U.S. Department of Health & Human Services

COMBATING THE SILENT EPIDEMIC of VIRAL HEPATITIS

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

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INTRODUCTION

Viral hepatitis is a silent epidemic in the United States. Although it is a leading infectious cause of death and claims the lives of 12,000–15,000 Americans each year, viral hepatitis remains virtually unknown to the general public, at-risk populations, and policymakers (1–3); even health-care providers lack knowledge and awareness about these infections (1). As a consequence, most of the 3.5–5.3 million Americans living with viral hepatitis do not know that they are infected, placing them at greater risk for severe, even fatal, complications from the disease and increasing the likelihood that they will spread the virus to others. Viral hepatitis is a major cause of liver cirrhosis and liver cancer in the United States (1–4); persons living with viral hepatitis are at increased risk for both conditions.

In January 2010, the Institute of Medicine (IOM) released the report *Hepatitis and Liver Cancer: a National Strategy for Prevention and Control of Hepatitis B and C* (1). In this report, IOM identifies viral hepatitis as an underappreciated health concern for the nation and outlines multiple barriers impeding efforts to prevent viral hepatitis transmission and disease. In its 2010 report, IOM provides 22 specific recommendations to help improve 1) disease surveillance, 2) knowledge and awareness of viral hepatitis among the public and providers, 3) access to vaccination, and 4) delivery of viral hepatitis prevention and care services (Appendix A).

In response to the IOM report, Assistant Secretary for Health Dr. Howard Koh convened a Viral Hepatitis Interagency Working Group comprised of subject matter experts from various U.S. Department of Health and Human Services (HHS) agencies (Appendix B). This group was charged with responding to the IOM comments by developing a comprehensive strategic viral hepatitis action plan that would:

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

To prepare the report *Combating the Silent Epidemic of Viral Hepatitis: U.S. Department of Health and Human Services Action Plan for the Prevention, Care and Treatment of Viral Hepatitis* (referred to as the Viral Hepatitis Action Plan), the Working Group convened expert panels from various HHS agencies and offices (Appendix B). Panel members were tasked with developing components of the action plan specific to their area of expertise. To engage key federal stakeholders in the planning process, the Working Group solicited input from other government agencies. Additionally, two meetings were held to solicit feedback from professional societies, community-based organizations, and other members of the public.

VIRAL HEPATITIS: THE SILENT EPIDEMIC

An estimated 3.5–5.3 million persons are living with viral hepatitis in the United States, and millions more are at risk for infection. Because viral hepatitis can persist for decades without symptoms, 65%–75% of infected Americans remain unaware of their infection status and are not receiving care and treatment (1). Most morbidity and mortality result from the chronic form of viral hepatitis caused by hepatitis B virus (HBV) and hepatitis C virus (HCV) infection.

Viral hepatitis is the leading cause of liver transplantation in the United States (5). In the absence of treatment, 15%–40% of persons living with viral hepatitis will develop liver cirrhosis (6–8) or experience other conditions that affect the liver, including liver cancer. Rates of liver cancer have tripled over the last several decades (4), with at least half of these cases attributable to HCV (9). In the decade to come, more than 150,000 Americans are expected to die from viral-hepatitis-associated liver cancer or end-stage liver disease (1).

Liver cancer and other liver diseases caused by viral hepatitis (e.g., cirrhosis) affect some U.S. populations more than others, resulting in substantial health disparities. Persons with certain risk behaviors, including men who have sex with men (MSM) and injection-drug users (IDUs), have high rates of viral hepatitis. Also at risk are baby boomers. Compared with other age groups, a greater proportion (about 1 in 33) of persons aged 46–64 years is infected with HCV (10). African Americans are twice as likely to be infected with HCV when compared with the general U.S. population (10), and approximately 1 in 12 Asian/Pacific Islanders (APIs) are living with hepatitis B, representing half of all HBV-infected persons in the United States (11). These health disparities are reflected in viral-hepatitis–associated morbidity and mortality; for example, liver cancer incidence is highest among APIs and is increasing among African Americans, persons aged 46–64 years, and men.

Persons with HIV also are disproportionately affected by viral hepatitis and related adverse health conditions. Because HIV, HBV, and HCV share common modes of transmission, one third of HIV-infected persons are coinfected with HBV or HCV. The progression of viral hepatitis is accelerated among persons with HIV; therefore, persons who are coinfected experience greater liver-related health problems than non-HIV infected persons (1–3,5,7,12).

Recipients of organs, blood, and tissue, along with persons working or receiving care in health settings continue to be at risk for viral hepatitis infection. Although dramatic progress has been made towards reducing the risk for health-care-associated HBV and HCV infections among these persons, outbreaks continue to occur as a result of breakdowns in basic infection control and limitations in the laboratory screening of donated organs, blood, and tissues.

In addition to causing substantial morbidity and mortality, viral hepatitis infection has adverse economic consequences. End-stage treatments for viral hepatitis (e.g., liver transplants) are expensive — the lifetime health-care costs for a person with viral hepatitis can easily total hundreds of thousands of dollars (1). During the 1990s and early 2000s, hospital discharges with an HBV diagnosis increased fourfold, with a rise in health-care costs from $357 million in 1990 to $1.3 billion in 2006 (13). Compared with other patients of similar age and sex, managed-care enrollees with HCV are hospitalized more frequently (24% for HCV-infected persons versus 7% for other patients) and have higher annual health-care expenses (approximately $21,000 per HCV-infected enrollee versus about $5,500 for each non-infected enrollees), exceeding the per-

person costs associated with diabetes (approximately $10,000 per year) (14–16). Hepatitis C also increases other societal costs. A study of 339,456 workers revealed that employees with HCV had significantly more lost work days than other employees, resulting in lost productivity (17).

Computer models indicate that cases of life-threatening liver disease caused by viral hepatitis infections and health-care-associated costs will increase as infected persons grow older and as their disease progresses (1,2). Fortunately, treatments for hepatitis B and hepatitis C can reduce morbidity and are cost-effective (18,19). Economic studies of therapy have yielded estimates of cost-saving to $33,900 per quality-adjusted life year (QALY) gained for HBV therapy and cost saving to $120,000 per QALY gained for HCV therapy (20–34).

VIRAL HEPATITIS: THE GLOBAL PERSPECTIVE

Current rates of viral hepatitis in the United States are reflective of the large global disease burden involving hundreds of millions of persons. One in every 12 persons worldwide is living with viral hepatitis; approximately 350–370 million persons are infected with HBV, and another 130–170 million are living with HCV infection (35–37). Globally, an estimated 78% of primary liver cancer and 57% of liver cirrhosis cases are caused by viral hepatitis (36), and 1 million deaths from viral hepatitis occur each year (35,36). The proportion of persons living with viral hepatitis is greatest in Asia, sub-Saharan Africa, and Egypt; however, prevalence of HCV infection is high among subpopulations (e.g., IDUs and persons living in correctional settings) in almost all parts of the world. Increasing immigration to the United States from endemic countries has resulted in more infections within U.S. borders; approximately 54,000 persons infected with hepatitis B immigrate to the United States annually (CDC, unpublished data).

THE EPIDEMIOLOGY OF VIRAL HEPATITIS

HEPATITIS B

In the United States, an estimated 800,000–1.4 million persons are infected with hepatitis B. Hepatitis B is a vaccine-preventable disease; immunization programs for infants and adolescents have resulted in substantial declines in the incidence of HBV infection (38). However, in 2008, an estimated 38,000 persons were newly infected with the virus (39). HBV is spread in several distinct ways: from mother to child at the time of birth, through incidental household exposures to blood, through injection-drug use, and through sexual contact (2,10,40). Globally, unsafe infection control in health-care settings represents a significant mode of viral hepatitis transmission. In the United States, outbreaks also occur in residential care and health-care settings, where poor infection control has been identified as the primary source of transmission (41). Rates of HBV infection are highest among adults, reflecting low hepatitis B vaccination coverage among persons with risks (2,10,38,40). Mother-to-child transmission of HBV is concerning, because 90% of HBV-infected newborns remain infected throughout their lives. Of these infants, one in four dies from complications of viral hepatitis in later life (42,43).

HEPATITIS C

In the United States, 2.7–3.9 million persons are estimated to be infected with HCV (10). Many of these persons were infected prior to the 1990s. Since then, the development of serologic screening tests and other prevention strategies have contributed to large declines in HCV transmission. Despite these advances, approximately 20,000 persons are newly infected with HCV in the United States each year (39). Because HCV is primarily spread through contact with blood, persons who inject drugs are at increased risk for HCV infection (1,2,5,13). HCV transmission also occurs through unsafe injection practices in health-care facilities (41), from mother to child at the time of birth, and infrequently through sexual contact with an infected partner (2).

HEPATITIS TYPES A, D, AND E

In addition to HBV and HCV, at least three other agents cause viral hepatitis in the United States: hepatitis A virus (HAV), hepatitis E virus (HEV), and hepatitis D virus (HDV) (2). Spread by the fecal-oral route, HAV is largely transmitted by person-to-person contact and through exposure to contaminated food and food products (44,45). Hepatitis A is vaccine preventable, with childhood vaccination contributing to substantial declines in hepatitis A incidence (45); however, adults at risk for hepatitis A have low rates of vaccination, and as a result, the highest incidence of disease (44). Also spread by the fecal-oral route, HEV represents the leading cause of viral hepatitis in south and central Asia, sub-Saharan Africa, and the Middle East (46). Although clinical cases of hepatitis E are rarely reported in the United States, serologic surveys suggest that a substantial number of persons have been exposed (47); additional data are needed to explain this discrepancy. The hepatitis D virus is unique, in that it can only replicate in the presence of HBV; therefore, it is only infectious among persons who have both types of infection (2,48). Hepatitis B vaccination is protective against both HBV and HDV infection.

NEW SCIENCE AND TOOLS FOR PREVENTION, CARE, AND TREATMENT

Recent developments in science, policy, communication, and health information technology [HIT] represent opportunities for reducing rates of viral hepatitis in the United States and improve health outcomes for infected persons. Researching new vaccines can improve the immune response following hepatitis B vaccination and enhance prevention interventions for other types of viral hepatitis (e.g., HCV and HEV). Seven agents are now licensed for the treatment of hepatitis B. Further, the licensure of the first agents designed to directly attack and eliminate HCV (i.e., direct acting agents) is anticipated in 2011; compared with standard treatment, these agents will substantially increase virologic cure rates while decreasing duration of therapy. A rapid point-of-care test for HCV (i.e., an HCV test that can be performed at or near the site of patient care) also is now available; rapid tests can expand access to HCV testing, particularly for injection-drug users and other marginalized and underserved populations.

Evolving health policies can play a critical role in improving viral-hepatitis–related prevention and care services (49). For instance, recent changes in federal policies governing the use of federal funds to support syringe service programs will expand access to prevention services that serve as an access point for substance abuse treatment (50). Substance abuse treatment is effective in

reducing injection drug use behaviors and promoting recovery from drug addiction (51). Recovery is an important step in reducing risk of viral hepatitis acquisition and transmission and achieving a healthy lifestyle (52).

Advances in the communication of health information, including on-line resources, can help improve the viral hepatitis knowledge base of providers. Computer applications can now provide algorithms for providers, assisting in the provision of testing, care, and treatment to their patients; further, web-based tools to promote social networking can help increase access to accurate viral hepatitis information tailored to persons in priority populations (i.e., those at high risk for viral hepatitis, such as IDUs, MSM, HIV-infected persons, baby boomers [persons born during 1945–1965], African Americans, APIs, and pregnant women).

Finally, changes in HIT can improve surveillance and provide public health data to ensure that persons at risk are receiving needed preventive and clinical care services. Implementation of standards for electronic medical records (EMRs) can expedite the reporting of laboratory and clinical information to public health surveillance systems, improving detection of disease outbreaks and emergence of new populations at risk. EMRs also create an opportunity for public health entities to monitor the quality of viral hepatitis prevention, care, and treatment services.

NEW OPPORTUNITIES FOR ADDRESSING VIRAL HEPATITIS IN A REFORMED HEALTH-CARE SYSTEM

The Viral Hepatitis Action Plan builds upon the 2010 Patient Protection and Affordable Care Act — the landmark law that will bring health insurance coverage to more than 30 million people and promote disease prevention, data collection and reporting, and quality improvement. The Act also calls for investments in public health that will facilitate health promotion and disease prevention activities for many Americans, particularly those experiencing health disparities. Through these provisions and several associated health initiatives (i.e., the National Strategy for Quality Improvement in Health Care, the National Prevention and Health Promotion Strategy, and the Community Transformation grant program), the Affordable Care Act presents multiple opportunities to identify persons infected with viral hepatitis and provide them with access to care.

