Chronic Viral Hepatitis and Health Care Reform

The purpose of this report is to outline and describe the basic required elements of health care for persons with chronic viral hepatitis infections.

BACKGROUND

“Hepatitis” means inflammation of the liver. Heavy alcohol use, toxins, certain medications, some diseases, and viral infections can cause hepatitis. Hepatitis is most often caused by one of several viruses, such as hepatitis A virus (HAV), hepatitis B virus (HBV), or hepatitis C virus (HCV) which attack the liver cells. Hepatitis B and C cause chronic infections which can result in cirrhosis, liver failure and liver cancer.

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

HBV is transmitted through infected blood and bodily fluids and HCV is transmitted through infected blood. HBV is 50 to 100 times more infectious than HIV and is most commonly spread through sexual contact. Sexual transmission of HCV is known but not common. Both HBV and HCV are also spread through sharing needles and other drug-injection equipment. Unlike HBV, which can be prevented with a safe and effective vaccine, there is no vaccine for HCV.

Facts about Viral Hepatitis

- The Centers for Disease Control and Prevention (CDC) estimates that 5.4 million Americans have chronic hepatitis B virus (HBV) and chronic hepatitis C virus (HCV) infection.
- In 2006, the CDC estimates that 46,000 Americans were newly infected with HBV and 19,000 Americans with HCV. However we believe that these are underestimates and are only the tip of the iceberg of new infections.
- Each year the CDC estimates that 2,000-4,000 Americans die from HBV related liver disease and 8,000-10,000 Americans die of HCV related liver disease.
- Chronic viral hepatitis is the leading cause of primary liver cancer, one of the fastest growing cancers in the U.S. at a time when most cancers are on the decline.
- At least 10 percent of people living with HIV/AIDS are also infected with HBV and at least 25 percent with HCV. Liver disease caused by chronic viral hepatitis is now the most common cause of non-AIDS deaths of Americans living with HIV/AIDS.
Failure to address chronic viral hepatitis has enormous consequences

- HBV infections result in an estimated $658 million in medical costs and lost wages annually.

- Without intervention, the HCV epidemic is expected to result in 3.1 million years of life lost over the next decade. The projected direct and indirect costs of the current HCV epidemic, if left unchecked, will be over $85 billion for the years 2010 through 2019.

- Without increased resources for counseling, testing, and medical referral services, HCV-related deaths and long-term complications are projected to increase dramatically by the year 2020: liver failure by 106 percent, liver cancer by 81 percent, and liver-related deaths by 180 percent.

**Chronic Viral Hepatitis Medical costs**

- Screening blood test for hepatitis B: $8.
- Hepatitis B vaccination: $60 for each of 3 vaccinations.
- Hepatitis B immune globulin for post-exposure prevention: $400.
- HBV treatment: $2,000 - $16,000 per year, ~10% are cured.
- Screening blood test for hepatitis C: $8.
- HCV treatment: $15,000 - $25,000, about 55% are cured.
- End stage liver disease: $30,980 - $110,576 per hospital admission.
- Liver transplantation: $314,000 (uncomplicated cases).

**GENERAL HEALTH CARE REFORM PRINCIPLES**

- Provide Access to High Quality and Comprehensive Health Care
- Guarantee Access to Affordable Health Care
- Address Ongoing Health Disparities
- Require Accountability and Encourage Innovation

**REQUIRED ELEMENTS FOR HEPATITIS CARE**

**Chronic Hepatitis Testing**: At least two out of three patients with chronic viral hepatitis infection remain undiagnosed because of testing barriers. All individuals at risk should be tested for hepatitis B and C.

**Hepatitis Vaccination**: Safe and effective vaccines exist to prevent hepatitis A and hepatitis B. All individuals considered to have at least one risk factor as designated by ACIP should be offered the vaccine. Persons with chronic viral hepatitis should be vaccinated for other vaccine-preventable hepatitis viruses to prevent additional liver infections. Persons with HIV/AIDS should be vaccinated against hepatitis A and B to prevent additional liver infections.

