

# Viral Hepatitis Policy Recommendations for the Obama Administration's First 100 Days



Hepatitis C Appropriations Partnership

## HEPATITIS B AND C DISEASE BURDEN

The Centers for Disease Control and Prevention (CDC) estimates that 5.4 million Americans have chronic hepatitis C virus (HCV) and hepatitis B virus (HBV) infection. In 2006, 19,000 Americans were newly infected with HCV and 46,000 with HBV. Each year 10,000 Americans die of HCV related liver disease and 4,000 die from HBV related liver disease. In addition, chronic viral hepatitis is the leading cause of liver cancer, now among the top 10 killers of Americans over the age of 25 years. At least 25 percent of people living with HIV/AIDS are also infected with HCV and up to 10 percent are also infected with HBV. End-stage liver disease is now a leading killer of Americans living with HIV/AIDS.

HCV is the most common cause of chronic liver disease in the U.S., accounting for 40 to 60 percent of all cases. Most liver transplants in the U.S. are due to complications of chronic HCV. Many could be averted by initiatives to educate those at risk, and diagnose and treat the chronically infected. Without increased resources for counseling, testing, and medical referral services, HCV-related deaths and long-term complications are projected to increase dramatically by the year 2020: liver failure by 106 percent, liver cancer by 81 percent, and liver-related deaths by 180 percent.

Many people with chronic HBV and HCV are unaware that they are infected because HBV and HCV are often asymptomatic until advanced liver damage has developed. Without knowledge of status, an individual cannot receive timely treatment or make life changes to stem the progression of the disease such as cessation of drinking alcohol, a good diet, and regular exercise. Without knowing they are infected, persons with HBV and HCV may unknowingly transmit the viruses to others.

Failure to address viral hepatitis has enormous consequences. HBV infections result in an estimated \$658 million in medical costs and lost wages annually. Without intervention, the HCV epidemic is expected to result in 3.1 million years of life lost over the next decade. The projected direct and indirect costs of the current HCV epidemic, if left unchecked, will be over \$85 billion for the years 2010 through 2019.

## HEPATITIS IS A SERIOUS PUBLIC HEALTH THREAT

HCV is ten times more infectious than HIV, and HBV is 100 times more infectious than HIV. These viruses can live for days outside of the human body. Yet HBV and HCV can be prevented. HBV can be prevented by a vaccine, and by the same measures that reduce HIV transmission risk. Although there is no vaccine to prevent HCV, it can be prevented through infection control procedures, and access to sterile injection equipment.

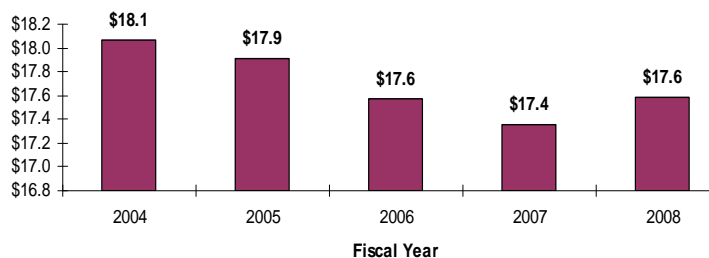
## FEDERAL RESPONSE TO VIRAL HEPATITIS LACKING

**There is no federal funding to provide core public health services for viral hepatitis.** Funds are needed for hepatitis B and C counseling, testing, and medical referral. States receive on average only \$90,000 annually for adult hepatitis prevention. This provides for little more than one staff position – the Adult Viral Hepatitis Prevention Coordinator (AVHPC) - in an entire state health department. The AVHPC works to integrate hepatitis prevention messages into existing programs without funding for actual services. Additionally, there is no funding for community-based organizations to provide services.

**There is no federally funded chronic hepatitis B and C surveillance system.** The first step to controlling infectious diseases such as hepatitis B and C is establishing a surveillance system to monitor disease incidence, prevalence, and trends. Without a national chronic hepatitis B and C surveillance system, prevention messages and interventions cannot be effectively targeted.

**Addressing hepatitis outbreak by outbreak is not disease prevention.** Due to lack of funding, CDC treats hepatitis outbreaks as sentinel events rather than systematically addressing hepatitis B and C epidemics with 5.4 million Americans infected. Addressing one outbreak at a time is not cost-effective nor is it prevention.

