



**Department of Health and Human Services**

**Centers for Disease Control and Prevention**

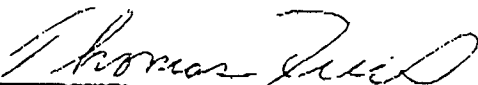
**Professional Judgment Budget**

**for**

**Comprehensive Viral Hepatitis Prevention and Control in the United States**

**as**

**Requested by the U.S. Senate Appropriations Committee**



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## Introduction

Viral hepatitis is a collective term used to describe liver inflammation or hepatitis that can be caused by a group of several different viruses. Three viruses, Hepatitis A virus (HAV), Hepatitis B virus (HBV), and Hepatitis C virus (HCV) cause the most viral hepatitis in the United States. All can cause disease acutely at the time of infection. However, HBV and HCV infections can persist for years, resulting in ongoing (chronic), but mostly asymptomatic, liver inflammation. Chronic viral hepatitis caused by infections with HBV and HCV is a major cause of liver cancer, chronic liver disease, and death in the United States. In 2010, the Institute of Medicine (IOM) called for an intensified, coordinated national effort to improve prevention of viral hepatitis and better protect the health of Americans. Their report, entitled *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, recommended evidence-based prevention strategies to significantly reduce viral hepatitis transmission and, most importantly, limit or reduce the adverse health impact and economic costs of viral hepatitis associated illness and death.

In Senate Report 111-66 on the fiscal year (FY) 2010 budget for the Department of Health and Human Services, the Senate Committee on Appropriations stated: "The Committee expects the CDC to put forward a professional judgment budget for viral hepatitis no later than August 15, 2010." This report responds to this Congressional request about the cost to develop a comprehensive national program to prevent viral hepatitis transmission and associated liver disease and cancer. It addresses IOM recommendations and is provided without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to Congress are developed. It takes into account current public health investments in viral hepatitis, including perinatal and adult hepatitis B immunization efforts.

## Viral Hepatitis Is an Underappreciated Health Risk for Many Americans

Viral hepatitis is a silent epidemic in this country. The damage that viral hepatitis does to the liver is usually asymptomatic until the advanced stages of disease, when it is often too late to treat successfully. An estimated 3.5 to 5.3 million Americans have chronic viral hepatitis, the vast majority (an estimated 70 percent) of whom are unaware of their infection. They are likewise unaware of the need to seek care for their infection, both to reduce the risk of exposing family members and other close contacts, and to minimize the adverse impact of the infection on their own health. In the absence of treatment and care, 15-20% of infected persons will progress to liver cirrhosis. Viral hepatitis is the leading cause of liver transplantation in the U.S. Moreover, in contrast to almost all other forms of cancer, liver cancer rates have tripled over the last several decades, fueled in large part by the population of persons with viral hepatitis who have progressed to end stage disease.

Approximately 12,000-15,000 Americans die of viral hepatitis each year, making it the fourth leading infectious cause of death. Coinfection with HIV and HCV is common, and end stage liver disease secondary to HCV is a leading cause of death for those with HIV. Deaths from viral hepatitis are projected to rise substantially in the coming years. Despite the impact of this disease, healthcare providers, the general public, at-risk populations, and policy makers are mostly unaware of the significant risk it poses to the nation's health.

Baby boomers, African Americans, and Asian Americans have far higher rates of viral hepatitis than the overall population. More than 1 in 33 "baby boomers," aged 46 to 64 years, are infected with viral hepatitis. Rates are even higher among racial and ethnic minorities, representing significant health disparities in this country. For example, one in seven African-American men in their 40s is living with HCV. Approximately one in 12 Asian Americans are living with HBV, and more than 50 percent of the people in the United States with HBV are Asian Americans. Liver cancer is twice as common among African Americans as among whites.

New HBV and HCV infections have declined in recent years, reflecting in part the impact of successful prevention strategies. However, transmission of these viruses is ongoing and adds to the burden of chronic viral hepatitis and liver disease. In 2007 there were an estimated 50,000 new cases of hepatitis B. HBV is spread from mother to child at the time of birth, among household contact through incidental blood exposures in the home, through injection drug use, through healthcare associated infections from exposure to blood, and through sexual contact. Rates are highest among adults with risks such as injection drug use and multiple sexual partners, reflecting low hepatitis B vaccination coverage in this age group. Foreign-born Americans are at risk due to high levels of hepatitis B transmission in many other countries. Outbreaks of hepatitis B also occur via healthcare acquired infection, to persons not currently recommended to receive vaccine, including diabetics, persons in outpatient settings, and residents of eldercare facilities.

Surveillance data suggest that about 20,000 persons are infected with HCV annually in the U.S. Sources of HCV transmission include sexual contact, injection drug use, and poor infection control in healthcare settings. There is no vaccine to prevent HCV.

