



# KY Hepatitis Connections

Happy 4<sup>th</sup> of July! We are pleased to share with you the July issue of *KY Hepatitis Connections*. The *KY Hepatitis Connections* provides current information, opportunities for viral Hepatitis continuing professional education and information about educational materials available.

Please feel free to forward and/or copy and distribute to other professionals in your network. Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral Hepatitis and its impact on our families throughout the Commonwealth. Join us on Facebook, KY Viral Hepatitis.

Kathy Sanders, RN MSN

# A Public Health and Healthcare Spending Time Bomb: Hepatitis C

Mina Marmor and Henry I. Miller

The relatively obscure liver inflammation caused by hepatitis C virus (HCV) is a significant threat worldwide, and its prevalence is growing. It demands greater attention from both public health officials and drug developers.

The World Health Organization estimates that 170 million people are chronically infected with HCV, which is transmitted via blood-to-blood contact. In the developed world, the majority of people with HCV were infected prior to the 1992 introduction of sensitive screening tests which curtailed transmission from blood transfusions or organ transplants.

The course of infection is variable, but viral infection is chronic in the majority of cases and can result decades later in cirrhosis, liver failure and liver cancer. (In the developing world, where screening tests are less available, there is surely a higher but hard to estimate rate of new infections.)

In the United States, the estimates of about 3 million people chronically infected with HCV (based on the National Health and Nutrition Examination Survey) are probably an underestimate because the surveys do not include incarcerated or homeless people; the addition of these high-risk populations could increase prevalence estimates by 500,000–1,000,000. Moreover, because the disease is asymptomatic for a long period of time, only about 30% of HCV-infected people in the United States have been diagnosed. Read More: <http://www.forbes.com/sites/henrymiller/2013/06/19/a-public-health-and-healthcare-spending-time-bomb-hepatitis-c/>

## HCV Transmission Rate Higher Among MSM with HIV

Transmission of hepatitis C virus among men who have sex with men has been occurring since early in the HIV epidemic, and the rates of infection are higher among those with HIV, according to data published in *Clinical Infectious Diseases*.

Researchers at Johns Hopkins University (JHU) prospectively followed 5,310 men who have sex with men (MSM) enrolled in the Multicenter AIDS Cohort Study. The participants were men with HIV infection and men at risk for HIV. All the participants tested negative for hepatitis C virus (HCV) antibody within two years of enrollment and at follow-up visits through September 30, 2011.

The researchers followed the group for a median of 7.1 years for a total of 55,343 years of follow-up. During follow-up, researchers documented 115 incidences of HCV infection, with an incidence rate of 2.08 per 1,000 person-years. HIV-positive men had a 4.22 HCV infection rate, approximately 8.5 times higher than the 0.5 rate for men who did not have HIV. The full report, “Incident Hepatitis C Virus Infection in Men Who Have Sex with Men: A Prospective Cohort Analysis, 1984–2011,” was published in the journal *Clinical Infectious Diseases*, (2013; 57 (1): 77–84). Read More: <http://cid.oxfordjournals.org/content/57/1/77>

## Vitamin D Deficiency May Help Spread of Hepatitis B Throughout Liver

GERMANY :: Viral Hepatitis / Medical Xpress (06.06.2013)

Researchers in Germany have concluded that low levels of vitamin D are associated with high levels of hepatitis B virus (HBV) in the blood. Between January 2009 and December 2010, Dr. Christian Lange of Johann Wolfgang Goethe University Hospital in Frankfurt, Germany, and colleagues recruited 203 patients with chronic HBV who had never been treated for the disease. The researchers excluded patients with HIV, hepatitis C, or hepatitis D co-infection, excessive alcohol use, liver cancer, or other malignancies.

The researchers measured levels of 25-hydroxyvitamin D in each patient. Results indicated that 34 percent had severe vitamin D deficiency, 47 percent had vitamin D insufficiency, and 19 percent had normal levels of vitamin D. Researchers discovered that the concentration of HBV in the blood (viral load) corresponded to vitamin levels; a high concentration of HBV was a strong indicator of low vitamin D levels. Researchers also determined that patients with hepatitis B antigen had lower vitamin D levels than patients who tested negative for the antigen. Inverse seasonal fluctuations in vitamin D and HBV levels suggested a link between the two.