Expanded health insurance coverage will improve patient access to viral-hepatitis–related prevention, care, and treatment services (e.g., health education, testing, vaccination, referral, antiviral therapy, counseling, substance abuse/addiction treatment, and medical monitoring), as will state-based Health Insurance Exchanges, which are anticipated to begin in 2014. The Exchanges, along with newly competitive private health insurance markets, will help individuals and their employers select and enroll in high-quality, affordable private health plans. The Exchanges will make the purchase of health insurance easier, more understandable, and more accessible to vulnerable, underserved populations. The Affordable Care Act requires health plans and encourages state-based Medicaid programs to cover 1) those clinical preventive services recommended by the U.S. Preventive Services Task Force (USPSTF) (i.e., those graded “A” or “B”), including viral hepatitis testing for pregnant women, and 2) immunizations recommended by the Advisory Committee on Immunization Practices (ACIP), such as those for hepatitis A and

hepatitis B; Medicare beneficiaries also will be entitled to an initial preventive physical exam and a personalized prevention plan.

Over the next 5 years, the Affordable Care Act will further expand access to preventive and primary health care by calling for an $11 billion investment in the Health Resources and Service Administration (HRSA) Community Health Center (CHC) program. The Act will enable this program to significantly increase preventive and primary health-care services for underserved populations, such as migrant and seasonal farm workers, people experiencing homelessness, and residents of public housing, many of which have been impacted by viral hepatitis. As a result of Affordable Care Act funding, HRSA expects to nearly double the number of patients served in CHCs over the next 5 years.

Finally, the Affordable Care Act is expected to improve the U.S. health infrastructure by fostering the development of new electronic medical records and health information exchanges and by further developing the nation's health-care workforce, leading to a more comprehensive approach to viral-hepatitis–related prevention, treatment, and care.

VIRAL HEPATITIS ACTION PLAN OVERVIEW

VISION AND PURPOSE

"A NATION COMMITTED TO COMBATING THE SILENT EPIDEMIC OF VIRAL HEPATITIS."

HHS is committed to ensuring that new cases of viral hepatitis are prevented and that persons who are already infected are tested; informed about their infection; and provided with counseling, care, and treatment. This increasing commitment is evidenced in the new *Healthy People 2020* (HP 2020) report, the first Healthy People publication to document increasing viral hepatitis awareness among infected persons as a formal HHS objective. In addition to moving the nation towards reaching HP 2020 objectives, by 2020, full implementation of the Viral Hepatitis Action Plan could result in:

- an increase in the proportion of persons who are aware of their hepatitis B virus infection, from 33% to 66%;*
- an increase in the proportion of persons who are aware of their hepatitis C virus infection, from 45% to 66%;†
- a 25% reduction in the number of new cases of HCV infection; and
- elimination of mother-to-child transmission of HBV.

The Action Plan will help HHS improve its current efforts to prevent viral hepatitis and related disease by 1) identifying steps that can be taken to reach specific goals; 2) leveraging opportunities to improve coordination of viral hepatitis activities across HHS operating divisions; 3) setting priorities for HHS to develop public-health and primary-care infrastructure needed for viral hepatitis prevention and care at the federal, state, and local levels; and 4) providing a framework for HHS to engage other governmental agencies and nongovernmental organizations in viral hepatitis prevention and care.

*Data source: The Racial and Ethnic Approaches to Community Health (REACH) Risk Factor Survey (www.cdc.gov/reach).

†Data source: National Health and Nutrition Examination Survey (NHANES) (www.cdc.gov/nchs/nhanes.htm).

STRUCTURE

The Viral Hepatitis Action Plan is organized by the following six topic areas, which correspond to the 2010 IOM recommendations:

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

For each topic area, the Action Plan offers a dedicated chapter that begins with background information and is followed by recommended goals, strategies, and actions to be undertaken by specified lead and participating HHS agencies and federal/external partners (listed alphabetically) (Appendix C). Recommended actions are listed by calendar year of initiation. Extensive reference lists for individual chapters are located at the end of the publication, along with several appendices.

IMPLEMENTATION

The actions presented in the Viral Hepatitis Action Plan primarily represent new efforts to begin in calendar year 2011, 2012, or 2013. Successful implementation of the Plan will require leveraging multiple opportunities. Some of the actions can be accomplished through improved coordination and integration of existing activities, whereas others are subject to the availability of funds.

Also critical to the overall success of this plan are policy-related support and system changes, which likely will be afforded by the Affordable Care Act and numerous national initiatives, including the National HIV/AIDS Strategy, the National Prevention and Health Promotion Strategy, the HHS Action Plan to Reduce Racial and Ethnic Health Disparities, the National Vaccine Plan, and the HHS Action Plan to Prevent Health-Care-Associated Infections. Components of each of these initiatives are reflected in the Viral Hepatitis Action Plan, resulting in a multifaceted, comprehensive approach to preventing viral hepatitis and improving the lives of millions of infected persons. Within a reformed health-care system, the Viral Hepatitis Action Plan will offer an unprecedented opportunity to provide Americans, particularly those in vulnerable and underserved populations, with improved viral hepatitis prevention, care, and treatment services.

1. EDUCATING PROVIDERS AND COMMUNITIES TO REDUCE HEALTH DISPARITIES

GOALS	
1.1	Build a U.S. health-care workforce prepared to prevent and diagnose viral hepatitis and provide care and treatment to infected persons.
1.2	Decrease health disparities by educating communities about the benefits of viral hepatitis prevention, care, and treatment.

Reducing the health disparities caused by viral hepatitis will require providers at all levels of the health-care system to become more educated and aware of opportunities for prevention, care, and treatment*. Providers should better recognize the diversity of patients at risk for viral hepatitis (e.g., Asian/Pacific Islanders [APIs], African Americans, HIV-infected persons, injection–drug users [IDUs], men who have sex with men [MSM], and baby boomers [persons born during 1945–1965]). These diverse patients are cared for by an equally diverse group of clinical care providers, from community health representatives in remote Alaskan villages to drug-treatment providers in inner cities. To be effective, any plan to improve provider education should encompass and engage a wide variety of health-care providers (1).

These opportunities currently are being missed on a daily basis. Providers who care for patients with risk factors for viral hepatitis often fail to provide them with viral-hepatitis–related services (2–5), resulting in unnecessary cases of chronic liver disease and death. Many providers remain uninformed about multiple aspects of viral hepatitis, including prevalence, risk-factors for infection, prevention, testing, and treatment (2). As suggested by the continuing cases of health-care-acquired hepatitis infections, providers may also need additional information regarding the infection-control practices that are integral to prevention in health-care settings (6–12).

*The term “prevention, care, and treatment” encompasses various viral-hepatitis–related services, including education, screening, testing, vaccination, referral, antiviral therapy, counseling, and medical monitoring.

Results from a 2007 hepatitis B knowledge survey of 196 primary-care providers indicated that 55% were unable to identify laboratory markers for chronic hepatitis B virus (HBV) infection (i.e., hepatitis B surface antigen [HBsAg]) (13), and a 2009 study of Asian-American primary-care providers who reported treating Asian-American adult patients revealed that only 18%–30% of these providers routinely test Asian-American patients for HBV infection (14). Although providers have been shown to have general knowledge about hepatitis C virus (HCV)-related modes of transmission, studies reveal that many providers lack understanding regarding prevention strategies. For example, a survey of 593 obstetrician/gynecologists (OBGYNs) demonstrated that nearly half provided HCV-infected patients with information that is inconsistent with CDC recommendations (15). Because the opinion of a medical provider is one of the strongest motivators for a patient to accept an intervention or change behaviors (16), increasing provider awareness of viral hepatitis is critical.

Increased provider knowledge has been shown to improve delivery of preventive services, including those for viral hepatitis (17–19); improving the number of providers knowledgeable about viral hepatitis testing, care, and treatment is key to maximizing the benefits afforded by new viral hepatitis testing and treatment options. Primary care providers should know who to test for viral hepatitis, how to interpret test results, what information is needed by their patients, and when patients need recommended preventive and care services. Providers caring for persons living with viral hepatitis should be skilled in managing co-factors that hasten the progression of liver disease (e.g., alcohol use), monitoring patients for signs of disease progression, and referring patients for consultation and therapy when appropriate. Clinicians who treat patients with viral hepatitis will need guidance regarding use of more effective but more complex regimens, including decision support tools (e.g., standing orders, electronic physician reminders, and telemedicine consultations). As testing options increase and therapeutic options become more effective and better tolerated, the need for a well-informed health-care workforce will become paramount.

To be effective, provider education should be initiated as early as possible, including as part of medical and other health professional school curricula, and should continue throughout providers' careers. HHS training centers can serve as important resources for improving provider knowledge regarding viral hepatitis, along with medical professional societies that can provide health-care professionals with continuing education.

While provider education is urgently needed, it is only part of the equation — the general public, especially persons in priority populations (i.e., those at high risk for viral hepatitis, such as IDUs, HIV-infected persons, MSM, baby boomers, African Americans, APIs, and pregnant women), also need to be knowledgeable and informed about how to prevent and treat hepatitis infections. As evidenced by several studies, levels of knowledge and awareness are low among those populations most affected by hepatitis B and hepatitis C, including various API subpopulations and IDUs (20–25). An education strategy that includes targeted outreach to populations at risk can raise awareness of viral hepatitis as a health concern, increase knowledge regarding the benefits of prevention and care, and encourage populations to seek and accept vaccination, testing, care, and treatment.

GOAL 1.1

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

Strategy 1.1.1

Develop an educational curriculum for viral hepatitis prevention, care, and treatment to be used by multiple disciplines of health professionals.

Current resources for educating providers about viral hepatitis prevention, care, and treatment are limited, and model education programs for viral hepatitis are non-existent. A viral hepatitis curriculum is needed to further educate and train the multidisciplinary health-care workforce (e.g., nursing, medical, behavioral, and mental health professionals) to provide effective viral hepatitis prevention, care, and treatment.

Actions to Be Initiated During 2011:

- Assess medical and health-education materials and programs on viral hepatitis and draft plans to improve quality and distribution.
- Leverage Affordable Care Act resources for workforce development to support creation of a viral hepatitis curriculum.
  Lead/Participating Agencies: CDC, HRSA, IHS, NIH, SAMHSA

Actions to Be Initiated During 2012:

- Conduct qualitative and quantitative research designed to understand the knowledge, skills, abilities, and attitudes of providers in regard to prevention, care, and treatment of viral hepatitis.
- Develop clinical decision aids as a component of electronic medical records (EMRs) to support appropriate prevention, care, and treatment related to viral hepatitis.
  Lead/Participating Agencies: CDC, HRSA, IHS, NIH, ONC, SAMHSA

Action to Be Initiated During 2013:

- Develop new professional education programs (e.g., telemedicine), materials, and tools addressing known gaps and needs concerning the prevention of viral hepatitis, identification of infected persons, and provision of care and treatment.
  Lead/Participating Agencies: CDC, HRSA, IHS, OASH

Strategy 1.1.2

Integrate a viral hepatitis component into the curricula of all HHS health-care provider training programs.

Programs for HIV, sexually transmitted disease (STD), and substance-abuse serve many of the same clients at risk for viral hepatitis. Increasing knowledge and skills among providers serving these populations — a strategy that aligns with objectives in the National HIV/AIDS Strategy — can integrate efforts to prevent new infections, identify infected persons, and provide better overall care and treatment.

- Implement the educational curriculum for viral hepatitis in CDC training programs (e.g., AIDS Education and Training Centers and National Network of STD/HIV Prevention Training Centers) to educate providers serving priority populations.
  Lead Agency: CDC
- Train all health-care providers in HHS-sponsored clinical programs (e.g., federally qualified health centers and clinics receiving funds associated with the Ryan White Comprehensive AIDS Resources Emergency [CARE] Act) to deliver viral hepatitis vaccination, early detection, testing, management of alcohol and other cofactors, and treatment.
  Lead/Participating Agencies: HRSA, IHS, OASH, SAMHSA
- Begin implementation of the viral hepatitis educational curriculum in drug-treatment centers (e.g., Addiction Technology Transfer Centers) to educate providers serving priority populations.
  Lead Agency: SAMHSA
- Fully integrate the HHS viral hepatitis curriculum within HHS provider training programs and begin to evaluate this activity.
  Lead/Participating Agencies: CDC, HRSA, IHS, OASH, SAMHSA

Strategy 1.1.3

Collaborate with professional, medical, and other organizations to build a workforce capable of providing viral hepatitis prevention, care, and treatment.

A team approach to viral hepatitis testing, care, and treatment involving primary-care providers and specialists (e.g., hepatologists and infectious disease physicians) is more effective than other care models. Engaging primary-care provider organizations (including those who provide behavioral, mental health, and social services as well as provider organizations for those disproportionately affected by viral hepatitis) will improve training and increase capability.