**Patient Education**: One of the primary obstacles to achieving successful chronic viral hepatitis treatment outcomes is lack of patient education. Patients are often anxious to initiate treatment without having a real understanding of the disease or treatment involved and lack guidance in the management of their chronic infection.
**Provider Education:** One of the major factors contributing to missed diagnoses of chronic viral hepatitis is the lack of health care provider awareness and education. Education would increase routine screening and testing of patients which should be offered independent of perceived risk factors, and support implementation of universal evidence-based management guidelines.

**Medical Care Services:** All patients with chronic viral hepatitis should be considered as candidates for therapy. No arbitrary exclusionary qualifications (e.g., race, ethnicity, gender, language, insurance status, active substance use, homelessness) should be allowed to substitute for the judgment of patients and their health care providers. These services should include medical care as well as other necessary health care such as mental health and substance abuse services.

**Laboratory and Diagnostics:** Lack of accessible hepatitis B and C testing contributes to missed diagnoses, misdiagnoses, missed treatment opportunities, and mismanagement of patients on treatment. Wider availability of and reimbursement for HBV and HCV virus testing to confirm chronic infection following a positive test is urgently needed. All available diagnostic and prognostic tests must be available and reimbursed at the point of care.

**Formulary:** In all phases of pretreatment, treatment and follow up, patients should have access to all drugs necessary for the successful treatment of HBV and HCV (and side-effects associated with HCV treatments) and related co-morbidities and co-infections.

**Chronic Viral Hepatitis Guidelines:** The Department of Health and Human Services (DHHS) and the American Association for the Study of Liver Diseases (AASLD) should coordinate a process similar to the panel that develops and regularly updates the *Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents*. Public and private health plans should be required to follow existing CDC guidelines for viral hepatitis screening; the CDC’s Advisory Committee on Immunization Practices (ACIP) guidelines for viral hepatitis immunization of infants and adults; and the National Institutes of Health (NIH) guidelines for chronic viral hepatitis management and care.
CHRONIC VIRAL HEPATITIS HEALTH CARE REFORM PRINCIPLES

PREAMBLE:

We call on our policymakers to enact national health care reform that secures full and continuous access to quality health care for all people living with chronic viral hepatitis.

- To protect public health it is essential that all people have access to health care when they need it. Chronic viral hepatitis affects everyone, rich and poor, insured and uninsured, thus it is vital that access to care be a universal right.
- Providing complete and quality care will ensure that health care reform is effective for those who need it most.
- All reform proposals must be designed with primary consideration to patient needs and participation and must empower individuals and communities to exercise their right to health.
- The vast majority of the 6 million people estimated to be living with chronic viral hepatitis in the U.S. currently are not in care.
- Many of those living with chronic viral hepatitis are uninsured and many more are underinsured. Providing comprehensive coverage for those chronically infected, independent of their ability to pay, is crucial and long overdue.

GENERAL PRINCIPLES:

Provide Access to High Quality and Comprehensive Health Care:

- Ensure meaningful, timely and reliable access to qualified health care providers and comprehensive care. Support services are necessary to effectively ensure that all people have this access.
- Provide comprehensive benefits regardless of a person’s ability to pay and without a financial limit. Benefits must reflect the comprehensive level of care needed to protect and improve public and personal health, with preventive care and health education as primary objectives. Benefits must include hepatitis A and B vaccinations where recommended by ACIP, routine hepatitis B and C screening, at minimum where recommended by CDC, education and counseling, and referral to care for those who test positive.
- Expand and strengthen the bases created by public health programs, including Medicaid and Medicare.
- Ensure high and consistent quality of care through evidence-based standards of care and mechanisms to measure and maintain effective high quality care, individual health outcomes, and to support good public health.
- Facilitate a patient’s local access to a qualified provider, continuity of care regardless of employment status and income, and portability of care benefits.
• Provide fair payment to health care providers in order to ensure a broad spectrum of providers and specialties, including infectious disease, gastroenterology and hepatology. This includes developing payment mechanisms that are transparent, focused on public needs, reflect public health priorities, and discourage costly administration.