Lange concluded that the data confirm an association between low vitamin D levels and high HBV concentration in the blood. The researchers suggested further study of vitamin D as a therapeutic intervention for controlling HBV. The full report, "Low Vitamin D Serum Concentration is Associated with High Levels of Hepatitis B Virus (HBV) Replication in Chronically Infected Patients," was published online in the journal *Hepatology* (2013; doi: 10, 1002/hep.26488).

Read more: <http://www.cdcnpin.org/scripts/display/NewsDisplay.asp?NewsNbr=61724>



## Input Sought on Renewal and 3- Year Extension of Viral Hepatitis Action Plan

The original Action Plan, released in May 2011, details steps that federal partners within HHS and the Departments of Justice and Veterans Affairs are undertaking, through the end of 2013, to address viral hepatitis in the United States.

As we work with federal partners to assess progress to date and chart a course for the next three years, we want to ensure that our non-federal partners and community stakeholders have an opportunity to share their thoughts and perspectives about how our nation can best achieve the long-term goals of the Viral Hepatitis Action Plan. To share your ideas and feedback – including suggestions for how federal agencies can better collaborate with non-governmental stakeholders – review the RFI and **send responses by July 5, 2013**. (For background, read the [current Action Plan](#) [PDF 672KB] and the first year [Implementation Progress Report](#) [PDF 588KB].)

Your input can strengthen the renewal of the Viral Hepatitis Action Plan and enhance national efforts to achieve its long-term goals of increasing the proportion of persons aware of their hepatitis B or hepatitis C infection infections, reducing the number of new cases of hepatitis C infection, and eliminating mother-to-child transmission of hepatitis B.

Read more: <http://blog.aids.gov/2013/06/input-sought-on-renewal-and-3-year-extension-of-viral-hepatitis-action-plan.html#sthash.ZZ5R9h3L.dpuf>

## Born with Hepatitis C

Although relatively rare, learn 12 facts about babies born with Hepatitis C.



A highly prevalent, infectious liver disease, Hepatitis C can infect people from all socioeconomic brackets, cultures and generations. Babies can even be born with the Hepatitis C virus. While children do not represent the most common age group of Hepatitis C patients, learn 12 facts about being born with this illness.

Read more: [http://www.hepatitis-central.com/mt/archives/2013/06/born-with-hepatitis-c.html?eml=hepcen187&utm\\_source=iContact&utm\\_medium=email&utm\\_campaign=Hepatitis%20Central&utm\\_content=HepCen+%23187+B+](http://www.hepatitis-central.com/mt/archives/2013/06/born-with-hepatitis-c.html?eml=hepcen187&utm_source=iContact&utm_medium=email&utm_campaign=Hepatitis%20Central&utm_content=HepCen+%23187+B+)

## Endoscopes Not Always Cleaned Properly: Study

THURSDAY, June 13 (HealthDay News) -- Three of every 20 flexible endoscopes used to examine patients' gastrointestinal tracts and colons were improperly cleaned, a new study finds.

Those 15 percent of endoscopes had unacceptable levels of "bio dirt" -- cells and matter from a patient's body that could pose a potential infection risk to other patients, according to the researchers.

They examined 275 flexible duodenoscopes, gastroscopes, and colonoscopes used at five U.S. hospitals and found that 30 percent, 24 percent and 3 percent, respectively, did not pass a cleanliness rating.

The study findings were to be presented last weekend at the annual meeting of the Association for Professionals in Infection Control and Epidemiology (APIC).

"Three out of 20 is an unexpectedly high number of endoscopes failing a cleanliness criterion," lead investigator Marco Bommarito, lead research specialist at 3M Infection Prevention Division, said in an APIC news release. "Clearly, we'd like no endoscopes to fail a cleanliness rating."

In recent years, improperly cleaned endoscopes at medical facilities in the United States have resulted in thousands of patients having to be checked for HIV and hepatitis B and C, according to the news release. More health-care-associated outbreaks have been linked to contaminated endoscopes than to any other medical device, the U.S. Centers for Disease Control and Prevention has reported.

