are needed beyond the health-service setting to address the prevention, care, and treatment of hepatitis infection for IDUs.

Several other factors contribute to increased rates of viral hepatitis in IDUs. For instance, although vaccination against HAV and HBV infection is an important component of comprehensive primary care for IDUs, studies have demonstrated that IDUs have low vaccination rates (5). Studies have also revealed that drug users lack knowledge concerning HBV infection; the need for educational programs is well documented (6). Education of IDUs on the prevention (e.g., vaccination) and transmission of hepatitis infection is paramount, particularly because studies have shown that most IDUs are not able to accurately self-report their vaccination status (7).

Despite these challenges, successes have been made in the prevention of viral hepatitis among IDUs. Studies have shown that hepatitis B vaccination programs and other large-scale hepatitis vaccination initiatives targeting IDUs are both feasible and effective (8, 9). In addition, outbreaks of HBV infection among IDUs have been successfully quelled by public health/community collaborative vaccination programs that have reduced the number of new infections, and other studies have demonstrated that IDUs are compliant with vaccination (10). Furthermore, the factors that influence the acceptance of hepatitis prevention services among IDUs have been elucidated (i.e., convenience, monetary incentive, needle sharing, increasing age, and length of contact with the SSPs) (11), facilitating the development of programs that maximize the availability of, access to, and acceptability of hepatitis prevention services for IDUs.

Prevention of viral hepatitis infection among IDUs calls for a comprehensive prevention, care, and treatment approach using a coordinated strategy involving federal, state, and local governments; community-based organizations; and health-care provider systems. Ideally, components of a comprehensive approach would include 1) more hepatitis prevention services (including community-based drug-prevention programs); 2) increased access to substance abuse

treatment, particularly medication assisted treatment for opioid dependent IDUs; 3) enhanced testing, vaccination, and risk reduction interventions; 4) safer injection services, including increased access to sterile syringes and utilization of syringe service programs as hepatitis prevention venues; 5) training and education of medical/health service providers to increase awareness, cultural competence, and ability to effectively serve IDUs; 6) improved community outreach and support for IDUs and their social networks; 7) enhanced hepatitis surveillance and screening programs in at-risk populations and communities; and 8) improved social and peer support community programs and better strategies for the medical management of hepatitis infection.

The challenge for hepatitis prevention among IDUs is to implement better coordinated and more comprehensive hepatitis services and promote full access to these services for this population. To meet this challenge and provide a framework to guide future hepatitis-prevention efforts, the Hepatitis Strategic Plan Working Group developed the following table, which not only outlines broad initiatives applicable to the IDU population, but identifies specific, tangible recommended actions.

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Initiative 1: Integrate comprehensive hepatitis prevention services as standard components of substance abuse treatment, and HIV prevention programs.

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **1a.** Integrate viral hepatitis prevention services as standard components of substance abuse treatment. Integrate hepatitis screening and prevention services in behavioral substance abuse and medication-assisted treatment (MAT) programs. ***Rationale:*** The prevalence of hepatitis infection in IDUs who seek drug treatment is high. Medical and behavioral service integration with hepatitis prevention services will enhance IDU access to hepatitis services when they seek drug treatment and general medical care. Providing evidence-based, effective behavioral drug-treatment services to IDUs and persons a-risk for injection drug use and integrating it with hepatitis screening and prevention services reduces hepatitis infection. Expanding access MAT programs as part of hepatitis screening and prevention services for people who are heroin dependent prevents viral hepatitis transmission. (add references)	***Lead Agency:*** SAMHSA ***Participating Agencies:*** HRSA, IHS, CDC, and CMS	Enhance hepatitis testing and vaccination services in drug prevention and treatment programs that serve IDUs.	2011 (ongoing)
Goal: 1b. Integrate viral hepatitis prevention services as standard	***Lead Agency:*** CDC	Integrate HCV and HBV testing into HIV testing and HIV	2011

components of HIV education and screening programs. ***Rationale:*** Integrating hepatitis services into existing HIV prevention services will greatly enhance IDU access to hepatitis-related services.	***Participating Agencies:*** HRSA, SAMHSA, IHS, and CMS	outreach services for IDUs	(ongoing)
Goal: **1c.** Educate and train primary-care providers, along with peer and health outreach workers, in Ryan White supported programs to provide viral hepatitis-prevention-services for IDUs, persons at risk for using these drugs, and persons who use other illegal drugs. ***Rationale:*** Equipping primary-care providers with training in cultural competence and hepatitis prevention will enhance access to and uptake of hepatitis prevention services for persons seeking general medical care. Providing evidence-based hepatitis prevention services in appropriate care settings will limit spread of viral hepatitis among IDUs and persons at-risk for injection-drug use.	***Lead Agency:*** HRSA ***Participating Agencies:*** SAMHSA, CDC, IHS, and CMS	Develop training modules for primary-care providers that address the provision of essential hepatitis services to IDUs and persons at-risk for using injection drugs.	2011 (ongoing)
Goal: **1d**. Expand outreach education and service programs to identify IDUs ready to enter drug treatment	***Lead Agency:*** CDC/SAMHSA ***Participating***	Develop for outreach workers a recommended package of initial hepatitis	2011 (ongoing)

(particularly young IDUs and drug users at risk of progressing to drug injection) and provide these persons prevention services. ***Rationale:*** Persons who have just begun using injection drugs and those at-risk for injection-drug use may not seek drug treatment or believe that they need drug treatment and hepatitis prevention services. Interventions that educate these persons on the need to seek prevention services and treatment reduce the transmission of and risk for HBV and HCV infection.	***Agencies:*** HRSA, IHS, and CMS	interventions for new IDUs and for persons at-risk for injecting drugs.	
Goal: **1e.** Coordinate federal, state, and local resources to expand and enhance IDU access to sterile syringes and hepatitis prevention interventions. ***Rationale:*** Access to sterile syringe programs (SSPs) through comprehensive, community- and pharmacy-based syringe programs prevents HBV and HCV infection in IDUs. Coordination of federal, state, and local resources will reduce barriers, maximize development of SSPs, and increase IDU access to these programs.	***Lead Agency:*** SAMHSA/CDC ***Participating Agencies:*** HRSA, IHS, and CMS	Encourage and develop comprehensive and targeted disease-prevention partnerships involving SSPs and federal, state, and local community representatives.	2011 (ongoing)

Initiative 2. Expand community awareness and health-care provider awareness and training of the need to provide IDUs with hepatitis prevention, care, and treatment services

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)

