



The Dawn of a New Era
Transforming our Domestic Response to
Hepatitis B&C

September 10-11, 2009 | Washington, DC

October 9, 2009

SCIENTIFIC PLANNING COMMITTEE

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Dear Colleague:

We recently convened a national forum in Washington, DC, focusing on viral hepatitis: **"The Dawn of a New Era: Transforming our Domestic Response to Hepatitis B & C."** This was a multi-stakeholder national forum convened to develop a coordinated national response to chronic viral hepatitis through improved prevention, detection and patient care.

As you are aware, chronic hepatitis B and C are often referred to as "silent killers" because they can be present for years without causing obvious symptoms. But over time, chronic hepatitis infection can slowly damage the liver, causing cirrhosis, liver cancer and other serious liver disease. For this reason, it is important that populations at high risk of infection undergo screening so that those who are infected can be connected to care before serious liver damage occurs.

It is estimated that more than \$1 billion is spent each year on hospitalization related to hepatitis B, and hepatitis C is responsible for more than \$600 million annually in medical costs and lost productivity. While there is no simple cure for either disease, there are a growing number of effective medications. In addition, a safe and effective vaccine for hepatitis B has been available for more than 20 years and more than 1 billion doses have been given worldwide. The challenge is to raise awareness of the virus, screen for the disease and to provide access to care to those persons who are found to be infected.

During the two-day forum we addressed these challenges and heard from many distinguished presenters on all aspects of viral hepatitis B&C.

The attached Executive Summary provides a brief summary of the topics addressed at the forum and the most salient points made in the presentations and discussions. It highlights those needs that must be addressed to develop a comprehensive approach to the challenges of viral hepatitis. We encourage you to review this summary and to single out those needs that you feel you may help address and to reach out to others in your profession, workplace and community to bring people together to design much needed strategies to meet some of these challenges.

Sincerely,

Anna S. F. Lok, MD
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Non-financial co-sponsorship is being provided by the AGA Institute, CDC, Department of Veterans Affairs, and NIAID.



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The Dawn of a New Era: Transforming our Domestic Response to **Hepatitis B&C**

September 10-11, 2009
Washington Marriott Wardman Park Hotel
Washington, DC

EXECUTIVE SUMMARY



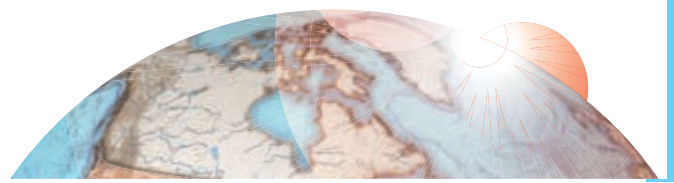
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THE DAWN OF A NEW ERA: TRANSFORMING OUR DOMESTIC RESPONSE TO HEPATITIS B&C

Diseases associated with chronic hepatitis B virus (HBV) and hepatitis C virus (HCV) create a considerable burden on the nation's health care system and pose many challenges in terms of effective identification, treatment, and patient management. Both HBV and HCV infections are often asymptomatic, earning them reputations as silent killers. Many individuals are unaware that they are infected until they develop signs or symptoms of cirrhosis or liver cancer. As many as 2 million Americans are infected with HBV, and 5 million are infected with HCV. Despite this large patient population, standards for prevention, screening, and clinical treatment of viral hepatitis are currently inadequate, resulting in a major unmet medical need.

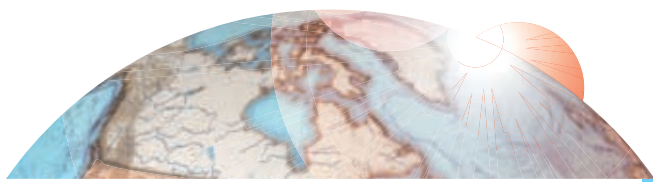
This 2-day forum, **The Dawn of a New Era: Transforming Our Domestic Response to Hepatitis B & C**, was held on September 10–11, 2009, in Washington, DC, with the purpose of developing the beginnings of a coordinated national response to chronic viral hepatitis B and C infection. Leaders in the fight against hepatitis B and C participated from the areas of government, academia, clinical medicine, patient advocacy, and the pharmaceutical industry to discuss several critical issues: prevention; strategies for timely and appropriate screening; accurate diagnosis; and the pressing need to provide access to care and to recognize and address disparities in access to care. As the burden of chronic HBV and HCV disease is expected only to increase in the United States in the near future, the time to transform the infrastructure to effectively combat chronic HBV infection and HCV infection is now.

Anna S. F. Lok, MD, FRCP, and Eugene R. Schiff, MD, MACP, FRCP, MACG, AGAF, served as cochairs for this forum and, in conjunction with the Scientific Planning Committee (see Faculty List, page 14), planned the program content (see Agenda, page 9) and invited the distinguished faculty. Cumulatively, the presentations sought to determine methods to ensure the identification of all those who are infected; examine current measures to prevent HBV and HCV transmission so that future strategies can be improved; identify methods to foster earlier diagnosis and access to treatment for individuals with HBV and/or HCV infection; and determine the considerations in human and financial resources needed to adequately care for the number of individuals infected with hepatitis B and C. This brief report summarizes the most salient points from the forum presentations.