Action to Be Initiated During 2011:

- Work with academic institutions and educational organizations to develop and promulgate standardized viral hepatitis curricula for students in post-graduate medical, dental, nursing, physician's assistant, alternative medicine, and other allied health schools.
  Lead/Participating Agencies: CDC, HRSA, NIH, CMS, IHS, OASH

Actions to Be Initiated During 2012:

- Work with specialty medical organizations (e.g., the Infectious Diseases Society of America [IDSA] and the American Association for the Study of Liver Diseases [AASLD]) to develop and disseminate guidelines for the evaluation, management, and treatment of viral hepatitis.
  Lead/Participating Agencies: CDC, HRSA, NIH, CMS, IHS, OASH
- In collaboration with primary-care organizations and associations (e.g., the American Academy of Family Practice [AAFP] and the American College of Physicians [ACP]), develop and disseminate educational programs, materials, and tools.
  Lead/Participating Agencies: CDC, HRSA, IHS, NIH, OASH
- In collaboration with behavioral, mental health, and social service provider organizations, networks, and groups, develop and disseminate training materials and programs on viral hepatitis prevention, care, and treatment.
  Lead/Participating Agencies: SAMHSA, CDC, HRSA, OASH

GOAL 1.2

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

Strategy 1.2.1

Increase the proportion of persons living with hepatitis B and hepatitis C who know that they are infected and are linked to timely care and treatment.

Most persons living with hepatitis B and hepatitis C are not aware they are infected. A national campaign will help raise awareness of these diseases and encourage testing of those at risk.

Actions to Be Initiated During 2011:

- Conduct formative research with populations at risk for HBV and HCV infection to understand knowledge, attitudes, and behaviors related to testing, care, and treatment of chronic viral hepatitis.
- Develop a national educational campaign and pre-test campaign materials with members of the target audience.
  Lead/Participating Agencies: CDC, HRSA, IHS

Actions to Be Initiated During 2012:

- Launch a pilot project in several U.S. cities to create and test educational messages, materials, and strategies to be used for a national campaign.
  Lead/Participating Agencies: CDC, HRSA, IHS
- Partner with regional, state, local, and tribal organizations for the planning and implementation of a national education campaign.
- Award community grants designed to reach specific at-risk populations with culturally sensitive and linguistically appropriate evidence-based interventions.
  Lead/Participating Agencies: CDC, HRSA, IHS, OASH/OMH

Actions to Be Initiated During 2013:

- Launch a national education campaign designed to increase awareness about hepatitis B and hepatitis C and to educate the public about risk and the benefits of prevention, care, and treatment, with particular emphasis on those areas with large populations of APIs, African Americans, baby boomers, and other priority populations.
- Survey communities to assess viral hepatitis knowledge and conduct additional surveys to measure impact of campaign messages on knowledge and health-seeking behavior.
  Lead/Participating Agencies: CDC, HRSA, IHS, OASH/OMH

Strategy 1.2.2

Establish and coordinate national and global health events and partnerships to raise public awareness about viral hepatitis.

Many hard-to-reach communities and populations remain uninformed about various facets of viral hepatitis, including associated adverse health effects, the need for testing and care, and the availability of treatment. Creating viral hepatitis media events and developing targeted, local campaigns to promote these events will raise awareness among those populations most affected by these infections and help attract sources of funding for viral-hepatitis–related initiatives.

Actions to Be Initiated During 2011:

- Continue to promote May as "Hepatitis Awareness Month" in the United States and work with the media to communicate timely viral hepatitis messages.
- In partnership with the World Health Organization, support and promote July 28th as "World Hepatitis Day" and work with the media to convey the global and national significance of viral hepatitis.
  Lead/Participating Agencies: CDC, HRSA, OASH

Action to Be Initiated During 2012

- Collaborate with federal partners, private industry, and the media to designate May 19th as "Hepatitis Testing Day" in the United States.
  Lead/Participating Agencies: CDC, HRSA, OASH
- Spur development of an annual global forum to promote communication and collaboration among diverse stakeholders (e.g. health ministries, non-governmental organizations, academia, industry).
  Lead/participating agencies: CDC, NIH, OASH

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

GOALS	
2.1	Identify persons infected with viral hepatitis early in the course of their disease.
2.2	Link and refer persons infected with viral hepatitis to care and treatment.
2.3	Improve access to and quality of care and treatment for persons infected with viral hepatitis.
2.4	Advance research to facilitate viral hepatitis prevention and enhance care and treatment for infected persons.

Successful testing for hepatitis B virus (HBV) and hepatitis C virus (HCV) and better provision of care and treatment to those who are infected can decrease the burden of cirrhosis and liver cancer, thereby reducing the need for liver transplantation in the United States. Provision of these services also can help reduce the viral-hepatitis–related health disparities experienced by certain priority populations (i.e., those at high risk for viral hepatitis, such as injection-drug users [IDUs], men who have sex with men [MSM], HIV-infected persons, baby boomers [persons born during 1945–1965], African Americans, Asians/Pacific Islanders [APIs], and pregnant women).

TESTING

Existing prevention initiatives aim to identify and test persons in priority populations as a first step to linking them to care and treatment. One such effort, CDC's perinatal hepatitis B prevention program, has led to high HBV testing rates among pregnant women delivering in the hospital setting (89%–96%) (1). Although this and other successful testing activities currently are being conducted in many health-care settings (e.g., prenatal-care settings, Ryan White CARE Act-funded clinics, and public and private clinics providing care to persons in priority populations), the following barriers exist:

- a low level of knowledge and awareness about viral hepatitis in the general public and among health-care providers has led to missed opportunities for testing (see Educating Providers and Communities to Reduce Health Disparities);
- persons at risk for viral hepatitis often lack health insurance and regular sources of health care (2);
- insufficient evidence exists to guide policy development for viral hepatitis testing and referral to care, resulting in conflicting federal guidelines and inadequate resources for implementation at the state and local level; and
- the effectiveness of risk-based approaches to testing are hindered by the reluctance of providers and patients to discuss behaviors not connected with the patient's chief complaint.

Also critical is the development of a robust infrastructure for testing that remains sensitive to the cultural, socioeconomic, racial, ethnic, and lifestyle differences of the subpopulations disproportionately affected by viral hepatitis (3).

The successes achieved by some programs illustrate that testing-related challenges can be overcome. For instance, the Hep B Free campaign, a community outreach initiative conducted in several U.S. cities with large API populations, has enhanced hepatitis B testing in populations at increased risk, as has Stanford University's Jade Ribbon Campaign (4,5). Other initiatives aim to improve testing for hepatitis C, including those undertaken by many U.S. clinics receiving Ryan White CARE Act funding that have successfully integrated HIV and HCV testing, resulting in high rates of testing (91%) for HIV/HCV coinfection (6).

Advancements have led to the development of tests for viral hepatitis. Point-of-care tests for HCV infection recently have been approved by FDA; these tests can facilitate testing, notification of results and post-test counseling, and referral to care at the time of the testing visit (7). HCV point-of-care tests are also advantageous because they can be used simultaneously with HIV rapid testing for persons at risk for both HCV and HIV infections (e.g., IDUs). Finally, CDC is conducting research to identify more effective HCV testing strategies. For persons with ongoing or recent risk behaviors, evaluations of point-of-care assays are in progress. For persons infected in the distant past, a risk-based approach is problematic, because most of these persons do not have ongoing risk behaviors. For this population, CDC is examining the merits of a health promotion model used for cancer and chronic disease, which employs a birth-cohort-based approach to screening baby boomers, a population that represents two thirds of persons living with hepatitis C in the United States (8).

CARE

Many infected persons are never offered appropriate care (e.g., medical monitoring, health education, and counseling), negatively affecting health outcomes of patients diagnosed with this life-long condition. To optimize care, patients also should receive accurate information about their hepatitis infection and about how to avoid transmitting the virus to others. Developing health-care delivery models and systems that facilitate the provision of a comprehensive package of care and support for persons infected with viral hepatitis would help prevent liver-related complications at the patient level and curb the spread of this disease.

TREATMENT

Intensive research on HBV and HCV has led to the development of new and effective therapies. Seven FDA-approved drugs are now available to treat patients living with hepatitis B. Five of these drugs are administered orally (rather than by injection), which is a major advancement in how treatments are administered for this infection; nearly 90% of patients with HBV treated with one of the new oral medications achieve viral suppression. For patients infected with HCV, treatment now consists of a long-acting interferon injection combined with oral doses of ribavirin, a regimen that has dramatically improved the health of many infected persons; approximately 40% of HCV-infected patients receiving this therapy achieve eradication of the infection. Despite this progress, side effects associated with the current HCV treatment regimen prevent many patients from initiating therapy or from completing the entire course of treatment.

Investments in molecular virology research have led to the recent discovery of new candidate therapies for HCV-infected persons. These medications, some of which are in the final clinical trial stages of development, hold the hope of greatly enhancing success rates of hepatitis C treatment while shortening the duration of therapy. Illustrating the achievements through scientific investments, results of phase III clinical trials with two new potential agents to augment the arsenal of therapies were presented at the American Association for the Study of Liver Diseases annual Liver Meeting in November 2010. The two drugs are protease inhibitors specific for the genotype 1 HCV infection. When each drug was used in combination with long-acting interferon and ribavirin, significantly improved rates of virus eradication could be achieved with shorter durations of therapy (9). Other candidate drugs directed at other HCV targets are in the preclinical stages of development and hold the hope for an all oral therapeutic approach to the treatment of chronic HCV (10). Furthermore, recent research has helped determine a genetic factor associated with favorable response to HCV treatment. Results from several 2009 studies revealed an association between inherited variants lying near the IL28B gene and response to pegylated interferon treatment among persons with chronic hepatitis C (11–13); the unfavorable version of this gene is more common among African Americans than other racial/ethnic groups (11), which explains, in part, observations of racial disparities in treatment response.

Despite this progress, the following barriers should be overcome:

- providers should be better educated regarding indications for screening, interpretation of diagnostic tests, and availability of effective treatments for HBV and HCV (see Educating Providers and Communities to Reduce Health Disparities);
- important questions remain regarding viral hepatitis treatment, including whether the virus could develop resistance to a drug, whether and when treatment can be started or discontinued, and whether it is safe to use drugs for hepatitis B over the long-term;
- additional investments in basic and translational research are needed to determine why many patients living with hepatitis C do not respond to currently available therapies and whether future directly acting agents against hepatitis C can be used effectively in combinations without long-acting interferon;
- factors contributing to treatment noncompliance should be better elucidated; and
- better models of health-care delivery are needed to promote screening, prompt entry into care after detection of viral hepatitis, and improve acceptance of and adherence to treatment regimens.

GOAL 2.1

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

Strategy 2.1.1

Create standard, consistent federal recommendations to guide hepatitis B and C testing and referral to care.

CDC and the U.S. Preventive Services Task Force (USPSTF) publish testing guidelines for hepatitis B and hepatitis C. However, these guidelines are not aligned across HHS operating divisions, which causes confusion for clinicians. Developing consistent HHS recommendations for hepatitis B and hepatitis C testing could lead to improved testing rates.

Actions to Be Initiated During 2011:

- Revise CDC guidelines for hepatitis C testing and linkage to care and treatment.
  Lead Agency: CDC
- Support USPSTF efforts to update guidelines for hepatitis C testing and treatment.
  Lead Agency: AHRQ
- To the extent possible, coordinate across agencies to ensure that guidelines for hepatitis B and hepatitis C testing, care, and treatment are aligned.
  Lead Agency: OASH

Strategy 2.1.2

Implement routine viral hepatitis testing as part of the standard of care in a reformed health-care system.

Testing for HBV and HCV is a prerequisite for entry into care and treatment programs. However, most persons have not been tested, reflecting weaknesses in testing capabilities of public health and clinical providers. The Affordable Care Act represents a new opportunity to identify millions of Americans who are unaware of their infection status. In addition to improving access to care, the Act will improve quality of care for viral hepatitis in a reformed health system.

Actions to Be Initiated During 2012:

- Develop a cross-agency process for identifying and eliminating barriers to the implementation of viral hepatitis testing and linkage of infected patients to care and treatment.
  Lead Agency: OASH
- Add viral hepatitis testing as a preventive service for Medicare-supported wellness visits and other patient-provider encounters.
  Lead Agency: CMS
- Promote HHS-recommended viral hepatitis testing as a standard of care in all federally sponsored primary-care programs (e.g., community health centers and IHS clinics).
  Lead/Participating Agencies: HRSA, IHS

- Implement HHS-recommended viral hepatitis testing as a standard of care in all federally sponsored HIV/sexually transmitted disease (STD) programs and other public health programs serving persons in priority populations.
  Lead/Participating Agencies: CDC, HRSA, IHS
- Implement HHS-recommended viral hepatitis testing as a standard of care in drug-treatment programs.
  Lead Agency: SAMHSA
- Strengthen community-based programs providing testing and linkages to care, particularly those serving foreign-born populations.
  Lead Agencies: CDC, OASH/OMH

Action to Be Initiated During 2013:

- Update CDC recommendations for HCV testing in correctional settings.
  Lead Agency: CDC
  Partner: DOJ/FBOP

Strategy 2.1.3

Use health information technology (HIT) to improve testing and enhance referral to viral hepatitis care in diverse clinical settings.

Advances in the tracking of health data and medical recordkeeping (e.g., electronic medical records [EMRs]) provide new opportunities for ensuring that persons in priority populations receive recommended prevention services (e.g., testing) and that persons infected with the virus are referred to care and receive care and treatment in a timely manner.