Goal: **2a**. Enhance education programs in communities at high risk for injection-drug use and associated viral hepatitis. ***Rationale:*** The limited knowledge of hepatitis infection in the community produces stigma and discrimination that in turn inhibits IDUs from accessing and receiving needed health-care services. Community education programs can facilitate community support for the provision of hepatitis prevention, care, and treatment services in an effort to improve public health.	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, IHS, and SAMHSA	Develop hepatitis awareness and education programs for communities and hepatitis training programs for community outreach workers	2012-2015
Goal: **2b**. Educate primary-care providers to obtain and discuss a history of drug use with their patients, assess their patients' risk for viral hepatitis, and appropriately deliver viral hepatitis screening and vaccination. ***Rationale:*** Health-care providers need to be educated to develop an effective patient-provider environment and relationship that fosters open discussions. Such discussions can facilitate the assessment of hepatitis risk factors, as well as ensure the provision of hepatitis- and drug-prevention services. An effective and truthful patient-provider relationship is	***Lead Agency:*** HRSA ***Participating Agencies:*** SAMHSA, CDC, and IHS	Develop a hepatitis service-provision training package for providers (particularly primary-care providers) that focuses on the prevention, care, and treatment of people who use or have used drugs.	2011-2015

fundamental to establishing the trusting relationship needed to prevent hepatitis infection.			
Goal: **2c**. Enhance hepatitis surveillance and case finding for IDUs through community screening, linkage, and prevention services. ***Rationale:*** Coupling national surveillance and case-finding programs to community services can enhance current efforts to identify persons who use drugs and need hepatitis services, and ultimately, bring them into community service programs.	***Lead Agency:*** CDC ***Participating Agencies:*** SAMHSA, CDC, and IHS	Enhance the hepatitis coordinators program at the state level to further link local, state, and federal hepatitis surveillance efforts.	2011-2015
Goal: **2d**. Facilitate community partnerships and linkages with service providers to enhance case finding and delivery of hepatitis prevention services. ***Rationale:*** Forging community hepatitis partnerships with hepatitis service providers enhances efforts to reduce local stigma and discrimination against IDUs who need and seek hepatitis services.	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, SAMHSA, and IHS	Develop hepatitis partnership trainings in hepatitis prevention, care, and treatment for community health-care providers and community leaders.	2011-2014
Goal: **2e**. Enhance provider training for integrated hepatitis screening and	***Lead Agency:*** SAMHSA	Develop a training curriculum and best-practice guidelines on	2012-2014

prevention in substance-abuse treatment settings. ***Rationale:*** Integrating hepatitis services, including screening and prevention services, into a substance-abuse treatment setting is highly effective and is an evidence-based best practice.	***Participating Agencies:*** CDC, HRSA, and IHS	integrated hepatitis screening, prevention, and care for health-care providers in drug treatment settings	

Initiative 3. To enhance peer-based and social support services for IDUs and those at-risk for injection-drug use

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)

Goal: **3a.** Develop peer-based social and case-management support strategies for IDUs. ***Rationale:*** Support strategies are important to reduce existing barriers to hepatitis prevention, care, and treatment services among IDUs (references of effectiveness). Specific strategies may be important in promoting hepatitis treatment and reducing the social factors that serve as barriers to hepatitis care and treatment.	***Lead Agency:*** SAMHSA ***Participating Agencies:*** HRSA, IHS, and CDC	Develop and deliver training for drug-treatment providers with a focus on hepatitis prevention, care, case management, and treatment needs and services for IDUs.	2011-2013
Goal: **3b.** As part of a comprehensive hepatitis prevention program, integrate interventions for the prevention of sex- and drug-associated transmission of hepatitis virus for people who use drugs and their sexual partners. ***Rationale:*** To eliminate drug use as cause of viral hepatitis, evidence-based interventions that reduce the sexual transmission of hepatitis viruses by people who use drugs must be developed and implemented.	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, IHS, and SAMHSA	Develop and deliver training curricula focused on the prevention and reduction of both sex- and drug-associated hepatitis for people who use drugs and members of their social networks.	2011-2013
Goal: **3c**. Develop peer-based and social support groups in a health-care setting for IDUs to reduce their	***Lead Agency:*** HRSA/SAMHSA ***Participating***	Develop and deliver peer-based prevention, care, and treatment programs in the health-	2011-2013

risk of acquiring viral hepatitis . ***Rationale:*** Peer-based support strategies for people who use drugs are important to reduce the social barriers to accessing hepatitis prevention, care, and treatment services. Strategies that employ peer and social groups can be important in promoting access and utilization of these services.	***Agencies:*** CDC and IHS	care setting to enhance community-based hepatitis support services	
Goal: **3d.** Develop and implement hepatitis prevention and behavioral intervention services for persons at risk for injection-drug use. ***Rationale:*** Addressing the needs of those at risk for injection-drug use is an important component of efforts to prevent hepatitis infection in at-risk populations. Providing behavioral interventions that prevent the progression to injection-drug use limits the risk of hepatitis infection in this population.	***Lead Agency:*** SAMHSA/CDC ***Participating Agencies:*** HRSA and IHS	Develop and deliver a training curriculum for case managers focusing on the prevention of hepatitis through behavioral health interventions for those at risk for hepatitis infection.	2011-2013

Initiative 4. To improve the medical management of viral hepatitis among IDUs

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)

Goal: **4a**. Enhance treatment access, acceptability, and readiness approaches for IDUs. ***Rationale:*** IDUs need medical care to address their drug using behavior and risk for hepatitis infection. Increasing access to health-care services through specific interventions that address both effective treatment of injection-drug use as well as the prevention and treatment of hepatitis infection promotes the elimination of hepatitis transmission in IDUs.	***Lead Agency:*** SAMHSA ***Participating Agencies:*** HRSA, IHS, CDC, and CMS	Adapt screening, brief intervention, and referral to treatment (SBIRT) programs to address hepatitis and alcohol consumption among IDUs.	2011-2014
Goal: **4b.** Promote integrated care and treatment approaches for the management of viral hepatitis and co-morbid health conditions. ***Rationale:*** The integration of mental health services, substance abuse treatment services, HIV services, and services to prevent and treat hepatitis infection in the health-care setting is an evidence-based best practice and an effective way to increase treatment hepatitis rates for those needing treatment.	***Lead Agency:*** SAMHSA ***Participating Agencies:*** HRSA, IHS, and CMS	Develop and deliver a pilot program to integrate hepatitis care and treatment with substance abuse and mental health services for IDUs in community health centers.	2012-2015

Goal: **4c**. Enhance vaccination services and other hepatitis-prevention services in medical settings, including those that offer primary care and substance-abuse treatment. ***Rationale:*** Introducing hepatitis vaccination programs into the health-care setting can increase access to hepatitis vaccination by IDUs. Providing additional prevention services beyond vaccination can enhance the health of people who use drugs and promote their entry into drug treatment programs and their use of additional health services.	***Lead Agency:*** HRSA ***Participating Agencies:*** SAMHSA, CDC, IHS, and CMS	Integrate alcohol screening and other prevention services into existing hepatitis vaccination programs to reduce alcohol consumption for people who use drugs.	2011-2014
Goal: **4d.** Develop prevention programs that address the risk for hepatitis re-infection among IDUs receiving successful HCV treatment. ***Rationale:*** Addressing the potential for HCV re-infection and chronic liver disease for IDUs who successfully receive hepatitis treatment is important, because drug dependence is a relapsing chronic disease that requires continued support to maintain abstinence from illicit drug use.	***Lead Agency:*** CDC ***Participating Agencies:*** HRSA, IHS, and SAMHSA	Implement SBIRT trainings in community-outreach programs to reduce alcohol consumption for IDUS as part of broader health education efforts.	2011 (ongoing)

Initiative 5. Expand the access and delivery of hepatitis prevention, care, and treatment services in correctional settings

Objectives and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)

