

Hepatitis C Reaching Crisis Levels; Requires Coverage for Routine Screenings

By Forum for Collaborative HIV Research

Published: Tuesday, Nov. 27, 2012 - 7:11 am

WASHINGTON, Nov. 27, 2012 -- Summit on HIV and Viral Hepatitis Charts Priorities to Accelerate Testing, Reduce Disparities in Care

WASHINGTON, Nov. 27, 2012 /PRNewswire-USNewswire/ -- As the countdown to implementation of the Affordable Care Act begins in earnest, experts on the front lines in fighting viral hepatitis and HIV/AIDS issued this harsh assessment regarding escalating levels of hepatitis C virus (HCV) infection: unless policymakers require insurers to cover the costs of screening everyone at potential risk for HCV, rates of cirrhosis and liver cancer will continue to rise and become a major drain on the healthcare system.

Responding to the decision by the U.S. Preventive Services Task Force (USPSTF) to limit HCV screenings to current and former intravenous drug users and other high risk groups, the more than 300 public health leaders attending the 2012 National Summit on HIV and Viral Hepatitis Diagnosis, Prevention and Access to Care in Washington urged policymakers to expand coverage requirements for one time screening to all baby boomers (born from 1945-1965), who are five times more likely than other adults to have HCV. Taking this step would align USPSTF's recommendations with new guidelines from the Centers for Disease Control and Prevention (CDC) that if followed, could identify up to 800,000 undiagnosed cases of HCV at an early stage.

This action is necessary now that chronic HCV infection is reaching crisis levels in the U.S. Today, an estimated 3.2 million Americans are infected, three times the number of people who have HIV. Disproportionately affected are ethnic minorities and especially, Native Americans, African Americans and Latinos, who are infected at significantly higher rates than the general population. However, because most cases of HCV go undiagnosed and untreated with effective therapies, CDC projects that illnesses and deaths due to chronic liver disease, cirrhosis or hepatocellular carcinoma (HCC), the most common type of liver cancer, will increase substantially over the next two decades. Although the healthcare costs associated with chronic HCV infection are difficult to determine, estimates for treating advanced liver disease in the affected population run as high as \$9 billion annually.

"As the federal government and the states work to implement the remaining provisions of the Affordable Care Act, no workable agenda can ignore the pressing need to expand access to a simple test, used just one time, that will identify more people with HCV and get them treated with effective therapies that can cure their infection," said Veronica Miller, Ph.D., Executive Director of the Forum for Collaborative HIV Research, which convened the summit. "As with HIV, we expect that finding all actively HCV-infected individuals and treating them for their infection – curing them in case of HCV – will profoundly reduce the spread of the virus."

Action Needed to Accelerate HCV Testing, Increase Resources to Fight HCV

In light of new estimates that 75 percent of people living in the U.S. with HCV do not know they are infected, the Forum for Collaborative HIV Research put the nation's viral hepatitis prevention and detection efforts at the top of the summit's agenda, recognizing a national mobilization is needed to expand testing of baby boomers and those with known risks for HCV (current and former injection drug users, chronic hemodialysis patients, people with HIV, children born to HCV-positive mothers, and those who received clotting factor concentrates, blood transfusions or solid organ transplants before improvements in the blood supply).

Towards this end, the summit leaders focused on reimbursement policies that are linked to coverage recommendations from the U.S. Preventive Services Task Force, an independent panel of private sector experts that determines which preventive services should be incorporated into primary medical care. Agreeing that screening tests for HCV should carry the same importance as those for cholesterol and triglyceride levels, where USPSTF gives an A or B grade and recommends coverage, summit leaders expressed disappointment with USPSTF's draft decision, announced November 26, to assign a B grade only to HCV testing for high risk individuals. For one-time testing of baby boomers, USPSTF proposes a C grade – defined as "offer or provide this service only if other considerations support the offering or providing the service in an individual patient" – meaning that Medicare and private insurers may limit coverage.

In contrast, summit attendees applauded draft USPSTF guidelines issued on November 19, which assigned routine HIV testing with an A grade, its highest recommendation, after concluding that earlier initiation of antiretroviral therapy (ART) is associated with a lower risk for AIDS or death, and that ART reduces sexual transmission of HIV. If the panel ultimately adopts those recommendations, Medicare and most private health insurers will be required to pay for the tests.