Actions to Be Initiated During 2011:

- Develop and implement performance measures for hepatitis testing in HHS-sponsored health programs (e.g., community health centers, IHS clinics, and HIV test sites).
  Lead/Participating Agencies: AHRQ, CMS, HRSA, IHS
- Implement data elements (e.g., those concerning disease staging, hepatocellular carcinoma [HCC] monitoring, and co-morbidity management) in EMRs to monitor hepatitis testing, care, and treatment in health-care settings.
  Lead/Participating Agencies: ONC, AHRQ, CDC, CMS, HRSA, IHS
  External Partner: VA

Strategy 2.1.4

Build the capacity of state and local health departments to prevent viral hepatitis.

State and local health departments directly provide viral hepatitis education and preventive services and can integrate and coordinate these services in appropriate community-based and care settings. CDC and its grantees should develop plans and program requirements for the development of comprehensive viral hepatitis prevention programs with capacity to integrate with HIV, STD, and other relevant prevention programs (e.g., cancer prevention) — a prevention

approach consistent with other federal efforts, such as the National HIV/AIDS Strategy.

Action to Be Initiated During 2012:

- In collaboration with viral hepatitis prevention coordinators now located in 49 states and six large cities, develop best practices for expanding viral hepatitis testing for clinical care providers and community-based organizations and for integrating vaccination and testing with HIV, STD, TB, and other prevention services.
  Lead/Participating Agencies: CDC, HRSA, OASH/OMH, SAMHSA

Action to Be Initiated During 2013:

- Build at least 10 Viral Hepatitis Centers of Excellence charged with providing the comprehensive array of interventions needed to prevent viral hepatitis infection and associated disease (e.g., vaccination, testing, education, and counseling); expand to additional states and areas as resources permit.
  Lead/Participating Agencies: CDC, HRSA, OASH/OMH, SAMHSA

GOAL 2.2

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

Strategy 2.2.1

Improve linkage to care and treatment among persons infected with viral hepatitis.

Given the diversity of the populations that experience increased rates of viral hepatitis and the complexity of current health-care systems, significant attrition occurs between the time of patient diagnosis and presentation to a health-care facility. Care coordination helps link persons to needed services after diagnosis. The development of effective medical management models will facilitate the expansion of these services.

Actions to Be Initiated During 2012:

- Identify and disseminate best practices for the prompt linkage of persons testing positive for viral hepatitis to needed care and treatment.
  Lead/Participating Agencies: CDC, HRSA, SAMHSA
- Create databases of testing and care referral services available in local areas.
  Lead/Participating Agencies: HRSA, CDC, IHS, NIH, SAMHSA
- Identify opportunities (e.g., those afforded by the Affordable Care Act) to improve the provision and coordination of comprehensive viral hepatitis services in public and private health plans.
  Lead/Participating Agencies: CMS, CDC
- Develop and implement effective medical management models for use in priority populations.
  Lead/Participating Agencies: HRSA, CDC, OASH/OMH, SAMHSA
  Partner: DOJ/FBOP

Strategy 2.2.2

Ensure that HBV-infected pregnant women receive timely care and treatment.

HBV testing of pregnant women represents the largest viral hepatitis program in the United States. Although most pregnant women (>89%) are being tested for HBV, limited public health resources result in missed opportunities for providing care referrals to HBV-infected mothers and other recommended preventive services to their household contacts.

Action to Be Initiated During 2011:

- Identify strategies to enhance referral to care and treatment for HBV-infected mothers.
  Lead/Participating Agencies: CDC, HRSA, IHS, OASH/OMH

Actions to Be Initiated During 2012:

- Identify Medicaid options (e.g., Section 11.15 waivers and health homes) to improve outreach and care coordination for HBV-infected women and their household contacts.
  Lead/Participating Agencies: CMS, OASH
- Establish the testing of pregnant women for viral hepatitis as a National Quality Forum (NQF)-endorsed quality measure under HIT regulation.
  Lead/Participating Agencies: HHS/ONC, CDC, CMS, HRSA

GOAL 2.3

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

Strategy 2.3.1

Improve viral hepatitis care and treatment in primary-care settings.

Primary-care providers will play a significant role in expanding testing, care, treatment in the United States. Studies reveal that collaborations of primary-care providers and specialists (e.g., hepatologists and mental health professionals) result in the best care for infected persons. Care- and treatment-associated recommendations for chronically infected patients should reflect this multidisciplinary approach to care. Further, the guideline development process for this rapidly evolving field should remain dynamic; providers should be provided with up-to-date information regarding optimal management of their patients.

Action to Be Initiated During 2011:

- Coordinate the development of recommendations to guide the provision of care and treatment to persons living with viral hepatitis.
  Lead/Participating Agencies: OASH, CDC, CMS, HRSA, IHS, SAMHSA

Actions to Be Initiated During 2012:

- Establish clinical quality measures to monitor performance.
  Lead/Participating Agencies: CMS, CDC, HRSA, IHS, NIH, OASH, SAMHSA
- In accordance with clinical quality measures, develop clinical decision schema and other tools to ensure quality care for patients living with viral hepatitis.
  Lead/Participating Agencies: CMS, CDC, HRSA, OASH
- Develop "brief interventions for alcohol" training and disseminate via federally funded training centers and other partner organizations.
  Lead/Participating Agencies: SAMHSA, CDC, HRSA, IHS
  Partner: VA

Action to Be Initiated During 2013:

- Replicate and disseminate models to expand capacity for the provision of hepatitis care and treatment in primary-care settings using telemedicine, mentoring, Centers of Excellence, and other models.
  Lead/Participating Agencies: HRSA, CDC, CMS, IHS
  Partner: VA

GOAL 2.4

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

Strategy 2.4.1

Assess new laboratory tests and laboratory testing procedures to more accurately identify persons infected with viral hepatitis, and develop methods for effectively providing testing to a wide range of populations.

For HCV infection, the development of tests capable of distinguishing between acute and chronic infection could improve tracking of recent transmission. Additionally, a point-of-care test for HCV has been recently approved by FDA, which will enable providers to offer rapid HCV testing. Because priority populations present unique challenges in case identification, identifying culturally and ethnically sensitive approaches to testing would increase knowledge of infection status among persons at risk.

Actions to Be Initiated During 2011:

- Support development of point-of-care assays to detect serologic evidence of both exposure to viral hepatitis and active viral hepatitis infection.
  Lead/Participating Agencies: NIH, CDC, FDA
- Conduct demonstration projects to guide integration of point-of-care testing for HCV and HIV.
  Lead/Participating Agencies: CDC, FDA, NIH

Actions to Be Initiated During 2012:

- In collaboration with industry, spur development of new tests (e.g., tests capable of distinguishing between acute and chronic hepatitis C and less costly alternatives to current HCV polymerase chain reaction [PCR] testing).
  Lead/Participating Agencies: NIH, CDC, FDA
- Conduct comparative research on culturally and ethnically sensitive approaches to, and operations associated with, viral hepatitis testing across diverse patient populations.
  Lead/Participating Agencies: CDC, AHRQ, OASH/OMH

Strategy 2.4.2

Develop care models to optimize management of the diverse populations living with viral hepatitis.

Management of viral hepatitis is complex. Not all persons who are infected progress to end-stage disease, complicating clinical decisions regarding the provision of treatment and care. When making care-related decisions, providers also should consider the unique issues faced by priority populations affected by viral hepatitis, including cultural and language barriers.

Action to Be Initiated During 2012:

- Coordinate development of a research agenda to better understand and address the multiple barriers for patients with co-occurring conditions.
  Lead/Participating Agencies: OASH, AHRQ, CDC, HRSA, NIH

Action to Be Initiated During 2012:

- Evaluate promising models of care to address the unique issues faced by priority populations affected by viral hepatitis.
  Lead/Participating Agencies: AHRQ, NIH, CMS, HRSA

Strategy 2.4.3

Improve current therapies for hepatitis B and hepatitis C and for the consequences of these infections (e.g., hepatocellular carcinoma).

Although safe and effective treatments exist for hepatitis B, the infection often recurs despite completion of the recommended therapeutic regimen. Ideally, treatment for hepatitis B would not only result in viral clearance, but minimize the likelihood of recurrence. Current therapy for hepatitis C, though effective, is associated with numerous side effects that either preclude many patients from starting treatment or prevent them from completing therapy. Clinical trials suggest that direct acting agents (DAAs) will greatly increase the proportion of treated patients achieving viral clearance while decreasing the length of therapy. The first DAAs are expected to be licensed in 2011, ushering in a new era of HCV-specific therapy. Nevertheless, new questions in access to care, therapeutic regimens, adverse events, and antiviral mutations will emerge.

Action to Be Initiated During 2011:

- Support investments in basic, translational, comparative, and effectiveness research to facilitate the discovery and development of effective and well tolerated treatments for viral hepatitis and related disease resulting from chronic viral hepatitis infection (e.g., hepatocellular carcinoma).
  Lead Agency: NIH

Actions to Be Initiated During 2012:

- Revise eligibility criteria for the AIDS clinical trials network and other HIV-related clinical trials to expand studies of viral hepatitis treatment, including DAA therapies for patients with hepatitis C and patients coinfected with HIV and HCV.
- Conduct studies aimed at determining how genetics influence individual susceptibility to the development of chronic liver disease, cirrhosis, and liver cancer. Develop global collaborations for the conduct of basic research and clinical trials and for monitoring adverse events and antiviral mutations.
  Lead Agency: NIH

3. STRENGTHENING SURVEILLANCE TO DETECT VIRAL HEPATITIS TRANSMISSION AND DISEASE

GOALS	
3.1	Build a network of state and local surveillance systems with sufficient capacity to monitor viral hepatitis transmission and disease.
3.2	Monitor viral-hepatitis-associated health disparities.
3.3	Monitor provision and impact of viral hepatitis prevention, care, and treatment services.
3.4	Develop and implement new technologies and laboratory procedures to improve viral hepatitis surveillance.

Surveillance data enable national, state, and local public health professionals to measure and monitor trends in the burden of disease, detect epidemics, identify and address health disparities, guide and evaluate public health programs and policies, and monitor changes in health-care practices (1,2). Public health surveillance requires standardized, systematic, ongoing collection and management of reliable data. However, as has been noted by the Institute of Medicine (IOM) (3), the national surveillance system for viral hepatitis in the United States is poorly funded and fragmented, resulting in incomplete coverage and inconsistent reporting of cases by jurisdictions.

The National Notifiable Disease Surveillance System (NNDSS) is the primary source of viral hepatitis surveillance data in the United States. However, inadequate capacity limits the data collected through NNDSS, resulting in incomplete information about the true burden of viral hepatitis (1). Chronic hepatitis B and hepatitis C are not reportable conditions in all states, and CDC/Council of State and Territorial Epidemiologists (CSTE)-approved case definitions for viral hepatitis are applied inconsistently by health jurisdictions. In addition, certain information about potential exposures and other characteristics (e.g., pregnancy status for child-bearing-aged women) is not collected through the current system. Health jurisdictions also lack the staff required to collect pertinent information from laboratory and clinical records, which results in inaccurate case counting and erroneous estimation of the true burden of disease.

To compensate for these recognized limitations, CDC supports enhanced surveillance projects at 10 sites. To supplement data collected through case reporting, CDC conducts surveys of the general population (e.g., the National Health and Nutrition Examination Survey [NHANES]), racial and ethnic populations experiencing health disparities (e.g., the Racial and Ethnic Approaches to Community Health [REACH] risk factor survey), and populations with behavioral risk for viral hepatitis (e.g., the National HIV Behavioral Surveillance [NHBS] program). All of these sources of viral-hepatitis–related data help provide insight into current disease prevalence and incidence at the state and local levels. However, because most persons living with viral hepatitis are unaware that they are infected, employing active surveillance and serologic surveys targeting priority populations (i.e., those at high risk for viral hepatitis, such as injection-drug users [IDUs], HIV-infected persons, men who have sex with men [MSM], baby boomers [persons born during 1945–1965], African Americans, Asians/Pacific Islanders [APIs], and pregnant women) would provide more accurate estimates of the burden of hepatitis B and C in the United States.

With additional resources, viral hepatitis surveillance can improve in several ways. For instance, automated surveillance systems can be linked to electronic medical records (EMRs), which incorporate essential information regarding patient demographics; test results; clinical conditions; and the prevention, care, and treatment services* rendered by health-care providers (4). Increases in resources also would enable case definitions to be revised to reflect the advent of new laboratory technologies and meet new data needs of prevention programs. Finally, data standards and IT systems could be employed to link viral hepatitis surveillance with other surveillance systems (e.g., those used to monitor HIV, cancer, and immunization).

GOAL 3.1

Build a network of state and local surveillance systems with sufficient capacity to monitor viral hepatitis transmission and disease.

Strategy 3.1.1

Strengthen the capacity of state and local health departments to collect a core set of viral hepatitis surveillance data.