Guarantee Access to Affordable Health Care:
• Guarantee affordable care with a level of beneficiary cost sharing that does not deter appropriate and timely care, particularly for low-income people. Care must never be denied because a person is unable to pay for it. Eliminate cost sharing for low-income people. Eliminate preexisting condition exclusion rules within insurance plans.
• Finance the health care system such that the costs are borne equitably, with higher income individuals and families bearing higher costs than low-income people. Health care financing must recognize that low-income people have little or no disposable income to pay for their health care costs.

Address Ongoing Health Disparities:
• Eliminate inequities in access to quality care based on race, ethnicity, gender or gender identification, sexual orientation, actual or perceived disability, age, primary language, immigration status, and geography—state of residence and type of community (urban or rural).
• Provide culturally and linguistically appropriate, patient-centered care with health care decisions made by patients and their health care providers. Care must include sufficient access to appropriate treatments and services to enable the patient to realize his/her human potential and contribute fully to his/her family and community.

Require Accountability and Encourage Innovation:
• Require accountability to the individual and to the public. An individual’s human right to health care must be enforceable and accessible. The proposal must provide mechanisms for expediting access to health care when emergencies occur. The public and private sectors must be publicly accountable for protecting and improving public health and meeting health needs.
• Encourage innovation in models of health care delivery for various populations, including those living with chronic viral hepatitis, and facilitate rapid access to new treatments and improvements in health care. Improvements and changes in health care must reflect sound scientific principles. Health care systems must reflect an individual’s ownership of her/his health information and her/his right to privacy of that information.

REQUIRED ELEMENTS FOR THE CARE OF VIRAL HEPATITIS: Issues Affecting Access to Care for Patients with Viral Hepatitis

1) Chronic Hepatitis Testing: At least two out of three patients with chronic viral hepatitis infection remain undiagnosed because of screening barriers. One such barrier to screening is lack of
knowledge regarding the risk factors associated with chronic viral hepatitis infection — many individuals simply do not realize they are at risk. In addition, chronically infected individuals do not seek HBV and HCV screening because they are often asymptomatic and have no cause to visit their healthcare provider. When they do visit their provider for other reasons, screening for hepatitis B and C risk factors and subsequent testing is not a standard of care for many primary care practices. Furthermore, there is a stigma associated with chronic viral hepatitis infection and when asked or offered testing, patients are often hesitant to admit to having risk factors. A viral hepatitis diagnosis is further complicated because a panel of two to three tests must be ordered and evaluated in order to discern the infection status of person. Hepatitis B and C test results can be confusing for providers who are unfamiliar with the different interpretations. To confirm a “chronic infection” diagnosis, HBV and HCV test results must be obtained and confirmed within a six month period. All patients, however, should be screened for HBV and HCV risk factors in a nonthreatening, nonjudgmental, and professional manner and testing should be recommended based on risk factor screening results.

a) All insurance must require the provision of information on risk factors for HBV and HCV and routine testing for all persons who may be or consider themselves to be at risk for chronic viral hepatitis infections. A unified program must be developed to educate health care providers on risk factors for HBV and HCV infection and for testing methodologies. These programs should be developed by the Guidelines Council described in point 6 and funded through public-private partnerships.

b) Hepatitis B and C testing must be covered for individuals with risk factors by all public and private insurers with payment for testing for uninsured and underinsured patients guaranteed by the federal government. At a minimum, testing must be made available for the following groups recommended for routine testing by the CDC and/or the US Preventive Services Task Force:

i) HBV testing recommendations:

(1) Persons born in regions of high and intermediate HBV endemicity (HBV prevalence ≥ 2%)

(2) U.S. born persons not vaccinated as infants whose parents were born outside the U.S. from regions with high HBV endemicity (≥ 8%)

(3) Injection-drug users (past or present)

(4) Men who have sex with men

(5) Persons needing immunosuppressive therapy, including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatologic or gastroenterologic disorders

(6) Persons with elevated ALT/AST of unknown etiology

(7) Donors of blood, plasma, organs, tissues, or semen
(8) Hemodialysis patients
(9) All pregnant women
(10) Infants born to HBV-positive mothers
(11) Household, needle-sharing, or sexual contacts of persons known to be HBV-positive
(12) Persons with known exposures to HBV such as needle stick injuries or direct contact with infected blood
(13) Persons who are the sources of blood or body fluids in the case of an exposure (e.g., needle stick, sexual assault) that might require post-exposure prophylaxis
(14) HIV-positive persons