THE NEED FOR A COORDINATED NATIONAL STRATEGY TO COMBAT VIRAL HEPATITIS

Although recent data suggest that approximately 800,000 have chronic HBV infection and 3.2 million Americans have chronic HCV infection, these rates most likely underestimate the true prevalence of viral hepatitis because national surveys do not assess high-prevalence subgroups, such as certain minority groups, the institutionalized, homeless, and incarcerated individuals. In actuality, 2 million US residents may be infected with chronic HBV and 5 million with chronic HCV, and many more remain unidentified and therefore untreated.

While the incidence of new HBV infections has substantially declined as a result of immunization strategies and universal precautions in the health care setting, the prevalence of chronic hepatitis B (CHB) infection has increased significantly, largely as a result of immigration of individuals from countries where HBV infection is endemic. The advent of effective antiviral agents may slow this rising trend; however, because current treatments control but do not eradicate



HBV, the number of Americans living with CHB will continue to grow, along with the complications of end-stage liver disease (ELD) and hepatocellular carcinoma (HCC). Since the 1980s, the incidence of new HCV infections in the United States has decreased, and the overall number of chronically infected individuals (primarily those born between 1945 and 1964) has stabilized; however, during the past 20 years, the prevalence of HCV-associated advanced liver disease has risen markedly. As the cohort of Americans with chronic HCV grows older and the number of individuals with chronic HBV expands, the associated burden of morbidity, mortality, and health care service utilization will only continue to increase.

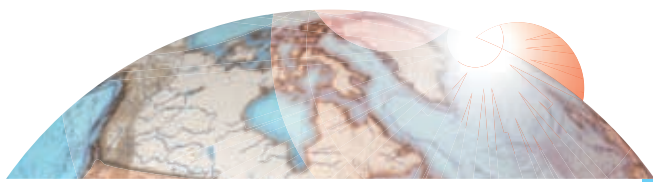
Among patients who are identified and receive treatment for chronic HBV and chronic HCV, a vast difference often exists between the efficacy of antiviral therapies in clinical trials and their effectiveness in clinical practice. Efficacy is the utility of a medical treatment evaluated under optimal conditions, whereas effectiveness is the usefulness of that same medical treatment in routine practice. Many external factors influence effectiveness, including access to care, provider knowledge, patient acceptance, and adherence. Other factors may also play a role; however, once all parameters are considered, the overall effectiveness of a treatment in clinical practice is typically much lower than its efficacy. In chronic HBV and HCV, it is essential to shift the balance toward greater effectiveness for existing therapies by improving recognition, diagnosis, and provider understanding of current testing and treatment approaches, in addition to expanding access to care, fostering patient acceptance of treatment (or providing support for patients receiving treatment), and enhancing adherence.

Significant improvement is also needed in the quality and consistency of care delivered for viral hepatitis, particularly for HCV. Quality deficits are systemic throughout the entire spectrum of care, from prevention to treatment. The US Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) has identified chronic HCV as one of the priority areas for quality measurement. HCV-specific quality indicators (QIs) are now part of Medicare's Pay-for-Performance Initiative and include confirmation of HCV viremia, hepatitis A and B vaccination, alcohol use counseling, antiviral treatment, genotype and viral load testing before treatment, viral load testing at treatment week 12, and contraception counseling. Suggested organizational-level strategies to enhance quality of care include patient registries, use of clinical reminders and templates, and quality-improvement collaboratives involving multiple practices and hospitals. The focus on quality measurement, coordination of care, and assessment of results should be included in the training of gastroenterologists and hepatologists.

TRANSFORMING STRATEGIES FOR PREVENTION, SCREENING, AND DIAGNOSIS OF HBV AND HCV

Both governmental and nongovernmental organizations (NGOs) must participate in the formulation and dissemination of up-to-date guidance on screening, diagnosis, and treatment of viral hepatitis if the burden of severe complications from untreated disease is to be reduced.

Early identification of HBV or HCV infection facilitates initiation of care to prevent, delay, or reverse liver disease and aids in the prevention of ongoing transmission. The US Centers for Disease Control and Prevention (CDC) released comprehensive HBV testing recommendations in 2008 to address the expanding need to identify and treat individuals with chronic HBV; the agency is currently developing similar recommendations for HCV, which are due by 2011. The 2008 HBV recommendations include testing individuals born in countries with a hepatitis B surface antigen (HBsAg) prevalence $\geq 2\%$ and those with behavioral exposures. Recommended



laboratory tests are as follows: HBsAg for screening high-prevalence populations; HBsAg and anti-hepatitis B core (HBc) or anti-HBsAg for populations recommended for vaccination; and all serologic markers for immunocompromised patients. HCV testing is recommended for persons from populations at increased risk for infection, including health care workers, and those with a history of the following: (1) any injection drug use, (2) receipt of clotting factors before 1987, (3) receipt of blood or organs earlier than July 1992, (4) chronic hemodialysis, or (5) liver disease. The HCV antibody enzyme immunoassay (EIA) is recommended for screening. For medical evaluation and management, RNA polymerase chain reaction/transcription-mediated amplification (PCR/TMA) is recommended. The updated HCV recommendations will incorporate advances in testing and treatment as well as possible new strategies for screening, such as birth-year-based and venue-based testing.

