American Association for the Study of Liver Diseases
AASLD
Trust for America's Health
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ISSUE BRIEF

HBV & HCV: America's Hidden Epidemics

EXECUTIVE SUMMARY

Hepatitis B and hepatitis C are silent epidemics in the United States. Nearly two percent of the U.S. population may have some form of the disease – and approximately five million of these individuals will develop a chronic form of the diseases, but many of them will not even know they have a hepatitis infection for years or decades, until it has caused significant, irreversible damage to their livers.[1]

Right now, thanks to health reform and new scientific advancements, we have an opportunity to transform how the country deals with viral hepatitis – to help identify millions of Americans who are unaware they are living with hepatitis B or C before they develop late-stage liver problems, to more effectively treat the more than five million Americans who have hepatitis B or C, and to prevent even more Americans from becoming infected. If we do not take this opportunity, we will all pay the price, as people with undiagnosed HBV and HCV infections – including large numbers of Baby Boomers with HCV infection – may develop cirrhosis, liver cancer, or other major liver complications as they age, and Medicare and Medicaid will have to pick up the tab for much of the care.

But, if the country acts now to take advantage of the new options provided by the Patient Protection and Affordable Care Act (ACA) and new treatment possibilities, we could identify earlier and treat the millions of Americans who are already infected – sparing them needless suffering, reducing health care costs and lowering the number of new infections.

In the next decade, the Institute of Medicine (IOM) estimates that 150,000 Americans could die from liver cancer or end-stage liver disease associated with HBV or HCV, and an independent analysis found total medical costs for HCV patients could more than double over the next 20 years – from $30 billion to $80 billion per year.

Of the more than five million Americans with HBV or HCV:

- Baby Boomers account for two-thirds of HCV cases -- and if left untreated this could lead to a major increase in upcoming Medicare spending;
- African Americans account for 22 percent of HCV cases;
- Asian and Pacific Islander Americans account for 50 percent of HBV cases; and
- Gay and bisexual men account for 15 percent to 25 percent of new HBV cases and are at increased risk for HCV infection.

SEPTEMBER 2010

PREVENTING EPIDEMICS.
PROTECTING PEOPLE.

The Trust for America's Health (TFAH) and the American Association for the Study of Liver Diseases (AASLD) developed the following recommendations for new strategies and policies to help ensure individuals can receive treatment before they develop serious liver diseases and to act to prevent the future spread of the viruses. There are a number of unique challenges that must be addressed when combating HBV and HCV, including: the health complications often take decades to develop; there are significant social stigmas connected to the viruses since they are spread through blood and sexual contact; the diseases disproportionately impact racial, ethnic and sexual minorities; and infectious disease prevention strategies have traditionally been siloed. Health reform provides new opportunities through changes in the law, but also provides the impetus to act on existing mechanisms and strategies that have been untapped or not fully engaged in the past. Some of the recommendations could be achieved through immediate policy changes, some would require modest levels of new resources and some would require a longer term significant investment. The following is a summary overview of recommendations from the full report. To effectively combat viral hepatitis in the United States, the nation needs to:

Develop a Better Understanding of the Impact of HBV and HCV:

- **Improve Surveillance:** The scope of the diseases have long been under-reported, which has hampered the nation's ability to reduce the spread of the diseases, identify those with the diseases, target treatment, and generate support for needed research. A comprehensive surveillance system is needed which should: 1) build on existing, more robust HIV and other infectious disease systems to leverage resources and create an integrated approach; 2) be part of any health information technology (HIT) infrastructure; and 3) include enough support for public health departments around the country to conduct and follow up on surveillance activities.

Identify the Millions of Americans With HBV and HCV:

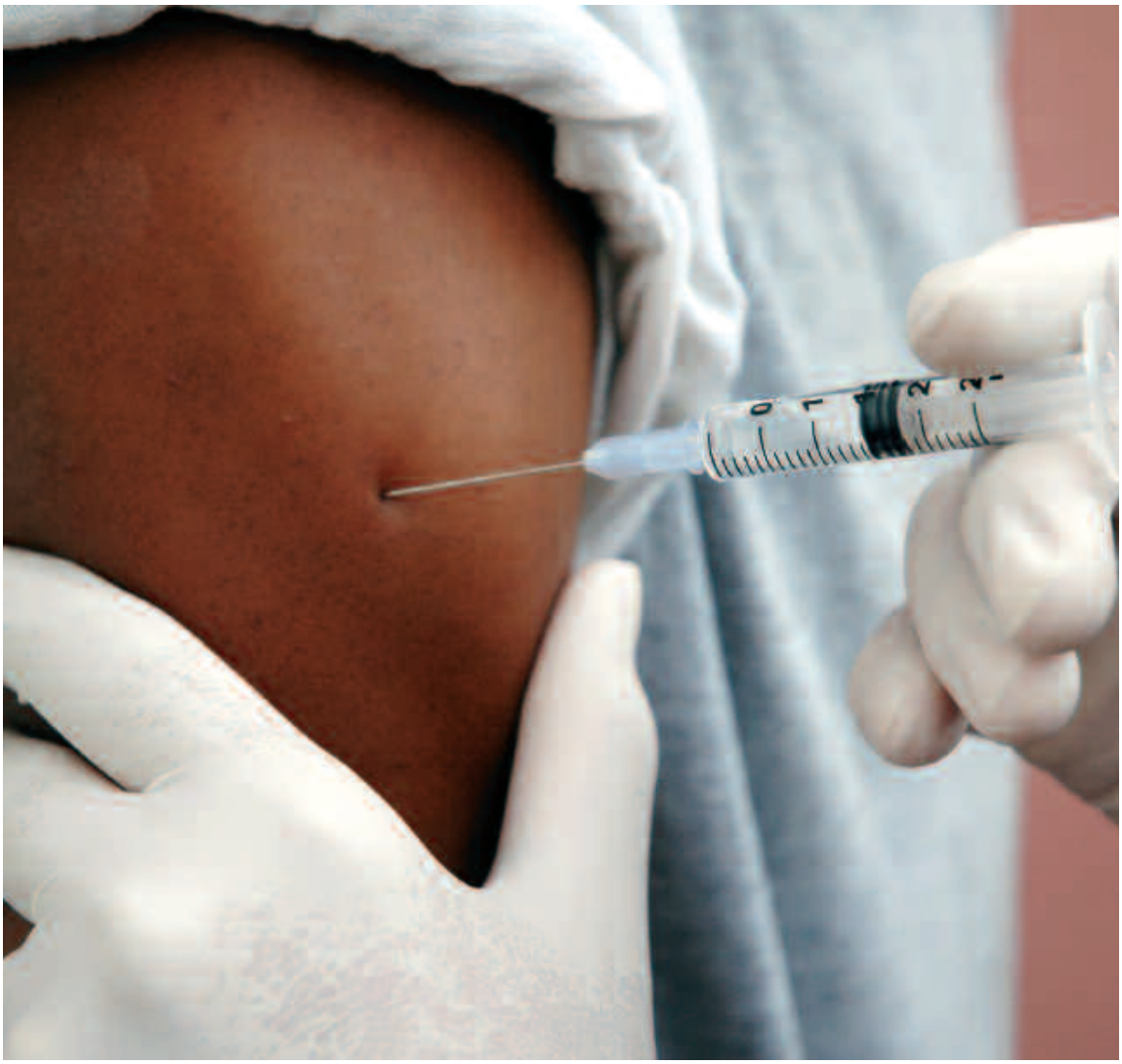
- **Make Hepatitis B and C Screening Routine under the Reformed Health System.** As part of a reformed system, the U.S. Secretary of Health and Human Services (HHS) can now designate HBV and HCV screening as an "essential health benefit," which would help identify millions of Americans who are infected but do not know it so they could receive treatment and avoid developing liver cancer, cirrhosis, or other late-stage liver complications, and stop inadvertently infecting others. Medicaid and community health centers should also move toward making screenings routine. Systems should be in place to support screenings in alternative care settings, such as family planning clinics, since even in a reformed health care system, millions of Americans will still not have regular access to care.

Improve Care and Research:

- **Ensure Everyone Who is Diagnosed Receives Appropriate Care:** All individuals who are diagnosed should receive the determined standard of care regardless of ability to pay and should receive support services to assure they can complete the needed care. In addition, new treatments are on the horizon, which promise to make treatment more effective. These should be made available as quickly as possible to all diagnosed individuals.
- **Invest in Biomedical, Behavioral and Health Services Research and Development:** Viral hepatitis research has been held back due to lack of resources, leaving many key questions unanswered, including the differential response to treatment among certain populations, improved screening and diagnostic tools, and new and better vaccines. Support should be increased to continue to advance the recent scientific breakthroughs around the diseases.

Prevent New Infections:

- **Develop an Integrated Approach to Reducing Risk for Infectious Diseases:** The United States should take an integrated approach to preventing infectious diseases, particularly integrating efforts around HIV, viral hepatitis and other sexually transmitted disease (STD) prevention, for those with overlapping risk behaviors for more efficient and effective use of scarce federal resources.
- **Eliminate Newborn HBV Infections:** An estimated 800 to 1,000 newborns are infected with HBV from their mothers through birth each year in the United States. These infections could be virtually eliminated through proper screening and care actions.
- **Eliminate Health Care-Associated HBV and HCV Infections:** The number of HBV and HCV infections spread to patients when they are receiving health care due to poor infection control practices has risen in recent years, but could be virtually eliminated with increased infection control practices and standards.
- **Promote Universal HBV Vaccination:** The HBV vaccine has helped cut infection rates by around 80 percent, but approximately 10 percent of infants are not vaccinated and millions of adults are not vaccinated, since they came of age before the vaccine was widely available in 1986. Universal vaccination would reduce rates of HBV infection.
- **Bolster Prevention Campaigns and Public Awareness:** HBV and HCV rates could be reduced by targeting prevention campaigns for at-risk populations, including promoting safe sex campaigns and expanding access to drug treatment, syringe exchange programs and education about the dangers of sharing needles. General public education campaigns should also be increased to inform the public about ways to reduce risk while reducing the stigma associated with the diseases.











Introduction

Hepatitis B and hepatitis C are silent epidemics in the United States. Nearly two percent of the U.S. population may have some form of the diseases – and approximately five million of these individuals will develop a chronic form of the diseases, but many of them will not even know they have a hepatitis infection for years or decades, until it has caused significant, irreversible damage to their livers.[2]

More than two million Americans live with chronic hepatitis B and 2.7 million to 3.9 million more live with chronic hepatitis C — but around 65 percent of people with the hepatitis B virus (HBV) and 75 percent of people with the hepatitis C virus (HCV) are unaware that they are infected with an infectious disease.[3] These individuals miss out on treatments that could spare them from serious liver diseases in the future while they also inadvertently may be spreading it to others. Two-thirds of the people with HCV are Baby Boomers who may have been infected decades ago but do not know they have it.

Right now, thanks to health reform and new scientific advancements, we have a new opportunity to transform how the country deals with viral hepatitis – to help identify millions of Americans who are unaware they are living with hepatitis B or C before they develop late-stage liver problems, to more effectively treat the more than five million Americans who have hepatitis B or C and to prevent even more Americans from becoming infected. If we do not take this opportunity, we will all pay the price, as people with undiagnosed HBV and HCV infections — including the large numbers of Baby Boomers with HCV infection — may develop cirrhosis, liver cancer or other major liver complications as they age, and Medicare and Medicaid will have to pick up the tab for much of the care.

In the next decade, the Institute of Medicine (IOM) estimates that 150,000 Americans could die from liver cancer or end-stage liver disease associated with HBV or HCV, and an independent analysis found total medical costs for HCV patients could more than double over the next 20 years – from $30 billion to $80 billion per year. However, we would reduce the number of deaths and lower costs if we act now to screen at-risk individuals so they can receive treatment earlier and work to prevent new cases of HBV and HCV.[4,5]

Health reform provides new opportunities through changes in the law, but also provides the impetus to act on existing mechanisms and strategies that have been untapped or not fully engaged in the past to:

- **Increase Screening to Help Prevent Cancer, Cirrhosis and Other Liver Diseases for Approximately Five Million Americans Estimated To Be Living with Undiagnosed HBV and HCV:** The Patient Protection and Affordable Care Act (Affordable Care Act) provides the opportunity to expand preventive health services, which could include screenings for HBV and HCV if the U.S. Department of Health and Human Services (HHS) takes action to define these screenings as a benefit under Medicare and as a general "essential health benefit." Routine screening for HBV and HCV, particularly among high-risk populations like the Baby Boomers, people who have injected drugs in the past, African Americans and Asian and Pacific Islander Americans, could help identify millions of Americans who are infected and help treat them at earlier stages of the disease. In addition, 32 million Americans who were previously uninsured will soon have health insurance options and increased access to screenings and care. If people receive earlier treatment for their HBV and HCV, their chances of developing liver cancer, cirrhosis or other forms of liver disease decrease dramatically.
- **Eliminate the Transmission of HBV from Mothers to Newborns:** Currently, an estimated 800 to 1,000 newborns are infected at birth each year. Newborns are at the highest risk of developing chronic hepatitis B and of having greatly increased risk of serious liver disease as they get older. If recommended screening and treatment actions were taken, the country has the chance to put an end to maternal-child hepatitis transmission.