Current treatments can halt or even reverse the liver damage caused by viral hepatitis. In addition, new treatments on the immediate horizon hold even greater promise for a definitive cure. All persons diagnosed with viral hepatitis should be referred to care to assess stage of disease, identify and manage co-factors (such as alcohol use, diabetes and obesity) that accelerate disease progression, and initiate treatment for those patients who can benefit from antiviral treatment. Of persons with hepatitis C who receive standard therapy, about 40 percent will respond, resulting in virologic cure of their infection. HCV treatment may be less effective for certain populations: however, the first HCV-specific therapies, expected to be licensed in the next several years, might eliminate these disparities in treatment. Despite these advances, most people with viral hepatitis are not aware they are infected until they develop symptoms of severe liver disease or cancer, at which time it is often too late to control the damage caused by their infection. Moreover, of those who are aware of their infection, few receive treatment or care.

Because of the high costs of end stage disease treatments (e.g., liver transplants), the lifetime health care costs for a person with viral hepatitis can easily total hundreds of thousands of dollars. Published studies estimate that the medical costs related to viral hepatitis run in the billions of dollars per year.<sup>12</sup> Numerous studies reveal the cost-effectiveness of screening and

<sup>1</sup> JB Wong, GM McQuillan, JG McHutchison and T Poynard Department of Medicine, New England Medical Center, Tufts University School of Medicine, Boston, Mass., USA. *Estimating future hepatitis C morbidity, mortality, and costs in the United States*, American Journal of Public Health, Vol 90, Issue 10 1562-1569.

<sup>2</sup> Milliman Study for Vertex Pharmaceuticals. *Consequences of Hepatitis C Virus – Costs of a Baby Boomer Epidemic of Liver Disease*. 2009

care for populations at risk for viral hepatitis.<sup>3</sup> Computer models indicate that the cases of life threatening liver disease due to viral hepatitis infections will increase as infected persons age and their disease progresses. As a result, more people in this country will die from liver cancer or end stage liver disease associated with HBV and HCV, raising medical expenditures and reducing productivity.

### Health Impact

The human and economic costs of viral hepatitis are projected to accelerate as chronically infected persons develop liver cancer and chronic liver disease. To prevent this from occurring, the Centers for Disease Control and Prevention (CDC) could undertake a phased plan to implement specific actions. These actions are broadly grouped under four programmatic priorities which are, in order of precedence (see table 1):

- 1) Identify Persons With Viral Hepatitis Early and Refer Them to Care;
- 2) Improve Monitoring of Viral Hepatitis;
- 3) Eliminate HBV Transmission; and
- 4) Develop, Test, and Translate into Action New HCV Prevention Tools

The actions are detailed in the appendix. Phase one describes the activities that could be accomplished in the next 3 years. Phase two activities could be accomplished in years 4–7, and phase three activities could be accomplished in years 8–10.

With full implementation of such a plan, by 2020 the nation could—

- Increase the number of individuals who know their hepatitis B status from 33% to 75%;
- Increase the number of individuals who know their hepatitis C status from 45% to 80%;
- Eliminate the transmission of HBV in the United States; and
- Reduce the number of new cases of hepatitis C by 50%.

<sup>3</sup> A Rajendra, JB Wong Economics of chronic hepatitis B and hepatitis C *Journal of Hepatology*, 2007 Oct; 47(4):608-17. Epub 2007 Jul 30

<sup>4</sup> Kanwal F, et al., Treatment alternatives for hepatitis B cirrhosis: a cost-effectiveness analysis. *The American Journal of Gastroenterology*, 2006;101(9):2067-2089.

<sup>5</sup> Spackman DE, Veenstra D. A cost-effectiveness analysis of currently approved treatments for HBeAg-positive chronic hepatitis B. *Pharmacoeconomics*, 2008;26(11):937-949.

<sup>6</sup> Wong JB, et al., Cost-effectiveness of interferon-alpha 2b treatment for hepatitis B e antigen-positive chronic hepatitis B. *Ann Intern Med*, 1995;122(9):664-675

