



# Eliminating Hepatitis: A Call To Action

National Viral Hepatitis Roundtable  
Plan to Eliminate Viral Hepatitis

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# Eliminating Hepatitis: A Call to Action

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Sometimes it takes only a thoughtful moment to act quickly and avert a tragedy. Sometimes, preventing a tragedy requires a long-term commitment bolstered by skill, passion, dedicated help and substantial resources. Viral hepatitis demands both.

In the fight against viral hepatitis, quick action is possible. We know how to prevent it and to treat it. Before you finish reading this paragraph you can take action by deciding to learn about how hepatitis can damage your liver and destroy your life. You can resolve to learn what you can do to prevent it. You can become involved in longer-term, more dedicated action as well. Preventive methods and critical clinical care don't reach all those who can benefit from them and real cures are still in the making.

You can help and together we can make history by eliminating a disease that has already devastated far too many people. We can offer hope to those who already suffer from viral hepatitis. We can protect those who are not already infected, saving them from the illnesses that rob people of their vitality and even their lives. Doing so will require a coordinated action plan and the dedicated, collaborative efforts of people in both public health and the private sector. We have developed the plan and will spearhead the partnership.

The National Viral Hepatitis Roundtable<sup>1</sup> has spent more than two years developing and debating the best way to prevent the unnecessary suffering and death caused by viral hepatitis. And now, with our action plan in place, we need your help. Our proposal for action builds on the strengths and successes of our collective membership and this country's existing healthcare system. It can be done. Here's how.

Our comprehensive study and discussions with national experts have netted four recommendations:

- Build the capacity to address the challenges of viral hepatitis.
- Vaccinate America to eliminate vaccine-preventable viral hepatitis
- Counsel, test and refer persons at risk for viral hepatitis to inform them about how to reduce their risks
- Care for persons with chronic hepatitis and help them participate in the management of their condition.

You can help us to make history by eliminating a disease that has already devastated far too many people.



# Who We Are: A Coalition to Eliminate Viral Hepatitis

The National Viral Hepatitis Roundtable<sup>1</sup>, a coalition of more than 100 organizations working to end viral hepatitis in the United States, is the only national coalition focused on all aspects of viral hepatitis. Membership includes advocacy groups, medical and nursing associations, public health agencies, drug treatment programs, AIDS and STD networks, correctional organizations, insurers and biopharmaceutical companies. We promote research and prevention, integration of public health and clinical care and improved health care for infected persons.

Now is the time to ensure that the available tools—education, vaccines, antiviral medicines, medical care and mental health and substance abuse treatments—are appropriately used and that new tools are developed to end the devastating impact of viral hepatitis.

Our goals are achievable. We have already succeeded in dramatically reducing hepatitis A and hepatitis B infections through childhood immunization programs and new therapies are increasingly effective in treating chronic hepatitis B and hepatitis C, improving and saving the lives of those already infected.

- Hepatitis A and hepatitis B adult immunization can likewise be effective.
- Outreach and educational efforts can help prevent hepatitis C infection.
- New research will discover more treatments and even cures.

Our interest in eradicating viral hepatitis recognizes the importance of the human liver, which performs many functions that are essential to life. Viral infections can damage the liver and cause permanent scarring, liver failure, liver cancer and death. Worse yet, because early-stage liver damage occurs without symptoms or pain, people with chronic hepatitis may not seek treatment until their illness is far advanced or they have transmitted the disease to others.

—Thelma King Thiel  
*Hepatitis Foundation International*

Nonetheless, challenges remain. Over the past 20 years a number of government advisory committees and professional medical organizations have developed recommendations to prevent, control and treat viral hepatitis and chronic liver disease. Unfortunately, many of these recommendations have not been implemented. Perhaps clinical, public health, and healthcare policy decision-makers were not aware of the scope and devastation of the diseases, or of how recommendations could be integrated into America's healthcare systems. As a result, few people knew that viral infections can cause hepatitis and most did not know how to protect themselves. Immunizations did not reach all those who needed

protection. Many of the people with chronic hepatitis B and hepatitis C were not tested and many who had been diagnosed did not receive adequate treatment. Research investments to develop new ways to prevent, identify and treat viral hepatitis were woefully inadequate.

Our plan builds on the strengths and successes of our members and America's healthcare system. Americans no longer suffer from polio, measles and smallpox. We have eliminated those diseases. In that spirit, we intend to ensure that no American suffers from viral hepatitis.



# What We Propose: NVHR Goals

## Goal 1: Build the capacity to eliminate viral hepatitis

Eliminating viral hepatitis will require building capacity—funding, infrastructure, information and manpower—in the public and private sectors.

- Develop capacity in states and territories. Congress should fund a comprehensive viral hepatitis program in each state and territory. The program should coordinate the use of existing resources, identify unmet needs and outline strategies to prevent and treat disease.
- Create a national surveillance network. Congress should fund a national chronic and acute viral hepatitis surveillance network to provide national, state, territorial and local data essential for program planning and evaluation. This network will also support detection of and rapid response to, new modes of transmission and new and mutated viruses. The network should collect data using sound epidemiologic principles and should make the data widely available to service providers, policy makers and the public.
- Fund vaccination programs. Congress should ensure hepatitis immunization for uninsured and underinsured adults by creating a Vaccines for Adults (VFA) program and by authorizing and appropriating funds to support the Vaccines for Children (VFC) program, which provides vaccines for underinsured children in public settings and juveniles under correctional supervision. Employers and private payers should fully cover hepatitis A and hepatitis B vaccination services and education and should not require patients or physicians to report patient risk factors.
- Fund counseling, screening and testing. Private and government-sponsored healthcare programs should cover and adequately reimburse for viral hepatitis screening, testing, counseling and behavior modification as part of primary care.
- Support comprehensive care for the uninsured. Congress should fund care for uninsured and underinsured persons with chronic viral hepatitis to ensure access to primary and specialty care; antiviral therapy; mental health, social and substance abuse services; and peer support.

- Improve community health center services. The U.S. Department of Health and Human Services (DHHS) should provide support to community health centers caring for persons with chronic hepatitis infection and education for grantees on the management of hepatitis/HIV co-infection.
- Fund prevention and care for incarcerated persons. Congress and the states should fund viral hepatitis screening, testing, counseling and care in corrections settings<sup>2</sup> and ensure post-release continuity of care. Prevention methods such as condoms should be available for incarcerated persons.
- Improve prevention for drug users. DHHS should expand access to treatment services for those who wish to stop using injected drugs and access to sterile syringes and injection equipment for those who continue to use injected drugs.
- Eliminate health disparities. DHHS should strengthen its partnerships to deliver education and awareness programs, prevention services and clinical care to racial and ethnic minorities and other socially marginalized high-risk populations who suffer disproportionately from viral hepatitis infections and their consequences.
- Improve laboratory tests. Federal agencies and industry should accelerate the development of more effective diagnostic and prognostic tests, particularly rapid tests for use at the point of care.
- Develop new treatments. Federal agencies and industry should accelerate the development of better treatments for chronic viral hepatitis and related diseases, including cirrhosis, liver failure and liver cancer.
- Support health systems research. Congress should fund research to determine the best methods to integrate prevention and treatment services for persons at risk for or infected with viral hepatitis and to improve patient knowledge and behaviors.
- Fund patient outreach and education. Congress should fund the Centers for Disease Control and Prevention (CDC) to develop education and training programs for counselors, social workers and volunteers to help patients and families manage all aspects of viral hepatitis, including behavior modification, immunization and medical evaluation.<sup>3</sup> Congress should fund DHHS to support national, state and local faith- and community-based groups to help patients and family members cope during care and treatment.
- Create an information network. Congress should fund a National Viral Hepatitis Information Network to assist all those involved in viral hepatitis elimination. The network should meet the needs of patients, public health providers and frontline clinicians by providing information on best practices in public health and on the prevention and care of acute and chronic infection, including the management of related conditions and co-morbidities such as substance addiction and HIV infection.<sup>4</sup>

## Goal 2: Vaccinate America

We must take the steps necessary to provide appropriate hepatitis A and hepatitis B immunization—the most humane and cost-effective intervention—so that these viruses no longer inflict pain and suffering on anyone living in this country. We must also develop a vaccine to prevent hepatitis C.

- Vaccinate at-risk populations. Congress should provide funds to ensure the implementation of Advisory Committee on Immunization Practices (ACIP) recommendations among all populations at risk for hepatitis A and B. Immunization against viral hepatitis should be a standard of care and healthcare providers and programs should integrate hepatitis A and hepatitis B vaccination into their services.
- Protect Americans through global outreach. U.S. agencies should work with the United Nations High Commissioner for Refugees (UNHCR), WHO and UNICEF<sup>5</sup> to provide all appropriate U.S.-recommended vaccinations to persons in refugee camps and to those bound for the United States or in detention awaiting deportation.<sup>6</sup> Congress should amend refugee, immigrant and asylee immunization and medical requirements to be consistent with ACIP recommendations.<sup>7</sup> The United States should provide technical assistance to other nations seeking to prevent hepatitis through immunization.
- Achieve universal hepatitis A/B immunization. Physicians should administer hepatitis A vaccination to every child between the ages of one and 18 and hepatitis B vaccination to every child between birth and age 18. In addition, they should encourage both hepatitis A and hepatitis B vaccination for every person aged 19 years and older who has not been immunized.<sup>8</sup>
- Protect hepatitis C patients. All persons diagnosed with, or at risk for, HCV infection should be vaccinated against hepatitis A and hepatitis B.
- Protect newborns. Healthcare providers, hospitals and insurers should ensure that every newborn receives the first dose of hepatitis B vaccine before hospital discharge to maximize protection of the infant and provide a safety net from chronic hepatitis B disease.
- Require vaccination for school entry. All states should require hepatitis A and hepatitis B vaccine series completion for entry into daycare centers and schools.
- Accelerate hepatitis C vaccine development. Vaccine and biotechnology companies, federal government and academia should accelerate development of an HCV vaccine and allocate funding to encourage collaborative research and clinical trials.

## Goal 3: Counsel, test and refer persons at risk for viral hepatitis

Persons who have contracted chronic viral hepatitis are best diagnosed and cared for early. Early intervention reduces morbidity and mortality in infected persons and helps control the

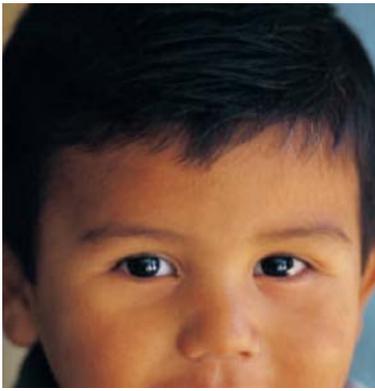
spread of viral hepatitis to others.

- Develop national awareness. DHHS should launch a campaign to increase public awareness and understanding of viral hepatitis, inform the public that treatment for chronic hepatitis is available and reduce the stigma and lessen the hopelessness faced by those who test positive for HBV and HCV.
- Create a CTR program. With the assistance of stakeholders, including patients, DHHS should launch a culturally sensitive national counseling, testing and referral (CTR) program that addresses screening, education, diagnostic testing and referral for medical evaluation and social support services. The program should be integrated into existing public health programs (e.g., HIV/AIDS, drug treatment, STDs).
- Improve patient information and access to testing. Healthcare providers should supply patients with information on risk factors for viral hepatitis and should routinely provide testing to persons who are most likely to be infected or who wish to know their infection status.
- Improve testing and laboratory quality. All clinicians and laboratorians should use the most up-to-date testing modalities to screen and evaluate patients.<sup>9</sup> DHHS should ensure that clinical laboratories participate in viral surveillance and proficiency testing, adopt common terms to describe viral hepatitis tests and results and comply with public health reporting requirements.