2) HCV testing recommendations

(1) Injection drug users (past or present, including even one time many years ago)
(2) Persons who have ever snorted illegal drugs - Use of snorting illegal drugs
(3) Recipients of clotting factor concentrates made before 1987
(4) Recipients of blood transfusions or solid organ transplants before July 1992
(5) Hemodialysis patients
(6) Persons with known exposures to HCV, such as
   (a) healthcare workers after needle sticks involving HCV-positive blood
   (b) recipients of blood or organs from a donor who later tested HCV-positive
(7) HIV-positive persons
(8) Persons with signs or symptoms of liver disease, e.g., elevated ALT/AST of unknown etiology
(9) Children born to HCV-positive mothers (to avoid detecting maternal antibody, these children should not be tested before age 18 months)
(10) Veterans
(11) Additional risk groups that become known as research regarding HCV risk factors emerges.

c) Programs to counsel and refer all patients who are found to be HBV and/or HCV infected must be developed and reimbursed by all public and private insurers with payment for counseling for uninsured and underinsured patients guaranteed by the federal government.

2) Hepatitis Vaccination: Safe and effective vaccines exist to prevent hepatitis A and hepatitis B. All individuals at risk should be offered the vaccine. Persons with chronic viral hepatitis should be vaccinated for other vaccine preventable hepatitis viruses to prevent additional liver infections.
a) HAV and HBV vaccines must be covered by all public and private insurers. Vaccinations for uninsured and underinsured must be provided by the federal government.

b) Hepatitis A vaccination must be made available for every child between the ages of one and 18 and hepatitis B vaccination must be available for every child between birth and age 18. In addition, hepatitis A and B vaccination must be available for every high-risk adult (19 years and older) and those who request to be vaccinated.

c) The first dose of hepatitis B vaccination must be available and administered according to ACIP’s recommendations for all newborns before hospital discharge.

d) Vaccinations for hepatitis A and B must be available for all patients diagnosed with or at risk for hepatitis C.

e) Vaccination for hepatitis A must be available for all patients diagnosed with hepatitis B.

f) Federal vaccination funds must cover reimbursement for the cost of storing and administering the vaccine, in addition to that of vaccine purchase.

3) **Patient Education:** One of the primary obstacles to achieving successful chronic viral hepatitis treatment outcomes is lack of patient education. Patients are often anxious to initiate treatment without having a real understanding of the disease or treatment involved, and lack guidance in the management of their chronic infection.

a) All insurance providers should offer reimbursement for and encourage the use of peer group education and support groups where the patients and their families, significant others, or close friends can receive education on hepatitis B and/or hepatitis C. Basic information on HBV or HCV, how it is transmitted, how transmission can be prevented, the need for HAV and HBV immunizations, expected outcomes (natural history), and treatment options must be understood by patients before initiating therapy to maximize the chances of treatment success. The impact of social behaviors on HBV or HCV, such as smoking, drinking alcohol, or injection drug use, also need to be included in their pretreatment education.

b) All insurance plans must provide a baseline of culturally and linguistically appropriate and easy to understand patient education materials and related programs for all people at risk of or infected with hepatitis B or C.

c) Medical case management must be made available to all patients considering or choosing to undertake HBV or HCV treatment to plan for and deal with the difficulties inherent in the standard of care, especially the challenges and side-effects associated with interferon therapy for chronic HCV. Case managers should also be prepared to support (and help find assistance where necessary) crucial life supports including nutrition, exercise, etc.

d) Funding for such activities should be provided pro-rata by insurers and drug manufacturers with staff and logistics support provided by care providers. The models developed for use in these activities should be developed by professional and non-profit groups with demonstrated experience in such programs.
e) All patient education must be based upon verified harm reduction models including safe syringe use, syringe exchange and disposal, injection and non-injection drug use-related risk reduction, sexual risk reduction, maternal transmission, and other blood exposures.