Table: Funding by Priority and Phase

PRIORITY	Base* Funding	Annual Cost Phase 1 (Years 1-3)		Annual Cost Phase 2 (Years 4-7)		Annual Cost Phase 3 (Years 8-10)	
		Total	Change from Base	Total	Change from Phase 1	Total	Change from Phase 2
1) Identify persons with viral hepatitis early and refer them to care	\$7.7M	\$32.7M	+\$25M	\$57.7M	+\$25M	\$107.7M	+\$50M
2) Improve the monitoring of viral hepatitis	\$9.8M	\$24.8M	+\$15M	\$44.8M	+\$20M	\$74.8M	+\$30M
3) Commit the nation to eliminate HBV transmission**	\$4.7M	\$22.7M	+\$18M	\$48.7M	+\$26M	\$94.7M	+\$46M
4) Develop, test, and translate into action new HCV prevention tools	\$3.6M	\$10.6M	+\$7M	\$19.1M	+\$8.5M	\$29.1M	+\$10M
<b>TOTAL</b>	<b>\$25.8M</b>	<b>\$90.8M</b>	<b>\$65M</b>	<b>\$170.3M</b>	<b>\$79.5</b>	<b>\$306.3M</b>	<b>\$136M</b>

\*Base funding is the amount estimated under the FY 2010 budget. Base funding for viral hepatitis comes from CDC's viral hepatitis, emerging infections, and vaccines for children and food safety budget lines. This funding is projected to increase by \$1.8 million under the President's FY 2011 budget request. The increase will be spent across the priority areas including education for screening and vaccination, surveillance and adaptation of HIV prevention interventions for prevention of HCV.

\*\* In addition to funds portrayed in the table above, CDC provides vaccine, mainly through the childhood vaccination programs, through Public Health Services Act Section 317 and the Vaccines for Children program. Amounts spent specifically on hepatitis vaccines for children are not tracked. Approximately \$16 million in Section 317 funding was made available in 2010 for states to purchase vaccine for use only in venues serving adults at risk for hepatitis B. However, these funds do not support the infrastructure for vaccine delivery. In addition, approximately \$300,000 in American Recovery and Reinvestment Act funds were allocated to the evaluation of that vaccine purchase program. States support perinatal HBV coordinators with their Section 317 funds; however, amounts spent on perinatal HBV coordinators are not tracked by CDC.

## Appendix: Overview of Priorities and Funding

### Priority 1: Identify Persons with Viral Hepatitis Early and Refer Them to Care

*Health services related to viral hepatitis prevention, screening, and medical management are both limited and fragmented among entities at the federal, state and local levels....Because there is no coordinated federal strategy for HBV and HCV prevention and control, those efforts are uneven in their application and funding.*

—IOM, 2010

**Goal:** Identify and treat persons with viral hepatitis infections

**Key Strategies:** (1) Wide access to testing; (2) screening and referral to care for persons living with viral hepatitis; (3) increased education and awareness; (4) case management for infected persons

**Base Funding:** \$7.7 million

**Costs:** \$25 million per year for phase one; final cost \$100 million per year (over base) (*See Table for a comprehensive picture of needed resources by year.*)

**Impact:** Reduce the public health and economic burdens of chronic liver disease

Because the vast majority of persons with viral hepatitis are unaware of their infection and because effective treatments and care can delay or halt disease progression, identifying those who are infected and referring them to appropriate care can greatly reduce the public health and economic consequences of viral hepatitis. For this reason, screening and referral are the highest priority actions for reducing illness and death related to viral hepatitis.

However, aside from support for vaccine purchase provided in the immunization program, current CDC support for adult viral hepatitis prevention is limited to the personnel cost of an adult prevention coordinator for 49 states and a few large cities. These coordinators are tasked with integrating viral hepatitis services with other public health efforts to reach populations at-risk. However, funding for this program is limited and does not support direct service provision (e.g., counseling, testing and referral to care). Additional resources are needed to provide prevention services to reach infected and at-risk persons.

With such resources, CDC and state and local health departments could implement a national program which, in collaboration with other programs and community partners, deliver viral hepatitis prevention, detection, outreach, education, vaccination, screening, and referral for care services to persons at risk for viral hepatitis. This program could actively seek and bring high-risk persons in for screening and care, and increase public awareness and education to reduce ignorance, stigma and other barriers to accessing viral hepatitis services. It could also provide case management to ensure that persons with viral hepatitis receive services to protect their health as well as that of others. These services include referral to care for the early detection of liver cancer and for care and treatment of chronic HCV infection. Finally, professional education activities would ensure that clinicians are trained to effectively deliver screening and care services.

At the state and local level, this comprehensive national program to prevent viral hepatitis and associated liver disease and cancer could be integrated with other community and public health

programs serving populations at risk for viral hepatitis. These include settings already supported by CDC, such as STD and HIV prevention programs, and the federally qualified health centers supported by the Health Resources and Services Administration. Similar integration opportunities could be extended to American Indians/Alaska Natives who are eligible for health services provided by the Indian Health Service or by a tribal organization. CDC could conduct prevention effectiveness research to guide prevention policy development for the agency and other Department of Health and Human Services operating divisions, including the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services.