#### Goal 4: Care for persons with chronic hepatitis

Quality care for persons with chronic hepatitis is imperative—and possible. Treatments are available to reverse the human suffering and the economic costs of chronic liver disease and liver cancer and to reduce the death rates from these diseases. We have the tools to save lives and reduce healthcare costs.

- Promote guidelines-based care. DHHS and the American Association for the Study of Liver Diseases (AASLD) should widely disseminate guidelines for medical management and treatment of persons with chronic viral hepatitis and evaluate their implementation. Guidelines should include coordinated bio-psychosocial care for persons with chronic viral hepatitis and hepatitis/HIV co-infection and should be updated and disseminated rapidly as new treatments become available.
- Expand access to expert care. Patients with chronic hepatitis should receive care from clinicians experienced in treating the disease or in consultation with those experts. Hepatitis care should be incorporated into medical and postgraduate education and information networks for clinicians and care networks for patients should be expanded.
- Update disability criteria. The Social Security Administration should revise disability criteria to reflect the level of disability experienced by patients with chronic viral hepatitis.



# Why We Are Committed: About Viral Hepatitis

Viral hepatitis is inflammation of the liver caused by one of five viruses – hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis D virus (HDV) and hepatitis E virus (HEV) – along with their respective diseases.

- In the United States, hepatitis A, hepatitis B and hepatitis C are the most common types.
- Hepatitis D is vaccine-preventable because immunization against Hepatitis B also protects against hepatitis D.
- Three forms of viral hepatitis – B, C and D – cause chronic liver disease.
- Hepatitis B and hepatitis C can be treated with medications.

## Hepatitis A

*Risk Factors.* Hepatitis A virus (HAV) is primarily spread by the “fecal-oral” route. Persons who are infected with hepatitis A have HAV in their stool. If infected persons don’t wash their hands well after using the toilet, they may touch and unknowingly contaminate food, water, or ice, with their hands and in doing so, infect other persons who eat these items. Most HAV infections result from contact with an infected household member or other close contact (e.g., sex partner). HAV can also be spread by certain sex practices or by sharing needles. Hepatitis A is not spread by casual contact in workplaces, communities, or schools. Hepatitis A is not spread by casual contact in offices, factories, or schools.

*Vaccination and Prevention.* Before the era of hepatitis A vaccination, children between the ages of five and 14 years had the highest incidence of hepatitis A.<sup>10</sup> Now we have a vaccine and hepatitis A is preventable. Vaccines have been available since 1995 and have resulted in a greater than 75% decline in national hepatitis A rates.<sup>11</sup>

*Disease and Treatment.* Approximately one-third of the U.S. population has been infected with hepatitis A<sup>12</sup>, a self-limiting infection. Although it can be serious, it is often without symptoms and does not produce a chronic infection or chronic liver disease. Those who become ill have fever, decreased energy, poor appetite, nausea, abdominal discomfort, dark urine and jaundice<sup>13</sup>, and about 15% are hospitalized. In rare instances, hepatitis A can cause death from acute liver failure, especially in older persons (generally over 40 years of age) and those with chronic liver disease.

The likelihood of developing symptoms is related to age. In children under age six, 70% of hepatitis A infections produce no symptoms.<sup>14</sup> Among older children and adults, hepatitis A infection usually leads to symptomatic illness.<sup>15</sup> Symptoms usually resolve in less than two months, although 10%-15% of infected persons have relapsing disease lasting up to six months.<sup>16</sup>

*“I thought that hepatitis A was a very mild disease, but I was wrong.” – Dr. Mark L. Rosenberg*

I had been trained as a physician in internal medicine, infectious diseases and public health, but I didn't really know hepatitis A. I thought that hepatitis A was a very mild disease. I was wrong. I found out in the most direct way, when my wife fell ill.

As we waited to find out what might be the problem, her mother called to say that she, too, had been ill and her tests indicated that she had hepatitis A. My wife's tests suggested she, too, had hepatitis. Her mother was not as sick but a similar illness in both, starting at the same time, suggested they had eaten common foods. My wife spent 14 days in bed, gradually improving, although she remained a bit more tired than usual and her liver tests were not quite back to normal.

Three months later, during a phone call with my wife, her mother couldn't remember our son's name. Friends in infectious disease explained that if my mother-in-law was forgetful, it could be a sign of hepatic encephalopathy, a worsening of mental function caused by failure of her liver to clear the usual toxins from her blood because it had been damaged by hepatitis A. This was a grave sign and an indication that her liver could be completely destroyed. As it turned out, only a liver transplant could save her life.

We were able to find one hospital that would do this transplant, even though she was over 60 and by the time she was admitted her symptoms had worsened. We waited for a matched liver. None was available and she died waiting for the transplant.

Since that experience I have had a new-found and profound, respect for hepatitis A. The ability to truly control hepatitis A from a public health perspective would be very, very important. It wasn't until my wife's mother died that I knew this for the first time.

## Hepatitis B

*Risk Factors.* Hepatitis B virus (HBV) produces a blood-borne infection and is 100 times more infectious than HIV. Infection occurs when blood or another body fluid from an infected person enters the body of a person who is not immune. Hepatitis B is most commonly spread through unprotected hetero- or homosexual intercourse; by sharing drugs, needles, or paraphernalia when injecting drugs; through needle sticks or “sharps” exposures on the job; or by perinatal transmission from an infected woman to her newborn.

Hepatitis B is not spread by food or water, sharing eating utensils, breastfeeding, hugging, kissing, coughing, sneezing, or casual contact in workplaces, communities, or schools.<sup>17</sup>

Most persons in the United States with chronic HBV infection acquired the disease as infants or young children although illness from the disease usually appears in adulthood. Persons with acute HBV infection usually acquire it as adolescents or adults most commonly between the ages of 20-49.<sup>18</sup> Some persons are at special risk. Although Asian-American Pacific Islanders (APIs), for example, represent only 4% of the U.S. population, they account for over half of the 1.3 million persons with chronic hepatitis B infection in this country and account for half of the U.S. deaths from chronic hepatitis B. They are more likely to die from liver cancer than Caucasians, with the risk six times higher for Chinese Americans, eight times higher for Korean Americans and 13 times higher for Vietnamese Americans.<sup>19</sup>

The U.S. Centers for Disease Control and Prevention, the Hepatitis B Foundation and the Asian Liver Center recommends that all immigrants from moderate and high endemic areas be screened for hepatitis B. This includes Asia and the Pacific Islands, Africa, the Amazon Basin, the Middle East and Eastern Europe.

*Vaccine and Prevention.* Hepatitis B infection is vaccine-preventable. A vaccine became available in 1982 and the incidence of acute hepatitis B cases has declined steadily since the late 1980s when vaccination became more widespread.<sup>20</sup> Between 1990 and 2002, acute hepatitis B incidence declined overall by 67%:

- by 94% among children ages 0-4 years;
- by 92% among children ages 5-9 years;
- by 93% among those ages 10-14 years;
- by 87% among adolescents ages 15-19 years;
- by 67% among persons ages 20-39 years; and
- by 39% among persons over age 40.

*Disease and Treatment.* Though symptoms are more common in adults than children, a person with acute hepatitis B infection may not know they have the disease. If they do have symptoms, they may feel fatigue, abdominal pain, nausea, vomiting, loss of appetite, joint pain and jaundice. In some cases, these symptoms resolve themselves; in some cases they become chronic. The risk of the disease becoming chronic is strongly influenced by the person's age at the time of infection; babies infected at birth are at greatest risk, followed by children under age 5. An estimated 15%-25% of persons with chronic hepatitis B infection eventually die from chronic liver disease. An estimated 25% of persons infected with HBV at birth or as young children will die prematurely from cirrhosis or liver cancer.

The Food and Drug Administration (FDA) has approved several medications for long-term treatment of chronic HBV infection. Long-term treatment of chronic HBV infection with interferon alfa, lamivudine, entecavir or adefovir suppresses viral replication in some patients; however, sustained response after the end of treatment occurs in only 10%-15% of those treated. Complete viral elimination and cure is rare.

Chronic hepatitis B is treatable and the future looks hopeful for persons living with the disease. There are five FDA-approved medications for adults, two for children and many promising new medications in development. These treatments appear to reduce or stop hepatitis B viral replication, which may also reduce the risk of progression to cirrhosis, liver

failure, or liver cancer. Although none of the approved drugs appear to provide a complete cure (except in rare cases), they still offer a lot of hope to those living with chronic hepatitis B.

*Interferon alfa-2b* (Intron A) is given by injection several times a week for six months to a year, or longer. This medication can cause side effects such as flu-like symptoms, depression and headaches. It was approved in 1991 and is available for children and adults.

*Pegylated interferon alfa-2a* (Pegasys) is given by injection once a week, usually for six months to a year. The drug can cause side effects such as flu-like symptoms, depression and other mental health problems. It was approved in 2005 and available only for adults.

*Lamivudine* (Epivir-HBV, Zeffix, or Heptodin) is a pill that is taken once a day for at least a year. The drug has few side effects, but a primary concern is the high rate of development of resistant viral strains (mutants) during and after treatment. It was approved in 1998 and is available for children and adults.

*Adefovir Dipivoxil* (Hepsera) is a pill taken once a day for at least a year. This medication has few side effects and the rate of viral resistance is low. However, a primary concern is that kidney problems can develop, but they are generally reversible when treatment stops. It was approved in 2002 and is available only for adults. Pediatric clinical trials are planned.

*Entecavir* (Baraclude) is a pill taken once a day for up to one year. It is considered to be the most potent oral antiviral drug for chronic hepatitis B to date. It was approved 2005 and is available only for adults. Pediatric clinical trials are planned.

“He is too young to talk, so I am speaking about hepatitis B for my baby.” – Mom, Debra

My name is Nickolas. My family first found out I was sick when I was eight months old. I am originally from a poor country that can't afford vaccinations for this terrible disease but my parents weren't too worried about the diagnosis, at first. They thought how lucky I was to be part of America now, home of the best medical care and cures. Boy, did they get a shock.

First, they had to find a doctor who had experience in hepatitis B in children and who knew what tests had to be done. Then they had to figure out how they were going to pay for the transportation to the hospital and the hotel bills for us to stay for clinic appointments. You see, my father is serving our new country overseas where there are no specialists we can use there.

My parents were happy when they heard there was a treatment; but this is not like a cold. There is only one medicine I can take and it doesn't cure me. They also found out that most people think that hepatitis B affects only bad people who do drugs and have unprotected sex, that it is “not a child's disease.”

I'm 13 months old now and I don't really understand all this. Why must I leave my dad, my four sisters and my home at our military station in Germany to go to Johns Hopkins to get the care I need from qualified specialists? Who is going to pay for this? Why won't the world's biggest HMO refer me to a specialist? Why do my parents have to venture out on their own? When my dad retires from the military, will they be able to afford the tests and treatments? Speaking of treatments, why does every doctor have different ideas about how to treat me? Wouldn't it be better if they agreed?