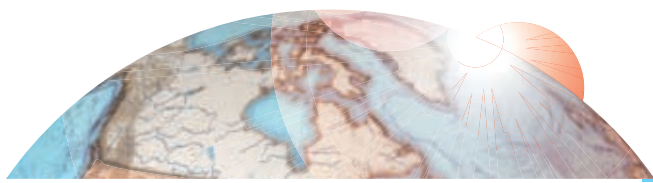
Medical societies are in a unique position to transform the national response to viral hepatitis. In the era of mass information, physicians rely more than ever on medical societies to lead them to high-quality, essential, and relevant guidelines. Unfortunately, few societies, particularly those associated with primary care, provide comprehensive and current HBV- or HCV-specific resources. A new vision needs to be presented and accepted by leading primary care medical societies in order to move physician behavior forward on screening and diagnosis of viral hepatitis.

ACHIEVING HEALTH EQUITY TO ELIMINATE RACIAL, ETHNIC, AND SOCIOECONOMIC DISPARITIES IN HBV- AND HCV-ASSOCIATED LIVER DISEASE

The significant disparities in HBV and HCV morbidity and mortality according to race, ethnicity, and socioeconomic status must be fully recognized and addressed in any strategies designed for prevention and control of viral hepatitis and its complications.

Although mortality rates have declined since 1985, chronic liver disease is the 12th leading cause of death in the United States, and deaths are unequally distributed among racial and ethnic groups. The highest mortality from liver disease resulting from all causes, not just from viral hepatitis, occurs in American Indians/Alaskan Natives (22/100,000), followed by Hispanics (13/100,000), white non-Hispanics (8.6/100,000), Blacks (7/100,000), and Asians/Pacific Islanders (3.5/100,000). [must clarify these mortality rates include all causes of liver disease, e.g. high mortality rate among American Indians is related to alcohol] In addition, mortality rates are twice as high among males as females, regardless of racial or ethnic group. In contrast to declines in the chronic liver disease mortality rates, incidence rates of HCC and other liver cancers have risen dramatically, increasing by 84% between 1993 and 2006. The greatest increases occurred in American Indians/Alaskan Natives (+104%) and non-Hispanic whites (+94%), followed by Hispanics (+73%) and Blacks (+71%); the smallest increases occurred in Asians/Pacific Islanders (6%). Although Asians/Pacific Islanders exhibited the smallest increase in incidence rates, this group continues to experience the highest prevalence of liver cancer, particularly HCC, in the US. Recent data indicate that while Asians/Pacific Islanders make up approximately 5% of the total US population, this group accounts for 24% of all HCC in the US. The reasons for these trends are not entirely clear; however, they may be attributable at least in part to the variable prevalence of risk factors among racial and ethnic groups. Much of the increase in non-API is probably related to HCV.

Because a national response to viral hepatitis is lacking, and primary care providers are often uninformed about current screening recommendations, community-based programs and NGOs have taken on the burden of improving HBV prevention and control. Within Asian/Pacific Islander com-



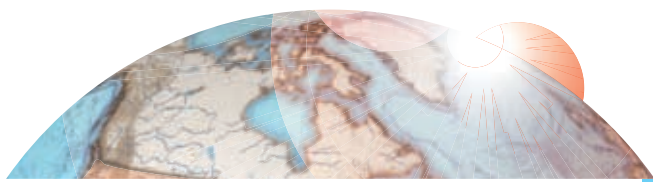
munities, several initiatives have demonstrated success in increasing HBV awareness, screening, diagnosis, and treatment, in addition to effecting change at the legislative level. Examples include the Jade Ribbon Campaign launched by the Asian Liver Center of Stanford University, the Asian American Hepatitis B Program in New York City, the Hepatitis B Initiative based in Baltimore and Washington DC, and the San Francisco Hep B Free program.