CDC Division of Viral Hepatitis Funding, FY2004-FY2008  
(millions)



# Hepatitis Policy Recommendations

**Education of the public and medical providers on preventing viral hepatitis must be stepped up.** Given recent hepatitis exposures in outpatient facilities in Nevada, New York, and North Carolina, it is clear that an investment in public and provider education is warranted. Established infection control procedures are not being adhered to, resulting in HBV and HCV infections. Also medical providers need to be educated on the value of vaccination and screening and how they are best delivered. State public health programs must be provided with resources to support education activities.

**There is no dedicated federal funding for adult vaccine, which is essential to eliminating hepatitis A and B.** Vaccines to prevent hepatitis A virus (HAV) and HBV have been available for over 10 and 20 years, respectively. The HBV vaccine prevents liver cancer. Although CDC recommends vaccination for high-risk adults, rates are low due to lack of dedicated funding for adult vaccine programs and infrastructure for delivery. Vaccination of persons living with or at risk for HCV and HIV is critical. HAV can be fatal in persons with chronic HCV and viral hepatitis co-infection accelerates liver disease progression.

**There is no hepatitis C vaccine.** Provision of basic prevention services, including harm reduction, is the only way to prevent new infections. Unfortunately, CDC's Division of Viral Hepatitis (DVH) received only \$17.6 million in FY2008 to provide for the prevention, control, and elimination of hepatitis. Furthermore, U.S. investment in hepatitis research is woefully inadequate.

**There is no dedicated federal funding to provide medical care to low-income persons with chronic hepatitis B or C.** Despite effective therapies that can eliminate HCV and control HBV, there is no funding for chronic disease management for those without insurance. Since chronic HBV and HCV are not disabling until their latest stage, low-income people don't qualify for Medicaid when they can best benefit from treatment, nor can they purchase non-employer based insurance, which is restricted by pre-existing condition exclusions.

**The federal government has a model prevention and care program for veterans that has not been replicated for all Americans.** The VA is the largest single provider of medical care to people with HCV in the U.S. The VA *National Hepatitis C Program* works to ensure that patients with or at risk for HCV receive quality health care services.

**Hepatitis disproportionately impacts minorities and must be addressed in the context of health disparities.** Approximately half of persons with chronic HBV are Asian Americans. HBV is most prevalent among immigrants from HBV-endemic countries (Asia and sub-Saharan Africa) who were infected at birth or childhood. Of the 24,000 HBV-infected women who give birth every year, half are Asian Americans. HCV infection is 2 to 3 times as prevalent among African Americans as it is whites.

## RECOMMENDATIONS

### LEADERSHIP

**Presidential recognition of chronic viral hepatitis as an urgent public health issue.** May 19, 2009 is World Hepatitis Day. World Hepatitis Day observances are planned in communities throughout the United States and by more than 200 organizations in 50 countries. The World Hepatitis Alliance is working to secure World Health Organization (WHO) recognition of this landmark event. U.S. encouragement of WHO recognition of World Hepatitis Day and a Presidential Proclamation will be an important step in educating Americans about the risks of contracting hepatitis, the consequences of chronic viral hepatitis and the importance of vaccination.

**Appointment of an individual in the Department of Health and Human Services (HHS) tasked with coordinating the intra-agency response to viral hepatitis.** To date, leadership on hepatitis at the HHS level has been non-existent. This is unacceptable given the prevalence of viral hepatitis: over 5 million Americans suffer from chronic hepatitis and are vulnerable to life threatening complications. Although hepatitis-related activities are occurring across HHS programs, including CDC, HRSA, NIH, OMH, and SAMHSA, there is no coordinated effort to maximize efficiency and ensure synergy across programs at these agencies.

**Develop a national plan for prevention and control of hepatitis B and C.** A Viral Hepatitis National Plan should be designed that will lower hepatitis incidence, increase research and access to care for the chronically infected, reduce racial disparities and integrate viral hepatitis with HIV, STD, TB, immunization and substance use prevention and treatment programs at the state and local level. The Plan should rely on evidence-based policy and programming, set ambitious and credible targets for improved outcomes, require annual reporting on progress towards goals, address social factors that increase vulnerability to infection, and engage multiple sectors (including people infected with HBV and HCV) in development of the Plan.

The National Plan must call for a coordinated federal response, including cross-Departmental programmatic standards for accountability and quality, as well as evaluation. Coordination should occur between (and within) the following agencies:

- Agency for Healthcare Quality and Research,
- Centers for Disease Control and Prevention,
- Center for Medicare and Medicaid Services,
- Health Resources and Services Administration,
- National Institutes of Health including National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Allergies and Infectious Disease, National Institute on Drug Abuse,

# Hepatitis Policy Recommendations

## HEPATITIS B AND C VIRUSES

They can cause mild illness, that lasts for a few weeks or develop into serious, lifelong conditions.