By the time I am 30, I may develop liver cancer and will have tests twice a year to find it if I do. I won't be able to play sports and if I tell my friends why I might become an outcast. I will need to decide early which career to pursue, since I may be unable to get a job or later use my skills because of my illness. I will have to choose to love or not to love; to have children or not to have children. In fact, I may have none of these choices; hepatitis B might make that choice. I might die at a young age.

I cry when they poke me with needles. My parents cry at night when they worry. They joined online support groups, where people who have this disease pool their resources and knowledge and vent their frustration and pain, all in private, some under assumed names. It helps a little, but not enough.

I am not a celebrity. I am just a child. I cannot drum up support or rally the public. But you can. Don't forget about me when you think about hepatitis B.

## Hepatitis C

*Risk Factors.* Hepatitis C virus (HCV) produces a blood-borne infection. Hepatitis C infection occurs when blood or another body fluid from an infected person enters the body of a person who is not infected. Hepatitis C is primarily spread by direct introduction of infected blood into the body from sharing needles or drug paraphernalia, from exposure to needle sticks or "sharps" on the job and, before 1990, transfusion of blood and blood products. As with other blood-borne pathogens, HCV can be transmitted by exposure to items that may be contaminated with blood, such as tattooing and piercing equipment. Transmission also occurs, but at a much lower rate, from an infected mother to her baby during birth and through high-risk homosexual and heterosexual activity involving blood exposure or multiple partners.

Unlike hepatitis B and HIV, hepatitis C is not efficiently transmitted by sexual contact. Hepatitis C is not spread by food or water, sharing eating utensils, breastfeeding, hugging, kissing, coughing, sneezing, or casual contact in workplaces, communities, or schools.

*Vaccine and Prevention.* There is currently no vaccine to prevent hepatitis C infection. Until a vaccine is available, other forms of prevention are important:

- primary prevention – teaching those with high-risk behaviors how to prevent the disease;
- secondary prevention – preventing the progression of chronic HCV infection to chronic liver disease; and

- tertiary prevention – caring for persons with chronic liver disease from hepatitis C to prevent mortality from cirrhosis and liver cancer.

“We eagerly await the day when researchers successfully develop a vaccine to protect people from hepatitis C, so that we will be able to eliminate this serious liver disease along with hepatitis A and B.

—Deborah Wexler, M.D.

Founding Chair, National Viral Hepatitis Roundtable  
Executive Director, Immunization Action Coalition

Other preventive measures include careful blood-banking practices, prompt identification of infected persons, awareness of

the potential for perinatal transmission, safe-injection practices, linking drug users to drug treatment programs and community-based education and support programs to modify risky behavior.

*Disease and Treatment.* Persons with acute hepatitis C infection usually have no symptoms or only mild symptoms that are unlikely to prompt a visit to a healthcare professional. Of persons who have symptoms, 10%-30% experience fatigue, abdominal pain, poor appetite, or jaundice.<sup>21</sup> Most infected persons—between 75 and 85%—become chronically infected and can transmit the virus to others.<sup>22</sup> Of those who are chronically infected, 60 to 70% will suffer active liver disease and 10 to 20% will develop cirrhosis (scarring of the liver). Hepatitis C is currently the leading indication for adult liver transplantation in the United States. An estimated 8,000-10,000 Americans die annually from hepatitis C and, without measures to stem the tide, the annual death rate is predicted to double or triple by 2010.

Before 1998, when hepatitis C combination therapy became available, clinicians were reluctant to order tests to detect an infection because they could not treat it. Today, however, the situation has changed. Due to improvements in therapy, approximately 50% of HCV-infected patients on combination antiviral therapy completely clear their infections. This reduces liver fibrosis and prevents further liver damage.<sup>23</sup> As a result, persons with chronic hepatitis C should be screened every six months to detect hepatocellular carcinoma (HCC). When treatment is successful—meaning that the virus remains undetectable in the patient’s bloodstream for six months after completion of treatment—it appears that the virus has been completely eliminated and the patient is not at risk of suffering further disease. This is referred to as a sustained virologic response (SVR), or viral clearance.

The therapy for chronic hepatitis C has evolved steadily since alpha interferon was first approved for use in this disease. At the present time, the optimal regimen appears to be a 24- or 48-week course of the combination of pegylated alpha interferon and ribavirin.

*Pegylated interferon alfa-2a* (Pegasys) is given by injection once a week usually for six months to a year. The drug can cause side effects such as flu-like symptoms, depression and other mental health problems. Pegasys was approved in 2005 and is available only for adults. Because of its ease of administration and better efficacy, peginterferon has been replacing standard interferon both as monotherapy and as combination therapy for hepatitis C.

*Interferon alfa-2b* (Intron A)—(Interferon alfa-2b, recombinant) for Injection is indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease who have a history of blood or blood-product exposure

and/or are HCV antibody positive. Studies in these patients demonstrated that INTRON A therapy can produce meaningful effects on this disease, manifested by normalization of serum alanine aminotransferase (ALT) and reduction in liver necrosis and degeneration.

*Ribavirin* (Copegus, Rebetol, Virazole) is a capsule taken twice a day. It is effective against a broad range of viruses. By itself, ribavirin has little effect on HCV, but adding it to interferon increases the sustained response rate two- to threefold. For these reasons, combination therapy is now recommended for hepatitis C and interferon monotherapy is applied only when there are specific reasons not to use ribavirin.

“My son lives a life without hepatitis C treatment.” – *Dorothy*

It is hard to tell people your son is infected with the hepatitis C virus. They look at you like you're a leper. The only people I tell are the doctors. This is the same doctor who does not want to do any treatments; we're stuck with him, because the insurance will not let me change doctors. So every day I wonder how much longer I have my boy before the disease takes him.

My son is 17 years old. If he tells girls, they suddenly find reasons to cancel dates. Dealing with hepatitis C is hard; having no friends makes it worse. We all need friends and people to talk to – especially teens. We have no teen support group in our area. All the groups are adults; there's no one in his age group that comes.

The few people who know about his condition just say, “don't worry, it will go away.” Perhaps they don't to be bothered; but they are wrong. It won't just “go away.” This is the loneliest I have ever felt in my life. I try very hard to look up positive things to tell my son about hepatitis C, but I cannot answer his questions about why the doctor refuses treatment.

“What a difference hepatitis C treatment can make!” – *Gay*

We adopted our Marina at age four from Russia and discovered on routine screening that she was infected with hepatitis C. The first liver biopsy, performed when she was five, showed only mild liver inflammation. I read everything I could and learned all I could from the Internet. The adult listservs were very distressing as I learned first-hand of the misery this disease causes.

When Marina was nine, a second biopsy and discovered fibrosis (liver scarring) developing. That's when we sought aggressive treatment; her liver disease was progressing.

We heard Schering-Plough Corporation was conducting a clinical trial of a combination interferon and ribavirin treatment. Deciding to enter that trial was the most difficult decision of my life! I was making a critical decision for someone who could not decide for herself. And because children had never been treated before with this particular combination drug, there were many unknowns. But one day, my adult son said to me, “What have you got to lose?” That made me really think. The consequences of the disease are so severe that we felt that we had to be aggressive.

The severity of a drug’s side effects are difficult to gauge in children like Marina. She received an injection three days each week. She would get anxious every time she thought about it, she was frequently nauseated and tired and had trouble staying focused at times.

After a dose of ibuprofen in the morning, the fever would usually disappear by school time, but she looked especially wiped out on those days. She had dry skin on parts of her body, especially on her fingertips. Between her dry skin and anxiety, she would pick at the skin around the fingernails until they bled. After we finished the treatment, the nausea disappeared, her appetite returned and there were no more fevers! We noticed that her anxiety level had gone way down and she began to leave her cuticles alone.

Marina completed a grueling, full 48 weeks of treatment, which ended on October 6, 2000. Tests conducted six months after treatment still show no signs of the virus in her blood!

Three weeks after Marina’s treatment ended, her teacher commented on how things were just “clicking” for her. She was able to pay attention, was more energetic, more involved in class and much less anxious. I thought it was interesting because neither her teachers or I had noticed these symptoms as they had crept up gradually, but their absence was striking!

Would we do it again? Definitely! When I asked Marina recently if she would recommend treatment to other kids, she said she emphatically would. She doesn’t want to have the hepatitis C virus. She wants to be just like all other kids. She told me, “I’ll do whatever it takes to get rid of the hepatitis C!” She is one tough kid!

## Hepatitis D

Hepatitis D is a liver disease caused by the hepatitis D virus (HDV), a defective virus that needs the hepatitis B virus to exist. HDV is found in the blood of persons chronically infected with HBV. Persons with hepatitis D and hepatitis B infections have more severe liver disease than those with hepatitis B alone. There is no vaccine to prevent hepatitis D infection, however, vaccination against hepatitis B infection protects against hepatitis D infection.

## Hepatitis E

Hepatitis E is a liver disease caused by the hepatitis E virus (HEV) that occurs in many developing countries, where it is primarily transmitted by contaminated water. Although hepatitis E rarely occurs in the United States, it does occur among persons who have traveled to countries where HEV is endemic, such as India, parts of Africa and Asia and Mexico. A vaccine for prevention of hepatitis E is currently under evaluation.

## Costs of viral hepatitis

Hepatitis A and hepatitis B continue to be among the most prevalent vaccine-preventable diseases in the United States (see table).

*Disease burden from hepatitis A, B and C, United States*

	Hepatitis A	Hepatitis B	Hepatitis C
Estimated infections, 2003	61,000	73,000	30,000
Number chronically infected	n/a	1.25 million	2.7 million
Estimated annual deaths due to chronic liver disease	n/a	5,000	8,000-10,000
Direct healthcare costs	\$133 million	\$300 million	\$300 million
Indirect costs	\$267 million	\$700 million	\$700 million

Yet each year, more than 60,000 persons are infected with Hepatitis A. Of those infected, between 11 and 21% are hospitalized and nearly 100 die.<sup>24</sup>

Each year, almost 75,000 Americans are infected with hepatitis B. Nearly 1.25 million people in the U.S. currently have chronic HBV infection; an estimated 5,000 of them will die from HBV-related liver diseases. The human toll is great and there is a tremendous financial burden as well. Hepatitis A and B cost Americans \$1.4 billion each year in direct and indirect costs. The Centers for Disease Control and Prevention (CDC) projects that vaccinating the one million high-risk adults would save up to \$100 million in future direct medical costs by preventing 50,000 new hepatitis B infections, 1,000-3,000 chronic hepatitis B infections and 150-450 deaths from cirrhosis and liver cancer.<sup>25</sup> How can we fail to do so?

HCV infected 30,000 persons in 2003 and an estimated 2.7 million persons in the United States have chronic HCV infections. The total direct and indirect costs associated with hepatitis C are estimated to be about \$1 billion.

Of the estimated one million<sup>26</sup> Americans living with HIV, 25 to 30% are co-infected with HCV, with most co-infections among intravenous drug users. Co-infection results in more

rapid progress of HIV and co-infected people are three times more likely to develop cirrhosis and six times more likely to experience hepatic decompensation than those with HCV mono-infection.<sup>27</sup>

Although combination therapy eliminates hepatitis C virus in less than 50% of patients, recent studies suggest that it provides substantial societal savings in terms of employer costs, disability payments and years of life lost.<sup>28</sup>



# What We Are Up Against: Promises and Pitfalls

## Prevention Strategies

Viral hepatitis can be prevented by blending public awareness, professional training, counseling, testing and medical referral, a vaccine program for adults and better adherence to established infant and adolescent vaccination programs. Indeed, it's the right time for public health officials to go beyond prevention toward the elimination of vaccine-preventable viral hepatitis. State-based hepatitis surveillance must be enhanced and should produce regular reports to enforce action and ensure that all people are appropriately protected.