Each year in the United States, between 15 million and 20 million endoscopy procedures are conducted with reusable endoscope devices to screen various parts of patients' gastrointestinal tracts and look for problems such as cancer.

Duodenoscopes examine the duodenum (the first section of the small intestine), while gastroscopes examine the stomach, and colonoscopes examine the colon.

"The cleaning protocols for flexible endoscopes need improvement, such as guidelines tailored to the type of scope or identifying if there is a critical step missing in the manual cleaning process, and documented quality-control measures," Bommarito said. "These types of improvements could have a positive impact on patient safety."

Because this study was presented at a medical meeting, the data and conclusions should be viewed as preliminary until published in a peer-reviewed journal.

SOURCE: Association for Professionals in Infection Control and Epidemiology, news release, June 7, 2013

## **Interferon-based therapy benefited HCV/HIV coinfecting patients despite viral relapse**

Berenguer J. J Hepatol. 2013;58:1104-1112.

June 12, 2013

Patients with HCV/HIV co-infection who experienced viral relapse after treatment with interferon-based therapy still experienced some clinical benefit, according to recent results.

Researchers evaluated 1,599 patients enrolled in the GESIDA 3603 cohort, which includes patients co-infected with HCV and HIV, and treated with interferon and ribavirin at 19 Spanish medical facilities. Incidence of mortality and liver-related complications was observed from completion of therapy to death or last follow-up visit (median 4 years).

Read more: <http://www.healio.com/infectious-disease/hepatitis-resource-center-2013/interferon-based-therapy-benefited-hcv-hiv-coinfecting-patients-despite-viral-relapse>

## **No impact on acute rejection from interferon/ribavirin HCV therapy among renal transplant recipients**

Sanai FM. J Hepatol. 2013;58:1096-1103.

Chronic hepatitis C-infected renal transplant recipients receiving interferon-based therapy experienced modest efficacy rates but were not at elevated risk for allograft rejection, according to recent results.

In a prospective, multicenter, open-label trial, researchers evaluated 32 adult patients with chronic HCV genotypes 1 (62.5%) or 4 (37.5%) and significant fibrosis who had undergone renal transplantation (RT) between November 2007 and December 2011. Participants received 135 mcg or 180 mcg pegylated interferon alfa-2a (PegIFN $\alpha$ -2a) weekly and between 200 mg and 1,200 mg ribavirin (RBV) daily for 48 weeks. Patients' renal safety was compared with that of 31 matched, untreated historical controls.

Sustained virologic response (SVR) was achieved by 37.5% of treated participants, 12.5% experienced rapid virologic response (RVR) and 56.3% achieved early virologic response (EVR). Patients who received 135 mcg/week peginterferon had a numerically higher SVR rate than 180 mcg patients (50% vs. 33.3%;  $P=.432$ ). Of all evaluated factors, only EVR was found to be independently predictive of SVR via binary logistic regression (OR=20.4; 95% CI, 2.2-192.6).

Read more: <http://www.healio.com/infectious-disease/hepatitis-resource-center-2013/no-impact-on-acute-rejection-from-interferon-ribavirin-hcv-therapy-among-renal-transplant-recipients>

## Simeprevir keeps HCV at bay in treatment-naive and experienced patients

By: NEIL OSTERWEIL, Internal Medicine News Digital Network

ORLANDO – The investigational protease inhibitor simeprevir was associated with high levels of sustained virologic response in patients with both treatment-naive and relapsed hepatitis C viral infections, reported investigators at the annual Digestive Disease Week.

In the QUEST-2 phase III trial, 81.3% of previously untreated patients with hepatitis C (HCV) genotype 1 infections randomized to simeprevir (TMC435) and pegylated interferon-alfa (pegIFN/RBV) had a sustained virologic response following 12 weeks of therapy (SVR12, the primary endpoint), compared with 50% of those assigned to pegIFN/RBV and placebo (*P* less than .001), reported Dr. Fred Poordad from the University of Texas Health Science Center in San Antonio.