### **Specific Actions**

CDC, working through state and local health departments, would provide direction and technical and financial assistance to comprehensive *Viral Hepatitis Intervention Programs (VHIPs)*. VHIP services must be planned using state and local epidemiologic profiles that assemble case tracking, vital statistics, and health care utilization data to document health disparities caused by viral hepatitis and subsequent liver disease and cancer to inform prevention planning. Key *VHIP* services include the following:

- Culturally competent public education about the risks of viral hepatitis, opportunities and benefits of testing, and barriers to testing (e.g., stigma);
- Outreach, recruitment, and public awareness activities to inform at-risk communities of the need for screening and bring at-risk persons into screening and evaluation programs;
- Screening of persons through public health and clinical care delivery systems;
- Case management of persons screened to ensure they receive timely services to stop transmission, and appropriate care and referrals to stop progression of disease; and
- Professional education to ensure the use of science-based, clinically appropriate, and high-quality counseling, screening, and follow-up.

**FY 2010 spending: \$7.7 million**

**Total increase needed (over base): \$100 million per year**

- **Phase 1 Increased need: \$25 million/year**  
10 states: Provide funding to implement a VHIP utilizing a comprehensive public health approach for the delivery of viral hepatitis public health services
- **Phase 2 Increased need over phase 1: \$25 million/year**  
25 states: Provide funding to implement a VHIP utilizing a comprehensive public health approach for the delivery of viral hepatitis public health services
- **Phase 3 Increased need over phase 2: \$50 million/year**  
50 states, the District of Columbia, and Puerto Rico: Provide funding to implement a VHIP utilizing a comprehensive public health approach for the delivery of viral hepatitis public health services

### **Health Impact**

- Given no change in current practice, approximately 20 percent of HCV-infected persons would learn their status before developing end stage liver disease or death. Preliminary data from a CDC-developed Markov-type model reveal that by identifying and referring for appropriate care (using current infrastructure), all HCV-infected persons who have at least one primary care visit per year, approximately 87,000 cases of end-stage liver disease and

11,000 liver transplants could be prevented; 840,000 undiscounted life years would be gained with an estimated cost per discounted QALY of \$43,000.<sup>7</sup>

- Similarly, these preliminary estimates reveal that expanded HBV screening and care could avert approximately 140,000 cases of end stage liver disease and gain 3.3 million QALYs, or 3.3 million years of potential life gained.<sup>8</sup>
- While funding has not been available to extend the model to estimate cost per discounted QALY for HBV, published literature provides information on the cost-effectiveness of hepatitis B screening. One study estimated \$40,000 per incremental QALY gained (2009 dollars) by systematically screening and treating Asian Americans with HBsAg as compared to no screening.<sup>9</sup> For HCV treatment only, three U.S. studies found a range of \$8,000 to \$67,000 per QALY gained depending on antiviral medications administered and the presence of HBeAg and elevated ALTs.<sup>10,11,12</sup>

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<sup>7</sup> CDC preliminary estimates from an ongoing study.

<sup>8</sup> Ibid.

<sup>9</sup> Hutton DW, Tan D, So SK, et al. Cost-effectiveness of screening and vaccinating Asian and Pacific Islander adults for hepatitis B. *Ann Intern Med*, 2007;147 (7):460-469.

<sup>10</sup> Kanwal F, et al. Treatment alternatives for hepatitis B cirrhosis: a cost-effectiveness analysis. *The American Journal of Gastroenterology*, 2006;101 (9):2067-2089.

<sup>11</sup> Spackman DE, Veenstra D. A cost-effectiveness analysis of currently approved treatments for HBeAg-positive chronic hepatitis B. *Pharmacoeconomics*, 2008;26(11):937-949.

<sup>12</sup> Wong JB, et al. Cost-effectiveness of interferon-alpha 2b treatment for hepatitis B e antigen-positive chronic hepatitis B. *Ann Intern Med*, 1995;122 (9):664-675.

## Priority 2: Improve the Monitoring of Viral Hepatitis

*Public health surveillance is an essential tool in the prevention and control of infectious and chronic diseases and the medical management of people who have the diseases. The viral hepatitis surveillance system in the United States is highly fragmented and poorly developed. The federal government has provided few resources to local and state health departments to perform surveillance for viral hepatitis.*

—IOM, 2010

**Goal:** Monitor viral hepatitis at the national, state, and local levels

**Key Strategies:** (1) Report all new infections; (2) detect disease outbreaks; and (3) refer chronically infected persons for care and treatment

**Base Funding:** \$9.8 million

**Costs:** \$15 million per year for phase one; final cost \$65 million per year (over base)

(See Table for a comprehensive picture of needed resources by year.)