Among African Americans and Latinos, a number of community initiatives have focused on the prevention, control, and treatment of HCV. Although documentation of their success is not yet available, a wealth of information exists underscoring the need for both public- and private-sector initiatives to address the significant disparities in access to care experienced by individuals in these populations. Although African Americans and Mexican Americans combined bear only 30% of the national burden of HCV disease, their outcomes are worse and mortality rates higher as compared with other groups. HCV screening of persons at risk for anti-HCV antibodies with subsequent evaluation and management of those infected is the central secondary-prevention strategy for HCV. However, a higher poverty rate and lower rate of private health insurance present significant obstacles to HCV screening for African Americans. In addition, racial disparities in the evaluation and management of HCV exist that are independent of health care system and payer status. For example, African Americans and Caucasian Americans evaluated at Veterans Health Administration (VHA) Medical Centers were equally likely to be referred for HCV treatment and to have biopsies, but African Americans were >50% less likely to actually receive treatment. In addition, African Americans and Latinos are underrepresented in clinical trials for novel antiviral therapies. Furthermore, African Americans with chronic HCV face barriers to referral for liver transplantation and are less likely to undergo live donor or repeat transplantation. The disproportionate impact of HCV on racial and ethnic minorities emphasizes the urgent need to better understand and address racial disparities in local, state, and national efforts to control HCV.

REPORTS FROM TODAY'S HEALTH CARE ENVIRONMENT ON IMPLEMENTATION OF SCREENING, DIAGNOSIS, AND TREATMENT RECOMMENDATIONS

Different systems, including the VHA, corrections, managed care, and primary care, have had different levels of success in following recommendations for HBV and HCV identification and care.

Because the VHA is the largest single provider of medical care to individuals with HCV in the United States, examination of trends in diagnosis and treatment within the system reveal important information on the status of HCV care in this country. As of December 2008, approximately 194,000 veterans in VHA care had evidence of HCV infection, and more than 147,000 of those had documented HCV viremia. The mean age of VHA patients with chronic HCV is 56 years; 97% are males; 41% of patients are white; and 25% are African American. Approximately 13% have documented cirrhosis, and 1.5% have HCC. Only 21% of patients with HCV viremia have ever received antiviral medication. Treatment with pegylated interferon and ribavirin resulted in sustained virologic response (SVR) rates of 24% for VHA patients with HCV genotype 1, 59% for genotype 2, and 48% for genotype 3, much lower than reported in clinical trials. A 2007 survey of VHA providers reported that the most frequent means of educating newly diagnosed patients included one-on-one counseling and referral to a formal HCV group-education clinic.



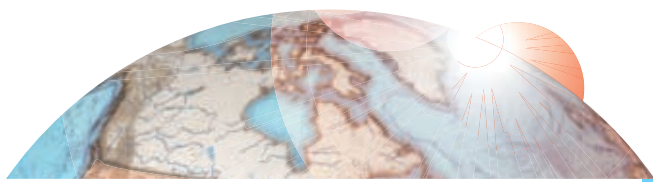
Another important setting in which to examine HCV prevention and control is the United States correctional system, which currently houses approximately 1.6 million persons. Prisons and jails are an integral part of communities, not only because most inmates eventually return to the community, but also because staff and visitors move between correctional facilities and social-service settings outside the correctional system. This is of major concern because the CDC estimates that 2% of inmates have chronic HBV and approximately 30% of all acute HBV cases occur in individuals who have previously been incarcerated. In addition, an estimated 15% of inmates have evidence of exposure to HCV, and one-third of all HCV-infected individuals pass through the correctional system each year. Thus, collaboration between corrections and public health is necessary and can facilitate prevention education, HBV immunization, HBV and HCV treatment, and continuity of care on discharge.

Evaluation of large managed-care populations also provides vital information about the screening and management of patients with HBV and HCV. The Kaiser Permanente Northern California (KPNC) Viral Hepatitis Registry includes 14,000 individuals with chronic HBV and 20,000 with HCV. In this population, the age-adjusted prevalence of HCV in adults is 0.7%; however, this is considered an underestimate based on NHANES data. KPNC is evaluating the feasibility of implementing birth-cohort-based HCV screening to improve identification. Late diagnosis for either HBV or HCV is associated with a reduced probability of survival after diagnosis with hepatitis-related liver cancer. Treatment rates of HCV in the KPNC registry are 21% (ranging from 13% to 35% among medical service areas). Premature discontinuation or non compliance with therapy (21%) and modest SVR rates (50%) are areas of additional research and quality improvement efforts. Data from a study of 2,500 patients treated for HCV indicate that, compared with those not achieving SVR, patients who achieved SVR had significant reductions in the incidence of hepatoma, decompensated cirrhosis, liver transplant, hospitalization for liver disease, and death due to liver disease. Incident diabetes, hospitalization for non-hepatic problems and deaths due to such conditions were also reduced. These findings point to the substantial long-term benefits of successfully treating hepatitis C.

Significant gaps exist in HBV recognition and diagnosis nationwide; among the estimated 1.4 to 2 million Americans with chronic HBV, only 300,000 have been screened and 50,000 are receiving treatment. Although multiple factors hinder screening and treatment, time constraints on primary care physicians are a major obstacle. Suggested strategies to promote compliance with HBV screening guidelines in primary care include increased physician education; using insurance mandates or pay-for-performance screening targets; providing clear and strong governmental and medical society recommendations; instituting electronic health records; and offering education and support to empower the patient.