*Public education.* General health information is more widely available today than ever before. Research results, an understanding of the basics of the human body and ways to diagnose and manage disease are a mouse-click away and can be perused while standing on line to buy groceries. Yet despite the growing body of readily available health information, a major factor in the spread of viral hepatitis is unknowing participation in liver-damaging activities.

Many infected persons were unaware of the risk behaviors that exposed them to viral infections and, ultimately, liver damage because people do not have the specific information they need about hepatitis and the liver. This information should be included in health education programs, but it is not. Knowledge is the key to prevention and is important for everyone –adults and even children—to understand the importance of the liver and how viruses and drugs can damage its ability to keep them alive and healthy. To be most effective, prevention education must be targeted to persons at highest risk and communicated in culturally appropriate language. Education will help people assess their own risky behaviors, seek testing, accept vaccination, avoid spreading infection to others and participate in their own healthcare and hepatitis disease management.

*Vaccination.* We in the United States are fortunate to have safe and effective vaccines to prevent hepatitis A infection, hepatitis B infection,<sup>29</sup> and the liver cancer and cirrhosis that can occur from chronic HBV infection. In 1999, we introduced the hepatitis A vaccination into areas with historically high rates of disease, including many western states<sup>30</sup> and Native American, Alaska Native and Hispanic communities.<sup>31</sup> In 1991,<sup>32</sup> we instituted universal infant hepatitis B immunization, provided case management to hepatitis B-infected mothers and their newborns and in 1995, expanded immunization programs to reach children and

adolescents. We have achieved dramatic improvements in prevention through these successful childhood and adolescent immunization programs.

The news for adults is not as good. Their rates of disease have not fallen as fast as those in children or adolescents. Rather, disease incidence has actually increased among some adults. It is time to take the next steps to protect those who remain at risk. Adult immunization must be our next priority. Naturally, we will never abandon the children; immunization programs for infants, children and adolescents must continue, but protecting children is not enough. Adults are at risk now and should be protected now. Success in immunizing them could eliminate transmission of HAV and HBV in the U.S.

*Vaccines for children.* The inability to pay for vaccines is a barrier to the best that public health has to offer—lifelong protection from serious disease through immunization. For 54.6% of American children 0-17 years of age, vaccination is covered by private healthcare plans.<sup>33</sup> For the 45% who are uninsured, or whose insurance plans don't cover vaccination, immunizations are covered by two federally funded programs, the Vaccines for Children (VFC) program<sup>34</sup> and the 317 Immunization Grant program.<sup>35</sup> Both programs have been instrumental in ensuring high coverage rates of ACIP-recommended vaccines among children and adolescents. In recent years, however, Federal disbursements to states under the 317 Immunization Program have not kept pace with program needs. Vaccine prices have increased, new vaccines have been added to the childhood and adolescent vaccination schedules and personnel and other service-delivery costs have risen. Budget shortfalls and competing demands in some states have led to cutbacks in public health funding, keeping some children from receiving age-appropriate vaccination. Public health funds have been redirected, reducing resources for important prevention and educational programs to decrease high-risk behaviors. Finally, in stark contrast to overall childhood immunization success, we have failed to adequately protect child refugees with vaccines.

*Vaccines for adults.* The consequence of viral hepatitis—severe disease, liver failure and death—are seen more often in adults than in children. Yet, adult hepatitis A and B immunization rates remain low in all risk groups, with the exception of hepatitis B for healthcare workers,<sup>36</sup> even though hepatitis A and hepatitis B vaccination for adults in high-risk groups is widely recommended by vaccine advisory groups, key government agencies,<sup>37</sup> physician societies and the Department of Veterans Affairs.<sup>38</sup> Limited payments for hepatitis A and B vaccines, lack of funding for targeted vaccination programs for high-risk populations, lack of funding for risk-reduction education by public health programs and private insurance plans and limited capacity to support adult immunization impede adequate prevention of these diseases in adults.

*Perinatal transmission of hepatitis B virus.* Administration of the hepatitis B vaccine at birth has reduced the rate of transmission of hepatitis B from mother to infant. Since each year 22,000 babies are born to HBV-infected women in this country, many in immigrant families, it is essential that the post-exposure prophylaxis vaccine be given at birth and in the months that follow. Without it, up to 8,800 (40%) of these infants would have become infected with HBV and 25% of those babies would be at higher risk late in life for premature death from cirrhosis or liver cancer. The CDC's Hepatitis B Coordinators serve as case managers and work with physicians and hospitals to ensure that HBV-infected pregnant women receive appropriate medical care to prevent the spread of hepatitis B virus to their babies. This goal is both effective and cost-effective. For perinatal hepatitis B prevention, every dollar spent

on vaccinating infants born to HBsAg-positive women, \$13 is saved in medical and work loss costs. Far too often, however, we fail in this country to fully protect these at-risk babies at birth. We must improve our vigilance on their behalf!

*Substance Abuse Prevention and Treatment.* In this country we provide services in the public and private sectors to prevent and treat drug addiction and alcoholism. These programs have major implications for the treatment of chronic viral hepatitis and HIV infection. The Center for Substance Abuse Treatment (CAST) of the Substance Abuse and Mental Health Services Administration (SAMHSA) confirms that treatment for drug addiction prevents uninfected persons from becoming infected with hepatitis viruses and HIV and slows disease progression and clinical deterioration from the combined effects of drug use and disease. Yet the social stigma remains and people are wary of seeking help. Moreover, funding is limited and demand far exceeds the resources required to care for those in need. The consequences of ignoring this problem are too grave. Our policies and funding must improve.

The most efficient, effective way to deliver hepatitis prevention services to at-risk or infected adolescents and adults is to integrate them into public health and community-based programs that provide other prevention services to people at risk for viral hepatitis and infection, such as HIV and STD prevention, harm-reduction and substance-abuse treatment programs. These programs have expert staff and the community's trust. Integration avoids duplication, increases productivity and reduces short- and long-term, public and private healthcare costs.

*Counseling, testing and referral.* Many persons who are chronically infected with hepatitis B or hepatitis C are initially asymptomatic or experience nonspecific symptoms that do not suggest liver disease. As a result, many are unaware that they have, or are at risk for, chronic liver disease until the symptoms of cirrhosis appear. They are also unaware that they can transmit infection to others. Risk-factor screening, counseling, diagnostic testing and vaccination for hepatitis A and hepatitis B are essential elements of appropriate medical treatment for those already infected. These measures can reduce the probability of hepatitis-related cirrhosis, liver failure and liver cancer and can prevent new cases of viral hepatitis among family and community contacts of infected persons.

Although screening and testing for chronic HCV and HBV infections require significant time and resources, they are cost-effective relative to other public health interventions. Currently, however, there is no national program to ensure implementation; no dedicated funding for state, tribal, or local programs; no funding for community-based testing programs; and no easy “point-of-use” diagnostic tests that provide rapid results. Without these essential elements, infected persons remain undiagnosed, their families and communities continue to be exposed to transmission and the nation and states cannot determine whether prevention activities are effective. As a result, the number of persons who are infected with the viruses or dying from related complications is undercounted and the economic burden is underestimated. This is especially true in settings with the highest concentrations of infected persons—that is, in substance abuse treatment and correctional settings.

Some sites of care have a financial disincentive to test for HBV and HCV. If they diagnose it, they have an obligation to provide clinical care and although care is cost-effective to the healthcare system overall, individual systems of care (e.g., correctional health care) do not benefit because the reduced costs are derived later, after the patient has left their system.

We should never be lulled into a false sense of security that focusing on today's "at-risk" persons will be sufficient. Hepatitis C, for example, affects a diverse population and risk factor screening models are unlikely to identify those who do not fall into an easily defined risk category. Those likely to be overlooked include people who received infected blood or blood products before 1992; injection drug users who maintain gainful employment and social status; persons who briefly experimented with drugs decades ago but have no other risk factors; and young adults born to mothers with undiagnosed HCV who unwittingly passed the infection to their children.

Persons in these groups represent a significant reservoir of hepatitis C and are at risk of severe liver disease and possibly death, if they are left unidentified and untreated. For these reasons it is critical that we increase awareness of viral hepatitis among healthcare providers and the public and reach out to improve detection and diagnosis of hepatitis C.

We need non-invasive laboratory markers of disease progression to be used in place of liver biopsies, tests that predict response to therapy, tests for early detection of liver cancer and genetic and molecular markers to predict risk of progression to cirrhosis and liver cancer.

## Caring for persons with viral hepatitis

As one of the wealthiest nations, this country has developed major health care systems that support public and private delivery of care. These services are fragmented, however, as illustrated by current viral hepatitis treatment and prevention programs. In the United States, we have the opportunity to optimize the management of chronic viral hepatitis by providing information and practical assistance to physicians, other caregivers and patients. We also have the capacity to develop and promote high standards of care that adapt to the medical and social conditions that may affect treatment. All we need is the will to do so—in particular, the will to provide the resources to support those who already work tirelessly in the field.

NVHR will participate in healthcare improvement discussions and, as appropriate, will represent the special needs of persons with viral hepatitis. Until the goal of integration is reached, NVHR will advocate for the special programs it believes will most benefit viral hepatitis patients and the nation.

## Current status of treatments for viral hepatitis

Chronic viral hepatitis is now a treatable disease, with standardized therapies for both hepatitis B and hepatitis C. Chronic HCV infection is curable in 50% of cases and most patients who receive antiviral therapy for HBV infection have a significant reduction in viral load and are at lower risk of developing liver cancer or chronic liver disease. Though treatments are not effective for all patients, the success rates and cost-effectiveness of drug regimens for chronic viral hepatitis approach those of other chronic diseases, such as diabetes and hypertension.

Treating patients with chronic viral hepatitis is not easy. Many people have silent, or asymptomatic, infections that may not be diagnosed until liver damage is far advanced. Treatments are long and are often poorly tolerated because of side effects. In some cases, patient care is complicated by alcoholism, drug addiction, HIV infection, incarceration, or mental health problems. Patients and clinicians must also contend with healthcare financing barriers. The majority of infected persons are men who are frequently ineligible for public assistance; they rely on patient assistance programs, public hospitals and community health centers for care and are a drain on these resources because of the high cost of hepatitis management.

Children and patients in rural areas also face difficulties. They have limited access to care and even more limited access to specialists. Currently, treatment of chronic viral hepatitis is performed by gastroenterologists, hepatologists and specialists in infectious diseases, although internal medicine, family practice, county clinics and centers managed by family nurse practitioners and physician assistants are growing rapidly. The lack of specialists and the difficulties of administering and monitoring medication have been eased somewhat through telemedicine consultations using videoconferencing technology. Expanding the use of telemedicine will increase access, improve local quality of care, save time and money and improve the knowledge of patients and local primary care teams as well. It is no surprise that telemedicine is highly rated by patients and physicians alike.

Approximately 10%, or 400,000 HCV patients, will progress to serious liver disease, including cirrhosis and cancer; some will need a liver transplant. The incidence of liver cancer is projected to triple in the next 20-30 years and despite donor willingness, transplantation is a limited and very costly option.