- **Reduce the Number of New Cases of HBV and HCV:** The U.S. Centers for Disease Control and Prevention (CDC) estimated that there were more than 43,000 new HBV infections and 17,000 HCV infections in 2007, but experts believe these estimate are very low due to limited surveillance.[6] Focused efforts to reach high-risk populations and increase public and provider education could significantly reduce the numbers of individuals who become infected. New transmissions of HCV occur most frequently among injection drug users, and there has been a rise in health care related infections in recent years. Beginning in fiscal year 2010, federal funds can now be used for syringe exchange programs (SEPs), a proven structural intervention to prevent HCV transmission among injection drug users. A vaccine is available for HBV, which has significantly reduced the rate of infection in the United States, but could reduce rates further if we increased vaccination rates – including the five percent of children who go unvaccinated and at-risk adults who came of age before the vaccine became available. There is no vaccine available for HCV, but work needs to be focused on developing an effective vaccine to prevent hepatitis C infections. In addition, the 2009 stimulus act provided increased funding for health information technology (HIT), which provides new, improved tools for public health professionals to target prevention efforts and track results.

- **Leverage New Opportunities for Treating HBV and HCV:** Under the Affordable Care Act, in addition to expanding coverage options to 32 million additional Americans, insurers will no longer be able to deny coverage based on pre-existing medical conditions, including HBV and HCV, or revoke coverage once a medical condition is identified. While most coverage expansion will occur in 2014, the new Pre-existing Condition Insurance Pool provides insurance for those with pre-existing conditions who have been denied coverage; this could be a critical means for immediate access to care for people living with hepatitis. This means millions of additional Americans will have greater access to care. And, new drug treatments on the horizon mean that HBV and HCV care will likely be much more effective in the near future. Researchers are on the cusp of new breakthroughs in research, including new therapies that could potentially cut treatment cycles for HCV from 48 weeks to 24 weeks and improve cure rates from around 40 percent to 75 percent. Therapies for hepatitis B have also improved dramatically in the past few years so that one pill per day can prevent disease progression, reduce risk of transmission to others and lead to a lower rate of long-term complications, such as liver cancer.

To help make sure the country takes advantage of this moment in time, in this issue brief, the Trust for America's Health (TFAH) and the American Association for the Study of Liver Diseases (AASLD) examine an overview of HBV and HCV policy concerns and examine policy considerations for:

- Meeting the challenges of creating an integrated approach to viral hepatitis;
- Identifying millions of infected Americans – many of whom do not know they have chronic HBV or HCV;
- Treating the more than five million Americans who currently have chronic HBV or HCV;
- Preventing new infections, including:
  - Eliminating the transmission of HBV to newborns;
  - Eliminating the health care transmission of HBV and HCV;
  - Eliminating new HBV and HCV infections among high-risk groups; and
- Recommending a strategic approach to address HBV and HCV in the United States.

SECTION 1

Overview of HBV and HCV Policy Concerns

> "Most people [with HBV and HCV] don't know they're infected. They can transmit the virus to others, and can't protect their own health by seeking care. Viral hepatitis is like high blood pressure. It silently attacks the body to cause disease in later life. The liver is a very stoic organ. Even though it's diseased, it doesn't cry out for help until very, very late."[7]
>
> —John W. Ward, MD director, division of viral hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, Centers for Disease Control and Prevention.

The silent epidemics of HBV and HCV take a toll on the health and economy of the United States, and the problem is expected to get exponentially worse in the coming decades as more people who do not even know they have the disease – particularly Baby Boomers – reach an age where they begin to experience the consequences of their infections.

HBV or HCV account for more than three-quarters of liver cancer cases and 57 percent of cirrhosis (permanent scarring of the liver) cases in the United States.[8] Almost half of the 6,500 annual liver transplants are related to HBV or HCV, and HBV alone is responsible for tripling the waiting list for liver transplants in the past five years.[9, 10] According to the 2010 IOM report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C,* HBV leads to around 3,000 to 4,000 deaths each year from liver cancer or severe liver disease and HCV contributes to an estimated 8,000 to 13,000 deaths each year.[11] Many experts believe these estimates are low. The death rate from HCV is expected to triple in the next 10 to 20 years.[12]

Although it is difficult to determine with existing data, the direct annual medical costs associated with HBV and HCV infections are estimated to be $7.6 billion.[13] A Milliman Report analysis found that HCV could actually cost the country approximately $30 billion a year, and these costs are expected to more than double over the next 20 years to $80 billion per year.[14] This growth is largely due to the number of Baby Boomers who will develop liver problems as they age. The Milliman researchers estimate the per-patient cost of people with chronic HCV will increase 3.5 times over 20 years, that in the next 10 years commercial and Medicare costs will more than double, and that in 20 years, Medicare costs will increase from $5 billion to $30 billion per year.

Treatment is also costly to the individual. For people who do not receive antiviral treatment, lifetime undiscounted costs for treating individuals with HCV costs range from an estimated $30,000 to $50,000 (year 2000 and 2003 values), according to a review by John B. Wong.[15] The Milliman Report modeling analysis used estimates that the cost of treating liver cancer (hepatocellular carcinoma) can be more than $62,000 for the first year and the first year cost of a liver transplant can be $267,000 (based on commercial reimbursement rate estimates).[16]

While the seriousness of the diseases is clear, a number of major issues exist that make developing HBV and HCV prevention, control and treatment policies particularly challenging:

- **Approximately five million Americans have HBV or HCV, but the vast majority do not know they have it and often live with the diseases for decades before having any symptoms.** It is difficult to create urgency for screenings, despite the seriousness of these diseases when they reach late stages, when people do not know they are at risk or feel the immediate impact in their daily lives. There has never been a concerted effort to try to screen Americans, even at-risk groups. In addition, many health care providers may not be aware their patients could be at risk and health insurance has not regularly covered routine screenings.

- **Social stigmas exist around addressing sexual practices and illegal injection drug use, which are two of the main ways HBV and HCV are spread.** Stigma also complicates outreach to individuals in other at-risk categories — such as individuals born in other countries or those who may have contracted the disease from birth or blood transfusion — who may be concerned with being associated with these stigmas. Additionally, there may be stigma for those at risk for or infected with HBV due to cultural issues in endemic countries.

- **Hepatitis disproportionately affects racial, ethnic, and sexual minorities which makes prevention, control, and treatment strategies challenging due to cultural barriers.**

- African Americans — who make up 14 percent of the U.S. population — account for 22 percent of HCV cases in the United States.[17]

  - Although Asian and Pacific Islander Americans make up only 4.5 percent of the U.S. population, they account for more than 50 percent of chronic HBV cases.[18] One in 10 Asian and Pacific Islander Americans has chronic HBV infection, which is significantly higher compared with Whites, African Americans and Latinos.[19]

  - An estimated 15 percent to 25 percent of new HBV infections in the United States occur in gay and bisexual men.[20] According to CDC, gay and bisexual men are also considered to be at increased risk for HCV if they engage in high risk behaviors.

- **Efforts to combat HBV and HCV have been hampered by siloed policies, inadequate surveillance and insufficient resources.** HBV and HCV kill far more Americans than HIV every year, but hepatitis received less than two percent of the budget from the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, while HIV received nearly 70 percent.[21] HBV and HCV policies and programs have been hindered by a siloed approach to disease prevention in the United States, where efforts to address diseases with overlapping risk patterns, such as HIV, tuberculosis, or other sexually transmitted diseases (STDs) have not been effectively integrated with HBV and HCV efforts – and the programs end up competing for scarce resources. An estimated 25 percent of people with HIV also have HCV.[22] There is inadequate surveillance and information about the scope and impact of HBV and HCV in the United States, which has created a cycle where there is inadequate evidence to show the need for greater resources to combat the diseases. The result is that prevention efforts and biomedical research to improve treatments have been severely limited.

- **The number of health care associated infections has risen in recent years, putting all Americans at increased risk for infection.** Individuals who received blood transfusions or other types of medical care that may have exposed them to blood or bodily fluids before 1992 may have been infected with HCV. Since then, measures have been taken to screen blood donations and to improve safety practices, including a "one needle, one syringe, only one time" practice. However, serious challenges remain in terms of health care setting safety. Since 1998, an estimated 100,000 patients were notified of potential exposure to HBV, HCV, and/or HIV due to lapses in health care safety.[23] Between 1998 and 2008, CDC identified 33 outbreaks of HBV and HCV in hospital settings, 12 in outpatient clinics, six in hemodialysis centers and 15 in long-term care facilities. Due to limited funding for disease surveillance to detect these outbreaks, this may under-represent the extent of the problem in the United States.

WHAT IS HEPATITIS?

Hepatitis is an inflammation of the liver. HBV and HCV are both blood-borne diseases caused by viral infections that lead to inflammation of the liver. The symptoms of acute viral hepatitis can include one or more of the following: fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, clay-colored bowel movements, joint pain and jaundice (yellowing of the skin and eyes). Individuals with acute or chronic hepatitis do not always show symptoms.

Hepatitis B (HBV) Fast Facts:

Cases of Chronic Hepatitis B in the United States: At least two million

Percent of HBV infected individuals unaware of infection: 65 percent

New infection rate: There is limited accurate data about new infection rates due to limited surveillance. According to CDC, in 2007, there were at least 43,000 new infections, but this number is considered to be a very low estimate.

How is it spread? Typically through sexual activity, from a mother to a baby during childbirth, or direct contact with infected blood, such as during household sharing of razors or contact with cuts or wounds, through sharing needles, or exposure in a health care setting resulting from poor infection control practices.

How often does HBV lead to a chronic infection? Around 90 percent of newborns who are exposed to HBV during childbirth or early childhood will develop a chronic infection unless they receive proper preventive care measures. For healthy young adults, around five percent of HBV infections develop into chronic HBV.

What are the medical complications? Cirrhosis (scarring of the liver), liver cancer, other liver problems. Some patients need liver transplants.

Is there a vaccine available? Yes, since 1982 an HBV vaccine has been available. Since 1991 an increasing percentage of American children have received hepatitis B vaccine; now more than 90 percent of American children have been vaccinated for HBV.[24] Americans who came of age before the vaccine was widely available or are born to mothers who have the disease are still at risk for exposure.

What is the treatment? Seven medications are approved for treating HBV. They often do not result in a full cure, but can significantly reduce liver damage particularly if treatment is started early. However, successful therapy of patients with advanced disease can prevent liver cancer, reduce the need for liver transplantation and save lives.

Hepatitis C (HCV) Fast Facts:

Cases in the United States: 2.7 million to 3.9 million

Percent of HCV infected individuals unaware of infection: 75 percent

New infections each year: There is limited accurate data about new infection rates due to limited surveillance. According to CDC, in 2007, there were at least 17,000 new infections, but this number is considered to be a very low estimate.

How is it spread? Typically through blood-to-blood contact, such as the reuse of contaminated drug injection equipment (needles, cookers, etc.) or through exposure in a health care setting resulting from poor infection control practices, or occasionally through sexual contact. Individuals who received blood transfusions or procedures before 1992, when blood started to be screened, may be at risk.

How often does HCV become chronic? 70 percent to 80 percent of people who contract an HCV infection develop chronic HCV.

What are the medical complications? Cirrhosis (scarring of the liver), liver cancer, other liver problems. Some patients need liver transplants. HCV is the most common cause of adult liver transplantation in the United States and the world today.

Is there a vaccine available? No.

What is the treatment? A combination of antiviral medications. Approximately 50 percent to 60 percent of patients respond to treatments initially. African Americans only have a 28 percent success rate.

DRAMATIC REDUCTION IN HEPATITIS INFECTIONS OVER TIME: A PUBLIC HEALTH SUCCESS

Dramatic reductions in hepatitis rates in the United States show how effective public health can be at improving the health of Americans.

Acute HBV rates declined 81 percent between 1990 and 2006 due to safer sex practices, a decline in needle-sharing among injection drug users, improved blood screening and the HBV vaccination.[25] Acute HCV infections have fallen from a peak of 230,000 new cases per year in the 1980s to an estimated 17,000 in 2007.[26]

These reductions reflect the successes of existing public health prevention efforts. Increasing efforts now could result in even lower rates and earlier identification and treatment of people who are currently infected but may not be aware they have HBV or HCV. However, given the recent increases of cases of HCV infection among young people who are injecting drugs and HIV infected men who have sex with men, there is indication of a new wave of the epidemic that current prevention efforts have not managed to control.