Case surveillance is a key source of information regarding disease outbreaks, changes in transmission patterns, and morbidity and mortality. All state and local surveillance programs should be capable of collecting a core set of surveillance data to include a variety of demographic and risk-related information. However, the number of viral hepatitis case reports received by health departments is large; the sheer volume of reports overwhelms most health departments, limiting their ability to make meaningful use of viral hepatitis data.

*The term "prevention, care, and treatment" encompasses various viral-hepatitis–related services, including education, screening, testing, vaccination, referral, antiviral therapy, counseling, and medical monitoring.

Actions to Be Initiated During 2011:

- Monitor the misclassification of viral hepatitis cases as a quality-assurance measure.
- Assure state and local health authorities receive timely epidemiologic and laboratory assistance in viral hepatitis outbreak investigation.
- In collaboration with Council of State and Territorial Epidemiologists (CSTE) and state and local partners, revise and implement standard reporting criteria for viral hepatitis.
  Lead Agency: CDC
  Partners: APHL, CSTE

Actions to Be Initiated During 2012:

- Identify current gaps in epidemiologic capacity and identify strategies to address them.
- Upgrade surveillance information technology (IT) to improve exchange of surveillance data among reporting sites (e.g., laboratories), state ad local health departments, and CDC.
  Lead/Participating Agencies: CDC, CMS, NIH
  Partner: CSTE

Strategy 3.1.2

Develop state and local Viral Hepatitis Centers of Excellence charged with collecting an enhanced set of viral hepatitis surveillance data.

The creation of Viral Hepatitis Centers of Excellence within state and local health departments would help them evaluate methods for collecting surveillance data; set best practices for other state and local surveillance programs; and collect enhanced data regarding transmission patterns, burden of disease, and viral characteristics. Initially, 10 such centers will be established, and additional centers will be added based on the availability of funds.

Actions to Be Initiated During 2012:

- Through the Centers of Excellence, develop models for linking viral hepatitis surveillance data to those obtained through other surveillance systems (e.g., HIV and cancer) and to electronic laboratory reports and medical records.
- Conduct special studies to investigate emerging modes of transmission, identify new or rare forms of viral hepatitis, and evaluate access to care for persons living with viral hepatitis.
  Lead/Participating Agencies: CDC, CMS, HRSA
  Partners: APHL, CSTE

Actions to Be Initiated During 2013:

- Provide data to case registries supported by state and local prevention programs seeking to link infected persons with care and treatment.
  Lead/Participating Agencies: CDC, CMS, HRSA
  Partners: APHL, CSTE

Strategy 3.1.3

Integrate EMRs as components of viral hepatitis surveillance.

Electronic reporting of laboratory data ensures timely reporting of laboratory-confirmed cases of infectious disease, including viral hepatitis. Further, the use of EMRs, which include both clinical and laboratory results, will lead to more accurate identification and classification of cases and a robust effort to monitor performance measures of viral hepatitis prevention, care, and treatment.

Action to Be Initiated During 2011:

- Use aggregated EMRs to monitor performance measures of hepatitis testing, care, and treatment and associated health outcomes.
  Lead/Participating Agencies: CDC, AHRQ, CMS

Actions to Be Initiated During 2012:

- Incorporate viral hepatitis diagnostic codes in federal EMR standards.
  Lead/Participating Agencies: ONC, AHRQ, CDC, CMS, IHS, NIH
- Pilot the use of EMRs in collaboration with health-care systems to improve surveillance.
  Lead/Participating Agencies: AHRQ, CDC, CMS, IHS, NIH
- Automate case detection of viral hepatitis using electronic records (i.e., electronic laboratory data and electronic health records from Medicare, Medicaid, and other datasets).
  Lead/Participating Agencies: CDC, CMS, HRSA, NIH

GOAL 3.2

Monitor viral-hepatitis-associated health disparities.

Strategy 3.2.1

Conduct national and multistate surveys to monitor health disparities in large population sub-groups in the United States.

NHANES and other national health surveys collect data representative of disease trends for large racial/ethnic sub-populations and other groups defined by social economic status, education, and other factors that contribute to health disparities. With sustained support, these surveys can reveal health disparities associated with viral hepatitis. Other federal systems can be strengthened to collect and report similar data.

Actions to Be Initiated During 2012:

- Revise federal surveys to expand the monitoring of health disparities among target populations.
- Publish periodic reports on viral-hepatitis-associated health disparities.
  Lead/Participating Agencies: CDC, HRSA, NIH, OASH/OMH, SAMHSA

Strategy 3.2.2

Collect data at the community level to help state and local programs identify and address viral-hepatitis–related health disparities.

Certain communities and settings (particularly those comprised of racial and ethnic minorities, persons who have recently immigrated to the United States, refugees, persons who are homeless, incarcerated persons, HIV-infected persons, MSM, and IDUs) are disproportionately affected by viral hepatitis. These populations often are underrepresented in large national surveys, necessitating the development and use of specific behavioral and serologic surveys targeting populations at the community level. Data obtained from these surveys will help HHS achieve goals for monitoring disparities in health as outlined in the HHS Strategic Action Plan to Reduce Racial and Ethnic Health Disparities.

Actions to Be Initiated During 2012:

- As a component of Viral Hepatitis Centers of Excellence, design and conduct state/local surveys of marginalized populations (e.g., foreign–born persons, those who were previously incarcerated, and IDUs) experiencing health disparities caused by viral hepatitis.
  Lead/Participating Agencies: CDC, OASH/OMH
- Gather data from non-traditional sources (e.g., U.S. Census data, clinical data sets, counseling and testing databases, and health records from correctional settings).
  Lead/Participating Agencies: CDC, CMS, HRSA

GOAL 3.3

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

Strategy 3.3.1

Document and monitor provision and impact of preventive services for viral hepatitis.

A central role of public health is to ensure delivery of prevention, care, and treatment services. The adoption of EMRs provides an unprecedented opportunity to identify persons at risk for viral hepatitis and monitor delivery of recommended interventions.

Actions to Be Initiated During 2012:

- Promote the development of systems to monitor where persons are tested for viral hepatitis and the quality of prevention and care services they receive.
  Lead/Participating Agencies: CDC, NIH, HRSA
- Create data-sharing agreements with federal agencies, health authorities and other partners (e.g. clinical laboratories) to facilitate collection and timely analysis of viral hepatitis immunization, testing, and other types of prevention information (e.g., datasets from Medicare/Medicaid, VA, FBOP, and WHO).
  Lead/Participating Agencies: OASH, CDC, CMS, HRSA, NIH
  Partners: VA, DOJ/FBOP

Strategy 3.3.2

Document and monitor the provision and impact of viral hepatitis care and treatment services.

Providing care and treatment to persons infected with viral hepatitis can prevent complications, including liver cirrhosis and liver cancer. The licensure of new direct acting agents for hepatitis C virus (HCV) is expected in 2011, increasing the benefits of early diagnosis and care. Data on disease severity and the provision and outcomes of recommended clinical interventions (including antiviral therapy) are integral to monitoring access to and impact of care and treatment services.

Action to Be Initiated During 2011:

- Create public-private partnerships to establish observational cohort studies and other evaluations of persons in care for viral hepatitis.
  Lead Agency: CDC

Action to Be Initiated During 2013:

- Issue periodic reports on access to viral hepatitis services by priority populations.
  Lead/Participating Agencies: CDC, CMS, HRSA, SAMHSA
  Partners: APHL, CSTE, DOJ/FBOP

GOAL 3.4

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

Strategy 3.4.1

Build the capacity for state public health laboratories to support outbreak investigations and other surveillance activities.

A recent Association of Public Health Laboratories (APHL) survey indicated that most public health laboratories (PHLs) conduct only serologic tests for HCV and hepatitis B virus (HBV). Few state and local laboratories have the polymerase chain reaction (PCR) capacity necessary to confirm active HCV infection or monitor viral load. Molecular diagnostic capacity is lacking in most of the participating PHLs, affecting capability for early response in outbreak investigations.

Actions to Be Initiated During 2012:

- Identify current gaps in laboratory capacity and identify strategies to address them.
- Provide technical assistance to public health laboratories by conducting viral hepatitis workshops and hands-on training for state PHL staff at the CDC/Division of Viral Hepatitis (DVH) laboratory.
- Engage PHLs in proficiency testing for viral hepatitis markers not available through other commercial sources.
  Lead/Participating Agencies: CDC, CMS
  Partner: APHL

Action to Be Initiated During 2013:

- Create virus detection systems to identify mutants resistant to vaccination, diagnosis, or therapy and to monitor the emergence of rare or previously unrecognized causes of viral hepatitis.
  Lead/Participating Agencies: CDC, CMS, HRSA
  Partners: APHL, CSTE

Strategy 3.4.2

Develop electronic infrastructure with the ability to capture results of existing and future laboratory markers of viral hepatitis infection.

There is limited efficiency and accuracy in laboratory reporting of viral hepatitis cases to health departments, primarily because of the passive nature of the current reporting system. Electronic monitoring, laboratory reporting through a centralized database, and application of standard laboratory-based case definitions can yield accurate reports that are ready for review, verification, and analysis.

Action to Be Initiated During 2012:

- Upgrade NNDSS and other surveillance systems to enable the collection of viral hepatitis test results from various sources, including public health and commercial laboratories.
  Lead/Participating Agencies: CDC, CMS

4. ELIMINATING TRANSMISSION OF VACCINE-PREVENTABLE VIRAL HEPATITIS

GOALS	
4.1	Eliminate mother-to-child transmission of hepatitis B.
4.2	Achieve universal hepatitis A and hepatitis B vaccination for vulnerable adults.
4.3	Design and test new or improved viral hepatitis vaccines and determine the indications for their optimal use.

Of the three types of viral hepatitis that contribute most substantially to disease burden in the United States, hepatitis A virus (HAV) and hepatitis B virus (HBV) are vaccine preventable. Vaccines to prevent infection with 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 their use (1–8) that progressively include more of the U.S. population. Development of a vaccine that prevents new HCV infections remains a high-priority task. Hepatitis E (HEV), which is a major cause of viral hepatitis infection in Asia and Africa, also likely will be preventable in the near future, as clinical trials have revealed two promising candidate vaccines.

Increasing hepatitis A vaccination among children has led to a striking reduction in incident HAV among all age groups across the country (9–11). The ACIP currently recommends that all U.S. children be vaccinated against HAV. However, while the Healthy People (HP) 2010 targets for hepatitis A disease reduction have been achieved for children, hepatitis A vaccination coverage (completion of the 2-dose series) in infants remains low, at approximately 40% (12).

Comprehensive hepatitis B vaccination recommendations, which 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% (10). Rates of hepatitis B vaccination coverage in infants and adolescents are high (93% in infants aged 19–35 months and 88% in adolescents aged 13–17 years) and now meet HP 2010 targets. However, non-U.S. born children who were not vaccinated at birth and have parents born in countries with high

background rates of hepatitis B are at risk for perinatal transmission and transmission through infected household contacts.

In its 2010 report, the Institute of Medicine (IOM) acknowledges vaccine-related achievements as well as identifies existing shortcomings and challenges, particularly those involving newborns. As noted by IOM, the goal of eliminating perinatal HBV transmission has not been achieved, largely because of incomplete coverage of newborns with a birth dose of hepatitis B vaccine. Vaccination coverage rates remain low for neonates (55% by the third day of life) (13). An estimated 800–1,000 new cases of perinatally acquired hepatitis B occur in the United States each year, which is far above the HP 2010 target of ≤400 infections annually. The number of perinatal hepatitis B cases is particularly concerning, because approximately 90% of HBV-infected newborns develop chronic infection; up to 25% of these children will die of cirrhosis, liver failure, or liver cancer later in life (14).

Hepatitis B vaccination programs for adults have been less successful than those targeting children. ACIP has recommended the vaccination of health-care workers and persons in other priority populations (i.e., those at high risk for hepatitis B infection, including persons with multiple sexual partners, men who have sex with men [MSM], and injection-drug users [IDUs]) since 1982 (6). The 2006 ACIP recommendation stressed the need for universal vaccination in health-care settings that serve adults in priority populations, including patients of sexually transmitted disease (STD) clinics, clients of substance-abuse treatment facilities, and incarcerated persons (8). Despite these recommendations, vaccination coverage among adults in priority populations remains low (45% in adults with high-risk behaviors) (15).

Barriers to vaccination 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 care coordination of hepatitis B-infected pregnant women, their newborn infants, and their household contacts; and 6) vaccination coverage estimates for adults in priority populations. HHS' 2010 National Vaccine Plan (NVP), the nation's roadmap for a 21st century vaccine and immunization enterprise (16), sets forth several priorities relevant to addressing these barriers, including the need to:

- increase awareness of vaccines, vaccine-preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders;
- use evidence-based science to enhance vaccine-preventable disease surveillance, measurement of vaccine coverage, and measurement of vaccine effectiveness; and
- eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines.