4) **Provider Education:** one of the major factors contributing to missed diagnoses of chronic viral hepatitis is the lack of health care provider awareness and education, routine screening independent of perceived risk factors, and universal evidence-based management guidelines.

**Health care providers must be educated on the following:**

a) Risk factor screening and testing recommendations.

b) Appropriate diagnostic testing to diagnose chronic hepatitis B and C infection.

c) Appropriate counseling and educational messages for patients at risk for and infected with chronic viral hepatitis.

d) Recommendations for follow up with household, sexual, and other contacts, e.g., testing, vaccination, and prevention precautions.

e) General primary care management recommendations including: vaccination for hepatitis A and/or B, routine testing for liver function, liver cancer markers, and liver disease progression, when to refer to specialty care for the liver, and referral to other specialists such as mental health and substance abuse professionals.

f) Continuing medical education programs such as found at www.cdc.gov/hepatitis and development of clinical and public health practice guidelines to facilitate the incorporation of recommendations for the prevention of viral hepatitis infection and its consequences into clinical and public health practice.

5) **Medical Care Services including Mental Health and Substance Abuse:** All patients with chronic viral hepatitis should be considered as candidates for therapy. No arbitrary exclusionary qualifications (e.g., race, ethnicity, gender or gender identity, language, insurance status, immigration status, HIV status, active substance use, homelessness, or mental illness) should be allowed to substitute for the judgment of patients and their health care providers.

a) Patients with chronic viral hepatitis must have access to care from clinicians experienced in treating the disease or in close and consistent consultation with those experts. The standard of care requires culturally and linguistically appropriate open access to specialists in liver disease, infectious disease, mental health and substance abuse, ideally in team centered systems.

b) Psychiatric disorders are some of the most common comorbidities seen in patients with HCV infection. The incidence of hepatitis C has been found to be 11 times greater in individuals with severe mental illness, and 25% of the population affected by schizophrenia has hepatitis C. In the past, these disorders have been cited as contraindications to antiviral therapy, but these preexisting conditions should not exclude patients from consideration for treatment. The 2002 NIH Consensus Conference on HCV management concluded patients with psychiatric, substance abuse, and medical and neuropsychiatric comorbidities should not be considered as
exclusionary criteria when considering treatment but that those conditions need to be managed in close coordination with their HCV care provider.

c) The consensus also recommended educating providers about needle-exchange in addition to providing access to sterile syringes through needle exchange, physician prescription, and pharmacy sales.

d) All validated substance use treatment methodologies must be available for all patients who need/request them. These include but are not limited to in-and outpatient counseling, methadone maintenance therapy, buprenorphine, soboxone or other modalities determined as necessary by patients and their care team.

e) Incentives for providers: a relatively large group of physicians, particularly gastroenterologists and hepatologists, are increasingly unwilling to provide specialty services to HCV patients, even as referral specialists, because reimbursement for office visits fail to cover the costs of providing the services, leading to provider financial losses for nearly all patients treated. Unless this problem is addressed, the already critical shortage of specialists willing to provide care for HCV patients will prevent any real public health solution to the issue of treating HCV in most patients willing to undergo therapy.

6) **Laboratory and Diagnostics:** Lack of accessible hepatitis B and C testing contributes to missed diagnoses, misdiagnoses, missed treatment opportunities, and mismanagement of patients on treatment. Wider availability of and reimbursement for HBV and HCV virus testing to confirm chronic infection following a positive test is urgently needed. All available diagnostic and prognostic tests must be available and reimbursed at the point of care.

a) All available diagnostic and prognostic tests, particularly rapid tests, must be available and reimbursed at the point of care. Wider availability of and reimbursement for HBV and HCV virus testing to confirm chronic infection following a positive test is urgently needed. New screening and diagnostic tests will encourage the development and promulgation of improved technology.

b) HBV diagnostic tests, including HBsAg (hepatitis B surface antigen which marks the presence of virus) to determine chronic infection and HBV viral load to determine the need for and efficacy of treatment for HBV must be available and reimbursed at the point of care.