ENTERING THE NEW ERA OF HBV AND HCV THERAPY

Lessons learned from the public health response to the human immunodeficiency virus (HIV) may apply to viral hepatitis. Chronic HBV and HCV infections are both similar to HIV in that they are associated with chronic infection that potentially results in significant morbidity and mortality. In addition, viral hepatitis and HIV are transmissible, preventable, and treatable. As with the response to HIV, including all fields of medicine, developing routine screening tests, participating in international efforts, and promoting societal acceptance are necessary components of a comprehensive response to viral hepatitis. In addition, recognizing the role of comorbidities;



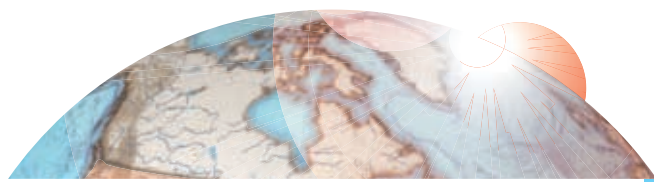
engaging governmental agencies such as the National Institutes of Health (NIH) and the Food and Drug Administration (FDA); and demonstrating the cost-effectiveness of treatment are key strategies to employ going forward as the epidemiology, understanding, and treatment of HBV and HCV evolve.

Comorbidities are common in viral hepatitis, and many affect the disease course, antiviral response, and adherence to treatment regimens. These include alcohol misuse and substance abuse disorders, coinfection with HIV, coinfection with other hepatitis viruses, psychiatric disease, and metabolic syndrome. Evidence indicates that alcohol consumption, metabolic syndrome, and steatosis are key factors that reduce antiviral response as well as promote fibrosis. However, evidence also suggests that contrary to some beliefs, viral hepatitis can be successfully treated using integrated care models in patients with comorbid psychiatric and substance abuse disorders.

Many of the individual institutes, offices, and centers at the NIH are engaged in clinical research programs for chronic viral hepatitis and are responsible for several recent and ongoing viral hepatitis studies. Examples include Viral Resistance to Antiviral Therapy of Chronic Hepatitis C (VIRAHEP-C), Pegylated Interferon +/- Ribavirin for Children With Hepatitis C (PEDS-C), Hepatitis C Antiviral Long-term Treatment against Cirrhosis (HALT-C), Silymarin Treatment in Chronic Hepatitis C (SynCH), Pre-Transplant Treatment to Prevent Recurrence of Hepatitis C After Liver Transplantation (LADR [A2ALL]), as well as the HBV Research Network. In addition, the NIH has produced several reports and plans for addressing viral hepatitis, such as the trans-NIH *Action Plan for Liver Disease Research* (2005), *The Burden of Digestive Diseases in the United States* (2007), and the *National Commission on Digestive Diseases: Opportunities and Challenges in Digestive Diseases Research*. The NIH will continue to be fully engaged in the response to viral hepatitis.

Recognizing the need for intensive collaboration to guide the most efficient and effective paths for viral hepatitis drug development, the FDA has identified research needs for HBV and principles for new drug development for HCV. According to this agency, HBV drug development should focus on relationships between surrogate end points and clinical outcomes, timing and duration of therapy, and outcomes of combination therapy. The principles for HCV drug development include the following: minimizing emergence of resistance and preserving treatment options; systematically defining optimal dose and duration; including relevant populations as early as possible in research; collaboration for studying combinations of investigational agents; and developing regimens for patients with no options.

Research into the comparative effectiveness of various interventions may direct future health care policy and determine allocation of limited funds. The Institute of Medicine defines comparative effectiveness as the generation and synthesis of evidence that compares the benefits and harms of alternative methods to treat and monitor the clinical condition. In addition to efficacy and effectiveness, HBV and HCV treatments may ultimately be judged by their efficiency and/or cost-effectiveness. To help policy makers appropriately plan for viral hepatitis, health care payers and physicians will need to work together to gauge the value of hepatitis treatments. Cost-effectiveness analyses are needed to complement HBV and HCV clinical studies that can translate health outcomes into standard health economic metrics.



TRANSFORMING STRATEGIES TO PROVIDE ACCESS TO CARE

Any national response to viral hepatitis must include strategies to ensure access to care for the uninsured, underinsured, and underserved. Suggestions include Medicaid expansion with the removal of the 5-year residency requirement, removal of preexisting conditions for insurance coverage, and closing the “doughnut hole” in Medicare Part D medication coverage. In addition, enhanced health informatics and delivery of culturally appropriate care are essential tools.

Increased support for federally qualified health centers that treat underserved populations is also greatly needed. One example is the Charles B. Wang Community Health Center (CBWCHC) in New York City, which provides medical services to a population with a high rate of chronic HBV. CBWCHC has an established history of successful screening, vaccination, and treatment programs. To improve clinical decision making and continuity of care, the center uses tools such as an HBV disease registry, HBV history forms, and flow sheets in electronic medical records as well as a patient self-tracker that serves as a portable medical record.