HBV AND HCV AROUND THE WORLD

Worldwide, about one in 12 persons -- 480 million to 520 million people -- are chronically infected with HBV or HCV.[27]

HBV: Approximately two billion people worldwide have been infected by HBV and about 350 million live with chronic infection.[28] An estimated 600,000 persons die each year due to the acute or chronic consequences of HBV.[29]

HBV is endemic to Southeast Asia and the Pacific Basin (except for Japan, Australia and New Zealand), sub-Saharan Africa, the Amazon Basin, parts of the Middle East, the central Asian Republics and in some Eastern European countries. In most of these areas, about 70 percent to 90 percent of the population becomes HBV-infected before age 40 and up to 20 percent are HBV carriers.[30] In countries such as China, Senegal and Thailand, infection rates are extremely high in infants and continue through early childhood. In other countries, such as Panama, Papua New Guinea, Solomon Islands and Greenland, infection rates among infants are low, but increase rapidly during early childhood. Infection rates are much lower in Western and Northern Europe, Australia and parts of South America. The carrier rate is less than two percent and less than 20 percent of the population has been infected with HBV.

HCV: An estimated 200 million or more individuals (about three percent of the world's population) are believed to be infected with HCV.[31] There are about four million carriers in Europe alone.[32] HCV is a particular problem in Egypt, where the virus spread over decades through contaminated needles used to treat widespread parasitic infections and in the former Soviet Union through poor infection control or injection drug use.[33]

CONGRESSMAN LIVING WITH HCV SPEAKS OUT

On December 7, 2009, Rep. Hank Johnson (D-GA), announced that he has been battling chronic HCV for more than a year with a course of drug therapy his physician hopes will eradicate the virus.[34]

Maria Sjogren, MD, of Walter Reed Army Medical Center, praised her patient's diligence in fighting the infection, saying he should serve as "an inspiration to thousands of people who suffer from this illness. He has been a model patient, sticking with his course of treatment even when it was most difficult."

Johnson said he hopes his disclosure will comfort others with this illness and give them the confidence to speak out. "The causes of this disease are many, but in the end it does not matter how someone contracted the virus," he said. "Like so many millions of others, I was infected many years without ever knowing how I contracted it."

He said he plans to use his position to help raise awareness of the disease and show that it is possible to be successful despite it. "Though this infection has caused me some discomfort and frustration, it has in no way affected my ability to legislate and serve my constituents," he said.

He is co-sponsor of a bill introduced by Representative Mike Honda (D-CA), H.R.3974 and by Senator John Kerry (D-MA), S.3711 -- Viral Hepatitis and Liver Cancer Control and Prevention Act of 2009, which would establish a comprehensive prevention, education, research and medical referral program for viral hepatitis.

SECTION 2

Meeting the Challenges of Creating an Integrated Approach to Viral Hepatitis

Resources and programs for HBV and HCV have been hampered by a siloed approach to disease management, a lack of understanding about the impact of the disease in the country and limited funding.

Traditionally, disease prevention policies in the Unites States focus on a disease-by-disease approach. This means that many diseases that have overlapping risk patterns and overlapping prevention and treatment strategies are not well integrated – and policies and programs end up competing for resources and often duplicating efforts. This is particularly true for viral hepatitis, which has been chronically underfunded compared to its impact on the public's health. For example, CDC provides cooperative agreements to 49 states, the District of Columbia and five cities to fund the salaries of adult viral hepatitis prevention coordinators (AVHPC) who are tasked with integrating viral hepatitis services with other local efforts to reach populations at-risk. However, CDC only has resources to fund a small number of jurisdictions for hepatitis surveillance or for other activities. As a result, CDC estimates that only 10 percent of new HCV cases are reported each year and only two-thirds of states currently report cases of chronic HCV.[35]

A strategic, integrated approach to address HBV and HCV in concert with HIV and other STDs could create synergies for improving surveillance, screening, prevention and treatment for all of the diseases. CDC has recognized the need to develop a more integrated approach to hepatitis with the addition of hepatitis in 2006 to the National Center for HIV/AIDS, STD and Tuberculosis Prevention (NCHSTP), now the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP). In addition, NCHHSTP has begun a Program Collaboration and Service Integration (PCSI) initiative to foster a client-centered integrated approach to HIV, STD, hepatitis and TB services at the state and local level. The new National Prevention and Public Health Promotion Strategy, mandated as part of health reform, offers an additional opportunity to make HBV and HCV prevention a much higher national priority across the federal government – not just within CDC – and to find ways to integrate approaches to related diseases for greater effectiveness and efficiency.

A. UPGRADING SURVEILLANCE

Challenge: The United States lacks a comprehensive surveillance system for hepatitis, resulting in partial understanding of the scope of the problem and, therefore, diminished capacity to constrain transmission, target prevention activities, and plan for treatment service needs.

According to the IOM, current surveillance for HBV and HCV is fragmented, poorly developed, and inconsistent across jurisdictions due to CDC having very limited resources to develop guidance or fund state health departments' activities.[36]

Without better situational awareness and surveillance, the country will continue to lack sufficient data to determine the scope of the problem and who is affected. This influences not only the ability to prevent and treat disease, but it also creates a vicious cycle of inadequate evidence to support greater public resources to address the problem.

As all systems are under review as part of health reform implementation, upgrading and integrating how HBV and HCV are monitored could be reconsidered. For instance, many experts recommend that HBV and HCV surveillance could be built on existing surveillance systems for HIV or other infectious diseases, which are more robust. While the diseases are different, many of the risk behaviors and affected populations overlap enough to make this expansion feasible. To be effective, a new system would also need to include expanded sentinel surveillance, where se-

lected facilities report infection rates, so new pockets of infection can be identified quickly to target new primary prevention efforts. Serosurveillance among at-risk populations that have limited access to health care, such as injection drug users and immigrants from HBV endemic countries, would also be useful in measuring incidence and determining the extent of the epidemic in those communities that standard surveillance will not be able to detect. The IOM recommends surveillance could be improved if CDC could provide cooperative agreements to states to enhance their surveillance of viral hepatitis similar to how HIV/AIDS surveillance is supported.[37]

In addition, changes in health information technology (HIT) systems provide new opportunities for improving surveillance, control and treatment of these diseases. As a result of passage of the 2009 stimulus (American Recovery and Reinvestment Act), Medicare and Medicaid eligible providers will have to follow certain standards, known as "meaningful use" of electronic health records (EHRs), in order to qualify for federal incentive payments and avoid penalties. The publication of HHS's final rule on meaningful use of EHRs in July may help with tracking childhood immunizations against HBV and lays the groundwork for better surveillance through requiring the capability to report data, but the rule does not require other measures that could improve hepatitis tracking and treatment, such as screening of pregnant women, adult immunization and recording risk factors.[38]

"MASSACHUSETTS DOES NOT HAVE FUNDING FROM THE CDC FOR VIRAL HEPATITIS SURVEILLANCE. OUR VIRAL HEPATITIS SURVEILLANCE HAS BEEN FUNDED, IN THE PAST, WITH STATE APPROPRIATIONS. CURRENTLY, ALL OF OUR STATE FUNDING FOR THESE PROGRAMS, INCLUDING SURVEILLANCE, HAS BEEN ELIMINATED….FUNDING FROM THE STATE TENDS TO FLUCTUATE GREATLY FROM YEAR TO YEAR…SO HEALTH DEPARTMENTS REALLY NEED TO RECEIVE FUNDING AND SUPPORT FROM CDC TO CREATE AND MAINTAIN SYSTEMS APPROPRIATELY."[39]

-- DANIEL CHURCH, EPIDEMIOLOGIST/VIRAL HEPATITIS COORDINATOR, MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

IOM RECOMMENDATIONS FOR AN HBV AND HCV SURVEILLANCE SYSTEM

- A federal funding mechanism and guidance for core surveillance activities.
- Viral hepatitis specific cooperative agreements with all state and territorial health departments.
- Implementation of performance standards regarding revised and standardized case definitions, specifically through the use of:
  - Revised case-reporting forms with required, standardized components; and
  - Case evaluation and follow up.
- Support for developing and implementing automated data-collection systems, including:
  - Electronic laboratory reporting;
  - Electronic medical-record extraction systems;
  - Web-based, Public Health Information Network-compliant reporting systems; and
  - Federal funding for targeted supplemental surveillance.

Improved surveillance would make it possible for CDC to implement a national collaborative network inclusive of other programs, community partners to deliver comprehensive outreach, education, intervention and management services to populations at risk.

SECTION 3

Increasing Screening and Testing

To Help Prevent Cancer, Cirrhosis and Other Liver Diseases for Millions of Infected Americans Who Do Not Know They Have HBV or HCV

Challenge: All who are at risk for hepatitis should be screened, so they know their status and are linked to appropriate prevention (including vaccination) and treatment services.

Identifying the millions of Americans who have HBV or HCV infections and who are unaware of their conditions is challenging, but routine screening and testing could get people into treatment before they develop late-stage liver complications, sparing needless suffering and significantly reducing health care costs while also improving survival.[40] Universal screening would also help reduce the stigmas associated with the diseases and provide a real basis of knowledge about the true scope and impact of the disease in the United States.

Rapid, reliable and relatively inexpensive diagnostic blood tests exist for both HBV and HCV, but most Americans have never been tested due to lack of access to preventive services, lack of information, or stigmas around the diseases:

- A significant portion of Americans have not had access to preventive care services;
- The U.S. Preventive Services Task Force (USPSTF) guidelines recommend against widespread screening for HBV and HCV, in contradiction to the view of CDC and other experts who believe there is sufficient evidence to support broader screening;
- Many health care providers are not aware of the risk groups for viral hepatitis, what tests to order for those at risk or how to interpret lab results and educate patients on prevention and medical management;
- Providers may be reluctant to ask patients about whether they engage in high-risk behaviors or previously did so; and
- Individuals may be reluctant to ask for testing due to fear of being associated with high-risk behaviors.

With an approach that combines both risk factors and demographic factors (including age) targeted testing could help identify a significant number of people living with the diseases.

- **Baby Boomers:** Currently, two-thirds of HCV cases are Baby Boomers (an estimated 1.8 million to 2.5 million individuals). The high number of Baby Boomers who have HCV and are not aware of it represents a particularly difficult public policy challenge. Many of them may have been exposed through blood transfusions or other medical procedures prior to 1992 when blood screening and other safety measures were not in place, or through at-risk behaviors, like injection drug use in the 1960s and 1970s, before there was knowledge about the dangers of sharing drug injection equipment. Because many of this generation do not identify with the behavioral risk factors for hepatitis, many have suggested that an age-based approach to screening and testing is needed in addition to a risk-based screening mechanism;[41]
- **African Americans:** 22 percent of HCV cases are African Americans (an estimated 540,000 to 858,000 individuals);[42]
- **Asian and Pacific Islander Americans:** One in 10 Asian and Pacific Islander Americans are estimated to have a chronic HBV infection.[43] More than 50 percent of chronic HBV cases are Asian and Pacific Islander Americans;[44]
- **Gay and Bisexual Men:** An estimated 15 percent to 25 percent of new HBV infections in the United States occur in gay and bisexual men and men who have sex with men.[45] Gay and bisexual men are also considered to be at increased risk for HCV if they engage in high risk behaviors;
- **Injection Drug Users:** Injection drug users are at particularly high risk for infection from both diseases. Supporting screenings outside of traditional medical settings for individuals, such as injection drug users – who may remain outside of the mainstream medical system even after health reform – will be important. Alternative testing sites could include: HIV, STD and TB clinics; substance abuse and mental health programs; harm reduction services including syringe exchange programs; federal and state and

juvenile correctional facilities; college campuses; and family planning clinics; and

- **The Incarcerated:** Chronic HCV can affect as many as 12 percent to 35 percent of prison populations.[46] Although some HCV transmission occurs within correctional settings, the vast majority of HCV-infected inmates were infected through injection drug use outside of prison, not during their incarceration.[47, 48, 49] The number of incarcerated adults living with chronic HBV is estimated to be between one percent and 3.7 percent.[50] Viral hepatitis specific cooperative grants should be established with state and territorial health departments.

Health reform creates some new authorities that could greatly expand the number of individuals screened for HBV and HCV and could provide the impetus for acting on existing authorities to expand screening. The HHS Secretary has the authority to consider HBV and HCV screening an "essential health benefit" for most private plans, which would mandate coverage and limit cost sharing, starting in 2014. The Centers for Medicare and Medicaid Services (CMS) should take immediate steps to cover routine screening for Medicare beneficiaries. The Health Resources and Services Administration (HRSA) could also make screening a mandated protocol for community health centers (CHC) and require that all CHC patients have a record of HBV vaccinations.