Development of new, more effective vaccines that provide long-term protection and reduce the number of doses required for immunoprotection could improve existing hepatitis A and hepatitis B vaccination coverage levels in the United States. The development of vaccines that induce protective immunity in those with reduced immune response rates, such as persons in older age groups and adults with co-morbidities, is equally important. Potentially, research can also yield new vaccines to prevent hepatitis C and hepatitis E infection.

The first priority defined in the NVP is development of a catalogue of priority vaccine targets of domestic and global health importance; this activity is already underway. However, completion of this activity will require the IOM Committee on Identifying and Prioritizing New Preventive Vaccines for Development (the group charged with undertaking the cataloguing process) to consider the evidence for developing improved hepatitis A and B vaccines, as well as new vaccines for hepatitis C and E.

GOAL 4.1

Eliminate mother-to-child transmission of hepatitis B.

Strategy 4.1.1

Provide postexposure prophylaxis (i.e., hepatitis B immune globulin and hepatitis B vaccine) and care coordination to all neonates born to HBV-infected women.

Care coordination is needed to ensure that infants born to HBV-infected women receive the services needed to protect them against hepatitis B. However, with the current public health capacity, recommended services are provided to only half of the estimated 24,000 infants born to HBV-infected mothers each year.

Actions to Be Initiated During 2012:

- Expand the capacity of perinatal programs to ensure that all HBV-infected mothers are identified and linked to care, their newborns receive postexposure prophylaxis, and their household contacts are tested and as appropriate, vaccinated and referred for care.
  Lead/Participating Agencies: CDC, CMS, OASH/OMH
- Identify all HBV-infected pregnant women by increasing laboratory reporting of pregnancy status on reports of hepatitis B surface antigen (HBsAg)-positive tests.
  Lead Agency: CMS
- In collaboration with professional organizations (e.g., APHL, Clinical Laboratory Improvement Amendments, and the American Association of Pathologists), promote inclusion of pregnancy status on all electronic and paper reports of positive HBsAg test results sent by laboratories to clinicians.
  Lead/Participating Agencies: CDC, CMS, IHS
- Lead or participate in supporting WHO strategies to vaccinate all infants at birth, and help regions and countries set and achieve goals for reducing hepatitis B infection among vaccinated cohorts.
  Lead/Participating Agencies: CDC, NIH, OASH

Strategy 4.1.2

Ensure that hospitals and birthing centers administer a "birth dose" of hepatitis B vaccine to all neonates prior to discharge.

Administration of a dose of hepatitis B vaccine to all newborns before discharge from hospitals or birthing centers provides a safety net for preventing perinatal and household transmission of hepatitis B. Including the provision of a birth dose of hepatitis B vaccine as a quality measure provides an incentive for routine administration to all newborns.

Action to Be Initiated During 2012:

- Identify and implement effective strategies to ensure that all neonates receive a birth dose of vaccine as the standard of care in hospitals and birthing centers.
  Lead Agency: CDC

Action to Be Initiated During 2013:

- Adopt birth-dose coverage of hepatitis B vaccine as a national quality measure.
  Lead/Participating Agencies: CDC, CMS

Strategy 4.1.3

Improve prevention for infants born to HBV-infected mothers with high viral loads.

Postexposure prophylaxis (i.e., administration of hepatitis B immune globulin) and vaccination prevent hepatitis B infection in most infants born to HBV-infected women. The low percentage of newborns that become infected with HBV despite having received these preventive measures typically have mothers with high viral loads. Research is needed to assess ways to identify women at high risk for delivering a neonate with hepatitis B infection and to inform public policies for viral load testing and antiviral prophylaxis among HBV-infected pregnant women.

Actions to Be Initiated During 2012:

- Determine the feasibility of integrating viral load testing into existing prenatal care services for HBV-infected pregnant women.
- In collaboration with partners, evaluate the efficacy and safety of antiviral prophylaxis in pregnant women with high viral loads to reduce the likelihood of disease transmission to their infants.
  Lead/Participating Agencies: CDC, FDA, NIH

Strategy 4.1.4

Ensure that children who were not vaccinated at birth and who have parents born in countries with high rates of hepatitis B are tested and vaccinated as needed.

Children born to parents from highly endemic countries who were not vaccinated at birth are at increased risk for acquiring hepatitis B perinatally or from contact with infected household contacts. If infected, 25%–50% of children <5 years of age will develop chronic infection, and 25%

of those children will later die of cirrhosis, liver failure, or liver cancer. These high-risk children should be tested for hepatitis B infection and referred for care and treatment as needed.

Action to Be Initiated During 2012:

- Educate clinical providers to screen for hepatitis B in children considered to be at increased risk because they were not vaccinated at birth and their parents were born in countries highly endemic for hepatitis B.
  Lead/Participating Agencies: CDC, ACF, OASH/OMH

GOAL 4.2

Achieve universal hepatitis A and hepatitis B vaccination for vulnerable adults.

Strategy 4.2.1

Increase availability and utilization of hepatitis A and hepatitis B vaccines for adults, including those in priority populations.

The cost of vaccine, along with inadequate reimbursement of providers for vaccination, is a barrier to hepatitis A and hepatitis B vaccination among adults. Provision of free or low-cost vaccine to targeted priority populations will increase vaccine access and improve vaccination coverage. The Affordable Care Act requires health plans to cover the purchase and administration of hepatitis A and hepatitis B vaccine to adults in ACIP-recommended priority groups without co-pays. Public health efforts should be directed toward helping health plans implement viral hepatitis vaccination for insured adults.

Actions to Be Initiated During 2012:

- Assist states in gathering and assessing evidence (e.g., number of adults in priority populations and hepatitis B incidence) and identifying barriers to prioritizing adult viral hepatitis vaccination, such as cost.
- Identify strategies, including Affordable Care Act requirements, to expand access to and use of viral hepatitis vaccine in all primary-care settings.
  Lead/Participating Agencies: CDC, CMS, HRSA, IHS, SAMHSA
- Integrate hepatitis A and hepatitis B vaccination as a standard of care in federal prevention and clinical programs that serve priority populations.
  Lead/Participating Agencies: CDC, HRSA, CMS, IHS, OASH/OMH, SAMHSA
  Partner: DOH/FBOP

Actions to Be Initiated During 2013:

- Expand delivery of vaccine through pharmacies, and evaluate the utility of this delivery method.
  Lead Agency: CDC

GOAL 4.3

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

Strategy 4.3.1

Determine long-term protection of the current hepatitis A and hepatitis B vaccine, and improve vaccine-related laboratory methodology.

Hepatitis A and hepatitis B vaccines are safe and effective. Although hepatitis B vaccine provides immunity for more than 20 years, research is needed to determine whether a booster dose is necessary for continuing immunity. Determining the duration of vaccine-induced immunity is particularly important for persons vaccinated as infants and for the minority of healthy persons and persons in certain populations (e.g., older persons and people with co-morbidities such as diabetes, chronic renal failure, HIV, and obesity) who have poor response or are nonresponsive to the vaccine. Ensuring the success of vaccination programs requires efforts to increase detection of viral variants that are resistant to vaccines and those that cause unusual clinical manifestations.

Actions to Be Initiated During 2012:

- Expand research to develop more effective vaccine strategies against HAV and HBV.
- Determine persistence of protective immune response to hepatitis B vaccination among persons vaccinated as infants, persons in older age groups, and adults with co-morbidities (e.g., diabetes, liver disease, HIV, and obesity), and assess need for a booster dose.
  Lead/Participating Agencies: CDC, NIH, FDA

Strategy 4.3.2

Promote development of a safe and effective hepatitis C vaccine.

More than 75% of HCV infections persist, often leading to serious, progressive, and fatal liver disease. Treatment options are available for persons infected with hepatitis C virus, but no vaccines against HCV have been developed.

Actions to Be Initiated During 2011:

- Work with IOM to assess the priority for the development of hepatitis C vaccines.
- Facilitate development of candidate hepatitis C vaccines designed to induce protective immune responses.
  Lead/Participating Agencies: NIH, CDC

Action to Be Initiated During 2013:

- Work with IOM and other partners to evaluate indications for hepatitis C vaccination in the United States and globally.
  Lead/Participating Agencies: NIH, CDC, FDA

Strategy 4.3.3

Assess effectiveness of hepatitis E vaccine candidates, and consider indications for use in the United States and globally.

Hepatitis E virus (HEV) is a leading cause of hepatitis in developing countries, particularly southern Asia and sub-Saharan Africa. For pregnant women infected with HEV, mortality approaches 20%. Clinical trials have shown hepatitis E vaccine candidates to be safe and effective. Additional research is needed to bring these candidate vaccines into production to benefit vulnerable populations.

Action to Be Initiated During 2011:

- Estimate the U.S. and global burden of hepatitis E.
  Lead/Participating Agencies: CDC, FDA, NIH

Action to Be Initiated During 2013:

- Collaborate with partners to evaluate hepatitis E vaccination in highly endemic countries.
  Lead/Participating Agencies: CDC, FDA, NIH

5. REDUCING VIRAL HEPATITIS CAUSED BY DRUG-USE BEHAVIORS

GOALS	
5.1	Ensure that persons who inject drugs have access to viral hepatitis prevention, care, and treatment services.
5.2	Mobilize community resources to prevent viral hepatitis caused by injection-drug use.
5.3	Provide persons who inject drugs with access to care and substance abuse treatment to prevent transmission and progression of disease.
5.4	Expand access to and delivery of hepatitis prevention, care, and treatment services in correctional settings.
5.5	Advance research to improve prevention of viral hepatitis among persons who use drugs.

Injection-drug use is a primary risk factor for three types of viral hepatitis: hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV). HAV, which is spread by the fecal-oral route, occurs in this population as a consequence of poor hygiene during drug-sharing practices and activities that involve personal contact. Needle-sharing and other drug-related behaviors associated with injection-drug use also increase the risk for HBV and HCV, both of which are blood-borne pathogens. Of new cases of hepatitis C reported to CDC, injection-drug use is the most common risk factor. Injection-drug users (IDUs) are not only disproportionately affected by these viruses, but are more likely to have adverse hepatitis-related health outcomes than other infected populations, primarily because of comorbidities and inadequate access to and receipt of health services (e.g., viral hepatitis prevention, care, and treatment* programs) (1,2). Several additional factors contribute to the suboptimal health outcomes experienced by many IDUs infected with viral hepatitis, including lack of awareness of infection status, late diagnosis, and lack of medical care and treatment.

*The term "prevention, care, and treatment" encompasses various viral-hepatitis–related services, including education, screening, testing, vaccination, referral, antiviral therapy, counseling, and medical monitoring.

Numerous cohort studies have determined that IDUs have high rates of viral hepatitis infection (3–5). In addition, IDUs contribute disproportionately to the burden of HBV infection in the United States: chronic HBV registries report that 4%–12% of chronically infected persons have a history of injection-drug use (6). Prevalence of HCV infection also is high (approximately 64%) among persons in this population (7). A decline in overall prevalence of HCV infection has been observed among some cohorts of IDUs, coinciding with provision of health services (8), including comprehensive syringe service programs, HCV testing, and efforts that promote awareness of infection status. Recovery from substance abuse through effective addiction treatment also can reduce risk for HCV infection (8). Despite this decline, other cohorts continue to have high rates of infection (9). Among IDUs, HCV is transmitted more easily than HIV. Present in high concentrations in the blood of infected persons, HCV is readily transmitted after exposure to blood-contaminated needles, syringes, and drug preparation equipment. Consequently, the incidence of HCV infection is high among new injectors (10,11).

Beyond routes of transmission, several additional factors contribute to increased rates of viral hepatitis in IDUs. For instance, hepatitis A and hepatitis B vaccination rates are low in this population (12,13). In addition, many drug users have a low level of knowledge about viral hepatitis infection (14). Education of IDUs is paramount, particularly because studies have shown that most IDUs are not able to accurately self-report their hepatitis B vaccination status (15) and because IDUs are at increased risk for becoming reinfected with HCV.

Despite these challenges, public health efforts have successfully prevented viral hepatitis among IDUs. Hepatitis B vaccination programs and other large-scale hepatitis vaccination initiatives targeting IDUs are both feasible and effective, particularly in a substance-abuse treatment setting (16,17). IDUs have been shown to accept vaccination when offered (18–20), and outbreaks of HBV infection among IDUs have been successfully quelled by public health/community collaborative vaccination programs. Furthermore, the factors that influence acceptance of hepatitis prevention services among IDUs (e.g., convenience, monetary incentive, increasing age, length of contact with comprehensive syringe service programs, and entry into substance abuse treatment) (20) will help inform the development of effective prevention programs.

GOAL 5.1

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

Strategy 5.1.1

Integrate viral hepatitis prevention and care services as standard components of substance abuse and treatment programs.

The prevalence of viral hepatitis is high among IDUs, including those entering substance-abuse treatment programs. Integrating evidence-based medical and behavioral drug-treatment services with viral hepatitis prevention, care, and treatment services can reduce the transmission of these

infections. One integrative approach is to link treatment venues with sites providing hepatitis testing and prevention services for people who are drug dependent.