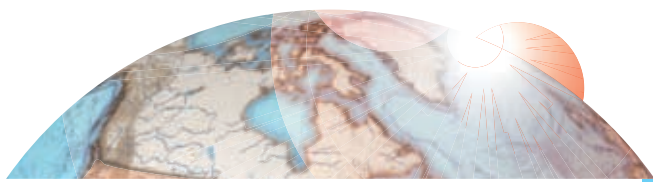
Incorporating HCV into the Ryan White Care Act (RWCA) may be one solution to increase access to care for persons with HCV, which disproportionately affects individuals with limited or no access to health care, such as those who inject drugs, are homeless, live below the poverty line, or move through the correctional system. Chronic HCV in these populations threatens to overwhelm the current health care system. The RWCA is a successful \$2 billion federal program that provides funding and resources for the full spectrum of care required by HIV-infected persons.

Expansion of Medicaid may improve HBV outcomes. A recent analysis of Medicaid fee-for-service claims from 2003 examined the effect earlier Medicaid eligibility for persons with HBV might have on long-term cost savings. Findings showed that early intervention could delay disease progression, transplants, and deaths, and yield long-term net savings. Recommendations for expanding Medicaid include allowing coverage to be based on income alone (up to at least 100% of the poverty level), eliminating the need for waivers or budget neutrality, and adopting federal legislation to allow states to implement disease-specific hepatitis coverage.

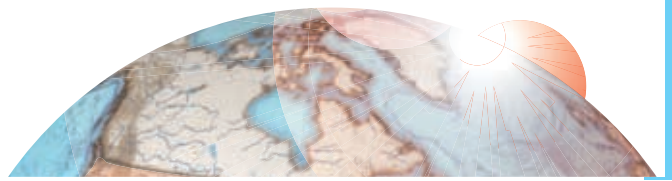
TRANSFORMING THE CURRENT INFRASTRUCTURE FOR COMBATING HEPATITIS B AND C

The national response to viral hepatitis must include that of the CDC and legislation to increase funding and resources for treatment. The CDC has a multifaceted plan for controlling viral hepatitis. The plan comprises 5 components: (1) research to develop an evidence base for disease prevention, (2) accurate and timely surveillance of acute infection and chronic disease that informs state and local action, (3) responsive health policies adopted by public and private providers trained to deliver recommended services, (4) systems and programs to support vaccination, screening, and other preventive services, and (5) education based on existing health disparities between communities in order to promote acceptance of viral hepatitis prevention services. The goals are to eliminate HBV transmission, reduce HCV incidence, and improve health outcomes for all viral hepatitis patients.

Changes in legislation are also needed. As mentioned above, expanding the RWCA to include HCV should be considered. Coinfection with HIV and HCV is common (15%-30%), and these patients suffer from a high and increasing rate of HCV-related morbidity and mortality, despite adequately controlled and well-treated HIV. The RWCA offers a potentially ideal infrastructure for



HIV/HCV integrated care, with the ability to fund a multidisciplinary team, a range of medical and support services needed for HCV treatment, training for clinicians, and capacity-building through education and technical assistance. In addition, national legislative support and advocacy for viral hepatitis and liver cancer control and prevention is imperative for all providers and patients. All Americans are vulnerable to viral hepatitis, and all will benefit from increased funding and resources for HBV and HCV screening, prevention, education, and treatment.



PROGRAM AGENDA

Thursday, September 10, 2009

SESSION ONE

KEYNOTE ADDRESS AND INTRODUCTORY PRESENTATIONS

Session Moderator: Anna S.F. Lok, MD

Welcome/Introduction

Anna S. F. Lok, MD, FRCP

Shannon Hader, MD

Keynote Address:

Addressing the Importance and Need for a Coordinated National Strategy to Prevent and Treat Viral Hepatitis in the US Today

Congressman Bill Cassidy

The Increasing Burden of Chronic Viral Hepatitis B and C

W. Ray Kim, MD

When Good Treatments Fail: The Disconnect Between Efficacy and Effectiveness

Hashem B. El-Serag, MD, MPH

Transforming Our Response to Chronic Viral Hepatitis B and C

Willis C. Maddrey, MD

SESSION TWO

THE PATH TO UNDERSTANDING CHRONIC VIRAL HEPATITIS B AND C AND THEIR CONSEQUENCES

Session Moderator: David L. Thomas, MD, MPH

What Happens When Hepatitis B Is Left Untreated?

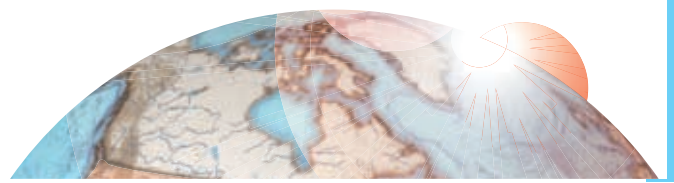
Adrian M. Di Bisceglie, MD, FACP

What Happens When Hepatitis C Is Left Untreated?