In the near-term, HHS should work with USPSTF in an expedited way to add routine HBV and HCV screening to the Task Force list of recommended services. CDC and other public health organizations, which have already recommended this addition, can continue to research the value of routine HBV and HCV screenings and provide this data to the USPSTF. If the USPSTF were to recommend a screening, under the new health reform law, it would become a mandated benefit with no cost sharing for most private plans and Medicare.

- **Opportunities for strategic integration with HIV and other STD screening:** HIV screening programs are more robust and well developed than HBV and HCV screening efforts. CDC estimates that only 20 percent of people with HIV infection do not know their status – compared to the 65 percent of people infected with HBV and 75 percent of people with HCV who do not know they are infected.[51] HIV screening programs have a history of conducting public education campaigns that encourage testing in de-stigmatizing ways and reaching targeted at-risk groups based on behavior patterns, including hard-to-reach groups, like injection drug users.

TARGETED SCREENING AT WORK: ASIAN AND PACIFIC ISLANDER AMERICANS

A 2005 HBV screening program in New York City of Asian and Pacific Islanders, mostly Chinese and South Korean, found that about 15 percent tested positive for chronic HBV infection.[52] Half of those with chronic HBV infection had been living in the United States for more than 10 years and likely acquired their infections in their countries of origin. Screening programs in Atlanta, Chicago, Philadelphia and California produced similar results.

ONE PROGRAM IN ACTION: CHARLES B. WANG COMMUNITY HEALTH CENTER, NEW YORK CITY

The Charles B. Wang Community Health Center (CBWCHC) in New York City extensively, and successfully, serves the city's large Asian population with affordable, high quality health services. According to CBWCHC, one in 10 New York City residents are Asian, and of the population they serve 98 percent do not speak English as their first language. CBWCHC's initial step in improving health services to this population was to provide services in at least five languages other than English, allowing staff to communicate and reach-out to the various Asian communities throughout the city.[53] CBWCHC is a general health clinic -- not just a hepatitis screening program -- but screening and treatment for hepatitis is considered an important component of care for this patient population. With the knowledge that HBV is affecting a large proportion of the population they serve, CBWCHC has developed the tools to more adequately screen and treat HBV.

Language and cultural barriers to HBV care are apparent within the New York City Asian population. These include: difficulty navigating the medical system, including treatment protocols and payment procedures; widespread use of herbal medications and complementary and alternative medicines (CAM); and diverse health beliefs which may prioritize different aspects of personal and social health. CBWCHC has the resources to appropriately address these barriers and they have. For example, through HBV outreach campaigns in various languages, using culturally competent terminology. Additionally, CBWCHC has successfully implemented an electronic HBV registry and HBV history form, allowing them to better track and treat all of their HBV cases. The "patient tracker" for hepatitis patients is a portable record that contains important hepatitis and liver health information about individuals.

CBWCHC is privately funded, and between 2004 and 2008 was able to screen more than 4,000 individuals for HBV. Twenty-two percent of the individuals tested were found to be positive and are now in their system for treatment.

SECTION 4

Treating More than Five Million Americans with HBV or HCV

> "We are talking about a cure for hepatitis C. We are on the threshold of an era of more effective treatment. We are where we were in the early 1990s with HIV and HAART [Highly Active AntiRetroviral Therapy]. We are about to have a game-changer in therapy for hepatitis C. With current treatments, about 35 percent to 40 percent of people clear HCV from their system. They have to take the drugs for 48 weeks. We think the new therapies will reduce that to a 24-week therapy period and that the chance for a cure will go up to about 75 percent. So, the studies indicate that the therapies will be more effective, people can take them for a shorter period of time, and they will have a greatly increased chance of a cure."[54]
>
> -- John W. Ward, MD

Challenge: To assure that all individuals diagnosed with hepatitis receive the standard of care regardless of ability to pay and receive the support services needed to assure completion of treatment.

Today, millions of Americans with hepatitis are not getting the potentially life-saving treatment they need. With the incredible promise of new treatments that could become available in the next few years, the importance of accessing treatments will become even greater as new therapies offer the hope of shorter treatment courses, with fewer side effects and higher rates of cure. While the United States has made an appropriate and very strong commitment to assuring access to non-curative treatment for HIV, which has dramatically changed the course of the epidemic for Americans living with HIV, we have not made a similar commitment to the more than five million people in the United State living with hepatitis – even with a time-limited treatment course that can provide a cure.

Health reform offers the potential to change this equation. The Affordable Care Act means 32 million previously uninsured Americans will now have health insurance options and individuals who were denied coverage for preexisting medical conditions, including HBV and HCV, will no longer be denied coverage or have their coverage revoked once a medical condition is found.

A. NAVIGATING TREATMENT AND COVERAGE

Treating chronic HBV and HCV is not cheap or easy. The earlier the diseases are found, however, there is greater chance for treatment to help lessen the long-term damage done to a patient's liver. And earlier treatment costs are significantly less than the costs associated with treatment for cirrhosis, liver cancer, or liver transplants. For people who do not receive antiviral treatment, lifetime undiscounted costs for treating individuals with hepatitis C range from an estimated $30,000 to $50,000 (year 2000 and 2003 values), according to a review by John B. Wong.[55] Costs can reach more than $267,000 for the first year costs of a liver transplant.[56]

Right now, some individuals who are identified as having HBV or HCV do not get into treatment programs due to lack of insurance coverage or they are not referred to providers who are equipped to provide full diagnostic exams and help the patient make treatment decisions. The lack of a good follow up and referral system means some patients fall through the cracks and do not receive care. Even with the Affordable Care Act, there are likely to be many HBV and HCV infected individuals who will remain uninsured or otherwise not have access to care.

In addition, there are hurdles to many patients getting proper care and ongoing support. Treatment can take a long time and requires lots of testing, follow up appointments and medications. Currently, there are not clear standards and guidelines for care, so providers may vary in how they treat the disease and may not use the most up-to-date treatments. Without these standards, insurers may also decide not to cover the range or scope of possible treatment options. In addition, insurance providers may also require copayments or not cover all of the necessary testing and medications.

Proper treatment requires a continuum of care and a patient who is fully committed to the process. Receiving support to help stay in treatment, including social support, mental health care, nutrition services, and other types of support, increases the likelihood a patient will finish the process.

- **Opportunities for integrating with treatment infrastructure for HIV and other STDs:** One model for providing a complete continuum of care, which includes coordination of services, is the Ryan White program for people living with HIV/AIDS. Like HIV, HBV and HCV require complex treatment cycles. Successful treatment strategies could be integrated with or, at a minimum, be informed by the Ryan White Care program. A number of states have already started to integrate viral hepatitis services into their existing public health infrastructure. For instance, Massachusetts has used state resources in the past to build upon its Ryan White Care program infrastructure to provide medical management services for viral hepatitis.[57]

Even for patients receiving care, the current drug treatments for HBV and HCV are limited and are not effective for clearing the infection for all patients. Because successful treatment is not guaranteed, an emphasis on preventing people from getting the diseases in the first place is particularly important.

THE AFFORDABLE CARE ACT AND HEPATITIS

The new health reform law provides a number of reforms that could dramatically improve prevention, screening and treatment of viral hepatitis -- some are immediate and others are required to take effect by 2014.

Immediate reforms include:

- Pre-existing Condition Insurance Plans (PCIPs) provide coverage for people who have been uninsured for six months and have been denied coverage for a pre-existing condition. Most uninsured people with hepatitis would fall in this category.
- Extended coverage for young adults who can remain on their parents' plans.
- USPSTF recommended preventive services and ACIP recommended vaccines and screenings are mandated to be covered without cost sharing for any new plans or existing plans that are significantly changed.
- Prohibition of rescission of coverage based on a newly identified condition.
- Prohibition of lifetime caps on payments.
- Regulation on annual limits on coverage.
- Optional expansion of Medicaid to include all persons who live below 133 percent of federal poverty level (FPL).

Reforms effective by 2014 include:

- Elimination of pre-existing condition exclusions, with insurance available for individuals and small businesses through exchanges that assure lower premiums.
- Expansion of the Medicaid program to cover all who live below 133 percent of FPL.
- Premium subsidies for those purchasing private insurance with incomes between 133 percent and 400 percent of FPL.
- Premiums adjusted for age and geography only, not medical condition.
- Essential health benefits requirements that include preventive services with reduced cost sharing (for those benefits not recommended by the USPSTF).

B. PROMISING NEW MEDICATIONS ON THE HORIZON -- BUT RESEARCH FUNDING IS LIMITED

Challenge: Key biomedical, behavioral, and other health services research questions impede our ability to better prevent and treat various forms of hepatitis.

Seven medications have been approved by the U.S. Food and Drug Administration (FDA) for treating chronic HBV. The drugs often do not result in a full cure, but they can significantly reduce the risk of liver damage by slowing or stopping the virus from reproducing. This in turn leads to improved outcome, less need for transplant and improved survival in patients with advanced disease. Studies are underway looking at the impact of various drug combinations for HBV. It appears that earlier treatment of chronic HBV increases the efficacy of treatment, underscoring the need for early identification of those who are infected.[58]

For chronic HCV, antiviral medications are used for treatment. Fifty percent to 60 percent of patients respond to treatment initially.[59] African Americans do not respond as well to HCV treatment compared with the general population, with a 28 percent success rate compared to 50 percent to 60 percent success rates among the overall population.[60] Researchers are continuing to investigate the reasons for this difference.

Scientists are optimistic about research into new therapies currently underway to treat HCV. Some experts compare the current state to the late 1980s and 1990s when combinations of

novel antiviral medications were introduced, changing HIV/AIDS from a uniformly fatal disease to a highly treatable chronic illness. Unlike HIV/AIDS, however, which cannot be eradicated but only suppressed, researchers hope that emerging HCV medications will result in significantly higher rates of sustained HCV clearance, that represent true cures and with fewer side effects.

Despite the advances in treatment research, progress has been hampered by limited funds. The investment into research for HBV and HCV is particularly disproportionate to the threat of the diseases – with one percent to two percent of Americans infected with chronic HBV or HCV. Combined, HBV and HCV research receive approximately five percent of the funds devoted to HIV research – $152 million compared to more than $3 billion. Although making per capita assessments is not appropriate for research funding, this level of difference does demonstrate a serious disconnect.

National Institutes of Health (NIH) Hepatitis Research Dollars

	FY 2009	FY 2010	FY 2011
HBV	$51 million	$52 million	$54 million
HCV	$97 million	$100 million	$102 million
HIV	$3,019 million	$3,086 million	$3,184 million

Source: U.S. Department of Health and Human Services.[61]
Note: FY 2009 dollars exclude American Recovery and Reinvestment Act funding.

With more funding, the National Institutes of Health (NIH) could better address some key issues, a number of which were identified during a May 2010 consensus building meeting convened by TFAH and AASLD including:

- Developing a single dose HBV vaccine, which could dramatically improve the chances of reaching universal vaccination;
- Continuing to study combination therapy for HCV, which will be critical for the better use of new treatments and for which there is little private sector incentive;
- Developing a preventive vaccine for hepatitis C;
- Studying racial and ethnic differences in response to hepatitis treatment. For instance, reports that African Americans only have a 28 percent success rate, compared to approximately 50 percent to 60 percent overall, requires a deeper scientific understanding that addresses this question during the research phase, not after a treatment is already in use;[62]
- Developing a rapid polymerase chain reaction (PCR) test for HCV, could identify those with active infections and permit fast referral to care; and
- Developing screening tests that can be performed at the point of care.

In addition, an IOM panel included research to compare the effectiveness of alternative clinical management strategies for HCV (including duration of therapy) for patients based on viral genomic profile and patient risk factors (such as behavior-related risk factors) among their top 100 priorities for comparative effectiveness research. It remains to be seen if this will be adopted as an objective of the new comparative effectiveness research program established with initial funding as part of American Recovery and Reinvestment Act.[63]

In addition, NIH, HRSA, the Agency for Healthcare Research and Quality (AHRQ) and CDC could develop a research agenda to determine the best mechanisms for delivering care, including resolving questions about types of social service supports needed and whether integrating HIV and hepatitis systems of care meet the needs of both affected populations.

Preventing New Cases of HBV and HCV

SECTION 5

Challenge: The United States does not take an integrated approach to reducing risk for related infectious diseases. Even though it is well known that risky sexual behaviors are associated with HIV, hepatitis, and STD transmission, and that injection drug use is often associated with HIV and hepatitis transmission, federal programming continues to take a categorical, stovepiped approach by disease.