Goal: **5a**. Enhance access and delivery to drug treatment services in closed correctional settings. ***Rationale:*** The prevalence of viral hepatitis infection in incarcerated population is high. Improving access to and delivery of effective, evidence-based drug treatment would reduce the transmission of viral hepatitis in this population.	***Lead Agency:*** DOJ/SAMHSA ***Participating Agencies:*** HRSA, IHS, and CDC	Enhance the access to and delivery of MAT in correctional settings.	2012 (ongoing)
Goal: **5b**.Enhance hepatitis screening and vaccination in closed correctional settings. ***Rationale:*** Identifying persons infected with viral hepatitis in a closed setting would allow for the full administration of prevention services, including vaccination.	***Lead Agency:*** CDC/DOJ ***Participating Agencies:*** SAMHSA, HRSA, and IHS	Update CDC recommended policy prevention services in correctional settings.	2011-2015
Goal: **5c**.Develop and implement effective hepatitis prevention programs as part of community correctional reentry programs. ***Rationale:*** Providing hepatitis prevention services as a component of community-correctional reentry programs would promote continuity of care and reduce viral	***Lead Agency:*** SAMHSA/DOJ ***Participating Agencies:*** HRSA, CDC, and IHS	Identify evidence-based best practices in providing hepatitis prevention services in community drug treatment programs participating in community reentry programs.	2011-2016

hepatitis transmission.			
Goal: **5d**. Develop and expand linkages between correctional facilities that screen for hepatitis infection and community care and treatment clinics. ***Rationale:*** Developing and expanding linkages to care and treatment as part of a community reentry program will promote the continuity of care and reduce viral hepatitis transmission.	***Lead Agency:*** HRSA/DOJ ***Participating Agencies:*** *CMS*, SAMHSA, and IHS	Identify evidence-based best practices in establishing re-entry medical services.	2011-2016

Initiative 6. Identify gaps in the knowledge base for providing hepatitis services to IDUs and those who use drugs

Objectives and Rationale	**Lead / Participating Agencies**	**Recommended Actions** **Type of Research**	**Year of Initiation (Duration)**

Goal: **6a.** Determine the appropriate mix, dose, duration, intensity, and fidelity of prevention intervention services to include the study of outreach, access, and effectiveness of essential hepatitis prevention services. ***Rationale:*** Studies investigating the most effective combination of preventive efforts, including an essential package of hepatitis prevention services for people who inject drugs and those at risk for injection-drug use, would allow for efficient and effective implementation of a public health approach to hepatitis prevention.	***Lead Agency:*** CDC ***Participating Agency:*** NIH	Determine the effectiveness of essential hepatitis prevention services.	2012 (ongoing)
Goal: **6b.** Further develop models of community and health-care provider training to enhance IDU access to hepatitis services. ***Rationale:*** Models of effective community programs and health-care provider programs are needed to enhance the public health approach to the prevention of viral hepatitis infection.	***Lead Agency:*** NIH ***Participating Agencies:*** HRSA, IHS, CDC, and SAMHSA	Identify the effective elements of community health prevention interventions and health-care provider interventions to prevent viral hepatitis infection.	2011 (ongoing)
Goal: **6c**. Further develop models of peer-based and social-support outreach useful in encouraging IDUs and members of their social networks to access hepatitis services; assess the effectiveness	***Lead Agency:*** NIH ***Participating Agencies:*** SAMHSA, CDC, and IHS	Develop IDU and non-IDU social network research cohorts to evaluate hepatitis transmission risk and efficacy of evidence-based prevention services.	2012 (ongoing)

of evidence-based interventions to reduce hepatitis risk behaviors and the transition from non-injection to injection-drug use; address the role of social networks in HCV transmission and transmission. ***Rationale:*** Studies of social networks and hepatitis infection will expand the knowledge base on hepatitis transmission pathways.			
Goal: **6d**. Further develop effective medical management models for the prevention, care, and treatment of hepatitis infection, and specifically address the increasing prevalence of HDV/HBV coinfection in IDUs using these models. ***Rationale:*** HDV/HBV coinfection is an emerging medical issue for IDUs and an increasing cause of liver disease	***Lead Agency:*** NIH ***Participating Agencies:*** HRSA, CDC, IHS, and SAMHSA	Develop a research agenda for HDV/HBV coinfection.	2012-2015
Goal: **6e**. Strengthen the evidence base regarding the delivery and effectiveness of SSPs in the prevention of viral hepatitis. ***Rationale:*** Expanding the knowledge base of hepatitis prevention interventions allows for evidence-based implementation of these prevention interventions	***Lead Agency:*** NIH ***Participating Agencies:*** HRSA, IHS, CDC, and SAMHSA	Develop a research agenda for the delivery of SSPs.	2012 (ongoing)
Goal:	***Lead Agency:***	Develop a research agenda for the study of	2012-2016

6f. Identify and study the recent emergence of injection-drug use and HCV transmission among high-risk adolescents and young injectors in suburban and rural communities; further enhance hepatitis surveillance and epidemiology to determine the metrics and indicators needed to determine access to and receipt of hepatitis prevention, care, and treatment services ***Rationale:*** An emerging cohort of new HCV infection is developing in urban and rural youth. Research into the risk factors for hepatitis transmission in young persons will inform the development of hepatitis prevention interventions.	CDC ***Participating Agencies:*** NIH, HRSA, IHS, CDC, and SAMHSA	hepatitis infection transmission in young injectors and high-risk adolescents.	

Preventing Viral Hepatitis Transmission through Vaccination

Preventing Viral Hepatitis through Vaccination

Of the three types of viral hepatitis that contribute most substantially to disease burden in the United States, only Hepatitis A virus (HAV) and Hepatitis B virus (HBV) currently are vaccine preventable. Vaccines to prevent HAV and HBV became available in the United States in 1995 and 1981, respectively. Since then, the Advisory Committee on Immunization Practices (ACIP) has issued several sets of recommendations regarding HAV and HBV vaccination (1-7), each progressively more inclusive to encompass a wider subset of the U.S. population. Currently, no vaccines are available to prevent HCV infection; insufficient knowledge of factors determining protection against HCV infection impedes progress towards the development of Hepatitis C vaccines. Development of a vaccine that prevents acute HCV infections remains a high-priority task for stakeholders in hepatitis control.

A fourth hepatitis virus, hepatitis E (HEV), is emerging as a potential health threat. The prevalence of seropositivity for antibody to HEV is thought to be high in the United States, but disease burden remains largely unknown. Currently, no vaccine is commercially available for HEV, although two candidate vaccines are undergoing the final stages of clinical trials. The effectiveness of these vaccines must still be evaluated in different epidemiologic settings, and the complex epidemiology of hepatitis E must be better understood. Development of accurate assays for the detection of HEV infections is critical for gaining a better understanding of the epidemiology of hepatitis E.

ACIP currently recommends that all U.S. children be vaccinated against HAV. As a result of these recommendations, a striking reduction in incident Hepatitis A has occurred among all age groups across the country (8-10). However, while the *Healthy People (HP) 2010* targets for Hepatitis A disease reduction have been achieved for children, Hepatitis A vaccination coverage (i.e., the 2-dose series) in infants remains low, at approximately 40%. (11)

Comprehensive hepatitis B vaccination recommendations to include all children aged ≤18 years have resulted in similar reductions in hepatitis B infections. Vaccination contributed to an 82% national decline in Hepatitis B incidence between 1990 and 2007; the decline was seen most dramatically among persons aged <24 years, in whom incidence fell by 93%-98% (12). Rates of Hepatitis B vaccination coverage in infants and adolescents are high (93% in infants and 88% in

adolescents aged 13–17 years) and now meet *HP 2010* targets, whereas rates remain low for neonates (55% by the third day of life) (13,14). Despite widespread use of HBV vaccine in children, recommendations for the prevention of perinatal Hepatitis B infection have not led to the dramatic reduction in HBV infections observed in older groups of children. The *HP 2010* target of ≤400 infections per year for this population has not yet been achieved.