## Support for persons receiving care

Some patients find medications to be miracles, but they still face daily struggles. Side effects, the financial burden and long-term disruption of family and work lives make it difficult for patients to complete a full course of treatment. Management of chronic hepatitis must help the patient and their family in comprehensive ways and not focus solely on the disease. Until new medicines produce more rapid healing with more tolerable side effects, support for patients, with attention to their quality of life and ongoing risk behaviors, is an important component of treatment. A number of medical and public health groups have outlined excellent models of care, but none go far enough in recommending the

full range of services that patients need, or in showing how these services can be provided to the large population needing support. Placing chronic hepatitis of any type on the Social Security Administration list of impairments, which means that individuals with any type of chronic hepatitis will be considered per se disabled and therefore entitled to receive some support for management and treatment, would alleviate some of the problems.

## State plans

Twenty-four (24) state health departments have developed comprehensive roadmaps for implementing hepatitis prevention programs, most for hepatitis C. However, only a few states and large metropolitan areas have been able to fund programs with local resources and then only for a short time. Although most efforts have been limited to small pilot projects in targeted settings, larger programs have been implemented on rare occasions. We must improve state attention to developing, implementing and monitoring progress through planning.

## Treatment needs for persons in the criminal justice system

Special attention must be given to the needs of people in the criminal justice system. More than 6.7 million persons in the United States are currently on probation, in jail or prison, or on parole.<sup>39</sup> Each year, more than 600,000 persons are released from U.S. prisons and at least 95% of persons currently incarcerated in U.S. prisons and jails will eventually be released back into the community. Because a disproportionate number of those who pass through the criminal justice system suffer from infectious diseases, the health of this population is intimately connected to community health.

In 1997, an estimated 34,000 prison and jail inmates were chronically infected with HBV and an estimated 255,000 were chronically infected with HCV. The prevalence of chronic hepatitis B among inmates is two to six times higher than in the general population and the prevalence of hepatitis C among inmates is 9 to 10 times higher. Of all persons in this country with chronic HBV infection, 12 to 15% have been in prison or jail at some time; 39% of persons with chronic HCV infection have been jailed or imprisoned.

Nonetheless, few offenders are tested for hepatitis infection and many of those who have been diagnosed do not receive treatment due to budget constraints and poor continuity of care. Correctional agency health budgets are insufficient to cover diagnostic testing and treatment for viral hepatitis. Few physicians with relevant expertise serve in correctional environments and a substantial proportion of infected inmates also require treatment for drug or alcohol abuse. Because there is a gap between an inmate's discharge from correctional supervision and his or her ability to access treatment in the community, infected offenders without a long remaining sentence are often excluded from treatment.



## What Else We Need: New Tools and Public Health Program Support

We have made progress, but we require new tools to help us forestall the crisis that looms ahead. Biomedical research has expanded our understanding of the epidemiology and natural history of viral hepatitis disease and continues to provide new ideas and products for diagnostic testing, vaccination and treatment. But important questions remain about viral processes that cause persistent infections, chronic liver disease and cancer and we need new therapeutic agents and vaccines as well as a better understanding of targets for antiviral therapy.

### Diagnostics

Standard diagnostic tests are available for the most widely used antigen, antibody and molecular markers of HBV infection. For HCV, antibody tests identify persons with current or resolved infection and molecular diagnostic tests identify those with active infection. However, except for HBV, development of a test to differentiate acute from chronic infection has been elusive and rapid serologic tests are not approved for use in the U.S.

### Vaccines

Hepatitis B vaccine research has yielded improved immunogenicity and a reduced number of doses. Development of a vaccine to prevent HCV infection is constrained by the inability to grow HCV in cell culture, the lack of a small animal model for HCV infection and the lack of a marker of protective immunity to HCV infection. However, in the past 3-4 months, three published articles have cited the fact that a culture system has been developed that effectively supports the growth of HCV, genotype 2, that may, in the future, improve the ability to develop a vaccine.<sup>40</sup>

### Clinical care research

We need large, population-based studies to determine the natural history and outcomes of HBV and HCV infection, especially among infected persons who have received antiviral therapy. In addition, we need population-based studies to monitor changes in viruses (mutations) caused by antiviral therapy and new tools to measure disease stages and response to treatment and vaccination. These include pre-treatment markers that correlate with clinical outcomes, such as iron deposition and patterns of fibrosis in liver biopsies; non-invasive markers of disease progression that can be used in place of liver biopsies, such as the assembly of several routine blood tests that infer progressive disease, specific markers

of fibrosis progression, new radiologic techniques and mechanical devices that measure liver stiffness; and post-exposure emergency treatment for persons with occupational or other known exposures to HCV. We know from research how to deliver effective prevention services to some populations at risk, including adults and teenagers. We do not know, however, how to link prevention and medical services for hepatitis with alcohol and drug treatment services.

## Clinical education

Many primary and family care physicians and nurses in practice today were trained before diagnostic testing and medical care for chronic viral hepatitis became available. These clinicians, along with occupational health physicians and nurses—who are usually the first to suspect or detect liver disease—must be provided with the information they need to determine which patients should be tested and counseled for viral hepatitis, which tests to order and how to interpret test results. They also need information that will help them determine which patients should be referred to specialists for treatment, where to refer them and how to support them during diagnosis and treatment in the workplace.

## Technological innovation

Research partnerships among academic medical centers, pharmaceutical and biotechnology companies, government agencies and professional societies, which have historically been successful in producing innovation, will likely continue as we seek new treatments for viral hepatitis disease. Other major partners include administrators and staff of model health care and outreach programs, who participate in studies to evaluate new tools and methods for educational outreach, disease prevention and medical management. NVHR supports the work of the National Institutes of Health (NIH), the Veterans' Administration (VA), the Health Resources and Services Administration (HRSA), CDC, FDA and pharmaceutical, vaccine, diagnostic and biotechnology companies in their pursuit of this knowledge. We are dismayed at the insufficient funding for these federal agencies by Congress to accomplish the goal of expanded biomedical research.

## Public health program funding

No hepatitis-specific funding streams or program language support the care of hepatitis patients in the public health system. As a result, the system is a frayed patchwork that meets the needs of some but not most infected and at-risk persons without access to education, counseling and treatment. The CDC recommends that state and local health agencies that provide related public health services build upon these programs to add services for viral hepatitis. These added services would include community outreach, screening to identify persons with risk factors, counseling, testing, vaccination and referral as appropriate. It not possible to create these services, however, without additional support for existing— and new— viral hepatitis programs.

*The Ryan White Comprehensive AIDS Resources Emergency Act.* The Ryan White Comprehensive AIDS Resources Emergency Act (RWCA) funds primary health care and support services for persons living with HIV/AIDS. This discretionary program serves as the “payer of last resort” for persons with HIV/AIDS and is the third largest source of federal funding for

HIV/AIDS care, following Medicaid and Medicare. Persons living with HIV can receive hepatitis B and hepatitis C screening, hepatitis A and hepatitis B vaccines and drug therapies for chronic viral hepatitis. However, services provided to HIV-infected persons vary, as each state is given broad authority in designing its program. In FY2003, only 20 states covered any approved therapy for hepatitis C under their AIDS Drug Assistance Programs (ADAPs). Furthermore, RWCA, with the exception of ADAP, has received level or decreased funding over the past several years and ADAP funding has been far less than the estimated annual \$100 million increase needed. With decreased funding from both state and federal sources, programs report difficulty in adding hepatitis B and hepatitis C services. Drug therapies are covered under Medicare and Medicaid, but many poor and sick patients are unable to use these programs. Moreover, most of the 4 million persons with hepatitis C in the United States do not have HIV infection and are not eligible for RWCA assistance.

*Support for CDC Division of Viral Hepatitis.* In FY2004, CDC's Division of Viral Hepatitis (DVH) had an estimated \$6 million to conduct surveillance activities regarding acute and chronic HAV, HBV and HCV through a number of systems, including Centers of Hepatitis Surveillance Excellence. However, additional resources are needed to provide more complete information about hepatitis infections in the United States. We need funding to support targeted seroprevalence studies to understand the burden of hepatitis disease in populations that are un- or under-represented groups in current public health surveillance activities.

*Support for Hepatitis C Coordinator Program.* In FY2004, CDC received a total of \$17.5 million to address hepatitis C, approximately \$4 million of which is used to fund the national hepatitis C coordinator program. Hepatitis C coordinators are responsible for increasing HCV awareness and education and they work at the state and local levels to integrate hepatitis services into existing programs. The average funding award for a coordinator position is \$77,000, which covers personnel costs but leaves few funds to support services. Due to funding rescissions by Congress, CDC has lost funding for three consecutive years, significantly affecting disease prevention and control efforts at the state and local levels. We need additional funds to support comprehensive Hepatitis C Coordinator activities.



# We Aren't Alone: Other Major Efforts to Eliminate Viral Hepatitis

All of the members of NVHR are engaged in activities to eliminate viral hepatitis and several national efforts that precede those of the Roundtable are highly laudable. We plan to work within them and build upon them.

## National Vaccine-Preventable Hepatitis B Strategy

The Advisory Committee on Immunization Practices (ACIP) to the U.S. Public Health Service developed a comprehensive strategy to eliminate HBV transmission in the US. This strategy includes the screening of all pregnant women for HBV surface antigen (HBsAg) and provision of post-exposure immunoprophylaxis beginning at birth to infants of HBsAg-positive mothers. It also includes routine infant vaccination, catch-up vaccination of previously unvaccinated children and adolescents and vaccination of adults in high-risk groups. A central program is the Hepatitis B Coordinator Program, DHHS Maternal and Child Health Program.

## Hepatitis C Epidemic Control and Prevention Act Proposed Legislation

The National Hepatitis C Prevention Strategy is the basis of the Hepatitis C Epidemic Prevention and Control Act. Enactment of this legislation, with its initial appropriations of approximately \$90 million, will lead to federally coordinated efforts to address the nation's hepatitis C crisis. Without this legislation and appropriations, piecemeal implementation of the National Hepatitis C Prevention Strategy will continue and chronic hepatitis C prevention and control efforts will be severely limited in scope and effectiveness. Specifically, the bill provides for:

- HCV counseling, testing and referral;
- Education and training about HCV for healthcare professionals and the public to facilitate testing and prevention;
- Immunization against hepatitis A and hepatitis B for persons infected with, or at risk for, hepatitis C;
- Hepatitis C surveillance programs and databases;
- Hepatitis C coordinators for each state to enhance prevention and control activities; and
- Coordinated research network to expedite progress in combating the disease.

## National Hepatitis C Prevention Strategy of the Centers of Disease Control and Prevention

In 2000, CDC developed a comprehensive National Hepatitis C Prevention Strategy that includes education of healthcare and public health professionals; education of the public and persons at risk of infection; outreach and community-based programs; clinical and public health activities, including testing, counseling and medical evaluation or referral; surveillance; and research. The strategy calls for integration of these components into existing clinical and public health programs to lower the incidence of HCV infection and reduce the disease burden from chronic HCV. Implementation of the strategy is estimated to cost \$100 million per year, with most funds devoted to hepatitis A and hepatitis B vaccination of persons infected with HCV.