Since HBV can be transmitted by an infected mother to her newborn at birth, and both HBV and HCV can be spread through medical care or through unprotected sex, sharing injection drug equipment, living in a household (or sharing nail clippers/razors/toothbrushes) with an infected person, or use of unsterilized needles (including tattoo or piercing needles) – strategies to prevent new cases should focus on limiting exposure to other people's blood and bodily fluids, and for HBV, encouraging individuals to get the available vaccine.[64]

A. ELIMINATING TRANSMISSION OF HBV TO NEWBORNS

Challenge: To set a goal of eliminating mother-to-child transmission in the United States, similar to the effort undertaken to eliminate such transmission of HIV.

An estimated 800 to 1,000 infants are infected each year by HBV from their mothers at birth. If preventive measures are not taken, children born to women with chronic HBV have a greater than 90 percent chance of also developing chronic HBV. In 2004, according to National Center for Health Statistics birth data, approximately 24 percent of all births in the United States were to foreign-born women, who account for a high proportion of HBV-positive pregnancies.[65] USPSTF and CDC have recommended screening all pregnant women for HBV.[66] If a mother is identified as having HBV, steps can be taken to reduce the risk of transmission to the baby through the co-administration of a hepatitis B immunogloblin (HBIG), allowing time for the infant to receive the HBV vaccination to try to build up immunity to the disease.

Currently, however, despite the recommendations by USPSTF and CDC, many pregnant women are not screened for HBV, and even in cases where HBV is identified in the mother, a 2006 CDC study found 33 percent of pregnant women and their babies testing positive did not receive treatment that could help the baby from developing HBV.[67]

- Only 26 states and Washington, DC have HBV prenatal screening mandates. (Alabama, Alaska, Arkansas, California, Colorado, DC, Florida, Hawaii, Illinois, Kansas, Kentucky, Massachusetts, Michigan, Missouri, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Utah and Virginia have screening requirements.)
- Only 26 states and Washington, DC have specific HBV-positive maternal reporting mandates. (Arkansas, California, Connecticut, DC, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont and Washington have reporting requirements.)[68]

In the mid-1990s, the United States undertook an effort to eliminate mother-to-child transmission of HIV. Because most of the mothers with HIV infection giving birth were already on the Medicaid program, federal officials worked with state Medicaid program officials to assure that appropriate prevention protocols were adopted during prenatal visits and during labor and delivery. New HIV cases in U.S. children have steadily declined over the years – from 855 in 1992 to 57 in 2005.[69] The dramatic reduction in cases was associated with increased HIV testing among pregnant women and the use of antiretrovial drugs to prevent mother-to-child transmission. Thus, a targeted effort involving the Medicaid programs might achieve similar results for HBV in a larger portion of the women. According to experts, if the recommended screening and early treatment measures were taken, the transmission of HBV from mothers to their newborns could be virtually eliminated in the United States.

Hepatitis B Prevention Mandates				
State	**Hep B Prenatal Screening Mandate**	**Specific Hep B Positive Maternal Reporting Mandate**	**Perinatal Hep Cooridinator**	**Hep B Childhood Vaccination Mandate**
Alabama	✓		✓	
Alaska	✓		✓	✓
Arizona			✓	✓
Arkansas	✓	✓	✓	✓
California	✓	✓	✓	✓
Colorado	✓		✓	✓
Connecticut		✓	✓	✓
Delaware			✓	✓
DC	✓	✓	✓	✓
Florida	✓	✓	✓	✓
Georgia		✓	✓	✓
Hawaii	✓	✓	✓	✓
Idaho			✓	✓
Illinois	✓	✓	✓	✓
Indiana		✓	✓	✓
Iowa			✓	✓
Kansas	✓	✓	✓	✓
Kentucky	✓	✓	✓	✓
Louisiana		✓	✓	✓
Maine			✓	✓
Maryland			✓	✓
Massachusetts	✓		✓	✓
Michigan	✓		✓	✓
Minnesota		✓	✓	✓
Mississippi			✓	✓
Missouri	✓	✓	✓	✓
Montana	✓	✓	✓	
Nebraska			✓	✓
Nevada	✓	✓	✓	✓
New Hampshire	✓	✓	✓	✓
New Jersey	✓	✓	✓	✓
New Mexico			✓	✓
New York	✓	✓	✓	✓
North Carolina	✓	✓	✓	✓
North Dakota			✓	✓
Ohio			✓	✓
Oklahoma	✓		✓	✓
Oregon	✓		✓	✓
Pennsylvania	✓		✓	✓
Rhode Island		✓	✓	✓
South Carolina		✓	✓	✓
South Dakota			✓	
Tennessee	✓	✓	✓	✓
Texas	✓	✓	✓	✓
Utah	✓	✓	✓	✓
Vermont		✓	✓	✓
Virginia	✓		✓	✓
Washington		✓	✓	✓
West Virginia			✓	✓
Wisconsin			✓	✓
Wyoming			✓	✓
Total	**26 + DC**	**26 + DC**	**50 + DC**	**47 + DC**

Sources: 1) Immunization Action Coalition. "State Information: Hepatitis B Prevention Mandates: Prenatal, Daycare and K-12." http://www.immunize.org/laws/hepb.asp (accessed May 24, 2010). 2) Centers for Disease Control and Prevention. "Maternal Hepatitis B Screening and Reporting Requirements." National Center for Immunizations and Respiratory Diseases http://www2a.cdc.gov/nip/StateVaccApp/statevaccsApp/HepatitisScreenandReport.asp (accessed May 24, 2010). 3) Centers for Disease Control and Prevention. "Perinatal Hepatitis B Coordinator List." http://www.cdc.gov/vaccines/vpd-vac/hepb/perinatal-contacts.htm (accessed May 24, 2010)

B. ELIMINATING HEALTH CARE TRANSMISSION OF HBV AND HCV

Since 1992, measures were taken to improve safety precautions and screen blood donations, which helped reduce the transmission of HCV infections in health care settings. However, experts are concerned that health care transmissions are increasing again due to lapses in infection control practices. In addition, there are also concerns about maintaining high standards of infection control in non-hospital facilities.

Meanwhile, limited surveillance means that data about the rates of health care acquired infections is lacking. At least 100,000 patients have been notified about potential exposure to HBV, HCV and/or HIV while receiving care since 1998.[70] Between 1998 and 2008, CDC identified 33 outbreaks of HBV and HCV in hospital settings, 12 in outpatient clinics, six in hemodialysis centers and 15 in long-term care facilities.

Some examples of health care settings and unsafe practices where transmissions are being identified with some frequency include:

- Syringe reuse and medical vial containment in a diverse array of outpatient clinics (endoscopy, surgical settings, cardiology);
- Improper use and handling of blood glucose monitoring equipment in long-term care settings. The prevention and containment of viral hepatitis in long-term residential care facilities is of growing concern as the number of Americans ages 65 and older will double to more than 70 million by the year 2030; and
- Lapses in cleaning and disinfection of equipment, supplies and hands of health care providers in hemodialysis settings. Reducing the risk of transmission in these settings requires aggressive practice and enforcement of standards of care including vaccination of staff and patients against HBV, segregation of patients with chronic viral hepatitis, careful sterilization of all equipment and machines, and preparing injection medications in a separate room from where dialysis occurs.

C. ELIMINATING NEW INFECTIONS AMONG HIGH-RISK POPULATIONS

Major opportunities for increased prevention include increasing HBV vaccination rates and bolstering prevention campaigns targeting at-risk communities – including through better integration with HIV and STD prevention efforts.

1. Increasing HBV Vaccination Rates

The most effective approach to preventing HBV is a vaccine that has been available in the United States since 1982. Since 1991, an increasing percentage of children born in the United States have been vaccinated for HBV, which has been shown to be an extremely safe vaccination.[71] Now, more than 90 percent of infants receive the hepatitis B vaccine. Most infants receive the first of three needed vaccination shots within three days of birth, though there is significant state-by-state variability in the number of children who receive their first shot within three days of birth – in 2008, the rates ranged from a high of 81.4 percent in Arizona to a low of 19.1 percent in Vermont. Experts recommend that all infants should be given their first vaccination before they are discharged from the birthing hospital, ideally within 12 hours of birth.

While the vaccine has contributed to an 81 percent drop in the HBV infection rate, at least 43,000 individuals are still infected by HBV each year, although experts believe this is a low estimate due to limited surveillance.[72]

To further reduce cases of HBV, CDC recommends all infants and children get vaccinated against HBV as well as any other persons seeking protection from HBV infection. In addition, CDC recommends hepatitis B vaccination for health care professionals and public safety workers, sexually active teens and adults (who have had more than one sex partner within the past six months), persons with chronic liver disease, gay and bisexual men, persons being evaluated for a sexually transmitted disease, persons with HIV infection, sex partners of people living with an infected person, injection-drug users, travelers to countries with high rates of HBV, patients with kidney disease or undergoing dialysis, persons with HIV, persons with HCV and residents and staff of correctional facilities and facilities for developmentally disabled persons. While more than 90 percent of U.S.-born children have been vaccinated for HBV, HBV infections could be reduced if more of the remaining children were vaccinated and if more adults who came of age before the vaccine became widely available were vaccinated.[73] Some barriers to increasing vaccine rates involve misperceptions about the safety of vaccines and lack of knowledge about the availability of the vaccine for sexually active adults.

The HBV vaccination gap could be decreased with 1) additional funding from CDC to support the efforts of state and local health departments to vaccinate individuals for HBV and 2) an increase in public education campaigns to educate parents, at-risk individuals and health care providers about the importance of the vaccine for the health and the safety of individuals at risk. Policies requiring proof of vaccinations for elementary school admittance have also proven to be an effective way to increase immunization rates. Under health reform, hepatitis B vaccinations will be covered without cost sharing, which should remove one barrier to reach a universal vaccination goal.

Estimated Vaccination Coverage for Hepatitis B Vaccine Among Children* from Birth to 3 Days of Age by State (National Immunization Survey, 2008)

[This data represents the first of three shots that children need.]

State	1 or more HepB dose w/in 3 days of birth (Percent and 95% confidence interval)	Rank
Alabama	66.5 (+/- 5.8)	19
Alaska	64.6 (+/- 6.9)	24
Arizona	81.4 (+/- 4.9)	1
Arkansas	73.8 (+/- 6.6)	5
California	36.3 (+/- 5.0)	45
Colorado	48.7 (+/- 8.9)	39
Connecticut	63.2 (+/- 7.2)	28
Delaware	58.6 (+/- 7.2)	33
DC	61.7 (+/- 7.1)	31
Florida	40.7 (+/- 6.7)	43
Georgia	65.8 (+/- 7.0)	21
Hawaii	68.3 (+/- 7.2)	11
Idaho	64.0 (+/- 6.6)	26
Illinois	56.4 (+/- 5.1)	34
Indiana	64.5 (+/- 7.3)	25
Iowa	31.4 (+/- 6.1)	48
Kansas	68.1 (+/- 6.7)	12
Kentucky	74.4 (+/- 6.2)	4
Louisiana	62.3 (+/- 6.2)	30
Maine	66.8 (+/- 6.1)	16
Maryland	67.8 (+/- 5.7)	13
Massachusetts	66.8 (+/- 7.3)	16
Michigan	75.7 (+/- 6.2)	3
Minnesota	21.7 (+/- 5.5)	50
Mississippi	67.3 (+/- 5.9)	14
Missouri	56.2 (+/- 6.6)	35
Montana	66.4 (+/- 6.6)	20
Nebraska	31.0 (+/- 6.0)	49
Nevada	65.5 (+/- 6.6)	22
New Hampshire	69.0 (+/- 6.0)	10
New Jersey	44.9 (+/- 7.1)	40
New Mexico	52.3 (+/- 7.6)	38
New York	34.4 (+/- 4.8)	47
North Carolina	72.2 (+/- 6.3)	7
North Dakota	72.0 (+/- 5.9)	8
Ohio	64.7 (+/- 7.0)	23
Oklahoma	61.4 (+/- 6.8)	32
Oregon	41.8 (+/- 7.7)	42
Pennsylvania	67.0 (+/- 5.5)	15
Rhode Island	69.4 (+/- 7.1)	9
South Carolina	62.8 (+/- 6.8)	29
South Dakota	40.5 (+/- 6.6)	44
Tennessee	35.8 (+/- 6.4)	46
Texas	66.6 (+/- 5.5)	18
Utah	78.6 (+/- 6.7)	2
Vermont	19.1 (+/- 6.3)	51
Virginia	42.2 (+/- 8.7)	41
Washington	72.6 (+/- 5.3)	6
West Virginia	55.3 (+/- 7.2)	37
Wisconsin	55.8 (+/- 7.6)	36
Wyoming	63.5 (+/- 6.4)	27
United States	**55.3 (+/- 1.3)**	**N/A**

Centers for Disease Control and Prevention. "Estimated Vaccination Coverage for Hepatitis B Vaccine Among Children from Birth to 3 Days of Age by State and Immunization Action Plan Area National Immunization Survey, 2008." http://www.cdc.gov/hepatitis/Partners/PeriHepB-Coord.htm (accessed May 24, 2010). * Information from children born between January 2005 and June 2007.