- Acute HBV or HCV infection are short-term illnesses, occurring within the first 6 months after exposure to HBV or HCV. Acute infection can — but does not always — lead to chronic infection. HCV can become chronic in 55 to 85 percent of people, and HBV will become chronic in 6 percent of adults. However, most children born to mothers with HBV are chronically infected, and are at risk for liver disease and liver cancer as they age. The likelihood of developing chronic HBV and HCV, and the risk and rate of liver disease progression are far greater for HIV-positive persons.
- Chronic HBV and HCV infection are lifelong illnesses. They can cause serious, life-threatening complications, such as cirrhosis (scarring of the liver), liver cancer, or liver failure. Most liver transplants in the U.S. are attributed to liver disease from chronic HCV.

- Office of Minority Health at HHS,
- Substance Abuse and Mental Health Services Administration,
- Department of Defense,
- Department of Justice, and
- Department of Veterans Affairs.

There are a number of foundational documents that we would recommend consulting including the following:

- CDC's [National Hepatitis C Prevention Strategy](#) (2001),
- NIH Consensus Development Conference Statement on [Management of Hepatitis C](#) (2002),
- NIH's [Action Plan for Liver Disease Research](#) (2004) and subsequent [annual updates](#) (2005-2007),
- National Viral Hepatitis Roundtable's [National Hepatitis Elimination Strategy](#) (2006),
- NIH Consensus Development Conference Statement on [Management of Hepatitis B](#) (2008), and
- CDC's [Testing and Public Health Management of Persons with chronic HBV](#) (2008).

While some of these documents have been available to policy makers for many years, leadership and adequate funding has been severely limited.

### **Lift the ban on federal funding for syringe exchange.**

Both CDC and NIH acknowledge the overwhelming scientific evidence that the transmission of HIV through injection drug use can be decreased significantly by needle exchange programs. Direct the HHS Secretary to certify that syringe exchange is an effective intervention for reducing the spread of infectious diseases, including HCV, and that it does not increase drug use. Additionally, the Obama Administration should support lifting the federal ban contained in federal funding bills to

evidence-based, effective prevention programs for injecting drug users. This could be achieved through a statement in your FY2010 budget as well as public support for Congressman Jose Serrano's (D-NY) "Community HIV/AIDS and Hepatitis Prevention Act" (HR 6680 in the 110<sup>th</sup> Congress) which would effectively end the ban on use of federal funds for syringe exchange programs.

## **FEDERAL FUNDING**

Federal funding for viral hepatitis has been woefully inadequate for too many years. The only dedicated funding for viral hepatitis is \$17.6 million, allocated to CDC's Division of Viral Hepatitis for prevention and control and \$20 million in one-time funding to purchase HAV and HBV vaccines for high-risk adults through the 317 Vaccine Program. In preparing the President's budget proposal for FY2010, we ask that you make public health, including hepatitis a priority.

Listed below are the priority areas that require funding to lower hepatitis incidence and increase access to care for the chronically infected.

### ***Prevention***

We request that the FY2010 budget proposal includes an allocation of \$50 million for CDC's Division of Viral Hepatitis. Currently CDC is funding a position in 55 health departments without any resources to provide core public health services or to track chronic cases of hepatitis. We seek to capitalize on the existing HIV and STD public health infrastructure by integrating hepatitis services. These additional resources should be directed to initiate the following activities:

**Funding for all 50 states and territories to establish a national chronic hepatitis surveillance system.** CDC currently is unable to fund all states and has only funded 7 sentinel projects to gather information on the epidemic. A surveillance system is essential to understanding the burden of the epidemic and for appropriately directing resources. Health departments are uniquely able to conduct surveillance because of the expertise, statutory authority, and confidentiality protection of existing public health disease surveillance and reporting systems.

**Funding for hepatitis B and C counseling and testing in public health settings.** Many people with chronic HBV and HCV are unaware that they are infected because HBV and HCV are often asymptomatic until advanced liver damage develops. Without knowledge of status, an individual cannot make life changes to stem the progression of the disease such as cessation of alcohol intake. Funding for counseling and testing is critical to increase the number of Americans who know their status and therefore can reduce mortality from chronic viral hepatitis and reduce disease transmission. This knowledge allows people to seek life-saving care and treatment and to avoid transmission to others.