c) HCV diagnostic tests, especially HCV viral load, must be reimbursed at the frequency necessary to assess treatment efficacy among HCV-infected persons. At minimum, such testing must be available: 1) twice before initiation of treatment as baseline and confirmation; 2) four weeks after treatment initiation as a crucial early indicator of treatment efficacy and duration, 3) twelve weeks after initiation of therapy which is generally considered to be the primary decision point on whether to continue treatment; 4) twenty-four weeks after initiation of therapy and forty-eight weeks after initiation of therapy as indicated for identified subgroups of patients, to indicate end of treatment response; and 5) twice in the year after treatment conclusion to assess durable treatment response.
d) Liver cancer screening must be available for both chronic HBV and HCV to those at risk as recommended by professional society guidelines and accessible at the point of care

7) **Formulary:** In all phases of pretreatment, treatment and follow up, patients should have access to all drugs necessary for the successful treatment of HBV and HCV (and side-effects associated with HCV treatments) and related co-morbidities and co-infections.

a) **PAYMENT and AFFORDABILITY:** In a draft report by the AIDS Treatment Data Network, of 1000 HCV-infected patients identified as willing to initiate treatment, 99% were unable to due primarily to excessive out-of-pocket costs. The factor most likely to prevent treatment initiation was excessively large co-pays, especially for injectable biologics including pegylated interferon. For HBV, at least 50% of individuals chronically infected are Asian and Pacific Islanders who are largely from immigrant populations with minimal to no health insurance. Hence, since a substantial proportion of patients with chronic viral hepatitis needing treatment are uninsured, underinsured, poor and/or near-poor, some provision must be included in any reform proposal to minimize these costs or treatment will continue to be impossible for a large portion of the affected population.

b) **Antiviral therapy:** Public plans must be required and private plans strongly encouraged to include all presently approved drugs to treat HBV and HCV onto plan formularies and to develop plans that require rapid inclusion of newly approved drugs as quickly as possible.

c) **Side-effects:** All side-effects must be aggressively addressed to improve the likelihood of positive treatment outcomes. This requires an open and expansive availability of available drugs necessary for these purposes (e.g. anemia treatment, nutritional support, etc.)

d) **Mental Health:** Approximately two-thirds of HCV patients suffer from mental disorders and many of those cases are treatment resistant. Other confections such as HIV both increase the risk of psychological problems and add complexity to addressing the issues. The best support for ultimate HCV treatment success lies in patients and their doctors having access to a full range of antidepressants, antipsychotics, antianxiolytics, etc. for at least one year before HCV treatment is undertaken, then during and immediately after treatment.

e) **Substance Abuse:** A large number of HCV patients have either a history of or a current struggle with drug use issues. All drugs approved for and commonly used to support either reducing the risks of drug use or of abstention including methadone and buprenorphine must be available in all public and private plans.

f) **AIDS Drug Assistance Programs** funded under Part B of the Ryan White Care Act should be strongly encouraged to provide drugs to treat HBV and HCV to HIV/HBV and HIV/HCV coinfected patients.

8) **Chronic Viral Hepatitis Guidelines:**

a) The Department of Health and Human Services and the American Association for the Study of Liver Diseases (AASLD) should coordinate a process similar to the panel that develops and
regularly updates the *Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents*. Evidence-based guidelines for chronic viral hepatitis must include, at minimum, regularly updated statements defining the standard of care for testing, counseling, diagnostics, and formulary. These guidelines should be widely disseminated and should provide consensus principles for medical management and treatment of persons with chronic viral hepatitis. Guidelines should include coordinated bio-psychosocial care for persons with chronic viral hepatitis and hepatitis/HIV co-infection and should be updated and disseminated rapidly as new treatments become available.

b) Public and private health plans should be required to follow existing CDC guidelines for viral hepatitis screening; ACIP guidelines for viral hepatitis immunization; and NIH guidelines for chronic viral hepatitis management and care.

The National Viral Hepatitis Roundtable is a coalition of public, private, and voluntary organizations dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis in the United States through strategic planning, leadership, coordination, advocacy, and research.

For more information on the National Viral Hepatitis Roundtable (NVHR) or on these principles, please contact Martha Saly at mbsaly@nvhr.org.