THE ADULT HEPATITIS VACCINE PROJECT -- CALIFORNIA, 2007-2008[74]

HBV vaccination rates for high-risk adults traditionally have been low. In 2006, ACIP recommended that HBV vaccination be offered to all adults as part of routine prevention services in settings where a high proportion of those served are at increased risk. CDC provided approximately $20 million to encourage states to purchase adult HBV vaccine.

In response, the California Department of Public Health established the Adult Hepatitis Vaccine Project to expand HBV vaccination in sites serving at-risk adults.[75] Between 2007 and 2008, 28,824 doses of HBV vaccine were administered at 29 participating sites during the first 19 months of the campaign; 13 sites administered HBV vaccine for the first time. Because the federal government was able to provide vaccine, many adults were vaccinated who otherwise might not have received it.

The California sites included 11 STD clinics, four correctional facilities, four community health centers, four substance abuse treatment programs, four syringe exchange programs and two HIV counseling, testing and treatment sites.

At the national level, between June 2007 and December 2008, the CDC initiative, in collaboration with 51 state and local vaccination programs and viral hepatitis prevention coordinators, administered 275,445 doses of HBV vaccine in 1,065 sites. Most were administered by local health departments (37 percent) and STD clinics (30 percent), followed by correctional facilities (22 percent). California administered 10.5 percent of the national doses available through the CDC initiative, a majority of which were administered in local STD clinics. California administered the second largest number of HBV vaccine doses in STD clinics of any state.

In 2008 and 2009, CDC distributed an additional $16 million each year to states and localities to buy adult HBV vaccine. The IOM report estimates that approximately $80 million would be needed to vaccinate just 75 percent of adults in STD/HIV and drug treatment centers alone.

In August 2010 CDC Immunization Services Division terminated this initiative and will not be providing funding to continue the adult hepatitis B vaccination initiative.

2. Bolstering Prevention Campaigns Targeting At-Risk Groups

New cases of hepatitis B and C could also be further reduced by strategically targeting programs and efforts around groups at the greatest risk for spreading the diseases. This is challenging since many individuals at high risk do not even know they are at risk.

Non-vaccinated individuals who are at the greatest risk for HBV include:

- Sexually active adults who have been with more than one partner in their lifetime and came of age before the vaccine was widely available in 1986;
- People who are exposed to HBV through relatives or friends who were born abroad and who are more likely to carry the disease than Americans. Estimates are that every year 40,000 to 45,000 people enter the United States legally from HBV-endemic countries. Currently, these people do not undergo mandatory screening for HBV unlike HIV;[76]
- People who live with children adopted internationally, especially if they come from areas where the disease is endemic, such as East or Southeast Asia and Eastern Europe;
- Health care workers and emergency response personnel, who can become exposed through blood or bodily fluids of patients;
- Injection drug users who share needles and other drug using equipment; and
- Institutionalized individuals.

There is no vaccine available for HCV, so other prevention efforts are essential to help reduce the spread of the disease. While rates have significantly decreased since the 1980s due to increased knowledge about safe sex practices, changes in safety in medical practices (such as screening blood transfusions) and practices to decrease the use of sharing needles, there are still at least an estimated 17,000 new cases of HCV each year, although experts believe this estimate is extremely low due to limited surveillance.[77]

Individuals at the greatest risk for HCV include:

- Injection drug users who share needles and other drug using equipment;
- Health care workers and emergency response personnel, who can become exposed through blood or bodily fluids of patients;

- People who have been pierced, tattooed, or received acupuncture in facilities that do not take careful measures not to reuse needles;
- Patients who receive health care in facilities where adherence to infection control practices is inadequate;
- People who received medical care in countries where they do not regularly screen blood or take measures to protect against HCV transmission;
- Sexually active adults who have been with more than one partner in their lifetime, although this is a less common way for HCV to be spread; and
- Institutionalized individuals.

Targeted public education campaigns, as well as enhanced efforts to educate medical providers that their patients are at risk, could help reduce the spread of HBV and HCV.

Campaigns to encourage safe sex and warn about the dangers of injection drug use are major strategies to fight HBV and HCV. However, it is also important to develop strategies and public education initiatives designed to reach other at-risk groups, including ones for communities where exposure rates are high, such as among Asian and Pacific Islander Americans; patients who receive care in facilities where adherence to infection control practices is inadequate; medical providers who may be at risk through exposure to patients; and for individuals who may be at risk through other activities, such as tattoos and piercings.

- **Opportunities for integrating HBV and HCV prevention strategies with HIV and other STDs:** Practices to prevent and limit the spread of HBV and HCV are consistent with those used to prevent HIV and other STDs. Currently, the United States does not have an integrated approach to reducing risk for HIV, hepatitis and STDs for those with overlapping risk behaviors, including unprotected sexual activity and needle sharing.

  - ▲ **Curbing Transmission through Drug Use –** Expanding Access to Drug Treatment, Syringe Exchange Programs and Education about the Dangers of Sharing Contaminated Drug Use Equipment: Sharing dirty needles and other injection drug use equipment is a major source of new infections of HCV in the United States; injection drug users are also at increased risk of contracting HBV and HIV.

    Injection drug users often end up sharing needles when clean ones are not available – nearly 32 percent of injecting-drug users report sharing needles.[78] Shared use of other drug injection equipment has also been implicated in the transmission of HCV.[79] Individuals are particularly vulnerable during the first few years of drug use, when HCV infection rates can exceed 40 percent.[80]

    Public health officials have designed syringe exchange programs (SEPs), where drug users can exchange used needles for clean ones so the diseases are not passed on from one drug user to another to help control the spread of these diseases. Prominent scientific and public health organizations and leaders, including the IOM and officials from NIH and CDC have endorsed the effectiveness of these programs. Hundreds of scientific studies have been conducted that have found syring exchange programs can help to reduce hepatitis and HIV transmission and do not promote illegal drug use.[81,82] There is also evidence that syringe exchange programs do not increase unsafe disposal of unused syringes among participants in these programs. Syringe exchange programs are often effective ways to find hard-to-reach drug users to connect them with a wide range of important health and social services, including substance abuse treatment and on-site testing for HIV, HBV and HCV.

    In December 2009, Congress lifted a longstanding ban on the use of federal funds for syringe exchange programs. In July 2010, HHS released interim guidance for the use of federal funds for syringe exchange programs. State and local health departments now have the option of using federal funds to create and/or expand syringe exchange programs in their communities.

    Many injection drug users do not have regular access to health care, making them hard to reach through standard care. Other ways to reach these individuals can be utilized, such as through drug treatment programs and health clinics.

  - ▲ **Safe Sex Education:** There are a lot of social stigmas around addressing sexual behavior in the United States, including worries about unintentionally encouraging teens' interest in sex. However, education about the dangers of unprotected sex and how diseases can be spread through sex are essential for prevention of a range of STDs, including HIV and HBV. For HBV, in particular, adults who came of age before 1982 are actually the most likely to contract the disease through sexual relations, since a vast majority of children and teens have received the vaccination, so adult education about safe sex practices is essential.

RISE OF HCV IN YOUNG INJECTION DRUG USERS

> "Hepatitis C is a largely unrecognized public health crisis. We are seeing a reemergence of the disease in young adults and injection drug users. Because of inadequate prevention and surveillance funding, there is only so much we can do."[83]
>
> -- Daniel Church, Epidemiologist/Viral Hepatitis Coordinator, Massachusetts Department of Public Health

New York State Department of Health (NYSDOH): In 2007, using targeted enhanced surveillance, NYSDOH staff noticed a high number of newly identified HCV infections among individuals under the age of 30, all of whom resided in the same postal code in suburban Buffalo, New York. The median age of these individuals was 19 (17-29 years), all of the new cases identified as White, and 75 percent were male. Over half of these young people reported injecting heroin and sharing drug equipment. While a relatively small number of youth were identified in total, there is no way of knowing how many additional young people may have become infected through the broader social network of youths and injection drug users in the greater Buffalo area.[84]

Massachusetts Department of Public Health (MDPH): In 2005, the state of Massachusetts began noticing an increasing proportion of young people being admitted to drug treatment programs and a rising proportion of young persons reporting injection drug use. After further investigation, using statewide disease surveillance data, the MDPH confirmed that since 2007 there have been more than 1,000 probable and confirmed new cases of HCV infection reported annually in persons under the age of 25, statewide. This is 13 percent of the total number of new cases in the state each year. Unlike with older cohorts both in Massachusetts and nationwide, which are overwhelmingly male, there are an approximate equal number of male and female youth being reported.[85]

Policy Recommendations

SECTION 6

> "Viral hepatitis is a silent but deadly threat to public health. The danger for the American people is compounded by widespread ignorance about it amongst health care providers especially those involved in primary care. The TFAH report builds on the IOM report by providing specific recommendations to increase awareness, establish widespread screening surveillance and primary preventive strategies. Importantly, it provides specific mechanisms to increase access to care for afflicted individuals. If implemented, these will go a long way to reduce the burden of chronic liver disease and liver cancer."[86]
>
> -- Arun J. Sanyal, MD, President of AASLD and Professor of Medicine and Chairman, Division of Gastroenterology, Virginia Commonwealth University Medical Center

Health reform combined with new scientific advances offers the chance to dramatically improve hepatitis prevention, control and treatment in the United States. The following are recommendations for actions to take advantage of this opportunity – to prevent new infections, to identify and provide earlier treatment to people who do not know they have the disease and to treat people in the most effective ways possible. If we invest in prevention and early treatment now, we could avoid new infections and spare millions of individuals the pain and financial burden of untreated liver disease – or we could delay the investment, and incur far greater costs and cause avoidable disease, disability and suffering for millions of Americans and their families.

The following recommendations offer a comprehensive policy response to the problem and continuous threat of viral hepatitis. Together, these recommendations can address three related public health goals: (1) assuring that our public health and health care delivery systems are ready for the new, more effective treatments for hepatitis that are on the horizon – to ensure that all individuals in the United States with viral hepatitis can benefit from improved health outcomes; (2) assuring that the current racial and ethnic disparities associated with hepatitis are addressed; and (3) reducing the financial impact of hepatitis on our health care delivery system, much of which will be borne by Medicare and Medicaid.

Some of the recommendations could be achieved through immediate policy changes, some would require modest levels of new resources and some would require a longer term significant investment. Some of the funding for these initiatives could come from the Prevention and Public Health Fund created by the Affordable Care Act.

A. SURVEILLANCE

Challenge: The United States lacks a comprehensive surveillance system for viral hepatitis, resulting in a partial understanding of the scope of the problem and, therefore, diminishing the capacity to target prevention activities and plan for treatment service needs. It is important to have a clear and accurate understanding of both the prevalence of hepatitis in the United States as well as incidence levels -- with the ability to rapidly identify new outbreaks of viral hepatitis that can lead to successful targeted interventions.

Viral hepatitis surveillance should build on the existing, more robust HIV and other infectious disease surveillance systems, creating an integrated infrastructure for surveillance. Appropriate adaptation of infectious disease surveillance systems in an era of electronic health records may free up resources to create this integrated capacity.

- Given limited resources and the availability of already developed surveillance systems for HIV, STDs or other infectious diseases, it is appropriate – both programmatically and fiscally – to integrate viral hepatitis surveillance where most appropriate. It is consistent with the policy decision to include viral hepatitis as part of the NCHHSTP and also in keeping with the Center's 2010-2015 strategic plan.
- CDC should work with HHS's Office of the National Coordinator for Health Information Technology (ONC) to assure that relevant hepatitis data are part of the developing HIT infrastructure, including infectious disease reporting and health care acquired infection reporting. This has the potential to dramatically increase data available while reducing the burden on surveillance programs in state and local health departments. Training for state surveillance officials will be needed to take advantage of the new data available through HIT.

CDC must create the capacity to better identify the number of new cases of hepatitis. Current approaches are more informative of the cumulative burden of hepatitis, without giving public health officials timely accessible data on new acute cases of hepatitis.

- CDC should support viral hepatitis specific cooperative agreements with all state and territorial health departments.
- CDC should explore expanding the network of sentinel reporting sites across the country that can become the early warning system for new outbreaks of hepatitis, especially HCV. These sentinel sites would collect the information needed to monitor the on-going transmission of hepatitis and assess the impact of primary prevention approaches.

Congress should appropriate additional funding for public health agencies to support their surveillance and related hepatitis prevention work.

- State and local health departments have faced serious cutbacks in their funding for core public health programs. CDC's hepatitis surveillance grants are currently insufficient to assure the comprehensive approach needed.
- CDC's surveillance programs (or other population-level studies that help determine hepatitis prevalence) need to be robust enough to determined prevalence levels among key high-risk populations such as Asian and Pacific Islander Americans.