# Hepatitis Policy Recommendations

**Funding for an adult hepatitis A and B vaccination program through CDC.** The gap between children and adults who have not benefited from routine childhood immunizations can be eliminated by programs targeting high-risk adults for vaccination. In FY2007, CDC redirected \$20 million in unused 317 vaccine funds for states to purchase HAV and HBV vaccine to immunize high risk adults. In FY2008, a smaller amount of funding will be available to states. States are integrating vaccination into service programs for persons at risk for viral hepatitis (e.g., STD clinics, HIV counseling and testing sites, correctional facilities and drug treatment programs). As these funds are not available on an ongoing basis, we are requesting dedicated funding for HAV and HBV vaccine and to support the infrastructure necessary for vaccine delivery.

**Funding for CDC-sponsored national viral hepatitis public awareness campaign.** Most Americans are not aware of what hepatitis is or what puts them at risk for HBV and HCV. Some are under the mistaken impression that they have been vaccinated for HCV when no such vaccine exists. Given the ongoing HBV and HCV exposures in outpatient and extended care facilities, it is critical that we raise the level of awareness of the public as well as the medical community.

## **Treatment and Medical Management**

HBV and HCV are treatable—in fact, HCV is curable. Yet, despite staggering numbers of chronically infected people, and projections of a dramatic increase in morbidity and mortality from viral hepatitis, there is no dedicated funding stream for chronic disease management of HBV and HCV. Furthermore, low-income Americans who can best benefit from treatment do not qualify for disability-based public insurance such as Medicaid. Access to care, treatment and support services are critical for preventing morbidity and mortality from viral hepatitis, and for preventing new infections by reducing the pool of infectious persons. While not all infected individuals will require treatment, they do need access to health care so that they are educated about self-care and can be monitored for disease progression.

**Funding for hepatitis B and C care and treatment for the mono-infected.** There is no dedicated funding stream for medical management and treatment of HBV and HCV, but low-income patients can and do seek services at Community Health Centers (CHCs). The administration can show leadership by adequately funding the CHCs, and through funding and directing

HRSA to initiate demonstration projects utilizing existing Ryan White Program infrastructure to provide case management and treatment for HBV and HCV mono-infected persons. In addition, more funding is needed for training and technical assistance initiatives for providers at CHCs so that they can incorporate viral hepatitis prevention, case management and treatment services for thousands of persons at risk for and living with viral hepatitis.

**Funding for hepatitis B and C care and treatment for those co-infected with HIV.** Most low-income HIV-positive individuals co-infected with HBV or HCV can obtain services through the Ryan White Program, but coverage for HBV and HCV treatment and viral load testing, which is crucial for diagnosis and monitoring response to treatment, is limited. Unfortunately, coverage for diagnostics, monitoring, treatment and vaccination against viral hepatitis are not uniformly covered by state AIDS Drug Assistance Programs (ADAPs), due to funding shortfalls. Increased resources for the Ryan White Program are needed for care, treatment, diagnostics, hepatitis vaccine, case management and support services for patients undergoing hepatitis treatment, as well as to improve provider education on HBV and HCV medical management and treatment.

Access to care for the mono- and co-infected would be vastly improved should the Obama Administration be successful in working with Congress to pass universal health care legislation, which we strongly support.

## **Research**

We request additional funding for NIH and CDC for hepatitis specific research. Support from NIH and CDC is critical for development of new drugs, diagnostics and interventions to prevent or control viral hepatitis such as behavioral research and preventive and therapeutic vaccines. Research is needed to increase understanding of the natural history of HBV and HCV, identify new targets for HBV treatments and explore efficacy of combination HBV therapy, develop more effective, less toxic treatments and refine treatment strategies for HCV as new antiviral agents are approved in the next few years, and explore interventions to slow the progression of liver disease among persons living with HBV and HCV. Research priorities for HBV and HCV are delineated in both the NIH *Action Plan for Liver Disease Research* and the NIH Consensus Development Conference Statement on *Management of Hepatitis B*.

**The Hepatitis C Appropriations Partnership (HCAP) was formed in June 2004 as a coalition of hepatitis C community-based organizations, public health and provider associations, national HIV and HCV organizations, and members of the diagnostics and pharmaceutical industry. We work with policy makers and public health officials to increase federal leadership and support for viral hepatitis prevention, testing, education, research, medical management and treatment. For more information, please contact Laura Hanen at 202.434.8091 or [lhane@nastad.org](mailto:lhane@nastad.org).**