## Veteran's Affairs Hepatitis C Resource Center Network

The major goal of the Veterans Affairs Hepatitis C Resource Center Network (<http://hepatitis.va.gov>) is to provide better treatment and care for persons with viral hepatitis through research to develop:

- models of interdisciplinary care to optimize treatment outcomes;
- improved screening and testing methods;
- methods for assessing and treating patients traditionally excluded from hepatitis C treatment, including those with mental illness, substance abuse and concurrent HIV infection; and
- clinical standards for treating patients at all stages of hepatitis C infection.

## 2002 Consensus Statement on the Management of Hepatitis C of the National Institutes of Health

The Consensus Statement included recommendations concerning prevention, treatment, access, research and collaboration. Highlights include:

### *Prevention*

- Provide general population-based awareness education regarding risk behaviors and exposures through schools, workplaces, public health and community-based groups.
- Target high-risk awareness education to include risk behaviors and encourage HCV screening for injection drug users (IDUs) and persons in correctional settings.
- In collaboration with health departments, healthcare organizations, community-based groups, initiate support groups for the general public, injection-drug users and persons in correctional settings.
- Expand substance use treatment capacity. Ensure that injection-drug users have access to sterile syringes through needle-exchange programs, physician prescription and pharmacy sales. Educate physicians and pharmacists to recognize that providing IDUs with access to sterile syringes and education in safe injection practices can be lifesaving.
- Educate IDUs not to use others' injection equipment, to wash hands before and after injecting and to avoid any contact with blood from other persons.
- Implement community-based education and support programs for IDUs.

- Implement HCV prevention education in correctional settings.
- Screen IDUs and incarcerated persons for HCV.

### *Treatment*

- Encourage collaboration among primary care providers and specialists to treat patients with HCV infection.
- Educate patients on treatment regimens and associated side effects and outcome expectations.
- Assess, monitor and support patients' adherence to treatment regimens. Assess, monitor and treat patients' psychological conditions, especially depression, while on hepatitis C therapy.
- Encourage collaboration among experts in HCV and substance abuse to treat patients with substance abuse. Make treatment decisions for active IDUs on a case-by-case basis.

### *Access*

- Establish programs to prevent, diagnose and treat all affected populations.
- Increase funding for preventive education in schools, workplaces and community-based organizations.
- Increase availability and funding of collaborative hepatitis C care and treatment.
- Increase the availability of treatment for IDUs and patients with psychological conditions.
- Increase the availability of diagnosis and treatment for African-American and Hispanic populations and for patients who are uninsured or have publicly funded health care.
- Establish programs to prevent, diagnose and treat hepatitis C in correctional facilities.

### *Research*

- Develop strategies to make treatment available to drug users, prisoners and patients with HIV co-infection or major psychiatric illness.
- Conduct research on managing side effects and increasing patient adherence.
- Conduct studies of the prevalence and management of hepatitis C in persons with publicly funded health care or no health insurance.
- Study the natural history of fibrosis in various groups, including IDUs.

### *Collaboration*

- Encourage collaboration among health professionals concerned with management of addiction, primary care physicians and specialists involved in various aspects of hepatitis C, to deal with the complex societal, medical and psychiatric issues of affected persons.



## We Need Your Help

Remember the thoughtful moment needed to act quickly and avert a tragedy? Take that moment now to reflect on what you have learned in this plan.

Decide what you can do for yourself and your loved ones – right now. Resolve to learn about liver health and wellness – and do it. Resolve to protect them by telling your partners and loved ones about what you have learned – and do it.

If you know someone who is already infected, encourage them to take their medicines and support them through any difficult months of treatment. Let them know that you care about them as a friend and that we care about them as well. Be sure they know that there are thousands of dedicated people working to prevent and cure viral hepatitis. Offer them our hopes that such dreadful disease will not cause them more suffering and will never take their lives.

Remember as well that preventing a tragedy sometimes also requires a long-term commitment bolstered by skill, passion, dedicated help and substantial resources.

If you have received this report from one of our members, it is because you are a leader in state or national government, in research, in public health or clinical care, in patient advocacy, in business, in education, in criminal justice. We ask that you determine what you can do over the long term to accelerate research into prevention and cures, to make care more accessible for patients and to protect the health of all Americans.

Please become acquainted with the devastation that the disease causes in the people you manage and work with in your company, with the individuals who are your constituents and who are looking to you for political leadership, or those who may be in your incarceration care. Focus some of each busy day on working within the four recommendations we have for the leaders of this nation:

- Build the capacity to address the challenges of viral hepatitis.
- Vaccinate America to eliminate vaccine-preventable viral hepatitis.
- Counsel, test and refer persons at risk for viral hepatitis to inform them about how to reduce their risks.
- Care for persons with chronic hepatitis and help them participate in the management of their condition.

If you do, it will help. We are certain of that.

This disease has devastated far too many people. Together we can offer hope to those who already suffer from viral hepatitis. We can protect those who are not already infected, saving them from the illnesses that rob people of their vitality and even their lives. Yes, we can do this.

Together.

Let's get started.

Today.

Right now.

# Resources

# Hepatitis A, B and C: Learn the Differences

	Hepatitis A caused by the hepatitis A virus (HAV)	Hepatitis B caused by the hepatitis B virus (HBV)	Hepatitis C caused by the hepatitis C virus (HCV)
How is it spread?	Hepatitis A is a serious liver disease caused by the hepatitis A virus (HAV). HAV is found in the feces of people with hepatitis A and is usually spread by close personal contact (including sex or sharing a household). It can also be spread by eating food or drinking water contaminated with HAV.	HBV is found in blood and certain body fluids. It is spread when blood or body fluid from an infected person enters the body of a person who is not immune. HBV is spread through having unprotected sex with an infected person, sharing needles or “works” when “shooting” drugs, needlesticks or sharps exposures on the job, or from an infected mother to her baby during birth. Exposure to infected blood in ANY situation can be a risk for transmission.	HCV is found in blood and certain body fluids. It is spread when blood or body fluid from an infected person enters another person’s body. HCV is spread through sharing needles or “works” when “shooting” drugs, through needlesticks or sharps exposures on the job, or sometimes from an infected mother to her baby during birth. It is possible to transmit HCV during sex, but it is uncommon.
Who is at risk?	<ul style="list-style-type: none"> <li>Household contacts of infected persons</li> <li>Sex partners of infected persons</li> <li>Children living in regions of the U.S. that had consistently elevated rates of hepatitis A during 1987-1997*</li> <li>Persons traveling to countries where hepatitis A is common (everywhere except Canada, Western Europe, Japan, Australia and New Zealand)</li> <li>Men who have sex with men</li> <li>Injecting and non-injecting drug users</li> </ul> <p>Persons with chronic liver disease should be vaccinated against hepatitis A.</p>	<ul style="list-style-type: none"> <li>Persons with more than one sex partner in a 6-month period</li> <li>Persons diagnosed with a sexually transmitted disease</li> <li>Men who have sex with men</li> <li>Sex partners of infected persons</li> <li>Injecting drug users</li> <li>Household contacts of chronically infected persons</li> <li>Infants born to infected mothers</li> <li>Immigrants and children of immigrants from areas with elevated HBV rates, including Asia, Africa, the Pacific Islands, Eastern Europe, the Middle East and the Amazon Basin.</li> <li>Healthcare and public safety workers who might be exposed to blood</li> <li>Chronic hemodialysis patients</li> </ul>	<ul style="list-style-type: none"> <li>Injecting drug users</li> <li>Recipients of clotting factors made before 1987</li> <li>Hemodialysis patients</li> <li>Recipients of blood or solid organ transplants before 1992</li> <li>Infants born to HCV-infected mothers</li> </ul> <p>Although HCV is not commonly spread through sex, persons having sex with multiple partners or with an infected steady partner may be at increased risk of HCV infection.</p> <p>People with undiagnosed abnormal liver test results should be tested for HCV infection.</p>
What if you are infected?	The only way to know if you have already been infected is to have your blood tested for HAV, HBV, or HCV infection. If you are in one of the risk groups listed above, talk to your healthcare provider about your need for blood testing. Viral hepatitis symptoms are similar no matter which type of hepatitis a person has. If symptoms occur, the individual may experience any or all of the following: jaundice, fever, loss of appetite, fatigue, dark urine, joint pain, abdominal pain, diarrhea, nausea and vomiting. Very rarely, a new case (acute) of viral hepatitis can cause liver failure and death. Sometimes in these instances a liver transplant (if a liver is available) can save a life. Note: Symptoms are less common in children than in adults and people who have HCV infection are less likely to experience symptoms.		
What treatment helps?	<p>Incubation period: 15 to 50 days, average 28 days</p> <p>There is no chronic (long-term) infection. Once you have had hepatitis A, you cannot get it again. About 15% of people infected with HAV will have prolonged illness or relapsing symptoms over a 6-9 month period.</p> <ul style="list-style-type: none"> <li>There is no treatment for hepatitis A.</li> <li>Avoid alcohol. It can worsen liver disease.</li> </ul>	<p>Incubation period: 45 to 160 days, average 120 days</p> <p>Chronic infection occurs in up to 90% of infants infected at birth; 30% of children infected at age 1-5 years; 2-6% of persons infected after age 5 years. In the U.S., 5000 people die each year from HBV. Death from chronic liver disease occurs in 15-25% of chronically infected persons. People who have chronic HBV infection have a much higher risk of liver failure (cirrhosis) and liver cancer.</p> <ul style="list-style-type: none"> <li>Persons with chronic HBV infection should have a medical evaluation for liver disease every 6-12 months. Several antiviral medications are currently licensed for the treatment of persons with chronic hepatitis B. These drugs are effective in up to 40% of patients. Liver transplant is the last resort, but livers are not always available.</li> <li>Avoid alcohol. It can worsen liver disease.</li> </ul>	<p>Incubation period: 14 to 180 days, average 45 days</p> <p>Chronic infection: 75-85% of infected persons</p> <p>Chronic liver disease: 70% of chronically infected persons. In the U.S., 8-10,000 people die each year from HCV. People who have chronic HCV infection have a much higher risk of liver failure (cirrhosis) and liver cancer. Chronic HCV-related liver disease is the leading indication for liver transplant.</p> <ul style="list-style-type: none"> <li>Persons with chronic HCV infection should have a medical evaluation for liver disease every 6-12 months. Interferon, pegylated interferon and ribavirin are the only drugs licensed for the treatment of persons with chronic hepatitis C. Combination therapy is currently the treatment of choice and can eliminate the virus in approximately 50% of patients (genotype 1).</li> <li>Get vaccinated against hepatitis A and ask your healthcare provider if you need hepatitis B vaccine as well.</li> <li>Avoid alcohol. It can worsen liver disease.</li> </ul>
How is it prevented?	<ul style="list-style-type: none"> <li>Hepatitis A vaccine is the best protection. It is recommended for all children at 1 year of age (i.e., 12-23 months) and individuals who are in risk groups for HAV infection or for severe outcomes from infection.</li> <li>For a recent exposure to someone with HAV or if travel is imminent (leaving in less than 4 weeks) to an area of the world where hepatitis A is common, see your healthcare provider about your need for a dose of immune globulin (IG).</li> <li>Always wash your hands with soap and water after using the toilet, changing a diaper and before preparing and eating food.</li> <li>There is no medical reason that hepatitis A vaccine cannot be given to anyone age 1 yr and older who wants it.</li> </ul>	<ul style="list-style-type: none"> <li>Hepatitis B vaccine is the best protection. Routine vaccination is recommended for all persons 0-18 years of age and for persons of all ages who are in risk groups for HBV infection. All newborns should be given their first dose of hepatitis B vaccine before leaving the hospital.</li> <li>There is no medical reason that hepatitis B vaccine cannot be given to anyone who wants it.</li> <li>Whenever a woman is pregnant, she should be tested for hepatitis B; infants born to HBV-infected mothers should be given HBIG (hepatitis B immune globulin) and vaccine within 12 hours of birth.</li> <li>Persons who are not in mutually monogamous relationships should use latex condoms correctly and for every sexual encounter. (The efficacy of latex condoms in preventing infection with HBV is unknown, but their proper use may reduce transmission.)</li> </ul>	<ul style="list-style-type: none"> <li>There is no vaccine to prevent hepatitis C.</li> <li>HCV can be spread by sex, but this is rare. If you are not in a mutually monogamous relationship, use condoms correctly and every time to prevent the spread of sexually transmitted diseases. (The efficacy of latex condoms in preventing infection with HCV is unknown, but their proper use may reduce transmission.) You should also get vaccinated against hepatitis B.</li> </ul>
	<p>More information to help you prevent hepatitis B and hepatitis C:</p> <ul style="list-style-type: none"> <li>Don’t share personal care items that might have blood on them, such as razors, toothbrushes and washcloths.</li> <li>Consider the risks if you are thinking about getting a tattoo or body piercing. You might get infected if the tools or dye have someone else’s blood on them or if the artist or piercer does not follow good sterilization practices.</li> <li>Healthcare or public safety workers should always follow routine barrier precautions and safely handle needles and other sharps. In addition, they should be vaccinated against hepatitis B.</li> <li>If you have or have had HBV or HCV infection, do not donate blood, organs, or tissue.</li> <li>Don’t shoot drugs. If you do, try to stop by getting into a treatment program. If you can’t stop, never share needles, syringes, water, or “works.” Get vaccinated against hepatitis A and B.</li> </ul>		