Harvey J. Alter, MD, MACP

Increasing Morbidity and Mortality of HBV- and HCV-Associated Chronic Liver Disease

Norah A. Terrault, MD, MPH



PROGRAM AGENDA (CONT'D)

SESSION THREE TRANSFORMING STRATEGIES FOR PREVENTION OF CHRONIC VIRAL HEPATITIS B AND C INFECTIONS

Session Moderator: John W. Ward, MD

Why Does Hepatitis B Infection Still Occur and How Can We Prevent It?

Dale J. Hu, MD, MPH

Why Does Hepatitis C Infection Still Occur and How Can We Prevent It?

Miriam J. Alter, PhD

Quality Indicators in the Management of Patients With Chronic Hepatitis C Virus Infection

Fasiha Kanwal, MD, MSHS

PANEL DISCUSSION

Transforming Strategies for the Prevention of CHB and CHC Infections

Chris Taylor, Moderator, *National Alliance of State & Territorial AIDS Directors*

Corinna Dan, *Association of Asian Pacific Community Health Organizations*

Joan M. Block, *Hepatitis B Foundation*

Denton Chase, *Asian Health Foundation*

Martha Saly, *National Viral Hepatitis Roundtable*

Lorren Sandt, *Caring Ambassadors Program*

Tracy Swan, *Treatment Action Group*

SESSION FOUR TRANSFORMING STRATEGIES FOR SCREENING AND DIAGNOSIS OF HBV AND HCV

Session Moderator: Marion G. Peters, MD, FRACP

HBV and HCV Testing and Management Recommendations: Review and Update

Cindy Weinbaum, MD, MPH

Role of Professional Medical Associations' Guidelines and Policies in Screening and Management of Chronic Hepatitis B and C

Litjen (LJ) Tan, MS, PhD

PANEL DISCUSSION

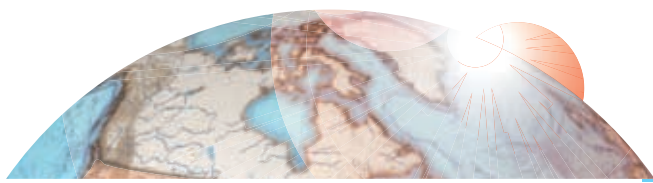
Implementing the New CDC HBV Screening Recommendations

William B. Baine, MD

Jules L. Dienstag, MD (AGA)

T. Jake Liang, MD (AASLD)

Samuel So, MD, FACS



PROGRAM AGENDA (CONT'D)

SESSION FIVE

ACHIEVING HEALTH EQUITY TO ELIMINATE RACIAL/ETHNIC/SOCIOECONOMIC DISPARITIES IN HBV- AND HCV-ASSOCIATED LIVER DISEASE

Session Moderator: Hashem B. El Serag, MD, MPH

Racial, Ethnic, and Socioeconomic Disparities in Chronic Liver Disease and HCC in the US

Katherine A. McGlynn, PhD, MPH

Achieving Health Equity to Eliminate Disparities in HBV-and HCV-Associated Liver Disease

Garth N. Graham, MD, MPH

Community Responses and Initiatives in HBV

Samuel So, MD, FACS

HCV Initiatives in the African American and Latino Communities

Charles D. Howell, MD

PANEL DISCUSSION

Achieving Health Equity to Eliminate Racial/Ethnic/Socioeconomic Disparities in HBV- and HCV-associated Liver Disease

Ted Fang

Janelle Tangonan Anderson

Thelma King Thiel, RN, BA

SESSION SIX

REPORTS FROM TODAY'S HEALTH CARE ENVIRONMENT ON IMPLEMENTATION OF SCREENING, DIAGNOSIS, AND TREATMENT RECOMMENDATIONS

Session Moderator: W. Ray Kim, MD

HCV Testing, Prevention Counseling, and Treatment Guidelines in the Veterans Health Administration (VHA)

Ronald O. Valdiserri, MD, MPH

Prevention and Control of Viral Hepatitis in Correctional Settings

Lester N. Wright, MD, MPH

The Practical Realities of Chronic Viral Hepatitis: What We Can Learn From Managed Care Populations

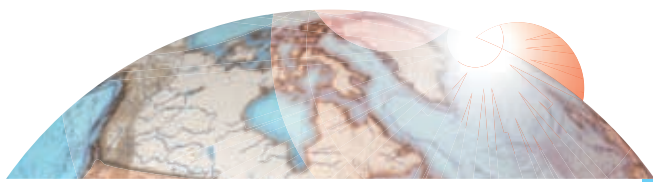
M. Michele Manos, PhD, MPH, DVM

Implementing HBV Screening and Treatment in the Real World

Son T. Do, MD

Day One Closing Remarks

Eugene R. Schiff, MD, MACP, FRCP, MACG, AGAF



PROGRAM AGENDA (CONT'D)

Friday, September 11, 2009

**SESSION SEVEN
DAY ONE OVERVIEW AND KEYNOTE PRESENTATION**

Opening Remarks: Review of Day One

Anna S.F. Lok, MD, FRCP

Keynote:

How Does a Public Health Response Have Public Health Impact? What Have We Learned From HIV?