**Impact:** Provide the information needed to guide and evaluate prevention efforts

*During fiscal year 2009 alone, the CDC responded 25 times to state requests about outbreaks of HBV or HCV infection in healthcare and other settings. A recent, highly publicized outbreak of viral hepatitis associated with poor infection control practices was detected through surveillance for acute cases of HCV. Detection of the outbreak allowed the state and CDC to investigate and confirm the source of transmission, notify thousands of persons served by the clinic of their risk of exposure, and intervene to stop the poor infection control practices that led to the transmission. This outbreak would not have been detected absent an effective surveillance system in that state.*

Effective prevention would entail a national network of state and local systems that provides consistent and reliable reporting of new infections, rapid detection of disease outbreaks, and the identification and referral of persons with chronic infection for appropriate care and treatment. Such a system is critical to identify and address health disparities affecting racial/ethnic minorities (e.g., Asian/Pacific Islanders, African Americans), and marginalized populations (e.g., homeless, immigrants, injection drug users, incarcerated persons) at risk for chronic viral hepatitis and to plan education, outreach, screening and referral to care.

However, current systems to monitor viral hepatitis at the national, state, and local levels are inadequate to guide and support prevention and control activities. Cases of acute HBV and HCV infection, as well as cases of hepatitis A, are reported in all states and are published annually by CDC. In addition, some states have policies in place to support surveillance of chronic hepatitis B and hepatitis C infection. However, such surveillance is under-resourced, and both acute and chronic infections are vastly under-reported. Although CDC does provide funding for viral hepatitis surveillance to a limited number of jurisdictions, CDC estimates that only 10 percent of new cases of viral hepatitis are reported through that system each year. Further, only two-thirds of states report cases of chronic HCV, and those that do have such large backlogs of cases that it is not possible to articulate a clear picture of chronic HCV infection.

To provide a more accurate national estimate of those living with chronic hepatitis infection, CDC relies on surveys, particularly the National Health and Nutrition Examination Survey (NHANES). However, national surveys under-represent key risk populations and do not provide

data needed for state and local planning. Support for state and local systems is needed to reliably identify modes of transmission and detect disease outbreaks, and inform planning and execution for outbreak investigations and prevention programs.

#### **Specific Actions**

Additional resources are needed to monitor the occurrence of viral hepatitis to—

- Guide and evaluate prevention programs providing outreach, education, vaccination, screening and referral to care;
- Assess health disparities related to viral hepatitis for racial/ethnic minorities (e.g., Asian/Pacific Islanders, African Americans, American Indians and Alaska Natives) and marginalized populations (e.g., homeless, immigrants, persons who inject drugs, incarcerated persons); and
- Identify new or previously unrecognized forms of viral hepatitis, and the emergence of viral mutations that compromise vaccination, diagnosis, and therapy.

Key components of such a system include the following:

- Expanding state/local epidemiologic and laboratory capacity to improve detection and investigation of viral transmission and outbreaks of viral hepatitis;
- Eliminating the state backlog of chronic viral hepatitis cases awaiting data entry for transmission to CDC;
- Implementing data standards for uniform reporting to the national viral hepatitis system;
- Identifying mutant viruses resistant to vaccination, diagnosis, or therapy, and rare or new forms of viral hepatitis;
- Linking data to monitor HIV/HCV and HIV/HBV co-infection and other co-factors that increase the risk of end stage liver disease and cancer for persons with chronic viral hepatitis;
- Meeting the information needs of state and local prevention programs;
- Developing disease registries to support referrals of infected persons to care and treatment;
- Conducting surveys of viral hepatitis among underrepresented racial/ethnic minorities and at-risk marginalized populations including the homeless, refugee, and immigrant populations who are affected disproportionately by viral hepatitis; and
- Monitoring persons in care to evaluate receipt of recommended prevention and treatment.

**FY 2010 spending: \$9.8 million**

**Total increased need (over base): \$65 million per year**

- **Phase 1** Increased need over base: \$15 million per year  
Support data collection for acute and chronic viral hepatitis in 10 states
- **Phase 2** Increased need over phase 1: \$20 million per year  
Support data collection for acute and chronic viral hepatitis in 25 states
- **Phase 3** Increased need over phase 2: \$30 million per year  
Support data collection for acute and chronic viral hepatitis in 50 states, the District of Columbia, and Puerto Rico

### **Health Impact**

Ultimately, improved monitoring of viral hepatitis will better inform planning and execution of prevention and care efforts, thereby increasing the proportion of infected persons referred to care and increasing vaccination and harm reduction for at-risk persons. Such as system would:

- Obtain complete and accurate demographic and risk information on 75 percent of new infections in order to target future prevention activities;
- Increase the capacity at state and local levels to detect outbreaks so that new infections are averted by the outbreak response; and
- Achieve early detection of mutant viruses that threaten prevention efforts.