Hepatitis B vaccination programs for adults have been less successful than those targeting children. ACIP has recommended the vaccination of health-care workers and other adults at high risk for incident Hepatitis B infection, including persons with multiple sexual partners, men who have sex with men (MSM), and injection-drug users (IDUs)since 1982 (6). In 2006 ACIP recommendation stressed the need for universal vaccination in health-care settings that serve high-risk adults, including STD clinics, substance-abuse treatment facilities, and correctional facilities (7). Despite these recommendations, vaccination coverage in high-risk adults remains low (45% in adults with high-risk behaviors) (15).

For those groups in which HBV vaccination coverage rates remain low (e.g., infants born to HBV-infected mothers and high-risk adults), several challenges have been identified that serve as barriers to vaccination programs. These challenges include the lack of 1) vaccine affordability for the patient and inadequate provider reimbursement for vaccine administration; 2) vaccine availability in public health settings; 3) alternative vaccination sites; 4) data collection and tracking systems available to all providers; 5) public health infrastructure for case-management of Hepatitis B-infected pregnant women, their newborn infants, and their household contacts; and 6) vaccination coverage estimates for high-risk adults.

The development of new, more effective vaccines that provide long-term protection after a single dose could potentially improve existing Hepatitis A and Hepatitis B vaccination coverage levels in the United States. The development of vaccines capable of inducing protective immunity in populations that have demonstrated reduced immune response rates (i.e., persons in older age groups and adults with co-morbidities) is equally important for the improvement of Hepatitis A and Hepatitis B prevention programs and ultimately, a decrease in new hepatitis infections.

Maintaining robust surveillance for all types of hepatitis viruses is critical to disease prevention and control. For instance, the successes of vaccination programs can only be evaluated through comprehensive surveillance mechanisms capable of accurately detecting viral infections. Viruses are capable of rapid adaptation to adverse conditions through the acquisition of genomic mutations, and extensive vaccination programs may serve as strong selection pressures. Vaccines can potentially affect viral evolution and, in addition to reducing the number of infections, may affect the composition of viral populations, potentially enriching them with vaccine-escape or more virulent variants. Changes in epidemiology caused by prevention measures need to be carefully monitored.

A comprehensive approach is needed to ensure comprehensive surveillance mechanisms are in place, more persons are protected against hepatitis viruses, and rates of vaccination coverage increase. Additionally, currently available vaccines must be used more widely, and new and improved vaccines must be developed. Overcoming vaccine-related challenges and identifying new barriers to vaccine uptake are necessary to prevent viral hepatitis infection and can be addressed as outlined in the initiatives and actions listed in the following table.

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Initiative 1: Eliminate perinatal hepatitis B transmission

Goals and Rationale	Lead / participating agencies	Recommended Actions	Year of initiation (duration)
Goal: **1a.** Increase laboratory reporting of pregnancy status on reports of HBsAg-positive tests. ***Rationale:*** HBsAg-positive women are identified by investigating all HBsAg-positive tests reported to public health. However, pregnancy status is not included on laboratory reports. Achieving this recommended goal will allow scarce public health resources to be used more effectively to improve identification of high-risk pregnant women.	***Lead Agency:*** CDC ***Participating Agencies:*** IHS	-Gain endorsement (e.g. from the Association of Public Health Laboratory, CLIA, and the American Association of Pathologists) of laboratory-based reporting of pregnancy status on electronic and paper requisitions for all hepatitis B positive tests. -Require federal agencies that contract laboratory work to report pregnancy status on reports of HBsAg positive tests.	2012 (5 years)
Goal: **1b**. Establish one or more national quality measures for reporting receipt of hepatitis B vaccine among newborns prior to discharge from hospitals or birthing centers (e.g., a birth dose). ***Rationale:*** Administration of a dose of hepatitis B vaccine to all newborns before discharge from hospitals or birthing centers provides a safety net	***Lead Agency:*** CDC ***Participating Agencies:*** none	-Complete feasibility testing and obtain adoption of a quality measure by the National Quality Forum. -Gain approval by the Joint Commission and/or CMS for the adoption of birth-dose coverage as a national quality measure. -Derive consensus for a national and international reporting definition of "birth dose."	2010 (5 years)

for preventing perinatal and household transmission of hepatitis B. A quality measure for a birth dose provides an incentive for routine administration of a birth dose for all newborns.			
Goal: **1c.** Develop model programs to ensure that all infants born to HBsAg-positive women complete post-exposure prophylaxis and case management. ***Rationale:*** Case-management to ensure life-long protection against hepatitis B infection, among infants exposed at birth requires 1 -2 years for completion. Achievement of high completion rates requires tracking systems and culturally competent personnel. Innovative approaches to achieve high rates of completion are needed.	***Lead Agency:*** CDC ***Participating Agencies:*** IHS, HRSA, SAMHSA, and ACF	-Develop and evaluate the outcomes of model programs that provide post-exposure prophylaxis and case-management to infants born to HBsAg positive mothers. -Evaluate infant case-management model programs that manage infants born to HBsAg positive foreign-born women.	2012 (5 years)
Goal: **1d.** Develop model programs to ensure that HBsAg-positive pregnant women and their household contacts receive prevention services, care, and treatment. ***Rationale:*** Limited health resources result in missed opportunities	***Lead Agency:*** CDC ***Participating Agencies:*** IHS, HRSA, SAMHSA, and ACF	-Develop and evaluate the outcomes of model programs that provide prevention services, care, and treatment to HBsAg positive pregnant women and their household contacts.	2012 (5 years)

for providing evaluation and care to HBsAg-positive women and for conducting screening and prevention activities among their contacts. Achieving high rates of these interventions requires cultural competent personnel as well as client access to laboratory testing, vaccination, and medical care. Innovative approaches are needed to provide prevention services, care, and treatment for HBsAg-positive pregnant women and their contacts.			
Goal: **1e**. Improve identification and management of pregnant women with the highest risk for perinatal hepatitis B transmission (i.e. pregnant women with high hepatitis B viral loads). ***Rationale:*** A small proportion of infants acquire hepatitis B infection at or before birth, despite appropriate post-exposure prophylaxis and vaccination. Recent evidence suggests that mothers of these infants can be identified prior to birth. Research is needed to determine cost-effective ways to identify women at high-risk for delivering a neonate with hepatitis B infection and to support development of public screening policies that	***Lead Agency:*** CDC ***Participating Agencies:*** IHS and HRSA	-Develop and perform clinical validation of a simple screening test to determine high levels of viral replication among HBsAg-positive pregnant women. -Develop criteria using viral load to define woman at increased risk for perinatal transmission despite standard post-exposure prophylaxis of the newborn. -Evaluate the efficacy and safety of interventions to reduce perinatal transmission of hepatitis B to neonates born to pregnant women with high hepatitis B viral loads.	2012 (5 years)

will ensure timely referral for evaluation for treatment.			