B. SCREENING AND TESTING FOR HBV AND HCV

Challenge: All who are at risk should be screened and tested so they know their status. In the case of HBV, those who are not infected should be vaccinated. If infected, individuals can be referred for immediate treatment, counseled about reducing the risk of transmission and how to manage the disease and educated about the progression of the disease.

HBV and HCV screening and HBV vaccination should be the standard of care in the reformed health care system.

- The HHS Secretary should move toward routine screening in the Medicare population under the Secretary's authority to define preventive benefits for Medicare beneficiaries. Given the high prevalence of HCV among aging "boomers," (46 – 64 years of age) this is a critically important population to target for testing and treatment as they age into Medicare. Hepatitis screening could be part of every initial Medicare health care encounter. This intervention could ultimately be a cost saving to the Medicare system if more serious liver disease is avoided.
- CDC should work with the USPSTF to assess the value of routine HBV and/or HCV screening. If supported by the USPSTF, screening would become a mandated benefit with no copayments under new health plans.

- While the USPSTF considers a screening recommendation, the HHS Secretary should exercise her authority under the new law to consider HBV and HCV screening an "essential health benefit." This will require coverage by public and new small and individual private plans with limited cost sharing.
- Medicaid should take all necessary steps to assure that routine screening is covered and encouraged. For children, this should be an Early and Periodic Screening, Diagnosis, and Treatment Program (EPSDT) benefit.
- HRSA should make routine screening a mandated protocol for community health centers.
- HRSA should mandate that all community health centers' patients have a record of HBV vaccination.
- CDC should undertake a policy initiative and national campaign to assure that all states require proof of hepatitis B vaccination for all students entering elementary schools.
- As CDC moves toward an integrated approach to supporting HIV, STD, TB and viral hepatitis funding for all states, sufficient funds should be made available to assure that each state has an individual with responsibilities for viral hepatitis coordination and perinatal hepatitis coordination. All states should have a comprehensive viral hepatitis plan in place by 2014, with sufficient federal funding to support its implementation.

Since not all individuals at risk for hepatitis are part of the health care system (even if they will be eligible for coverage with the implementation of health reform), alternative methods for reaching those at risk will be needed. The federal government should assure (through policy and funding) that screening for hepatitis occurs within programs more likely to encounter those with hepatitis. CMS should direct states to coordinate services within above listed programs to determine Medicaid (and other insurance) eligibility of clients and give enrollment guidance on-site. CDC should work with non-governmental organizations that work with immigrant populations to assure that all immigrants arriving from countries where the prevalence of HBV is greater than two percent are routinely and appropriately screened upon entry to the United States, as recommended by CDC and an NIH 2008 consensus conference on HBV.[87]

Other care settings include:

- HIV, STD and TB clinics;
- Substance abuse and mental health programs;
- Syringe exchange and other harm reduction programs;
- Federal, state and adult and juvenile correctional facilities; and
- Family planning clinics.

Programs and policies will be needed to help individuals overcome their reluctance and limited understanding of the need to be screened, either because they do not perceive themselves to be at risk or because of the stigma associated with the hepatitis infection. These approaches must be carefully and creatively designed to reflect cultural and linguistic competencies and be implemented in places where high-risk populations reside. Public education campaigns will be needed to raise awareness about HBV and HCV in ways that reduce the stigma associated with the diseases and inform people about their need to be screened and ways to avoid infection.

- A special focus on hepatitis should be part of the outreach and national education program for consumers regarding preventive services benefits authorized under health reform. This should include the value of screening and the potential of new treatments to eradicate infection. Such outreach efforts could include the spectrum of technological devices, social networking sites, public service announcements (PSAs) and celebrities to champion the cause. At the same time, these efforts can be combined with existing health promotion work already underway with CDC.
- CDC should consider a social marketing campaign that promotes HBV vaccination, testing for hepatitis and addresses the stigma and knowledge gaps associated with hepatitis. Such a program could include other infectious diseases and could be funded through the Prevention and Public Health Fund created under health reform.

C. PRIMARY PREVENTION OF HEPATITIS

Challenge: The United States does not take an integrated approach to reducing risk for related infectious diseases. Even though it is well known that risky sexual behaviors are associated with HIV, hepatitis, and STD transmission, and that injection drug use is often associated with HIV and hepatitis transmission, federal programming continues to take a categorical, stovepiped approach by disease.

CDC should require an integrated approach to HIV, hepatitis and STD prevention for those with overlapping risk behaviors. This would lead to more efficient and effective use of scarce federal resources.

- Prevention programs that address hepatitis must be cognizant of the fact that a large number of individuals with hepatitis do not know their status. Therefore, prevention must focus on changing risky behaviors of all people, not just the individuals already identified as infected with hepatitis.
- New funding for prevention across the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention should emphasize the Program Collaboration and Service Integration (PCSI) initiative, which is designed to break down the stovepipes among prevention efforts targeting those with overlapping risk.
- States and localities should be encouraged to use their prevention funds for syringe exchange programs as a proven structural intervention to reduce transmission of HIV and hepatitis.
- Substance abuse prevention and treatment should be seen as part of hepatitis prevention.

CDC should support state and local health department efforts to vaccinate individuals for HBV to close gaps in vaccination coverage.

- This should include a targeted effort among the incarcerated, people in drug treatment programs and immigrants, who are at highest risk, and to fill any gaps in vaccination coverage among individuals who may not have been vaccinated as infants before the vaccine became available in 1982.
- The ONC, as part of the meaningful use HIT regulations, should mandate that hepatitis B vaccination information be part of each medical record, with clinical reminders for all individuals at risk who have not been vaccinated and for follow-up doses. Hepatitis B vaccination is now recommended by ACIP for all individuals seen in settings that care for individuals at increased risk of HBV infection, all children and adolescents, and can be given to any individual who wishes to be protected.

CDC, in developing the community transformation grants authorized in health reform, should assure grantees can develop interventions that address the policy and structural factors related to hepatitis transmission.

D. PREVENTION OF HEPATITIS TRANSMISSION DURING HEALTH CARE

CDC, CMS, FDA, and AHRQ should develop policies to assure that health care associated hepatitis infections are treated as a "never" event in infection control and reimbursement policy.

- Federal, state, and local governments and the health care community should work to increase education requirements and certification requirements for health care providers based on CDC's recommendations for infection control.
- There should be increased oversight in non-hospital health care settings to ensure adherence to CDC's evidence based recommended infection control guidelines.
- Capacity should be strengthened in state health departments to identify and respond to outbreaks in health care settings.
- Systems should be developed and implemented for gathering data on adherence to CDC's recommendations for infection control and performance on preventing infection.
- Advances in engineering and technology should be supported to prevent reuse of syringes and other injection equipment.

E. REFERRAL SYSTEMS TO CARE

Challenge: When testing occurs in a non-clinical setting or in a health setting that does not provide hepatitis treatment, a referral system is needed to identify providers who are equipped to do a full diagnostic examination and help the individual make treatment decisions. The referral system must assure that both appropriate referral and follow-up appointments are made and kept.

Patients, service providers, and primary care providers should have ready access to databases of qualified providers of hepatitis care.

- Where public health agencies support screening for hepatitis, they should be required and funded to create databases of clinics or providers (including information on what insurance plans they accept).
- Health plans should be required and funded to have web-based access to specialists or appropriate providers as part of demonstrating "network sufficiency" to participate in Health Exchanges created by the new health reform law.
- For all patients who are reported to state health departments as having tested positive for HBV or HCV, public health agencies should be required to do telephone, electronic, or other means of communication to follow-up with patients to confirm that they have been connected to care. Significant increases in funding for state hepatitis programs would be required.
  - ▲ Alternative: Private plans can be required to provide case management that assures follow-up after a positive test result. Also, individuals screened at public sites or without insurance can receive case management support from a public health agency program. This could be part of a larger case management program for those in treatment.
- Professional education about viral hepatitis should be increased for health care providers.

F. TREATMENT PROVISION

Challenge: To assure that all individuals diagnosed with hepatitis receive the standard of care and that there are a sufficient number of quality health professionals who can provide the standard of care.

HHS should create a public-private partnership that articulates and revises treatment guidelines on a regular basis, similar to the HHS panel on HIV antiretroviral treatment.

- As new treatments come on line, and as more is known about their efficacy, treatment protocols are likely to change and become more complex (and more individualized). This is very similar to the HIV experience. Having a federal agency define the range of options is critical to assuring appropriate treatment.

The newly created Health Exchanges and Medicaid programs should define a minimum standard regarding quantity and expertise of allied health professionals available to treat people with hepatitis.

- To define this standard, HHS should convene a panel of consumers, hepatitis specialists, public health officials, researchers and representatives of the insurance industry to define the range of people who should be eligible to meet the network sufficiency requirement, including what level of specialty is needed for routine treatment and more complex cases and the role that mid-level professionals can play in hepatitis care.

A safety net system of care delivery will be needed for those with hepatitis who do not have a regular source of care (including those who remain uninsured after reform).

- If the IOM recommendation to make Community Health Centers the safety net provider for hepatitis is adopted, additional resources will need to be provided by HRSA to create the capacity within the health center system, including training of personnel.
  - ▲ Alternative: Provide support for currently funded Part C programs under the Ryan White program to provide care for people with hepatitis, regardless of their HIV infection status.

Public health agencies should play a "quality assurance" role through monitoring and assisting in medical management of hepatitis treatment.

- As we enter a new treatment era, it will be critical to assure that funds are available to state/local viral hepatitis programs so they can monitor treatment in the community and provide assistance and care coordination to providers as needed.

G. PAYMENT FOR TREATMENT

Challenge: To assure that all who need care receive it regardless of ability to pay.

All public plans should assure coverage of treatment guidelines for their beneficiaries without copayments.

HHS should assure that all plans participating in the Pre-existing Condition Insurance Program will provide coverage for the protocols in the treatment guidelines, with no more than standard out-of-pocket costs. HHS should further assure that those eligible for other programs (e.g., Ryan White) can use resources from those programs to meet coinsurance requirements.

HHS should assure that following the treatment guidelines is considered an essential health benefit in all plans subject to the Patient Protection and Affordable Care Act.

Congress should expand and adequately fund the Ryan White program (in particular the AIDS Drug Assistance Program) to pay for treatment costs incurred by following the HHS hepatitis guidelines for those with hepatitis who are not co-infected with HIV.

- If community health centers or other safety net providers are offering care services to those who remain uninsured (or underinsured), they can only be effective if there is a third party able to pay for medications.

H. KEEPING PEOPLE IN CARE: SUPPORT SERVICES

Challenge: To provide support services to the individual patient to help him/her stay in treatment until treatment is completed (or stay in treatment/monitoring if treatment fails).

HHS should assure that public plans cover care coordination services for people with HBV or HCV.

HHS should require that some level of care coordination be provided by private plans.

HHS should create an integrated system of care coordination as a separate categorical program to assure case management for individuals from point of diagnosis through maintenance in treatment for however long treatment or post-treatment care is necessary. This would include providing support services that will assist people to stay in care.

- This system could be an expansion of the Ryan White program or a separate program.
  - Discussion will be needed regarding the pros and cons of: (1) creating hepatitis-specific eligibility; and (2) integration with HIV.

I. RESEARCH NEEDS

Challenge: Key biomedical, behavioral and other health services research questions impede our ability to better prevent and treat various forms of hepatitis. While this is not a comprehensive set of research recommendations, during a TFAH/AASLD consultation meeting held in May 2010, several issues arose that suggest the need for particularly focused research studies, as well as increased investment and better coordination of research efforts. Many of the comprehensive issues associated with hepatitis and biomedical and behavioral research are contained in the NIH Action Plan on Liver Disease.

The United States should invest in hepatitis research at NIH, CDC and AHRQ that is more proportionate to the public health threat associated with hepatitis. Given that biomedical and behavioral research issues associated with hepatitis cross many NIH institutes, centers and divisions, a central coordinating mechanism is needed within NIH. In addition, HHS should assure strategic coordination of the plan.

- NIH spending on hepatitis is just over $150 million a year; this is about five percent of spending on HIV/AIDS, even though the number of individuals in the United States infected with hepatitis is four to five times that of HIV. While it is not appropriate to make per capita assessments regarding research funding, the disconnect in this instance is rather stark.
- With more funding, NIH could better address some key issues raised at the TFAH/AASLD consultation meeting, including:
  - Developing a single dose HBV vaccine, would dramatically improve the chances of achieving universal HBV vaccination.
  - Developing a preventive vaccine against HCV, indicated as a need in the IOM report.

- Continuing to study combination therapy for HCV, which will be critical to better use of new treatments and for which there is little private sector incentive.

- FDA, as a condition of approval of new therapies for HCV, should require manufacturers to participate in Phase IV combination trials.