Read more: <http://www.internalmedicineneeds.com/single-view/simeprevir-keeps-hcv-at-bay-in-treatment-naive-and-experienced-patients/1dfa9308fdd1aa236878b11cbb8281ac.html>

## Hyaluronic acid levels can predict risk of serious liver events in people living with HIV and hepatitis B or C co-infection

Michael Carter

A simple blood test can predict the risk of liver-related death or hepatic encephalopathy for people living with HIV who have hepatitis B or hepatitis C co-infection, investigators from the EuroSIDA cohort report in *PLoS One*.

Their results showed that baseline elevations in plasma levels of hyaluronic acid (HA) were associated with a significant increase in the risk of serious liver-related events. Levels of this biomarker remained stable in people who remained 'event free', but increased in those experiencing disease progression.

“The present study indicates that HA could be a useful biomarker to estimate the long-term risk of liver disease,” write the authors.

Many people with HIV have viral hepatitis co-infections and liver disease related to hepatitis B virus (HBV) or hepatitis C virus (HCV) is now an important cause of serious illness and death in people with these co-infections.

Read more: <http://www.aidsmap.com/Hyaluronic-acid-levels-can-predict-risk-of-serious-liver-events-in-people-living-with-HIV-and-hepatitis-B-or-C-co-infection/page/2669457/>

## **CDC Launches First National HBV Testing Campaign for Asian-Americans and Pacific Islanders**

UNITED STATES :: Viral Hepatitis  
Infection Control Today (06.14.2013)

CDC has partnered with Hep B United to develop and launch “Know Hepatitis B,” a national, multi-year communications campaign that aims to increase hepatitis B virus (HBV) testing among Asian Americans and Pacific Islanders. The campaign, developed with input from Asian Americans and Pacific Islanders, will share culturally competent messages in English, Chinese, Korean, and Vietnamese; messaging will focus on strong family ties common among these populations. Asian Americans and Pacific Islanders account for more than half of the 1.2 million HBV-infected Americans, although they comprise only 5 percent of the US population.

HBV is very common in some Asian and Pacific Island countries; many people born in these countries became HBV-infected as infants or young children. Because HBV may have no symptoms for many years, two out of three HBV-infected individuals may be unaware of their infection. Left untreated, HBV can cause liver damage, but treatment can “delay or reverse” liver disease.

Howard Koh, MD, assistant secretary for health at the US Department of Health and Human Services, advised every American born in Asia or the Pacific Islands or born to parents from these countries to be tested for HBV. The Know Hepatitis B campaign channels will include media outlets serving Asian-American and Pacific Islander communities, social media and digital materials, Hep B United and local partners’ outreach to local communities, and outreach to healthcare professionals.

### **TIP... Addressing Viral Hepatitis in People with Substance Use Disorders**

See the link below for a guide and reference for clinicians working with hepatitis in people with substance use disorders. For information to download or order brochures:

<http://store.samhsa.gov/product/TIP-53-Addressing-Viral-Hepatitis-in-People-With-Substance-Use-Disorders/SMA11-4656>



## **HCV Genotype Test Kit OK'd**

By John Gever, Deputy Managing Editor, MedPage Today

Published: June 20, 2013

SILVER SPRING, Md. -- The first standardized test kit for hepatitis C virus (HCV) genotyping has won FDA approval, the agency said Thursday.

Abbott Molecular's RealTime HCV Genotype II test identifies the specific viral genotype -- classified as 1, 1a, 1b, 2, 3, 4, or 5 -- present in clinical samples. This information is vital for treatment planning, as available treatments for HCV infection vary in effectiveness according to genotype.

HCV genotyping was previously available only with lightly regulated "home brew" tests performed at individual clinical laboratories using their own recipes. The Abbott test runs on the company's fully automated m2000 instrument platform for clinical labs.

The FDA emphasized that Abbott's test is not approved for diagnosing infection or for screening for the virus's presence in blood, blood products, or donor tissue.

Approval was based partly on evaluations of the test's accuracy in differentiating specific HCV viral genotypes compared with a validated gene sequencing method. The agency said it also "reviewed data from investigators demonstrating the relationship between HCV genotype and effectiveness of drug therapy."

"Tests such as this one can help physicians gain an understanding of a patient's HCV status," said Alberto Gutierrez, PhD, director of the Office of In Vitro Diagnostics and Radiological Health in FDA's Center for Devices and Radiological Health, in a statement announcing the approval.