Goal: **2a**. Increase availability and utilization of hepatitis A and hepatitis B vaccines for uninsured and underinsured adults. ***Rationale:*** Inadequate provider reimbursement and lack of adequate funding for vaccine purchase and the implementation of vaccination programs are barriers to adult hepatitis A and hepatitis B vaccination. Provision of free or low cost vaccine to targeted high-risk populations will increase vaccine access and improve vaccination coverage.	***Lead Agency:*** CDC ***Participating Agencies:*** IHS, HRSA, SAMHSA, and CMS	-Identify opportunities in health-care reform for hepatitis A and hepatitis B vaccination of high-risk adults. -Identify barriers and develop strategies to address barriers to hepatitis A and hepatitis B vaccination in uninsured and underinsured adults. -Facilitate use of State authority to purchase federal contract vaccine. -Establish an HHS interagency coordinating committee to monitor federal vaccination programs. -Establish guidelines for the adoption of evidence-based interventions as part of adult hepatitis vaccination programs. -Ensure that ACIP recommendations for vaccination are fully implemented in federally funded healthcare facilities, including Federally Qualified Health Centers (FQHC) and IHS facilities	2012 (5 years)
Goal: **2b.** Increase access to and implementation (e.g. immunization infrastructure and staffing) of hepatitis vaccination programs in risk settings. ***Rationale:*** Health-care settings that serve adults at high-risk for incident hepatitis B infection (i.e. "risk settings" such as STD clinics, prisons/jails,	***Lead Agency:*** HRSA ***Participating Agencies:*** CDC, IHS, SAMHSA, and CMS	-Identify opportunities in health-care reform for vaccination in risk settings and other health-care settings that serve high-risk adults. -Identify barriers and develop strategies to address barriers to hepatitis A and hepatitis B vaccination in risk settings and other healthcare settings that serve high-risk adults. -Increase the proportion of risk settings (and other health-care settings serving	2012 (5 years)

substance abuse treatment programs, and Ryan White programs as well as other healthcare settings such as FQHCs) present a unique opportunity for vaccination. An estimated 40% of people with acute hepatitis B were incarcerated within the 12 months prior to infection, 33% had sought STI screening, and 25% were in substance abuse treatment or needle exchange programs.		high-risk adults) that provide vaccination onsite or through referral.	
Goal: **2c.** Increase hepatitis vaccination coverage among men who have sex with men, injection drug users, and other high-risk adults. ***Rationale:*** Most new cases of hepatitis B occur among adults with high-risk behaviors. Although high-risk adults are recommended for hepatitis B vaccination, vaccination coverage remains low.	***Lead Agencies:*** CDC and SAMHSA ***Participating Agencies:*** IHS and HRSA	-Identify barriers and develop strategies to address barriers to hepatitis vaccination among MSM, IDU, and other high-risk adults.	2011 (5 years)
Goal: **2d.** Increase hepatitis B vaccination coverage among health-care workers (HCWs)**.** ***Rationale:*** HCWs are at high risk of exposure to and possible transmission of hepatitis B as a result of direct patient contact or contact with infective patient materials. Coverage among HCWs	***Lead Agency:*** CDC ***Participating Agencies:*** IHS, HRSA, and SAMHSA	-Identify barriers and develop strategies to address barriers to hepatitis B vaccination among HCWs.	2011 (5 years)

remains below HP 2010 goals.			
Goal **2e**. Increase access to and utilization of hepatitis B vaccine in primary-care settings. ***Rationale:*** Many persons with hepatitis B risk factors are seen in the primary care system. Lack of screening for risk factors and/or patient reluctance to discuss risk behaviors with their provider deters the identification and vaccination of persons at risk. In addition, inadequate reimbursement is a barrier to vaccination in these settings.	***Lead Agency:*** CDC ***Participating Agencies:*** IHS, HRSA, and CMS	-Identify opportunities in health-care reform for vaccination in primary-care settings -Identify barriers and develop strategies to address barriers to hepatitis B vaccination in primary-care settings (e.g. reimbursement for vaccination) among all high risk groups -Educate primary-care providers about screening for hepatitis B risk factors, and develop tools to assist providers in screening for risk factors. -Ensure that ACIP recommendations for vaccination are fully implemented in federally funded health-care facilities, including FQHCs and IHS facilities.	2011 (5 years)
Goal: **2f.** Expand delivery of vaccine through pharmacies, and evaluate the utility of this delivery method. ***Rationale:*** Pharmacists have limited or full authority to administer vaccination in all 50 states and have successfully vaccinated large numbers of people for influenza. Expanding vaccine administration through pharmacies may increase access to hepatitis B vaccination.	***Lead Agency:*** CDC ***Participating Agencies:*** IHS and SAMHSA	-Identify advantages and barriers to use of pharmacies as vaccination sites. -Identify means, strategies, and partners to expand vaccination efforts to pharmacies. -Evaluate the effectiveness of using pharmacies to increase hepatitis vaccination rates. -Evaluate the ability of pharmacies to report client vaccination to Immunization Information Systems (IIS).	2012 (5 years)

Initiative 3: Design, develop, and test novel or improved vaccines against hepatitis viruses, and determine the indications for their optimum use

Goals and Rationale	Lead / participating agencies	Recommended Actions	Year of initiation (duration)
Goal: **3a.** Study virologic and host immune factors to HCV infection that would assist in the development of a hepatitis C vaccine, and conduct population-based studies to determine vaccine need. ***Rationale:*** More than 75 % of HCV infections result in chronic persistence, often leading to serious, progressive, and fatal liver disease. Current treatment options for hepatitis C are lengthy, only moderately efficacious, poorly tolerated, and expensive. No vaccines against HCV are available, primarily because of insufficient basic knowledge of the parameters that determine immunity and protection. Therefore, efforts should be focused on obtaining a better understanding of protective host immune responses to guide the development of vaccines and to evaluate them.	***Lead Agency:*** NIH ***Participating Agencies:*** CDC and FDA	-Study immune responses to HCV infection in both humans and in animal models, primarily chimpanzees, to identify correlates of immunity. -Facilitate development of candidate hepatitis C vaccines that are designed to induce protective immune responses and can overcome viral evasive and heterogeneity factors. -Study mechanisms of HCV cell entry and early steps of infection. -Determine the role of HCV genome heterogeneity and evolution in the evasion of host immune responses and disease progression. -Define host genetic determinants, immune factors, racial differences, and co-morbidities that contribute to viral clearance or progression to chronic infection. -Establish indications for hepatitis C vaccine in the United States and globally.	All actions have been initiated (ongoing)
Goal: **3b.** Improve laboratory methodology to monitor the effectiveness of vaccination programs. ***Rationale:*** Monitoring the effect of vaccination on prevalence of infections and the rates of reduction in morbidity and	***Lead Agency:*** CDC ***Participating Agencies:*** NIH and FDA	-Develop rapid assays to accurately identify hepatitis A, hepatitis B, and hepatitis E transmission. -Develop rapid assays to genetically characterize hepatitis B vaccine escape variants. -Develop approaches to assess HBV and HEV virulence. -Develop assays to genetically	All actions have been initiated (ongoing)