Action to Be Initiated During 2011:

- Disseminate evidence-based best practices through a new SAMSHA Treatment Improvement Protocol (TIP) to guide integration of drug treatment and hepatitis prevention, care, and treatment.
  Lead/Participating Agencies: SAMHSA, CDC, CMS, HRSA, IHS

Actions to Be Initiated During 2012:

- Link viral hepatitis prevention and care services in all federally sponsored drug prevention and treatment programs that serve IDUs.
- Strengthen technical assistance to drug-treatment providers to facilitate the integration and effective delivery of viral hepatitis prevention, care, and treatment services.
  Lead/Participating Agencies: SAMHSA, CDC, CMS, HRSA, IHS

Strategy 5.1.2

Integrate viral hepatitis prevention services with HIV prevention programs.

Approximately one in 10 persons with HIV is infected with HBV, and one in four is infected with HCV. Of HIV-infected IDUs, 80% are coinfected with HCV. Viral hepatitis has become a leading cause of death for HIV-infected persons. Integrating hepatitis services into existing HIV prevention services — an effort consistent with those initiatives outlined in the National HIV/AIDS Strategy — will greatly enhance IDU access to hepatitis-related services.

Actions to Be Initiated During 2012:

- Identify and implement feasible options for integrating viral hepatitis prevention services with HIV prevention activities targeting IDUs and other populations at risk for both viral hepatitis and HIV.
- Strengthen technical assistance and training to help prevention programs integrate viral hepatitis and HIV prevention strategies.
  Lead/Participating Agencies: CDC, SAMHSA, CMS, HRSA, IHS

GOAL 5.2

Mobilize community resources to prevent viral hepatitis caused by injection-drug use.

Strategy 5.2.1

Launch and strengthen community partnerships connecting local health departments, law enforcement, other government agencies, community-based organizations, and health-care providers.

Forging viral hepatitis prevention partnerships with community-based hepatitis service providers synergizes efforts to enhance case finding, deliver hepatitis prevention services, and reduce stigma and discrimination against IDUs who need and seek hepatitis services.

Action to Be Initiated During 2012:

- Build comprehensive Viral Hepatitis Centers of Excellence at the state and local level to 1) gather and analyze public health, law enforcement, and other data to identify high risk communities; 2) raise awareness of viral hepatitis among policy makers and other local stakeholders; 3) assist educational efforts of community-based organizations and local partners; 4) increase access to substance-abuse treatment; 5) expand access to testing, vaccination, and risk-reduction interventions for IDUs; and 6) develop comprehensive syringe service programs as a platform for hepatitis prevention, care, and treatment.
  Lead/Participating Agencies: CDC, HRSA, IHS, SAMHSA

Strategy 5.2.2

Coordinate federal, state, and local resources to expand and enhance IDU access to sterile syringes and hepatitis prevention interventions.

Access to syringe service programs through comprehensive, community- and pharmacy-based syringe programs can help prevent HBV and HCV infection in IDUs. In accordance with local laws, coordination of federal, state, and local resources will reduce barriers, maximize development of syringe service programs, and increase access to these programs.

Action to Be Initiated During 2012:

- Increase support for comprehensive and targeted disease-prevention partnerships involving syringe service programs, state and local health departments, other government agencies (e.g., law enforcement), and community representatives.
  Lead/Participating Agencies: CDC, SAMHSA, CMS, HRSA, IHS

Actions to Be Initiated During 2013:

- Develop policy guidance to help states and municipalities remove barriers to receipt of comprehensive syringe services.
- Promote partnerships with pharmacists to increase access to syringe service programs.
  Lead/Participating Agencies: CDC, SAMHSA, CMS, HRSA, IHS

GOAL 5.3

Provide persons who inject drugs with access to care and substance abuse treatment to prevent transmission and progression of disease.

Strategy 5.3.1

Promote integrated care and treatment approaches for the management of viral hepatitis and co-morbid health-care conditions.

As outlined within the National HIV/AIDS Strategy, integrating services for mental health, substance abuse treatment, HIV, and viral hepatitis in the health-care setting is an evidence-based best practice that can increase hepatitis treatment rates.

Actions to Be Initiated During 2012:

- Implement screening, brief intervention, and referral to treatment (SBIRT) trainings in community-outreach programs to reduce alcohol consumption and decrease the likelihood that former IDUs will resume drug use.
  Lead Agency: SAMHSA
- Pilot different approaches to preventing persons from returning to injection drug use after successful clearance of HCV infections following anti-viral therapy.
  Lead/Participating Agencies: SAMHSA, HRSA, IHS
- As part of Community Health Center and Ryan White CARE Act-funded programs, build a network of primary care physicians trained and equipped to provide prevention and care services for persons at risk for or infected with viral hepatitis.
  Lead Agency: HRSA

GOAL 5.4

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

Strategy 5.4.1

Enhance drug treatment and viral hepatitis prevention, care, and treatment in correctional programs.

The prevalence of viral hepatitis is high among persons who are incarcerated, many of whom have a history of injection-drug use. Identifying persons infected with viral hepatitis in correctional settings would allow for the full administration of prevention services, including drug treatment services and vaccination.

Action to Be Initiated During 2012:

- Survey correctional facilities to assess current drug treatment and viral hepatitis prevention, care, and treatment services.
  Lead/Participating Agencies: CDC, SAMHSA
  Partner: DOJ/FBOP
- Identify best practices to help correctional facilities improve drug treatment programs offering viral hepatitis testing, care and treatment to incarcerated populations.
  Lead/Participating Agencies: CDC, SAMHSA, IHS
  Partner: DOJ/FBOP

Action to Be Initiated During 2013:

- Develop and implement joint HHS/DOJ policies to stimulate and guide development of viral hepatitis prevention, care, and treatment services and those that provide drug treatment in correctional settings.
  Lead/Participating Agencies: SAMHSA, CDC, IHS
  Partner: DOJ/FBOP

Strategy 5.4.2

Promote continuity of viral hepatitis care and drug treatment for inmates who are released from incarceration and are re-entering the community.

Providing viral hepatitis and drug-treatment services as a component of community-based correctional re-entry programs would promote continuity of care for infected persons and reduce the transmission of viral hepatitis.

Actions to Be Initiated During 2013:

- Identify and implement evidence-based best practices for providing hepatitis prevention services in community re-entry programs.
- Strengthen partnerships between community-based re-entry programs and community health centers to ensure that released inmates complete therapy for viral hepatitis.
  Lead/Participating Agencies: HRSA, CMS, IHS, SAMHSA
  Partner: DOJ

GOAL 5.5

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

Strategy 5.5.1

Expand the knowledge base to improve viral hepatitis prevention among persons who currently use drugs.

Studying the social networks of drug users will provide insight into hepatitis transmission pathways and opportunities for prevention.

Actions to Be Initiated During 2012:

- Expand comparative and effectiveness research to improve viral hepatitis prevention for IDUs.
- Determine the effectiveness of interventions to prevent non-injection drug users from initiating injection-drug use.
  Lead/Participating Agencies: NIH, CDC, IHS, SAMHSA
- Develop collaborations with international partners to identify emerging trends in drug use and viral hepatitis transmission and to accelerate the development of effective prevention strategies.
  Lead/Participating Agencies: NIH, CDC, SAMHSA

Strategy 5.5.2

Identify and study the recent emergence of injection-drug use and HCV transmission among young persons in suburban and rural communities.

New cases of HCV have been detected among urban and rural youth who have recently initiated drug use. Research into the risk factors for hepatitis transmission in young persons can inform prevention interventions for this population.

Action to Be Initiated During 2011:

- Examine patterns of HCV transmission of among young IDUs infected with HCV.
  Lead/Participating Agencies: CDC, NIH, HRSA, SAMHSA

Action to Be Initiated During 2012:

- Expand prevention research to intervene and prevent HCV among young IDUs.
  Lead/Participating Agencies: CDC, NIH, HRSA, SAMHSA

Strategy 5.5.3

Develop approaches to detect and treat acute HCV in IDUs.

IDUs rapidly acquire HCV within the first years of initiating injection-drug use. HCV therapies are most effective for persons with newly acquired HCV infection, and drugs with the potential to increase the benefits associated with current treatments are being developed. Additional studies are needed to assess the public health benefits of HCV therapy among persons who inject drugs.

Actions to Be Initiated During 2012:

- Assess the timing of serial HCV antibody testing of IDU cohorts to detect acute (or recent) infection.
- Conduct clinical trials of treatments for acute HCV to assess sustained viral clearance and their impact on prevention of secondary transmission among IDUs.
  Lead/Participating Agencies: NIH, CDC

6. PROTECTING PATIENTS AND WORKERS FROM HEALTH-CARE-ASSOCIATED VIRAL HEPATITIS

GOALS	
6.1	Reduce transmission of viral hepatitis to patients resulting from misuse of medical devices and drugs.
6.2	Reduce iatrogenic transmission of viral hepatitis associated with blood, organs, and tissues.
6.3	Reduce occupational transmission of viral hepatitis.
6.4	Enhance understanding of the preventable causes of viral hepatitis transmission in health-care settings.

A wide variety of health-care settings have been implicated in the transmission of hepatitis B virus (HBV) and hepatitis C virus (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 in the United States, the past several decades have witnessed substantial progress in reducing the risk of acquiring HBV and HCV from transfused blood products. The primary causes of the decline have been rigorous donor selection and improved testing of donated blood (1,2).

Currently, health-care-associated infections are primarily caused by breaches in infection control, sharps injuries, and other unsafe health-care practices. The annual number of new HBV infections among health-care workers is estimated to have dropped from over 10,000 (1983) to approximately 400 (2002) (3), largely because of widespread hepatitis B vaccination among patients and health-care workers, adoption of standard infection-control procedures, and use of safety devices (3). Patient protections also have been enhanced with the incorporation of safe injection practices as part of CDC's evidence-based infection-control guidelines (e.g., Standard Precautions) and a recent CMS-CDC interagency agreement aimed at strengthening infection-control requirements and inspection methods for licensed facilities.

Despite these successes, the challenge of providing completely safe medical care is not always met, as reflected in increasing reports of health-care-associated outbreaks of HBV and HCV infection attributed to unsafe injection practices and inadequate infection control (4). Such unsafe

practices have included 1) syringe reuse and medication vial contamination involving diverse types of outpatient clinics (e.g., those performing endoscopy, providing oral surgery, and 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 (5). These incidents and others involving lapses in the reprocessing of patient equipment (e.g., endoscopes) have impacted tens of thousands of patients who have had to be notified of potential exposure to blood-borne pathogens. Hepatitis transmission results from breaches in infection control in a variety of health-care facilities, with outbreaks increasingly being identified in non-hospital settings.

To further reduce the risk for health-care–acquired viral hepatitis among patients and their providers, public health professionals should 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 and medications — activities that will facilitate infection-control compliance among the professionals who use them.

Current efforts to ensure the safety of blood in the United States are well recognized; viral nucleic acid testing (NAT) and serologic testing have dramatically reduced the number of viral hepatitis infections attributable to blood transfusions and tissue transplants. However, additional improvements in testing could bring the risk for transmission of viral hepatitis to recipients of blood and tissue closer to zero. Improvements also are needed to better protect patients receiving solid organ transplants. Because of the high demand for and limited supply of organs, persons with risk factors for hepatitis are accepted as donors. In addition, although NAT can more accurately and promptly detect viral hepatitis infection than other testing platforms, this type of screening currently is not mandatory; consequently, not all organ procurement organizations are using NAT to screen donors. This lack of a universal approach to NAT leaves a variable, residual risk for HBV and HCV transmission to transplant recipients. To further protect transplant patients from viral hepatitis, revisions to federal recommendations concerning organ donor screening (both laboratory and risk factor) are needed. Moreover, additional data are needed to compare the benefits of existing and proposed screening strategies for donated blood, organs, and tissues through a national biovigilance program.

Neither patients nor providers should be at risk for acquiring HBV, HCV, or other blood-borne pathogens when receiving or providing health care. Behaviors and activities taking place within the health-care system can be monitored and controlled. A comprehensive approach is needed to ensure that all entities involved in the delivery of health care achieve the minimal levels of risk currently associated with blood and blood products. To be effective, this approach should be integrated with existing efforts, including the HHS Action Plan to Prevent Healthcare-Associated Infections (6), a national roadmap for reducing the burden of infections occurring in acute-care hospitals, ambulatory surgical centers, end-stage renal disease facilities, and other settings. Comprehensive prevention efforts will require the involvement of the entire medical community — including hospital, ambulatory care, and long-term care industries — as well as those charged with quality and oversight.

GOAL 6.1

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

Strategy 6.1.1

Reduce risk of transmission resulting from improper handling of point-of-care devices (e.g., blood glucose monitors) and reusable equipment.

Outbreak investigations, largely in long-term care settings, have repeatedly demonstrated that diagnostic devices designed for individual use can transmit disease when used for multiple patients. For example, finger-stick devices, or lancets, have been a major source of HBV transmission when they are used on multiple patients. Failure to clean and disinfect blood glucose monitors between patients has also been a source of HBV transmission.