"USPSTF's new coverage recommendations have the potential to rapidly expand routine HIV testing and therefore, get immediate attention for the nearly one in five people who don't know they are infected," said John G. Bartlett, MD, Professor of Medicine in the Division of Infectious Diseases at The Johns Hopkins University School of Medicine. "We urgently need the same coverage recommendations for HCV testing, which has the same potential to alleviate the impact of chronic hepatitis C infection. An increased focus on providing quality care to those at greatest risk for HCV is crucial to overcoming this epidemic and thus, must become a priority issue for the public health community."

Another important priority for the summit leaders is to achieve parity in federal resources for HCV research, public health interventions and public and physician programs with what the National Institutes of Health, CDC and the Health Resources and Services Administration allocate for HIV/AIDS prevention and treatment. Currently, public funds for HCV and viral hepatitis programs pales in comparison to HIV/AIDS despite a higher morbidity and mortality burden for HCV and the reality that HCV is now curable.

Targeting Those at Greatest Risk

Mobilizing the public health community around early detection of is especially warranted now that HCV is on the rise and occurs disproportionately among ethnic minorities and the medically underserved, which is why summit leaders advocate concentrating resources on reaching those Americans who face significant barriers in access to care.

Based on what is now known about the epidemiology of hepatitis C, those most impacted by the epidemic are Native Americans, blacks and Latinos, who often go undiagnosed and don't get treated with newly available therapies that can cure the majority of HCV infections. According to the latest findings:

American Indian/Alaska Natives are 2.8 times more likely to develop Hepatitis C, based on 2010 estimates, and AI/AN women are 2.6 times as likely to die from viral hepatitis, as compared to whites.

Approximately 22 percent of those infected with HCV are African Americans. In addition, blacks are also more likely to be infected with genotype 1, the most difficult type of HCV to treat, and therefore, have high rates of cirrhosis, liver cancer and HVC mortality.

HCV affects 2.1 percent of the Latino population compared to between 1 percent and 1.5 percent of the general population. Latinos also face substantial barriers to access to medical care, including language and cultural differences and along with blacks, have less desirable treatment outcomes from standard therapy.

Underscoring these findings, John Ward, MD, Director of the CDC's Division of Viral Hepatitis, called hepatitis C a large and under-appreciated public health problem where action is needed to provide vulnerable populations greater access to education, screening and testing programs so those who are infected will get appropriate care and treatment.

Confronting the HIV/AIDS Epidemic

While elevating viral hepatitis as a public health priority, the 2012 summit also focuses on the realities of today's HIV/AIDS epidemic, which disproportionately affects men who have sex with men (MSM), minority populations, the poor and the disenfranchised living in discreet geographic regions, especially in urban areas of the Northeast and West Coast and cities and small towns in the South.

Describing the evolving face of HIV/AIDS in the U.S., Kenneth H. Mayer, MD, Director of HIV Prevention at Beth Israel Deaconess Hospital and the Medical Research Director of The Fenway Institute in Boston, said: African Americans now represent 46 percent (21,679 cases in 2010) of all new infections but are the least likely to have their virus under control. This is confirmed by new research, which finds that only one in five (21 percent) African Americans achieves viral suppression compared to 26 percent of Latinos and 30 percent of whites.

Besides African Americans, Hispanics and Native Americans are disproportionately affected by HIV/AIDS. In 2010, Latinos accounted for 20 percent of all new HIV infections, or 9,653 cases, yet due to such barriers as poverty, lack of insurance, low education, limited access to health care, and language difficulties, nearly four in 10 (38 percent) are tested for HIV late in their illness and diagnosed with AIDS within a year. Recent data also indicate that HIV/AIDS has reached epidemic levels among American Indians and Alaska Natives. Despite their small number within the overall U.S. population, American Indians/Alaska Natives have a 30 percent higher rate of AIDS and HIV infection as compared to the white population when their infection rates are weighted based on their population size.