mortality associated with these infections is crucial for the successful implementation of prevention programs. Such monitoring requires detection of viral variants resistant to vaccine-induced immunity and those that cause unusual clinical manifestations.		characterize HAV viral variants. -Develop an assay to distinguish between hepatitis A vaccine-induced immunity and immunity associated with natural or breakthrough infection.	
Goal: **3c.** Determine long-term protection of the current hepatitis B vaccine and evaluate new hepatitis B vaccine(s) that demonstrate improved immune response. ***Rationale:*** The current hepatitis B vaccine provides immunity that lasts for over 20 years. Research is needed to determine if a booster dose is necessary for continuing immunity; this is particularly important for persons vaccinated as infants. In addition, a small minority of healthy persons and persons from certain populations (e.g. older persons and people with co-morbidities such as chronic renal failure, HIV, and obesity) have poor response or are nonresponsive to vaccination. Ideally, new vaccines that demonstrate improved protection would also be administered in fewer doses.	***Lead Agency:*** CDC ***Participating Agencies:*** NIH and FDA	-Determine immune markers that predict a booster response to hepatitis B vaccine and differences by age at primary vaccination. -Conduct basic research to develop more effective vaccine strategies against HBV. -Determine persistence of protective immune response to vaccination among extreme age groups and among adults with co-morbidities (e.g. diabetes, liver disease, HIV, and obesity).	All actions have been initiated (ongoing)
Goal: **3d.** Assess effectiveness of hepatitis E vaccine candidates and define indications for use in the United States and globally. ***Rationale:*** Exposure to HEV is common in the United States. However, the burden of disease is unknown. Availability of reliable assays for the detection of HEV infections is crucial for assessing need for	***Lead Agency:*** CDC ***Participating Agencies:*** NIH and FDA	-Assess need and establish indications for implementation of hepatitis E vaccination in the United States and globally. -Determine utility of a hepatitis E vaccine in outbreak settings. -Evaluate hepatitis E vaccines that are useful in providing protection in developing countries.	Actions to begin in 2011 (ongoing) Action to

vaccination. Additionally, a commercial HEV vaccine with proven effectiveness against different HEV genotypes is needed.		-Convene an international consultation to review candidate HEV vaccines and to discuss the public health role of HEV vaccination.	occur in 2010
Goal: **3e.** Determine long-term protection of the current hepatitis A vaccine**.** ***Rationale:*** The inactivated hepatitis A vaccine is safe and highly effective. However, the duration of protective immunity is not known, and therefore, the need for booster immunizations has not been determined. In addition, vaccination programs would be greatly enhanced if a single dose vaccine could produce long-term immunity.	***Lead Agency:*** CDC ***Participating Agencies:*** none	-Seek opportunities to determine long-term protection after 1 dose versus 2 or 3 doses of hepatitis A vaccine.	2012 (ongoing)

Initiative 4: Establish national estimates and regularly measure hepatitis A and B vaccination coverage

Goals and Rationale	Lead / participating agencies	Recommended Actions	Year of initiation (duration)
Goal: **4a.** Require federally funded adult hepatitis vaccination programs to routinely collect and report, to the funding agency, all vaccination coverage data (i.e., individual 1 and 3 dose data and demographics) obtained from adults with risk behaviors. ***Rationale:***	***Lead Agency:*** SAMHSA ***Participating Agency:*** CDC	-Establish reporting requirements for vaccination coverage.	2012 (5 years)

A requirement for routine collection and reporting of adult vaccination coverage will increase accountability of federally funded disease-prevention and clinical-care programs and will provide estimates of vaccination coverage among high-risk adults.			
Goal: **4b.** Add individual risk factor/risk behavior questions and multi-dose hepatitis A and hepatitis B vaccination coverage questions (e.g., for doses 1, 2, and 3) to national surveys. ***Rationale:*** Rates of viral hepatitis vaccination coverage among certain high-risk populations (e.g. MSM and IDUs) are not well known. Addition of individual risk questions to national surveys (e.g. the Behavioral Risk Factor Surveillance Survey [BRFSS], the National Health Interview Survey [NHIS] and the National Survey of Substance Abuse Treatment Services [N-SSATS]) will better help estimate vaccination coverage among high-risk populations and will help measure progress toward *Healthy People 2020* goals.	***Lead Agency:*** CDC ***Participating Agency:*** SAMHSA	-Add appropriate questions to the BRFSS. -Add appropriate questions to the NHIS or to an adult National Immunization Survey. -Add appropriate questions to the N-SSATS or to the National Household Survey on Drug Abuse. -Maintain such questions so they are asked at least every 3 years.	2012 (3 years)
Goal: **4c.** Increase utilization of data collection and tracking systems for adult vaccination, and enhance interoperability with immunization information systems (IIS). ***Rationale:*** The inability of programs to adequately track multi-dose	***Lead Agency:*** CDC ***Participating Agencies:*** IHS, SAMHSA, and CMS	-Increase the proportion of vaccination programs that are using data collection and tracking systems. -Increase support (e.g., personnel and other resources) for data collection and tracking for adult vaccination. -Structure EMRs so that	2011 (5 years)

hepatitis B vaccination is a barrier to tracking client completion of the 3 doses necessary for protective levels of immunity. Increased use of data collection/tracking systems, such as electronic medical records (EMR), that are interoperable with IIS will enhance documentation of vaccination and facilitate provider follow-up for second and third doses.		providers can input and query vaccination data. -Increase proportion of IIS tracking adult immunizations and increase the proportion of data collection and tracking systems that can exchange adult immunization information with IIS. -Increase the number of private vaccine providers that enter adult vaccinations in IIS. -Determine barriers to access of adult vaccination records within IIS, and develop and implement strategies to improve provider access to adult vaccination records within IIS.	
Goal: **4d.** Strengthen IIS for children so that these systems can be used to estimate national vaccination coverage. ***Rationale:*** IIS are useful data sources to assess vaccination coverage because their data reflects the most recent data available; are provider-verified; can be used to track vaccination patterns; and can assess coverage among children and adolescents. Improving documentation of child and adolescent vaccination and assuring high levels of provider participation (≥85%) will allow rapid assessment of national coverage for hepatitis A and hepatitis B vaccines.	***Lead Agency:*** CDC ***Participating Agency:*** IHS	- Increase the proportion of children in the United States who are captured within states' IIS.	2012 (5 years)

Preventing Health care - Associated Viral Hepatitis

Preventing Health care - Associated Viral Hepatitis

Ensuring Safe Health Care for All Patients and Providers

HBV and HCV infections are common in the United States – an estimated 3.5-5.3 million persons are living with chronic disease.[i,ii] These persons represent a reservoir of infection for subsequent bloodborne transmission to patients and health-care providers. A wide variety of health-care settings have been implicated in the transmission of HBV and HCV, both of which are transmitted more easily than HIV. Although receipt of transfused blood products was once a significant risk factor for the acquisition of viral hepatitis, the current risks for health-care-associated infections are primarily breaches in infection control, sharps injuries, and other unsafe health-care practices.

Fortunately, over the past several decades, significant progress has been made toward reducing the risk of acquiring HBV and HCV from transfused blood products. The primary cause of the decline is rigorous risk-factor screening and improved testing of donated blood in the United States.[iii,iv] Risks to health-care providers from sharps injuries and other blood and body-fluid exposures have also been reduced as a consequence of widespread hepatitis B vaccination of patients and health-care workers, the adoption of standard infection-control procedures, and the use of safety devices.[v] The number of incident HBV infections among health-care workers is estimated to have dropped from over 10,000 in 1983 to approximately 400 in 2002.[vi] Outbreak investigation techniques have also been refined.