### **Priority 3: Commit the Nation to Eliminate HBV Transmission**

*Hepatitis B is a vaccine preventable disease for which a safe and effective vaccine has been available for nearly three decades. The longstanding availability of effective hepatitis B vaccine makes the elimination of new HBV infections possible.*  
— IOM, 2010

**Goal:** Eliminate HBV transmission in the United States

**Key Strategies:** (1) Case management for HBV-infected pregnant women and their families; and (2) immunize adults at public health and health care venues serving those at-risk for infection

**Base Funding:** \$4.7 million

**Costs:** \$18 million for phase one; final cost \$90 million per year (over base) (See Table for a comprehensive picture of needed resources by year.)

**Impact:** Prevent disease and death resulting from HBV infections

Vaccination is the most effective method of preventing HBV infection and is the basis for the national strategy to eliminate HBV transmission. In 1992, CDC and the Advisory committee for Immunization Practices (ACIP) established a vaccine-based strategy for the elimination of HBV transmission in the U.S. Two expert panels, most recently the IOM, both found that elimination of HBV transmission in the United States is feasible. The ACIP strategy involves vaccinating children beginning at birth adolescents, and at-risk adults. While hepatitis B incidence has declined significantly, particularly among children, new infections continue to occur. Barriers to vaccination include cost and the acceptability of a three dose vaccine series. Missed opportunities to vaccinate allow continued disease transmission. In addition, transmission of HBV has emerged in new populations.

While vaccine purchase is supported through other programs in the public and private sector, a successful strategy involves not only provision of vaccine itself, but services and programs that reach at-risk persons to encourage them to be immunized. These include case management programs to provide preventions services to HBV-exposed newborns, refer mothers for appropriate care for chronic HBV infection, and provide household members with hepatitis B vaccination and screening. This effort would build upon CDC's existing network of perinatal hepatitis coordinators. CDC would also expand efforts to immunize other at-risk adults using a venue based approach.

### Prevention and Control for HBV-Infected Mothers, Their Infants, and Their Family Contacts

Vaccination of infants has successfully driven down rates of HBV transmission and acute cases of disease. However, much more should be done. In the United States, 24,000 HBV-infected women give birth each year. These women are at risk of transmitting HBV to their infants and to other household members, as HBV is readily transmitted in household settings. Of infants infected at birth, 90 percent will remain infected and one in four will die prematurely of HBV-related liver disease or cancer.

Since the early 1990s, CDC has supported state/local efforts to prevent mother-child transmission of HBV as part of its childhood immunization efforts. This effort included ensuring screening of pregnant women, vaccination at birth, follow-up with infants to ensure completion of the three dose series, and testing of infants to ensure the development of antibodies. However, the number of HBV-infected women giving birth has greatly increased since that time and current prevention program resources are inadequate to care for all HBV infected mothers, infants and household contacts. States currently do not have the capacity to manage all of the newborns estimated to be exposed to HBV, resulting in avoidable perinatal transmission and new, chronic HBV infections.

CDC also recommends that HBV-infected women identified at the time of pregnancy be referred for medical management of their infection, because they are at risk for chronic liver disease and liver cancer later in life. However, few states have resources to provide such referrals. Family contacts of HBV infected persons are at high risk for HBV infection. Many such contacts are members of racial/ethnic minorities. Although hepatitis B vaccination of such persons has been recommended since 1982, few states have the capacity to provide culturally appropriate hepatitis B screening and vaccination services.

Comprehensive case management program can refer HBV-infected pregnant women to care, prevent infection among their infants through vaccination and monitoring from birth through 18 months of age, and prevent HBV infection and its sequelae among other household members through screening, vaccination, and referral to care. Studies have shown that such an approach is cost-effective. One dollar spent on perinatal hepatitis B vaccine saves about three dollars in medical and work-loss costs and vaccinating 15 infants of HBsAg-positive mothers prevents one death. Studies also have established the cost-effectiveness of screening and immunization for household contacts of persons infected with HBV.<sup>13</sup>

### Hepatitis B Prevention Among at-risk Adults

Although childhood hepatitis B vaccination coverage has remained above the national goals of 90% for the past 10 years, it has remained low among high risk adults. As a result, most new HBV infections occur among persons engaged in risky sex and injection drug-related behaviors. Hepatitis B immunization is routinely recommended for men who have sex with men, persons with multiple sex partners, and injection drug users (IDUs). Emerging populations of concern include persons with diabetes and others at risk for exposures associated with health care or in residential care facilities, persons vaccinated as infants who may require a booster dose, and persons born in other countries where HBV is prevalent, who represent an ongoing source of

<sup>13</sup> Hutton DW, Tan D, So SK, et al. Cost-effectiveness of screening and vaccinating Asian and Pacific Islander adults for hepatitis B. *Ann Intern Med*, 2007;147(7):460-469.

transmission. All of these groups need access to and attention services from an HBV elimination program.