\*Disease rates are available from your state or local health department.

# Advisory Committee on Immunization Practices (ACIP): Hepatitis A Vaccination Recommendations

## Provisional ACIP Recommendations for Hepatitis A Vaccination of Children

- All children should receive hepatitis A vaccine at age 1 year (i.e., 12-23 months). Vaccination should be completed according to the licensed schedules and integrated into the routine childhood and adolescent vaccination schedule. Children who are not vaccinated by age 2 years can be vaccinated at subsequent visits.
- States, counties and communities with existing hepatitis A vaccination programs for children ages 2-18 years are encouraged to maintain these programs. In these areas, new efforts focused on routine vaccination of children, who are 1 year of age, should enhance, not replace, ongoing programs directed at a broader population of children.
- In areas without existing hepatitis A vaccination programs, catch-up vaccination of unvaccinated children ages 2-18 years can be considered. Such programs might especially be warranted in the context of rising incidence or ongoing outbreaks among children or adolescents.

## ACIP Hepatitis A Vaccination Recommendations

### *Persons for Whom Hepatitis A Vaccine is Recommended*

- See provisional recommendations for children above.
- Travelers to areas with intermediate or high rates of HAV infection.
- Men who have sex with men.
- Injecting and non-injecting drug users.
- Persons with clotting-factor disorders (e.g., hemophilia).
- Persons with chronic liver disease.

### *Persons at Increased Risk for Hepatitis A or Severe Outcomes*

- Persons traveling to, or working in, countries that have a high or intermediate rate of HAV infection (excludes Japan, Australia, New Zealand and developed countries in Europe) should begin vaccination at least four weeks prior to departure.
- Men who have sex with men (both adolescents and adults).
- Injection and non-injection illegal drug users.
- Persons who work with hepatitis A virus (HAV)-infected primates or with HAV in a research laboratory setting.
- Persons who have clotting-factor disorders.
- Household contacts of HAV-infected persons.
- Sex contacts of HAV-infected persons.
- Persons with chronic liver disease.

## We Need Your Help

# Advisory Committee on Immunization Practices (ACIP): Hepatitis B Vaccination Recommendations

## Infants at birth

- Infants born to mothers who are HBsAg positive should receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) by 12 hours of birth.
- Infants born to mothers whose HBsAg status is unknown should receive hepatitis B vaccine by 12 hours of birth. The mother should have blood drawn as soon as possible to determine her HBsAg status; if she is HBsAg positive, the infant should receive HBIG as soon as possible (no later than age 1 week).
- Full-term infants who are medically stable and weigh at least 2 kg (4.4lbs) born to HBsAg-negative mothers should receive single-antigen hepatitis B vaccine before hospital discharge.
- Preterm infants weighing less than 2 kg (4.4lbs) born to HBsAg-negative mothers should receive the first dose of vaccine 1 month after birth or at hospital discharge. Preterm infants born to HBsAg-positive mothers should receive the first dose of vaccine within 12 hours of birth (this dose is not counted for series completion).

## Infants after the birth dose

- All infants should complete the hepatitis B vaccine series with either single-antigen vaccine or combination vaccine, according to a recommended vaccination schedule.
- Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg after completion of the hepatitis B vaccine series at age 9-18 months.

## Vaccination of Children and Adolescents

- All unvaccinated children and adolescents aged less than age 19 years should receive the hepatitis B vaccine series.

## Other Persons for Whom Hepatitis B Vaccine Is Recommended by ACIP

- Men and women who are diagnosed with an STD, who are seeking treatment for an STD, who are commercial sex workers, or who have a history of sexual activity with more than one partner in previous 6 months.
- Sexually active men who have sex with men.
- Injection drug users.
- Household and sex contacts of persons with chronic HBV infection.
- Healthcare and public safety workers, including those in training, who have a reasonable risk of exposure to blood on the job.
- Persons who travel or live in a country with intermediate or high endemicity of HBV infection.
- Hemodialysis patients.
- Patients with clotting-factor disorders.
- Clients and staff in institutions for the developmentally challenged.
- Inmates of long-term correctional facilities.

## Provisional ACIP Recommendations for Hepatitis B Vaccination of Adults

- Hepatitis B vaccination is recommended for all unvaccinated adults at risk for HBV infection and for all adults seeking protection from HBV infection. Acknowledgment of a specific risk factor is not a requirement for vaccination.
- In settings where a high proportion of adults are likely to have risk factors for HBV infection, all unvaccinated adults should be assumed to be at risk and should receive hepatitis B vaccination. These settings include STD treatment facilities, human immunodeficiency virus (HIV) testing facilities, HIV treatment facilities, facilities providing drug abuse treatment and prevention, correctional facilities, healthcare settings serving men who have sex with men, chronic hemodialysis facilities and end-stage renal disease programs and institutions and nonresidential daycare facilities for developmentally challenged persons.
- Standing orders should be implemented to identify and vaccinate eligible adults in primary care and specialty medical settings. If ascertainment of risk for HBV infection is a barrier to vaccination in these settings, providers may use alternative vaccination strategies such as offering hepatitis B vaccine to all unvaccinated adults in age groups with highest risk for infection (e.g., less than age 45 years).

## ACIP Recommendations for Routine Screening for HBV Infection (HBsAg testing)

- All foreign-born persons (including immigrants, refugees, asylum seekers and internationally adopted children) born in Asia, the Pacific Islands, Africa and other regions with high endemicity of HBV infection, regardless of vaccination status.
- All pregnant women.
- Persons who tested positive for antibody to hepatitis B core antigen on prevaccination testing.
- Hemodialysis patients.
- Nonresponders to hepatitis B vaccination (two full series).

## Persons at Risk for Hepatitis B Virus (HBV) Infection

- Persons with multiple (more than one sex partner in six months) sex partners or a diagnosis of a sexually transmitted disease (STD).
- Men who have sex with men.
- Sex contacts of infected persons.
- Injection drug users.
- Household contacts of persons with chronic HBV infection.
- Infants born to HBV-infected mothers.
- Infants/children of immigrants from areas with intermediate or high rates of HBV infection.
- Healthcare and public safety workers who have a reasonable risk of exposure to blood on the job.
- Travelers to countries with intermediate or high rates of HBV infection.
- Hemodialysis patients.

# Centers for Disease Control and Prevention (CDC): Recommendations for the Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease

## Persons at Risk for HCV Infection

HCV is spread primarily by direct contact with human blood. For example, persons can get infected with HCV if they:

- ever injected street drugs, as the needles and/or other drug “works” used to prepare or inject the drug(s) may have had someone else’s blood that contained HCV on them.
- received blood, blood products, or solid organs from a donor whose blood contained HCV.
- were ever on long-term kidney dialysis as you may have unknowingly shared supplies/equipment that had someone else’s blood on them.
- were ever a healthcare worker and had frequent contact with blood on the job, especially accidental needlesticks.
- had a mother who had hepatitis C at the time she gave birth.
- ever had sex with a person infected with HCV.
- lived with someone who was infected with HCV and shared items such as razors or toothbrushes that might have had his/her blood on them.

## Persons Who Should Be Tested Routinely for HCV Infection

- persons who ever injected illegal drugs, including those who injected once or a few times many years ago.
- persons who were treated for clotting problems with a blood product made before 1987 when more advanced methods for manufacturing the products were developed .
- persons who were notified that they received blood from a donor who later tested positive for hepatitis C.
- persons who received a blood transfusion or solid organ transplant before July 1992 when better testing of blood donors became available.
- long-term hemodialysis patients.
- persons who have signs or symptoms of liver disease (e.g., abnormal liver enzyme tests).
- healthcare workers after exposures (e.g., needle sticks or splashes to the eye ) to HCV-positive blood on the job.
- children born to HCV-positive women.

## Prevention

The prevention of HCV infection and HCV-related chronic liver disease presents a multifaceted approach.

*Primary Prevention: preventing new HCV infections*

- Routine HCV testing for persons at increased risk of HCV infection.
- Education and risk reduction counseling for persons at risk.

- Evidence-based substance abuse treatment and increased availability of such treatment.
- Access to sterile syringes and other injection equipment.
- Repeal of paraphernalia and syringe-prescription laws.
- Education of physicians and pharmacists on sterile syringe availability.
- Community-based out reach to injection drug users that includes education of safer injection practices.
- Education of the public about risk factors for HCV infection.
- Education and training of healthcare professionals.
- Collaboration with professional licensing boards.

*Secondary Prevention: preventing chronic liver disease due to HCV infection; and Tertiary Prevention: preventing mortality for consequences of chronic liver disease*

- Integration of prevention and care services for persons with HCV infection to ensure referral for diagnosis, medical management and treatment if appropriate.
- Expanded access to quality medical treatment for underserved populations.
- Integration of medical, mental health, substance use and social services.
- Provision of prevention and treatment services to persons who are incarcerated.

### *Surveillance*

Surveillance is essential to determine the effectiveness of national, state and local hepatitis C prevention efforts. However, surveillance for hepatitis C is complicated by the absence of a laboratory test that can differentiate newly acquired infections from infections acquired in the past. More support is needed for the improvement of national surveillance and monitoring of hepatitis C, both acute and chronic. Studies to determine the effectiveness of HCV prevention and control activities are lacking.