Despite these successes, the challenge of consistently providing completely safe medical care is not always met, as reflected in increasing reports of health-care-associated HBV and HCV outbreaks attributed to unsafe injection practices and other breakdowns in basic infection control.[vii] Unsafe practices have been implicated in recent outbreaks in a variety of health-care settings, including 1) syringe reuse and medication vial contamination involving diverse types of outpatient clinics (e.g., those performing endoscopy, those providing oral surgery, and those specializing in cardiology); 2) improper use and handling of blood glucose monitoring equipment in long-term care settings; and 3) diversion of narcotics (e.g., fentanyl), resulting in exposure to reused syringes and contaminated medications in hospital settings.[viii] These incidents and others involving lapses in reprocessing patient equipment (e.g., endoscopes) have impacted tens of thousands of patients who have had to be notified of potential exposure to bloodborne pathogens. Findings from a

recent case-control study that examined risk factors for acute HBV or HCV among older persons (i.e., those aged ≥ 55 years) confirm that unsafe injections and other health-care exposures represent a significant, but under-recognized, source of transmission.[ix] Although hepatitis transmission resulting from breaches in infection control has occurred in a variety of health-care settings, outbreaks are increasingly being identified in non-hospital settings where infection-control infrastructure and oversight may be lacking.

Beyond infection control, eliminating exposure to HBV and HCV among recipients of tissues and organs remains challenging. Although the risk for acquiring HBV and HCV from transfused blood and blood products has been significantly reduced in the past few decades, comparable reductions for tissues and organs have not been realized

The inadequacy of current public health efforts to ensure optimal infection-control practices in the United States has only compounded the problem; patients continue to be placed at risk by health-care providers who fail to follow basic infection-control practices. To realize improvements in clinical practices, it is essential to engage public health in efforts to provide continuing infection-control education to all health-care providers, enhance professional and institutional accountability, and improve practice oversight. In addition, collaboration between public and private health sectors is needed to improve the design and labeling of medical devices -- activities that will facilitate infection-control compliance among the professionals who use them.

Gaps also exist in public health efforts to ensure the safety of patients receiving transfusions and transplants. Currently, blood and tissue screening using nucleic acid testing to detect antibodies represents the most effective option to reduce transmission; although this screening has dramatically reduced the number of viral hepatitis infections attributable to these procedures, additional refinement is needed to bring the risk closer to zero. The situation for solid-organ donor screening is much different. Because of the high demand for and limited supply of organs, persons with risk factors for hepatitis are accepted as donors. In addition, because of the time sensitive nature of organ transplant procedures, only serology testing is performed on organs prior to transplantation; the window period for antibody detection leaves residual risk for HBV and HCV transmission in transplant recipients recommendations concerning organ donor screening (concerning both laboratory and risk-factor screening) are outdated and need to be revised through an evidenced-based process. Public health surveillance for transplant-transmitted infections is also

lacking; additional data are needed to compare the benefits of existing and proposed screening strategies for donated blood, organs, and tissues.

Neither patients nor providers should be at risk for acquiring HBV, HCV, or other bloodborne pathogens when receiving or providing healthcare. Unlike personal risk behaviors (e.g., unsafe use of injection drugs and unprotected sexual activity), which are difficult to modify for every individual at risk in every situation, behaviors and activities taking place within the health-care system are more easily monitored and controlled. Therefore, a comprehensive approach is needed to ensure that all entities involved in the delivery of healthcare achieve the minimal levels of risk currently associated with blood and blood products. To be effective, this approach must be integrated with the Department of Health and Human Services' initiative on the prevention of health-care-associated infections.[x] It will also require the involvement of the entire medical community – including hospital, ambulatory care, and residential care industries – as well as those charged with quality and oversight.

The HHS Viral Hepatitis Working Group has identified several specific objectives to help promote patient and provider safety in the United States. These objectives include 1) eliminating medical device-related transmission of viral hepatitis to patients and providers and 2) reducing the risk of HBV/HCV transmission associated with blood, organs, and tissues by 75%. While many of the more specific initiatives and goals listed in the following table focus on specific actions for particular medical devices or products, a multifaceted approach drawing on all available public health techniques is needed to completely prevent the transmission of bloodborne pathogens in all health-care settings. This approach includes enhanced surveillance and vaccination activities, along with improved patient and provider education about the need to always follow Standard Precautions and adhere to basic infection control measures. These issues are addressed more thoroughly in other sections of this report (see XXXX).

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Initiative 1: Reduce iatrogenic transmission of viral hepatitis associated with misuse of medical devices and drugs

Goals and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **1a.** Reduce device- and drug-related iatrogenic transmission in long-term care, assisted living, and residential-care facilities ***Rationale:*** Outbreaks of viral hepatitis are increasing in nursing homes, assisted living facilities, and ambulatory care settings.	***Lead Agency:*** CMS	-Engage the affected industries in efforts to reduce iatrogenic transmission in their facilities.	2011 (2 years)
Goal: **1b.** Reduce iatrogenic transmission related to point-of-care diagnostic devices. ***Rationale:*** Outbreak investigations, largely in long-term care settings, have repeatedly demonstrated that diagnostic devices designed for personal use can transmit disease when used to care for multiple patients. Failure to clean and disinfect blood glucose monitors between each use has been a major source of HBV transmission in this context.	***Lead Agency:*** FDA ***Participating Agencies:*** CDC and CMS	-Review validation data for cleaning and disinfecting procedures in manufacturers' premarket submissions. -Issue guidance documents on appropriate device design and cleaning procedures for devices used on multiple patients. -Develop and conduct an educational campaign targeted to manufacturers, user facilities (with a particular emphasis on assisted living facilities), and	*Guidance document*: 2011 (3 years) *Educational campaign*: 2012 (ongoing)

		clinicians.	
Goal: **1c.** Reduce iatrogenic transmission related to the use of lancets ***Rationale:*** Blood lancing devices used on multiple patients have repeatedly been implicated in HBV outbreaks.	***Lead Agency:*** FDA ***Participating Agencies:*** CDC and CMS	-Issue health advisories on this topic. -Review the current regulatory status and labeling of lancets.	*Health Advisory:* 2010 (ongoing) *Review FDA regulatory status and labeling:* 2010 (1 year)
Goal: **1d.** Reduce iatrogenic transmission risks associated with failure to appropriately reprocess endoscopes. ***Rationale:*** The causes of endoscope-related exposure include use of incorrect disinfectant; failure to adequately manually clean the endoscope; failure to perfuse all endoscope channels with disinfectant; and inadequate disinfectant performance.	***Lead Agency:*** FDA ***Participating Agencies:*** CDC and CMS	-Issue an FDA *Guidance for Industry* on the validation of the cleaning, disinfection, and sterilization of endoscopes. -Conduct a workshop for manufacturers to educate them about the Guidance.	*Guidance document:* 2011 (3 years) *Workshop:* 2012 (2 years)
Goal: **1e.** Reduce iatrogenic transmission related to the contamination of medication vials. ***Rationale:*** Medication vials have transmitted viral hepatitis when used for multiple	***Lead Agency:*** CDC ***Participating Agency:*** FDA	-Enhance provider and purchaser education regarding the need to limit use of single-dose vials to only one patient to encourage increased uptake of prefilled syringes and "right-sized" medication vials. -Issue guidance on	*Educational campaign:* 2010 (ongoing) *Guidance document:* 2010 (2 years)