Multiple studies have established the cost-effectiveness of immunizing against hepatitis B at STD/HIV testing/counseling sites, correctional institutions, and drug-abuse treatment centers.<sup>14,15,16,17</sup> However, the lack of resources for adult vaccination programs has limited vaccination for these persons, allowing continued disease transmission. For example, although CDC has recommended that persons with STDs receive hepatitis B vaccination, 30 percent of people diagnosed with acute hepatitis B had previously been treated for an STD. A similar proportion had been imprisoned. Sexual health clinics and correctional facilities are important settings for education, testing, and vaccination. In fact, an adult hepatitis B vaccination program based on routine immunization at these and other public health clinics serving adults at increased risk of infection would eliminate HBV transmission among adults in the United States by 2020.

Through its Adult Hepatitis B Vaccination Initiative, CDC has begun to close the gap in vaccination of at-risk adults. Since the beginning of the Initiative in FY 2007, CDC has made approximately \$42 million in Section 317 funds available for the purchase of hepatitis B vaccine for use in more than 2600 venues. However, funding of this initiative in future years is not assured.

But much work remains to be done. An estimated 6 million persons are eligible for vaccination through this program, which has barely scratched the surface in addressing their needs. Furthermore, an effective vaccination program requires much more than just vaccine itself. Increased capacity is needed at the federal, state, and local levels to establish and implement vaccination plans and procedures, to educate patients at risk for infection, to train providers, and to monitor both the efficiency and efficacy of efforts to insure that vaccine gets to the venues where it is needed and is administered to individuals at risk for infection. The IOM estimated that it would cost \$80 million per year for vaccine purchase alone to reach 75 percent of at-risk persons seen in STD/HIV testing/treatment sites and drug treatment centers.

### Specific Actions

A comprehensive approach to the elimination of transmission of HBV will—

- Facilitate identification of HBV-infected pregnant women by developing methods to assure positive HBsAg test results are reported directly to local and state health departments;
- Facilitate accurate assessment of hepatitis B infection status of women in labor and for management of their infants;
- Improve access to laboratory testing for HBV infection among cases managed exposed infants and household contacts;

<sup>14</sup> Miriti MK, Billah K, Weinbaum C, et al. Economic benefits of hepatitis B vaccination at sexually transmitted disease clinics in the U.S. *Public Health Rep.* 2008;123(4):504-13

<sup>15</sup> Hu Y, Grau LE, Scott G, et al. Economic evaluation of delivering hepatitis B vaccine to injection drug users. *Am J Prev Med.* 2008;35(1):25-32.

<sup>16</sup> Pisu M, Meltzer MI, Lyster R. Cost-effectiveness of hepatitis B vaccination of prison inmates. *Vaccine.* 2002;21(3-4):312-21

<sup>17</sup> Kim SY, Billah K, Licu TA, et al. Cost effectiveness of hepatitis B vaccination at HIV counseling and testing sites. *Am J Prev Med.* 2006;30(6):498-506.

- Assure that women infected with HBV, their infants, and their household contacts receive services that they need to prevent transmission and prevent or delay disease progression;
- Test and validate a system to monitor the effectiveness of prevention programs for pregnant women with chronic HBV infection;
- Develop culturally-sensitive educational materials about perinatal HBV and chronic HBV for care providers and families;
- Evaluate the efficacy of hepatitis B vaccine and the need for a booster dose in adolescents;
- Collaborate with WHO and others to support HBV prevention programs in countries where HBV is endemic;
- Assure capacity to administer hepatitis B vaccines in public health settings caring for adults at risk for infection; support sufficient headquarters staff to provide technical assistance and oversight;
- Develop and disseminate community education and provider training to improve acceptance of hepatitis B vaccination; and
- Integrate HBV screening and vaccination in correctional, HIV, and STD treatment settings.

**FY 2010 spending: \$4.7 million**

**Total increased need (all phases): \$90 million per year**

- **Phase 1** Increased need: \$18 million per year.  
Support comprehensive case management for mothers and families (\$6 million), as well as programs for at-risk adults (\$12 million) in 10 states.
- **Phase 2** Increased need over phase 1: \$26 million per year.  
Support comprehensive case management for mothers and families (increase of \$6 million), as well as programs for at-risk adults (increase of \$20 million), in 25 states.
- **Phase 3** Increased need over phase 2: \$46 million per year.

#### **Health Impact**

- Provide prevention services to 25,000 families, including HBV-infected pregnant women, newborns, and other household members.
- Increase hepatitis B vaccination coverage in high-risk adult populations to 75 percent by 2020.