### *Research*

Much has been learned about the transmission of HCV infection since the discovery of HCV; however, much more needs to be done. There is a tremendous need to find effective approaches to hepatitis C care for children and adolescents. There is still much to be known about how HCV infection affects users of alcohol and illicit drugs as well as patients who are clinically depressed. Very little has been done among underserved populations who bear the largest burden of this disease; such as, injection drug users, incarcerated persons and ethnic minorities. Research is needed to determine effective approaches for the care of high-risk adolescents, pregnant women and their babies. In addition, support is needed to find better testing methodologies to differentiate recently acquired HCV infection from chronic HCV infection, as well as for vaccine research.

## National Viral Hepatitis Roundtable Member Organizations

Albert Sabin Vaccine Institute  
American Academy of Physician Assistants  
American Association of Occupational Health Nurses  
American Cancer Society  
American Correctional Association  
American Liver Foundation  
American Medical Association  
American Social Health Association  
Asian Liver Center, Stanford University  
Association of Asian Pacific Community Health Organizations  
Association of State and Territorial Health Officials  
Center for Health Improvement  
Center for Study of Hepatitis C, Columbia University  
Center for the Study of Asian American Health  
Council of State and Territorial Epidemiologists  
FAIR Foundation  
Frontline Health Worker Safety  
H.E.A.L.S. of North Georgia  
Harm Reduction Coalition  
HBV Adoption Support Group  
Health Partners, Regions Hospital  
Hep C Connection  
Hepatitis B Foundation  
Hepatitis B Initiative  
Hepatitis B Support List  
Hepatitis C Association  
Hepatitis C Caring Ambassadors  
Hepatitis C MultiCultural Outreach  
Hepatitis C Strategy Group  
Hepatitis C Support Project  
Hepatitis Education Project  
Hepatitis Foundation International  
Hepatitis Magazine  
Hep-C Alert  
Hep-Can  
Hope for Hepatitis C Foundation  
Immunization Action Coalition  
Institute for Criminal Justice Healthcare  
Julia Spears Foundation  
Kaiser Permanente  
Latino Organization for Liver Awareness  
Liver Hope, Inc.  
Liver Research Institute  
Maryland Hepatitis C Action  
Missouri Hepatitis C Alliance  
National AIDS Treatment Advocacy Project  
National Alliance of Methadone Advocates  
National Alliance of State and Territorial AIDS Directors  
National Association of Community Health Centers  
National Association of County and City Health Officials  
National Association of Hepatitis Task Forces  
National Coalition for the Homeless  
National Coalition of STD Directors (NCSDD)  
National Hepatitis C Advocacy Council  
National Medical Association  
National Task Force on Hepatitis B  
Parents of Kids with Infectious Diseases  
Positive Health Project  
Taskforce for Child Survival and Development  
The AIDS Institute  
The Bruckner Group  
The Harm Reduction Project  
Therapeutic Communities of America  
Treatment Action Group  
University of New Mexico

### Associate Members

Arundel County Health Department  
California Department of Health  
Colorado Department of Health  
Connecticut Department of Health  
Indiana Department of Health  
Michigan Department of Health  
New Mexico Hepatitis Program  
North Dakota Department of Health  
Iowa Department of Health  
Utah Department of Health  
Washington State Department of Health

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Department of Veterans Affairs  
Federal Bureau of Prisons  
Indian Health Service  
National Institute of Diabetes and  
Digestive and Kidney Diseases  
Substance Abuse and Mental Health  
Services Administration

## Viral Hepatitis Resources

<http://www.sabin.org/>  
<http://www.aapa.org/>  
<http://www.aohn.org/>  
<http://www.cancer.org/docroot/home/index.asp>  
<http://www.aca.org/>  
<http://www.liverfoundation.org/>  
<http://www.ama-assn.org/>  
<http://www.ashastd.org/>  
<http://livercancer.stanford.edu/>  
<http://www.aapcho.org/site/aapcho/>  
<http://www.astho.org/>  
<http://www.chipolicy.org/doc.asp?id=5417>  
<http://www.hepccenter.org/transplant.php>  
<http://www.med.nyu.edu/csah/>  
<http://www.cste.org/>  
<http://www.fairfoundation.org/>  
<http://www.frontlinefoundation.org/>  
<http://www.healsofnga.org/>  
<http://www.harmreduction.org/>  
<http://health.groups.yahoo.com/group/hbv-adoption/>  
<http://www.regionshospital.com/Regions/Menu/0,1640,16659,00.html>  
<http://www.hepc-connection.org/>  
<http://www.hepb.org/>  
<http://www.hepbinitiative.org/>  
<http://www.geocities.com/Heartland/Estates/9350/hblist.html>  
<http://www.hepcassoc.org/>  
<http://www.hepcchallenge.org/>  
<http://www.hepcmo.org/>  
<http://www.hcvadvocate.org/>  
<http://hepeducation.org/>  
<http://www.hepfi.org/>  
<http://www.hepatitismag.com/>  
<http://hep-c-alert.org/index.htm>  
<http://www.hepcan.org/>  
<http://www.hopeforhepatitisc.com/>  
<http://www.immunize.org/>  
<http://www.icjh.org/>  
<http://www.helpwithhepc.com/>  
<http://www.kaiserpermanente.org/>  
<http://www.lola-national.org/>  
<http://www.liverhope.com/>  
<http://www.missourihsca.com/>  
<http://www.natap.org/>  
<http://www.methadone.org/>  
<http://www.nastad.org/>  
<http://www.nachc.org/>  
<http://www.naccho.org/>  
<http://www.nahtf.org/>  
<http://www.nationalhomeless.org/>  
<http://www.ncsddc.org/>  
<http://www.hepcnetwork.org/>  
<http://www.nmanet.org/>  
<http://www.hepbinitiative.org/taskforce/>  
<http://www.pkids.org/>  
<http://www.positivehealthproject.org/>  
<http://www.taskforce.org/>  
<http://www.theaidsinstitute.org/>  
<http://www.brucknergroupp.com/index.php>  
<http://www.harmredu.org/>  
<http://www.therapeuticcommunitiesofamerica.org/>  
<http://www.aidsinfonyc.org/tag/>  
<http://www.unm.edu/>

### Associate Members

<http://www.aahealth.org/>  
<http://www.dhs.ca.gov/>  
<http://www.cdph.state.co.us/cdphehom.asp>  
<http://www.dph.state.ct.us/>  
<http://www.in.gov/isdh/>  
<http://www.michigan.gov/mdch>  
<http://www.healthlinknm.org/nmhepline/>  
<http://www.health.state.nd.us/>  
<http://www.idph.state.ia.us/>  
<http://health.utah.gov/>  
<http://www.doh.wa.gov/>

## Sponsors

<http://www.bms.com/>

<http://www.gen-probe.com/>

<http://www.gilead.com/wt/home>

<http://www.gsk-us.com/>

<http://www.roche.com/home.html>

<http://www.merck.com/>

[http://www.schering-plough.com/schering\\_plough/index.jsp](http://www.schering-plough.com/schering_plough/index.jsp)

<http://www.valeant.com/>

## Advisory Board

<http://www.cdc.gov/hepatitis>

<http://www.va.gov/>

<http://www.bop.gov/>

<http://www.ihs.gov/>

<http://www.niddk.nih.gov/>

<http://dpt.samhsa.gov/>

## Endnotes

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<sup>1</sup> In recognition of anti lobbying restrictions for Federal employees, no Federal Agency staff participated in any NVHR discussions relating to funding issues or legislation mentioned in this document.

<sup>2</sup> Components of this effort would include: 1) using a case-management approach for discharge planning and after-release follow-up of patients who begin treatment while in prison or jail; 2) working with CMS and FBP to develop a mechanism for re-registering prison and jail inmates for Medicaid immediately on release to ensure that funds are available to continue treatment regimens initiated in prison or jail; 3) creating linkages between physicians at correctional health clinics and physicians in the community who can continue post-release treatment and care; and 4) instituting programs to improve knowledge of viral hepatitis prevention and treatment among prison and jail staff.

<sup>3</sup> Guidance on how to join or form patient support groups (in-person and online) is available from the American Liver Foundation ([www.liverfoundation.org](http://www.liverfoundation.org)), Hepatitis B Foundation ([www.hepb.org](http://www.hepb.org)), Hepatitis Foundation International ([www.hepfi.org](http://www.hepfi.org)), and HepNet ([www.hepnet.org](http://www.hepnet.org)).

<sup>4</sup> CDC. Recommendations for preventing transmission of infections among chronic hemodialysis patients. *Morbidity and Mortality Weekly Report (MMWR)* 2001;50(RR-5):1-43. [www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm).

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<sup>5</sup> Children in refugee camps often go unvaccinated, because of their stateless status. Refugee children are sometimes immunized against measles or polio-but almost never against hepatitis B-with vaccines that are provided by UNHCR and administered by local non-governmental organizations. Babies born in refugee camps to HBV-infected mothers rarely receive prophylactic treatment with hepatitis B immune globulin or hepatitis B vaccine.

<sup>6</sup> That is, by testing pregnant women and providing prophylactic treatment and vaccination, as needed, to their infants.

<sup>7</sup> Asylees are persons who have taken refuge in the United States or in a U.S. embassy. Although the majority of U.S.-bound refugees come from countries where hepatitis B infection is endemic, refugees-unlike immigrants-are not required to provide evidence of vaccination with hepatitis B or other ACIP-recommended vaccines unless and until they apply for permanent residency. Moreover, although refugees become eligible for permanent residency after one year, they are not required to change their status and may therefore remain indefinitely in the United States without receiving immunizations.

<sup>8</sup> Per CDC Personal Communication.

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<sup>30</sup> According to the 1999 ACIP guidelines, routine hepatitis A vaccination is recommended in Alaska, Arizona, California, Idaho, Nevada, New Mexico, Oklahoma, Oregon, South Dakota, Utah, and Washington. Routine vaccination should be considered in Arkansas, Colorado, Missouri, Montana, Texas, and Wyoming.

<sup>31</sup> CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report (MMWR)* 1999;48(RR-12):1-37.

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<sup>32</sup> ACIP for hepatitis B 1991.

<sup>33</sup> "Financing Vaccines in the 21st Century, Assuring Access and Availability," Institute of Medicine of the National Academies, National Academies Press, Copyright 2004. p. 64.

<sup>34</sup> Website for VFC vaccine information. [www.cdc.gov/nip/vfc](http://www.cdc.gov/nip/vfc).

<sup>35</sup> Website for 317 Immunization Grant program information. [www.cdc.gov/programs/immun03.htm](http://www.cdc.gov/programs/immun03.htm).

<sup>36</sup> Immunization of healthcare workers and workers routinely exposed to blood or other potentially infectious materials is mandated under the 1991 Occupational Safety and Health Administration (OSHA) Occupational Exposure to Bloodborne Pathogens Standard (1919.1030), which was revised in 2001.  
[www.osha.gov/needlesticks/needlefact.html](http://www.osha.gov/needlesticks/needlefact.html).

<sup>37</sup> CDC recommendation on hepatitis B vaccination for adults:  
[www.cdc.gov/nip/recs/provisional\\_rec/s/hepB\\_adult.pdf](http://www.cdc.gov/nip/recs/provisional_rec/s/hepB_adult.pdf).

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<sup>39</sup> Bureau of Justice Statistics Correctional Surveys (The Annual Probation Survey, National Prisoner Statistics, Survey of Jails, and The Annual Parole Survey) as presented in *Correctional Populations in the United States, Annual, Prisoners in 2001 and Probation and Parole in the United States, 2001*.

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