Actions to Be Initiated During 2011:

- Issue a Draft Guidance for Industry on the reprocessing of reusable medical devices in health-care settings that addresses the validation of device cleaning, disinfection, and sterilization.
- Review and take necessary action on the regulatory status of blood lancets.
  Lead/Participating Agencies: FDA, CDC

Actions to Be Initiated During 2012:

- Develop innovative approaches to effective device cleaning.
- Issue a Draft Guidance for Industry addressing the validation of cleaning, disinfection, and sterilization of endoscopes.
- Develop an educational campaign for device manufacturers, user facilities, and clinicians to address cleaning, disinfection, and sterilization of reusable devices.
  Lead/Participating Agencies: FDA, CDC, CMS

Strategy 6.1.2

Reduce transmission associated with the improper use of syringes and the contamination of medication vials.

Syringes can transmit viral hepatitis if 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.

Actions to Be Initiated During 2011:

- In collaboration with United States Pharmacopeia, revise label content for medication vials.
  Lead/Participating Agencies: FDA, CDC

- Encourage industry to develop reuse-prevention equipment and/or devices that indicate prior use of injection equipment.
- Expand educational campaigns (including injection-safety checklists) and infection control and/or regulatory guidance, and use campaigns and materials to promote safe use of syringes and injectable medications.
  Lead/Participating Agencies: CDC, CMS, FDA

Strategy 6.1.3

Improve provider education regarding basic infection control across all health-care settings.

Messages for appropriate use and reprocessing of medical devices and appropriate preparation and administration of parenteral medications should be reinforced at the educational and institutional level.

Actions to Be Initiated During 2011:

- Enhance provider and purchaser education regarding limiting use of single-dose vials to only one patient to encourage increased uptake of prefilled syringes and "right-sized" medication vials.
  Lead/Participating Agencies: CDC, FDA
- Identify opportunities to improve infection-control education, and expand requirements for continuing education and related competency certifications for health-care providers.
- Engage the affected industries to raise awareness of infection-control standards, guidelines, and training needs.
  Lead Agency: CDC

Strategy 6.1.4

Improve oversight of long-term care and outpatient facilities to ensure compliance with proper infection-control procedures.

Outbreaks of viral hepatitis are increasingly recognized in dialysis clinics, assisted living facilities, and ambulatory care settings. State and local regulatory mandates are inconsistent with respect to infection-control requirements.

Actions to Be Initiated During 2011:

- Incorporate evidence-based infection-control components into applicable health and safety standards.
- Assist oversight authorities with ensuring the appropriate use of medical devices and the provision of associated training within health-care settings.
- Develop model legislation or regulations at state and local levels to promote optimal infection control in health-care facilities.
  Lead/Participating Agencies: CMS, OASH, CDC

GOAL 6.2

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

Strategy 6.2.1

Improve sensitivity testing for HBV and HCV in blood, and explore the use of pathogen reduction technology.

The sensitivity of HBV and HCV testing can be increased by improving nucleic acid extraction from test samples and by using smaller pools of samples, or even single samples without pooling, for testing. Pathogen reduction technology, which is used to process blood products to render them safe for transfusion or infusion, has the potential to reduce the residual risks for viral hepatitis.

Actions to Be Initiated During 2011:

- Engage manufacturers to promote development of rapid, high-sensitivity nucleic acid testing systems for HBV and HCV.
  Lead Agency: FDA
- Explore the development of new pathogen reduction technology by examining FDA's current regulatory approach.
  Lead Agency: FDA

Strategy 6.2.2

Improve existing biovigilance systems for blood, organs, and tissues.

A national surveillance system is needed to detect and assess the circumstances, risk behaviors, and modes of transmission underlying transfusion- and transplantation-related infections.

Action to Be Initiated During 2011:

- Undertake a coordinated cross-agency and public-private collaborative effort to collect, analyze, and share data on adverse events associated with the donation, processing, distribution, and transfusion/transplantation process.
  Lead/Participating Agencies: OASH, CDC, CMS, FDA, HRSA

Strategy 6.2.3

Revise existing policies to implement nucleic acid testing for HCV among organ donors.

Potential blood and tissue donors who have risk factors for HCV are excluded, and both antibody and nucleic acid testing are required. However, organs from donors with risk factors generally are offered for transplantation under current policies if the HCV antibody test is negative. This policy results in unrecognized HCV transmission and failed transplants. The use of advanced-generation antigen/antibody tests can help eliminate transplant-associated transmission of HCV.

Actions to Be Initiated During 2011:

- Update policies to facilitate implementation of nucleic acid testing for HCV among organ donors.
- Promote the development and FDA-approval of advanced-generation (i.e., fourth generation and beyond) antigen/antibody tests for organ donors.
  Lead/Participating Agencies: CDC, CMS, FDA, HRSA

GOAL 6.3

Reduce occupational transmission of viral hepatitis.

Strategy 6.3.1

Increase hepatitis B vaccination coverage among health-care workers and persons training to enter the health-care workforce.

Health-care workers are at high risk for exposure to and transmission of hepatitis B as a result of direct patient contact or contact with infective patient materials. Vaccination coverage among health-care workers remains below HP 2010 targets.

Action to Be Initiated During 2011:

- Identify barriers and develop strategies to address barriers to hepatitis B vaccination among health-care workers and trainees.
  Lead/Participating Agencies: CDC, HRSA, IHS, SAMHSA
  Partner: OSHA

Strategy 6.3.2

Reduce device-related percutaneous exposures among health-care workers.

Hollow-bore needle injuries are associated with a higher risk of blood-borne virus transmission than injuries from solid sharps, because these needles involve exposure to a larger volume of blood. Safety devices and engineering controls for hollow-bore needles have been developed and, at least in some settings, widely implemented; nonetheless, sharps injuries remain a continuing source of blood-borne pathogen exposure among health-care workers. Sharp-tip suture needles also continue to place certain health-care workers at risk for blood-borne virus transmission, accounting 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.

Actions to Be Initiated During 2011:

- Improve surveillance and prevention of sharps injuries (e.g., by increased reporting of sharps injuries to the National Healthcare Safety Network's Blood and Body Fluid Exposure Module).

- Release a joint Safety Alert/Advisory recommending the use of blunt surgical needles for the suturing of fascia.
  Lead Agencies: CDC/NIOSH, FDA
  Partner: OSHA

Strategy 6.3.3

Update existing guidelines for the management of HBV and HCV exposures among health-care personnel.

Hepatitis B vaccination coverage for health-care workers, particularly those working in residential-care facilities, remains inadequate. Guidelines on the management of HBV- and HCV-infected health-care workers and on the management of occupational viral hepatitis exposures have not been published since 1999 and 2001, respectively.

Actions to Be Initiated During 2012:

- Update and publish revised guidelines on the management of HBV- and HCV-infected health-care workers.
- Update and publish revised guidelines on the management of occupational viral hepatitis exposures.
  Lead/Participating Agencies: CDC, NIH

GOAL 6.4

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

Strategy 6.4.1

Expand support for health departments to thoroughly investigate possible outbreaks of health-care-associated viral hepatitis.

Health departments often lack resources to identify and investigate newly diagnosed hepatitis infections in patients who have no traditional risk factors.

Actions to Be Initiated During 2011:

- Link state health-care-associated infection programs to viral hepatitis surveillance programs.
- Develop and disseminate best practices for the investigation of potential cases of health-care-associated viral hepatitis.
  Lead Agency: CDC

Strategy 6.4.2

Evaluate strategies to help providers adhere to recommended practices for the safe use of medical devices.

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.

Actions to Be Initiated During 2011:

- Commission a study to evaluate purchasing practices of health-care facilities to understand the patterns of use that contribute to poor compliance.
- Conduct site visits and/or focus groups to identify barriers to use of safety devices and single-patient medication vials.
  Lead Agency: CDC

Strategy 6.4.3

Support research on best practices for preventing viral hepatitis transmission associated with opioid and anesthetic abuse by health-care personnel.

Narcotics diversion has emerged as the leading cause of provider-to-patient HCV transmission.

Actions to Be Initiated During 2011:

- Engage stakeholders to improve current practices related to narcotics security.
- Generate a "best practices" document outlining recommended steps for investigation and management when diversion is suspected.
  Lead/Participating Agencies: CDC, CMS, NIH, SAMHSA

Strategy 6.4.4

Support research to identify the next generation of pathogen reduction technologies for red blood cells.

Pathogen reduction technology can virtually eliminate transfusion risks from established threats (e.g., HIV and viral hepatitis) and most new or emerging infectious agents, including bacterial contaminants. This technology also can reduce non-infectious complications of transfusions (e.g., transfusion-related immunomodulation). These and other approaches should be further developed for the treatment of all blood components.

Actions to Be Initiated During 2011:

- Support clinical trials to explore the safety and efficacy of technologies currently being used in other parts of the world.
- Support grants to promote the development of new processing technologies.
  Lead Agency: NIH

CONCLUSION

The Viral Hepatitis Action Plan presents robust and dynamic steps for improving the prevention of viral hepatitis and the care and treatment provided to infected persons and for moving the nation towards achieving Healthy People 2020 goals. Some of these life-saving actions already are well underway. Other actions, representing innovations in practice, technology, and therapy, will require new strategic directions and commitment. The success of these actions is contingent on departmental and interagency collaboration, stakeholder support, and engagement of the diverse communities being served. Also critical to the success of the plan are policy-related support and system changes, which likely will be brought about by the Affordable Care Act. In this unique era of unprecedented opportunity, viral hepatitis activities can be better coordinated and aligned with the nation's reformed infrastructure for health. This Viral Hepatitis Action Plan will serve as the guide for HHS agencies working to combat the silent epidemic of viral hepatitis.

APPENDIX A

2010 INSTITUTE OF MEDICINE (IOM) RECOMMENDATIONS FOR IMPROVING VIRAL HEPATITIS PREVENTION, CARE, AND TREATMENT IN THE UNITED STATES*

SURVEILLANCE

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

KNOWLEDGE AND AWARENESS ABOUT CHRONIC HEPATITIS B AND HEPATITIS C

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

IMMUNIZATION

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

*IOM (Institute of Medicine). Hepatitis and liver cancer: a national strategy for prevention and control of hepatitis B and C. Washington, DC: The National Academies Press; 2010.

- The federal government should work to ensure an adequate, accessible, and sustainable hepatitis B vaccine supply.
- Studies to develop a vaccine to prevent chronic hepatitis C virus infection should continue.

VIRAL HEPATITIS SERVICES

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

APPENDIX B
VIRAL HEPATITIS INTERAGENCY WORKING GROUP MEMBERS AND AFFILIATIONS

VIRAL HEPATITIS INTERAGENCY WORKING GROUP

Chair: Howard Koh, HHS

Co-Chairs: Rosemarie Henson, HHS and John W. Ward, CDC

Members: Christopher Bates, PSC; Laura Cheever, HRSA; Edward Doo, NIH; Kevin Fenton, CDC; Bruce Gellin, HHS; Sally Hojvat, FDA; Jerry Holmberg, HHS; Jay Hoofnagle, NIH; Susan Karol, IHS; Leilani Liggins, AHRQ; Kenneth Lin, AHRQ; Robert Lubran, SAMHSA; Kate Moraras, HHS; Anand Parekh, HHS; Marcus Plescia, CDC; John T. Redd, IHS; Britt Reid, NIH; Kyu Rhee, HRSA; Jeffrey Roche, CMS; Barry Straube, CMS; Sophie Tan, OMH; Ron Valdiserri, HHS; Edwin Walker, AoA; Lee Wilson, HHS; and Hui-Hsing Wong, HHS

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APPENDIX C
LEAD/PARTICIPATING AGENCY AND PARTNER ABBREVIATIONS

ACF	**Administration for Children and Families**
AHRQ	**Agency for Healthcare Research and Quality**
AoA	**Administration on Aging**
APHL	**Association of Public Health Laboratories**
CDC	**Centers for Disease Control and Prevention**
CMS	**Centers for Medicare and Medicaid Services**
CSTE	**Council of State and Territorial Epidemiologists**
DOJ	**Department of Justice**
EIP	**CDC's Emerging Infections Program**
FBOP	**Federal Bureau of Prisons**
FDA	**Food and Drug Administration**
HHS/ONC	**Department of Health and Human Services/Office of the National Coordinator**
HRSA	**Health Resources and Services Administration**
IHS	**Indian Health Service**
NIH	**National Institutes of Health**
NIOSH	**National Institute for Occupational Safety and Health**
OASH	**HHS Office of the Assistant Secretary for Health**
OASH/OMH	**Office of the Assistant Secretary for Health/Office of Minority Health**
OPHS	**Office of Public Health and Science**
OSHA	**Occupational Safety and Health Administration**
SAMHSA	**Substance Abuse and Mental Health Services Administration**
VA	**U.S. Department of Veterans Affairs**

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CHAPTER 2. IMPROVING TESTING, CARE, AND TREATMENT TO PREVENT LIVER DISEASE AND CANCER

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