Complementing the new demographics of HIV/AIDS, Dr. Mayer said the U.S. epidemic is concentrated in specific neighborhoods around the country – the urban areas of the Northeast and West Coast and in the South – and especially in underserved areas known as HIV "hot spots" where transmission rates are as high as the most HIV-infected areas of sub-Saharan Africa. Citing new evidence from the HIV Prevention Trials Network's (HPTN) 064 Women's HIV Seroincidence Study (ISIS), Dr. Mayer said black women living in six HIV "hot spots" have a five-fold higher incidence rate of HIV than the overall rate of infection among black women estimated by the CDC. Besides living in poor and disenfranchised neighborhoods, the ISIS study attributed these higher rates of HIV in at-risk women to substance abuse, food insecurity, and contact with partners who either did not know or did not disclose their HIV status. The six cities where the hot spots are located are Atlanta, Baltimore, Newark, New York City, Raleigh-Durham, and Washington, DC.

In the HPTN061 study, 12 percent of 1,553 black MSM from Boston, Harlem NYC, Washington DC, Los Angeles, San Francisco and Atlanta were newly diagnosed HIV positive. The previously undiagnosed positive men were younger, more likely to be unemployed and present with STI's. Study authors attribute the very high rate of undiagnosed HIV and STI infection to structural, behavioral and biologic factors, such as poverty, unemployment, local environment, unprotected receptive anal sex)

"What we are finding is that the HIV epidemic today is concentrated among the disenfranchised and socially marginalized living in underserved communities," said Dr. Mayer. "If we are to reverse the tide of this epidemic, we must focus on the root causes of HIV disparities in at-risk communities, including stigma, poverty, STI prevalence, incarceration, and limited social mobility."

Closing the Gaps in Testing and Treatment

High rates of undiagnosed and untreated viral hepatitis and HIV exist side-by-side with unprecedented drug discovery, which has produced a robust arsenal of new therapies and scientifically-proven interventions that achieve a virologic cure of hepatitis C and suppress viral load in the case of HIV. Thus, closing this divide is the "end game" for both the viral hepatitis and HIV/AIDS communities.

Summarizing the state of the science on HIV/AIDS, Dr. Bartlett said that new treatment guidelines could be a "game changer" if fully implemented, by accelerating the use of ART in everyone diagnosed with HIV.

The HHS Panel on Antiretroviral Guidelines for Adults and Adolescents, which Dr. Bartlett chairs, also recommended ART for all pregnant women with HIV regardless of their CD4 count as well as those who are co-infected with the hepatitis B virus, have HIV-associated nephropathy or have a history of an AIDS-defining illness. Moreover, the new guidelines calls for the use of ART to prevent transmission of HIV from an infected individual to a sexual partner, a strategy known as treatment as prevention.

"After years of debate on when to initiate antiretroviral therapy, there is now scientific consensus that ART is an important strategy for reducing HIV transmission and should be made available to everyone, regardless of their CD4 count.," said Dr. Bartlett. "Based on what we know today, it can be argued that all patients diagnosed with HIV infection are candidates for ART."

Because testing is considered the single most important strategy for curbing the HIV and HCV epidemics, summit leaders welcomed the meaningful changes now taking place under the Affordable Care Act to expand preventive care but agreed much can be learned from new approaches and experiments that are expanding screening and detection efforts in local communities. One successful community-based approach is social networking, which enlists HIV-positive and high-risk HIV negative persons in communities of color to identify and recruit high risk individuals from their social, sexual, or drug-using networks. Other successful strategies include telemedicine support to clinical providers in managing viral hepatitis, the use of health system navigators in community and HIV clinics, mobile street vans that deliver medical and supportive services to patients in inner city neighborhoods, and transitional care management to retain ex-offenders in care.

About the Forum for Collaborative HIV Research

Now part of the University of California (UC), Berkeley School of Public Health and based in Washington, DC, the Forum was founded in 1997 as the outgrowth of the Keystone Center's report "The Keystone National Policy Dialogue on Establishment of Studies to Optimize Medical Management of HIV Infection," which called for an ongoing collaboration among stakeholders to address emerging issues in HIV/AIDS and set the research strategy. Representing government, industry, patient advocates, healthcare providers, foundations and academia, the Forum is a public/private partnership that is guided by an Executive Committee that sets the research agenda. The Forum organizes roundtables and issues reports on a range of global HIV/AIDS issues, including treatment-related toxicities, immune-based therapies, health services research, co-infections, prevention, and the transference of research results into care. Forum recommendations have changed how clinical trials are conducted, accelerated the delivery of new classes of drugs, heightened awareness of TB/HIV co-infection, and helped to spur national momentum toward universal testing for HIV. <http://www.hivforum.org>

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