#### **Priority 4: Develop, Test, and Translate into Action New HCV Prevention Tools**

*Hepatitis C became a global epidemic in the 20<sup>th</sup> century as blood transfusions, hemodialysis, and the use of injection needles to administer licit and illicit drugs increased throughout the world. Because HCV prevention is a function of multiple factors- safe injection, education, testing, and drug treatment, an integrated program that includes all these essential elements is more likely to be effective in preventing hepatitis C.*

— IOM, 2010

**Goal:** Prevent new HCV infections

**Key Strategies:** Develop, test, and utilize new tools to prevent transmission

**Base Funding:** \$3.6 million

**Costs:** \$7 million for phase one; final cost \$25.5 million per year (over base) (See Table for a comprehensive picture of needed resources by year.)

**Impact:** Prevent disease and death resulting from HCV infection

The identification of the hepatitis C virus and the development of screening tests have led to a significant decline in HCV transmission. However, surveillance data suggest that about 20,000 persons are infected annually. HCV is efficiently transmitted via direct percutaneous exposure to infected blood. Injecting drug use is the cause of most new HCV infections, and incidence remains high in most U.S. cohorts. However, numerous outbreaks of HCV infection also continue to occur in health care settings, linked to inadequate infection control practices. Other populations have emerged as priorities for viral hepatitis prevention. For example, while often considered an urban phenomenon, HCV transmission among injecting drug users recently has been detected among youth in suburban communities and small towns. A trend seen in Europe for several years is now evident in the United States with sexual transmission of HCV being detected among U.S. cohorts of HIV-infected MSM.

CDC currently conducts surveillance of HCV infection and has initiated a pilot cohort study of chronic HBV and HCV. CDC has responded to numerous suspected outbreaks of HCV transmission and is currently developing guidelines for HCV screening. The agency also provides assistance to efforts to prevent HIV among injecting drug users and aims to release guidance later this year regarding the use of syringe services programs.

Although there is not yet a vaccine to protect against hepatitis C, HCV can be prevented by avoiding factors that lead to its transmission. Effective HCV prevention among IDUs is a function of multiple factors—drug treatment, safe-injection intervention strategies, education, and testing. Drug treatment can help to reduce injection frequency and help injectors to quit. Safe-injection interventions have been shown to reduce HIV transmission, but have not been systematically studied or adapted for use in preventing HCV infection.

Studies of strategies tailored to prevent HCV can promote the development of integrated programs equally effective in preventing HIV and HCV. Prevention programs also need to have the tools to prevent the at-risk individual's transition from non-injection drug user who snorts heroin, cocaine, and other drugs to injecting drug user. Critical to HCV prevention is the development of evidence-based education strategies that focus not only on the messages about how behavior change can or should be made, but also on the context in which those messages are delivered.

Similarly, changes in policies and technologies, along with training of personnel, can reduce transmission in healthcare settings; rapid assays can improve access to screening, and new assays may improve detection of recent HCV infection; studies of sexual transmission will form the evidence basis for new interventions. Lastly, studies suggest that, if detected early, many HCV infections could be cured. As new and improved therapies are introduced, research should be conducted to guide how best to use them to preserve the health of those infected and prevent transmission among networks of IDUs.

### **Specific Actions**

1. Develop novel laboratory tests to improve screening for acute or recent HCV infection;
2. Test new technology and model laws and policies to reduce infections among drug users and improve infection control in outpatient and congregant living facilities (e.g., nursing homes, assisted living facilities, residential care settings);
3. Conduct epidemiologic and laboratory research to assess provider behavior, equipment design, and viral factors associated with transmission of HCV in health care settings;
4. Study social networks of young drug users and tailor new interventions to identify emerging trends of HCV transmission in suburban and rural communities;
5. Develop and test innovative strategies to achieve declines in HCV transmission among IDUs comparable to the reductions attained for HIV infection;
6. Monitor and assess the emergence of sexual transmission of HCV among persons with HIV infection in the United States;
7. Evaluate and implement science-based educational tools and strategies to increase knowledge of HCV among healthcare staff and staff of drug treatment and correctional facilities; and
8. Evaluate and disseminate science-based education and counseling messages that lead to drug cessation or safer injection practices.

**FY 2010 spending: \$3.6 million**

**Increased need (all phases): \$25.5 million**

- **Phase 1** Increased need over base: \$7 million per year  
Develop and implement actions one, two, and three
- **Phase 2** Increased need over phase 1: \$8.5 million per year  
Develop and implement actions one through six
- **Phase 3** Increased need over phase 2: \$10 million  
Develop and implement actions one through eight

### **Health Impact**

Reduce the number of new cases of hepatitis C by 50 percent by 2020.