- Studying racial and ethnic differences in response to hepatitis treatment. For instance, reports that African Americans respond at lower rates to current treatments requires a deeper scientific understanding of this difference and assurance that research for new treatments addresses this question during the research phase, not after a treatment enters the community.

- Developing a rapid polymerase chain reaction (PCR) test for HCV, could identify those with active infection and assure appropriate referral to care. Point-of-care testing for HBV and HCV would also be extremely useful (e.g. at STD clinics).

AHRQ should invest in comparative effectiveness research for hepatitis, in accordance with the IOM recommendation.

- An IOM panel convened to identify the top 100 priorities for comparative effectiveness research, which included calling for comparing the effectiveness of alternative clinical management strategies for HCV (including alternative duration of therapy) for patients based on viral genomic profile and patient risk factors (e.g., behavior-related risk factors).[88]

Conduct public health and health systems research to better understand the service needs of people with hepatitis and the best systems of delivering those services.

- NIH, HRSA, AHRQ, in collaboration with CDC should develop an appropriate research agenda that can better determine the best mechanisms for delivering care (e.g., resolving questions regarding the kind of social service support needed for hepatitis care; whether integrating HIV and hepatitis systems of care would meet the needs of both affected populations; what the most effective methods of HCV prevention for injection drug users are; determining the level of experience or specialty needed to provide hepatitis care).

J. SPECIAL POLICY INITIATIVE: ELIMINATING PERINATAL TRANSMISSION OF HBV

Challenge: To set a goal in the United States of eliminating perinatal transmission of HBV. The model for this initiative is the very successful effort to virtually eliminate perinatal transmission of HIV. Given that a very substantial portion of pregnant women with HBV are likely to be covered by Medicaid, this is something the federal government can undertake as an initiative in cooperation with the states.

CMS should undertake a major education campaign among Medicaid providers to assure timely screening and diagnosis for HBV among pregnant women and appropriate health interventions with the mother and infant and provide financial incentives to follow treatment protocols that will reduce perinatal transmission.

- Medicaid should make every effort to ensure that all children are vaccinated at birth and that all infants born to mothers known to have chronic HBV also receive the HBIG (immunoglobulin) at birth.

- CMS should establish screening of pregnant women for hepatitis as a quality measure under its new HIT regulations. The proposed regulations call for screening pregnant women for HIV, but not for hepatitis, chlamydia, syphilis or gonorrhea.

- Enhanced reimbursement should be given to providers or plans that successfully reduce HBV transmission.

- Medicaid should provide funding to state/local health departments and other maternal and child health programs to assure outreach and care coordination for women at-risk and their household contacts.

- Case management services should begin with identification of the mother having HBV and continue until it is assured that the infant has a full series of immunological testing and immunizations, and the mother has been offered and linked to ongoing care.

- Medicaid benefits for mothers should be extended for the duration of her hepatitis treatment, if this is longer than the standard post-partum period.

- CDC and CMS should undertake a policy initiative and national campaign to require hospitals receiving federal funds to have preprinted orders in place to adhere to CDC guidelines regarding screenings, vaccines, and treatment. They should also require discharge planning.
- HRSA should also include appropriate preventive protocols for HBV as part of Bright Futures, to assure appropriate coverage in private plans.

To assure appropriate and timely intervention to prevent perinatal transmission of HBV, pregnancy status should be part of any laboratory-based reporting of hepatitis tests.

- Currently, a mechanism does not exist for public health officials to immediately identify whether positive hepatitis tests reported to them are from pregnant women. This requires very time-consuming follow-up that could be eliminated with a change in reporting requirements.
- CMS should work with the American College of Pathologists to direct all Clinical Laboratory Improvement Amendment (CLIA)-certified laboratories to require pregnancy status on all HBV test requisitions. All pregnant women should be screened for HBV.
- All states should require routine HBV, HIV and syphilis screening of pregnant women. State health department follow-up of pregnant women with positive results is of high priority. Pregnancy status and other patient-specific data would alert clinical and public health professionals of the need for immediate investigation, and allow appropriate prioritization when resources are scarce.

HRSA's Maternal and Child Health Bureau should assure that all prenatal care programs encourage HBV and HCV screening and preventive intervention.

APPENDIX A: TYPES OF VIRAL HEPATITIS

	Hepatitis A	Hepatitis B	Hepatitis C	Hepatitis D	Hepatitis E
Type of Disease	Acute, lasting from a few weeks to several months. Does not lead to chronic infection.	Varies in severity from a mild illness that is acute and lasts for a few weeks to a chronic disease that is serious and long-lasting, leading to liver disease or liver cancer.	Can result in an acute illness, but typically results in a chronic infection that can lead to cirrhosis of the liver and liver cancer.	Serious disease that relies on the Hepatitis B virus to replicate. Uncommon in the United States.	Typically results in an acute infection. Does not lead to chronic illness. Rare in the United States but common in many international countries.
Populations At Risk	Travelers to international countries; those living or working in areas during outbreaks; men who have sex with men; use of illegal drugs (injected or otherwise); persons who reside with someone infected with hepatitis A; individuals who have anal sexual contact with someone who has hepatitis A; and those who have a clotting-factor disorder such as hemophilia.	People who live with or have sexual contact with an infected person; men who have sex with men; individuals with multiple sex partners; injection drug users; immigrants and children of immigrants from areas with high rates of hepatitis B; infants born to infected mothers; health care workers; hemodialysis patients; individuals who received blood transfusions or blood products before 1987 when more effective screening tests were developed; international travelers to areas where the virus is endemic; and those who received clotting factors produced before 1987, when manufacturing methods for these products were improved.	Injection drug users; individuals who received blood or blood products before July 1992 when sensitive tests for hepatitis C were introduced; people who live with or have sexual contact with an infected person; individuals with multiple sex partners; immigrants from areas with high rates of hepatitis C; infants born to infected mothers; hemodialysis patients; and those who received clotting factors produced before 1987, when manufacturing for these products were improved.	Individuals who are infected with the Hepatitis B virus.	Individuals living in countries with poor sanitation and contaminated water.
Transmission	Ingestion of fecal matter -- even in microscopic amounts -- from contact with objects, food, or drinks contaminated by the feces of an infected person.	Contact with infectious blood, semen, and other body fluids from having sex with an infected person; sharing contaminated needles used to inject drugs; through birth from an infected mother to her newborn.	Contact with infectious blood, primarily through sharing contaminated equipment used to inject drugs.	Similar to the spread of Hepatitis B, requiring contact with infectious blood.	Like Hepatitis A, spread through the ingestion of fecal matter, even in microscopic amounts; and a contaminated water supply (in countries with poor sanitation)
Vaccine-Preventable	Yes	Yes	No	No -- although vaccination against HBV will prevent HDV infection	No

APPENDIX B: LIVER CANCER CASES BY SEX, RACE/ETHNICITY (2001-2006)

Liver Cancer Average Annual Cases by Sex, Race/Ethnicity, and Age Group 2001-2006						
	Both Sexes		Male		Female	
	Ave Annual Cases	Ave Rate of Cases*	Ave Annual Cases	Ave Rate of Cases*	Ave Annual Cases	Ave Rate of Cases*
Overall	8,099	3.0	6,162	5.0	1,938	1.3
Race						
White	6,032	2.6	4,598	4.4	1,434	1.1
Black	1,136	4.2	872	7.4	265	1.8
American Indian/Alaska Native	58	3.2	40	4.6	17	2.0
Asian/Pacific Islander	804	7.8	597	12.6	207	3.9
Ethnicity						
Non-Hispanic	6,946	2.8	5,304	4.7	1,642	1.2
Hispanic	1,154	5.7	858	9.0	296	2.9
Age group (yrs)						
0-19	38	0.1	21	0.1	18	0.1
20-29	51	0.1	32	0.2	18	0.1
30-39	129	0.4	95	0.5	34	0.2
40-49	861	2.1	716	3.5	145	0.7
50-59	2,184	6.8	1,848	11.8	337	2
60-69	1,912	9.6	1,469	15.7	443	4.2
70-79	1,990	13.7	1,393	22.3	596	7.2
≥ 0	935	10.0	587	17.9	347	5.8

Sources: CDC's National Program of Cancer Registries and the National Cancer Institute's Surveillance, Epidemiology, and End Results Surveillance System; data from 45 cancer registries covering 90.4% of the U.S. population

*Per 100,000 persons

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The American Association for the Study of Liver Diseases (AASLD) is the leading organization of scientists and healthcare professionals committed to preventing and curing liver disease and who's vision is to prevent and cure liver disease through its mission to advance the science and practice of Hepatology, Liver Transplantation and Hepatobiliary Surgery, thereby promoting liver health and optimal care of patients with liver and biliary tract diseases.

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Glossary of Terms and Acronyms

Acute hepatitis: Inflammation of the liver that lasts less than six months. It is characterized by elevation of liver tests (aminotransferases) and may or may not cause symptoms. It may resolve, go on to chronic hepatitis or, more rarely, result in death.

CDC: The Centers for Disease Control and Prevention is the federal agency that is responsible for investigating disease outbreaks, preventing and controlling infectious and chronic diseases, injuries, and workplace hazards. More information can be found at www.cdc.gov.

Chronic hepatitis: Inflammation of the liver that goes on for more than six months. It is characterized by elevation of liver tests (aminotransferases) usually at levels that are not as high as in acute hepatitis. It is usually asymptomatic. Chronic hepatitis, if untreated, may go on to cirrhosis, liver cancer and death.

Cirrhosis: A condition in which scar tissue replaces healthy liver tissue, leading to high pressure in the veins that go to the liver, to liver malfunction and, ultimately, to death. Any illness that affects the liver over a long period of time may lead to cirrhosis. .

FDA: The Food and Drug Administration is the federal agency responsible for regulating the safety and efficacy of drugs and medical devices, and the safety of foods. More information can be found at www.fda.gov.

HAV: Hepatitis A Virus (HAV) is primarily transmitted by the fecal-oral route, by either person-to-person contact or consumption of contaminated food or water. Symptoms are usually mild and show up two to six weeks after exposure. It causes acute hepatitis but does not cause chronic hepatitis.

HBV: Hepatitis B Virus (HBV) is transmitted through activities that involve percutaneous (i.e., puncture through the skin) or mucosal contact with infectious blood or body fluids (e.g., semen, saliva). It can cause acute or chronic hepatitis. The latter, if untreated, can lead to cirrhosis, liver cancer, liver failure, and death.

HCV: Hepatitis C Virus (HCV) is primarily transmitted through large or repeated percutaneous (i.e., passage through the skin) exposures to infectious blood. It can cause acute or chronic disease. Most cases of acute hepatitis C lead to chronic hepatitis C. The latter, if untreated, can persist for many years and lead to cirrhosis, liver cancer, liver failure, and death.

Hepatitis: Refers to inflammation of the liver that is most commonly caused by viruses. There are five viruses (Hepatitis A, B, C, D, E) that can cause hepatitis. . The most common types are Hepatitis A, Hepatitis B, and Hepatitis C. Treatment against the virus is indicated in chronic hepatitis B or C but specific therapy is different for each of them. **Hepatocellular Carcinoma:** Liver cancer, often the result of years of chronic infection with hepatitis B or C.

HIV: Human Immunodeficiency Virus, the cause of AIDS.

Liver: A large, reddish-brown, organ located in the upper right portion of the abdominal cavity. It is the largest solid organ in the body and has many important functions. It makes vital proteins

(like albumin and blood clotting factors), it makes and secretes bile that helps digest food, it metabolizes toxins and eliminates bacteria and it is active in the metabolism and storage of carbohydrates, fats, and vitamins.

NIH: The National Institutes of Health is the federal government's biomedical research agency and consists of 20 individual institutes and seven centers, each involved in a specific area of medical research. More information can be found at www.nih.gov.

NIAID: The National Institute of Allergy and Infectious Diseases is a research institute within the National Institutes of Health, primarily concerned with studying how to better treat, and ultimately prevent infectious, immunologic, and allergic diseases. NIAID conducts its own research and also financially supports research conducted by non-government scientists and companies. More information can be found at www.niaid.nih.gov

NIDDK: The National Institute of Diabetes and Digestive and Kidney Diseases. NIDDK is one of the institutes within NIH. It conducts and supports basic and applied research and provides leadership for a national program in diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases. More information can be found at http://www2.niddk.nih.gov/

Perinatal: The period of time before, during, immediately after birth.

Therapeutic vaccine: A vaccine intended to provoke an immune response against a disease after infection. This type of vaccine is different from a traditional prophylactic vaccine, which is intended to prompt a protective immune response to prevent infection.

Vaccine: A preparation of a weakened or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure that stimulates the production of protective antibodies or cellular immunity against the organism, but cannot itself cause a severe infection.

WHO: The World Health Organization is the United Nations specialized agency for health. Information about the WHO can be found at www.who.org.