patients after becoming contaminated by used syringes or after being handled in a contaminated environment.		improved medication vial labeling.	
Goal: **1f.** Reduce iatrogenic transmission related to improper use of syringes. ***Rationale:*** A syringe can transmit viral hepatitis if it is reused from patient to patient or, more commonly, when a medication vial is reentered with the same syringe and then used as a source of medication for subsequent patients.	***Lead Agency:*** CDC ***Participating Agencies:*** FDA and CMS	-Develop injection safety check-lists for providers. -Expand educational campaigns and infection control and/or regulatory guidance and use campaigns and materials to promote increased uptake of reuse-prevention equipment. -Encourage industry to develop reuse-prevention equipment and/or devices that identify when injection equipment has been used.	*Injection safety check-list:* 2011 (1 year) *Educational campaign:* 2010 (ongoing) *Work with industry on reuse-prevention technology:* 2011 (3 years)
Goal: **1g.** Improve provider education regarding basic infection control and improve oversight of all facilities where health-care services are provided. ***Rationale:*** Messages for appropriate use and reprocessing of medical devices and appropriate preparation and administration of parenteral medications must be reinforced at the educational	***Lead Agency:*** CMS and CDC *Participating Institutions:* Joint Commission, CDC, and state and local Health Departments	-Identify opportunities to improve infection control education, and expand requirements for continuing education and related competency certifications for health-care providers. -Incorporate evidence-based infection control elements into applicable health and safety standards. -Engage entities with oversight responsibilities to	2011 (ongoing)

and institutional level.		include in their inspections monitoring for appropriate use and cleaning of medical devices. Such inspections should also confirm that related training activities are in place.	

Initiative 2: Reduce iatrogenic transmission of viral hepatitis associated with blood, organs and tissues

Goals and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **2a**. Promote improved sensitivity testing for HBV and HCV in blood. ***Rationale:*** Increasing the sensitivity of HBV testing can be accomplished by improving nucleic acid extraction from test samples and by using smaller pools of samples for testing — or even testing single samples. The latter will have ripple effects upon the transmission of other viruses, including HCV.	***Lead Agency:*** FDA	-Engage in technical discussions with manufacturers to assist them in developing high-throughput, high-sensitivity nucleic acid testing systems for detecting HBV and HCV.	2011 (2 years)
Goal: **2b**. Explore pathogen reduction technology (PRT) for HBV and	***Lead Agency:*** FDA ***Participating Agency:*** OPHS	-Examine FDA's current regulatory approach to see whether the development of new PRTs can be encouraged.	2011 (3 years)

HCV in blood. ***Rationale:*** The goal of PRT is to process blood products to render them safe for transfusion or injection. PRT has the potential to reduce not only the residual risks of HBV and HCV, but also those of other emerging infectious diseases.			
Goal: **2c.** Improve existing biovigilance systems for blood, organs, and tissues. ***Rationale:*** A national surveillance system is needed to understand the circumstances, risk behaviors, and modes of transmission underlying transfusion- and transplantation-related infections.	***Lead Agency:*** OPHS ***Participating Agencies:*** CDC, HRSA, FDA, and CMS	-Undertake a coordinated cross-agency and public-private collaborative effort to collect, analyze, and share data on adverse events during the donation, processing, distribution, and transfusion/transplantation process.	2010 (2 years)
Goal: **2d.** Implement nucleic acid testing for HCV in organ donor screening. ***Rationale:*** Potential blood and tissue donors who have risk factors for HCV are excluded, and both	*Lead Agencies:* CDC and CMS ***Participating Agencies:*** FDA and HRSA	-Use PHS guidelines and CMS regulations/interpretive guidance to implement HCV nucleic acid testing or tests with equivalent accuracy for all organ donors. This may provide an incentive for the development of 4th generation antigen/antibody tests for organ donor screening.	2011 (3 years)

antibody and nucleic acid testing are required. However, organ donors with risk factors generally are accepted under current policies if the antibody test is negative. This policy has been estimated to result in dozens of unrecognized HCV transmissions and potentially failed transplants each year.			

Initiative 3: Reduce occupational transmission of viral hepatitis

Goals and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **3a**. Reduce device-related percutaneous exposures among health-care workers. ***Rationale:*** Needlestick injuries are a continuing source of bloodborne pathogen exposures among health-care workers. Sharp-tip suture needles are responsible for almost half of percutaneous injuries among surgeons. Since 2005, the American College of Surgeons has recommended the use of blunt surgical needles for the suturing of fascia.	***Lead Agency:*** FDA ***Participating Agencies:*** OSHA and CDC/NIOSH	-Release a joint Safety Alert/Advisory recommending the use of blunt surgical needles for the suturing of fascia.	2011 (1 year)

Goal: **3b.** Revise existing guidelines for the management of HBV and HCV exposures among healthcare personnel ***Rationale:*** Current guidelines on the management of occupational viral hepatitis exposures have not been published since 2001. HBV vaccination levels of health-care workers, particularly those working in residential-care facilities, are not currently adequate.	***Lead Agency:*** CDC ***Participating Agency:*** NIH	-Update and publish revised guidelines on the management of occupational viral hepatitis exposures.	2011 (3 years)

Initiative 4: Enhance understanding of the preventable causes of viral hepatitis transmission in healthcare

Goals and Rationale	Lead/Participating Agencies	Recommended Actions	Year of Initiation (Duration)
Goal: **4a**. Expand support for health departments to thoroughly investigate possible outbreaks of health-care-associated viral hepatitis. ***Rationale:*** Health departments are often lacking resources to identify and investigate newly diagnosed hepatitis infections in patients who	***Lead Agency:*** CDC	-Link state health-care-associated infection (HAI) programs to viral hepatitis surveillance programs. -Develop a toolkit outlining best practices for the investigation of potential cases of health-care-associated viral hepatitis.	*HAI linkage:* 2010 (ongoing) *Toolkit development:* 2010 (3 years)

lack traditional risk factors.			
Goal: **4b**. Expand research on barriers to adherence to recommended practices for safe use of medical devices and reprocessing of endoscopes by health-care personnel. ***Rationale:*** Despite infection control recommendations to the contrary, facilities continue to purchase medication vials and devices not suitable for the practices being performed in the facility.	***Lead Agency:*** CDC	-Commission study to evaluate purchasing practices of health-care facilities to understand patterns of use. -Conduct site visits and/or focus groups to identify barriers to use of safety devices and single-patient medication vials.	2012 (pending funding)
Goal: **4c**. Support research on best practices for evaluating, managing, and preventing viral hepatitis transmission associated with opioid and anesthetic abuse by health-care personnel. ***Rationale:*** Narcotics diversion has emerged as the leading cause of provider-to-patient HCV transmission.	***Lead Agency:*** CDC, SAMHSA, and NIH	-Engage stakeholders to improve current practices related to narcotics security. Generate best practices document outlining recommended steps for investigation and management when diversion is suspected.	2011 (3 years)
Goal: **4d**. Support research to identify the next generation of PRTs for red cell blood	***Lead Agency:*** NIH	-Fund clinical trials to explore the safety and efficacy of technologies currently in the early stages of	2011 (ongoing)

products. ***Rationale:*** PRT should virtually eliminate transfusion risks from established threats such as HIV and viral hepatitis and most new or emerging infectious agents, including bacterial contaminants. They should also reduce non-infectious complications, such as transfusion-related immunomodulation. These and other approaches must be further developed for the treatment of all blood components.		use in other parts of the world. -Fund grants to support basic science investigations to promote the development of new processing technologies.	