John G. Bartlett, MD

**SESSION EIGHT
ENTERING THE NEW ERA OF THERAPY FOR HEPATITIS B AND C**

Session Moderator: Marion G. Peters, MD, FRACP

HBV: Whom to Treat, When to Treat, and Gaps in Medical Knowledge

Robert P. Perrillo, MD

Hepatitis C: Whom to Treat, When to Treat, and New Treatments

Ira M. Jacobson, MD

The Impact of Comorbidities on the Management & Prognosis of Chronic Liver Disease

David B. Ross, MD, PhD

Hepatitis C: The Next Battle for HIV-infected Patients

David L. Thomas, MD, MPH

**NIH Clinical Research Programs in Chronic Viral Hepatitis B and C: Where Are We
and Where Are We Going?**

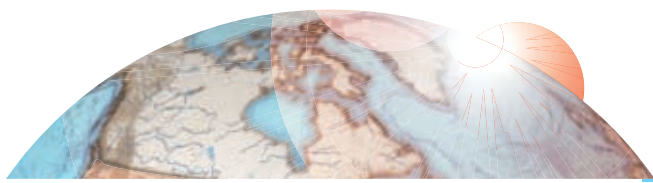
Edward C. Doo, MD

**Role of the FDA for New Drug Approvals and Clinical Trial Strategies for Chronic Hepatitis B and C
in the Era of More Effective Therapy**

Jeffrey S. Murray, MD, MPH

Economic Justification for Treatment of Chronic Viral Hepatitis B and C

John B. Wong, MD



PROGRAM AGENDA (CONT'D)

SESSION NINE

TRANSFORMING STRATEGIES TO PROVIDE ACCESS TO CARE

Session Moderator: Ira M. Jacobson, MD

Hepatitis B: Summarizing Gaps/Potential Solutions in Insurance Coverage and Care for the Uninsured, Underinsured, and the Poor

Su Wang, MD, MPH

Hepatitis C: Gaps in Care and Potential Solutions for the Underserved

Brian R. Edlin, MD

Medicaid Hepatitis Expansion Project—Overview of Findings

Vernon K. Smith, PhD

Panel Discussion

Edward A. Chow, MD

Brian R. Edlin, MD

Vernon K. Smith, PhD

Su Wang, MD, MPH

SESSION TEN

TRANSFORMING THE CURRENT INFRASTRUCTURE FOR COMBATING HEPATITIS B AND C

Session Moderator: W. Ray Kim, MD

Modernizing the CDC's Public Health Approach to the Control of Chronic Viral Hepatitis B and C

John W. Ward, MD

Creating a Health Care Safety Net for Hepatitis B and C Patients

Laura Cheever, MD, ScM

Panel Discussion

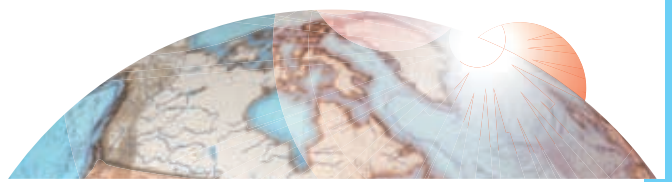
Corinna Dan, RN, MPH

Lynda Dee, JD

Janet Zola, MPH

Call for a National Strategic Plan for Chronic Viral Hepatitis B and C

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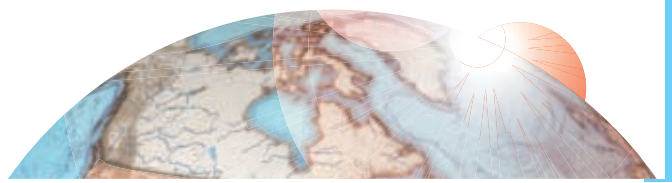
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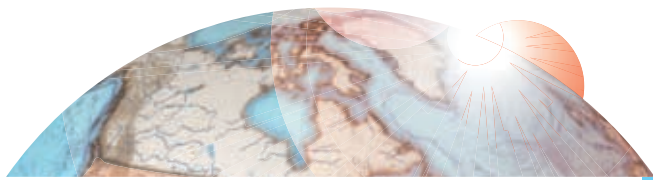
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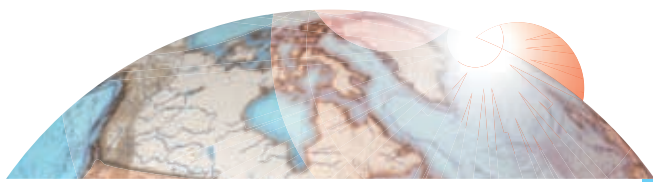
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