"Along with other clinical factors, the particular type of HCV is an important consideration in aiding healthcare professionals in determining if and when to initiate treatment and the appropriate type of treatment."

## **US Assembly passes hepatitis C test bill**

The week of June 17<sup>th</sup> there was an announcement that, the US House of Representatives had passed a bill requiring certain health service providers to offer hepatitis C tests to people born between 1945 and 1965 is to be welcomed.

Under the bill, if the test should come out positive, the insurance provider must now offer follow-up healthcare including a hep C diagnostic test, or refer the patient to a provider who can do so.

The bill would also require the state health commissioner to evaluate the impact of the legislation and report the findings to the state governor.

Before the bill can be enacted into law it must now also be passed by the US Senate, but this is a great step forward for campaigners demanding tests and treatment for the baby-boomer generation, and shows that the US government is committed to providing treatment and support for people with hep C.

## **World Hepatitis Day 2013**

### **World Hepatitis Day 2013: This is hepatitis. Know it. Confront it.**

This year on the 28th July we will be celebrating our 6th World Hepatitis Day, working in partnership with the World Health Organization (WHO).

2013 posters are now available at:

<http://www.worldhepatitisalliance.org/WorldHepatitisDay/WHD2013.aspx>

You can use the online tool to edit any of the WHD 2013 posters. You can change the text or language, and can add in your own pictures and logos to make it more relevant to your campaign.

This year the focus is two main themes:

1. **This is hepatitis. Know it. Confront it:** This theme has seen big success since its launch in 2010, as it focuses on the real-life impact of viral hepatitis.
2. **See No Evil, Hear No Evil, Speak No Evil:** The message from this theme is that hepatitis is being ignored around the world, and we are calling for that to change.

## **HCV Advocate Training offered at Midway College August 22<sup>nd</sup>**

Mark your calendars! Alan Franciscus with the HCV Advocate is coming to Midway College on August 22<sup>nd</sup> to provide an all-day training to healthcare providers, clinicians and counselors on Hepatitis C. The training is free, there is no CEU or CME offered with this training. Lunch and snacks are provided. Space is limited; you must register for this training by August 1<sup>st</sup>, 2013 online, <http://www.Ky.train.gov>. For more information, contact Kathy Sanders at [kathyj.sanders@ky.gov](mailto:kathyj.sanders@ky.gov).

# USPSTF Recommends Screening for HCV Infection in Baby Boomers

**“Recommendation:** The USPSTF recommends screening for HCV infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965.

This is great news as the USPSTF recommendations will be incorporated into the prevention benefit for health plans as required by the ACA. “The Patient Protection and Affordable Care Act (PPACA) is aimed at expanding access to health care and lowering cost barriers to seeking and receiving care, particularly high-value preventive care. The legislation requires Medicare and all qualified commercial health plans (except grandfathered individual and employer-sponsored plans) to cover routine preventive services graded A and B by the U.S. Preventive Services Task Force (USPSTF) at no cost to the consumer, along with recommended immunizations and additional preventive care and screenings for women. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6039a3.htm>.

When new recommendations are adopted, health plans are not required to make changes in prevention coverage until the first plan year beginning one year after the effective date of the new recommendation. Thus the one-time screening of baby boomers born from 1945 through 1965 will be phased into health plan coverage for prevention benefits. Some health plans may choose to adopt these recommendations more quickly.

Local health departments and local providers will have increased opportunities to bill third parties for these services, allowing them to redirect health department resources to other priorities. Health departments are starting to ramp up their (and their contracted providers’) billing and revenue generation capacity. Health departments should ensure that community partners are aware of the new USPSTF recommendation and its impact on HCV screening coverage by public and private insurers.

Most importantly, the USPSTF recommendations for hepatitis C screening in adults now align with the CDC campaign for hepatitis C screening of baby boomers, <http://www.cdc.gov/vitalsigns/hepatitisc/index.html>.

- Recommendation Statement - <http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfinalrs.htm>
- Clinical Summary - <http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcsumm.htm>
- Consumer Fact Sheet - <http://www.uspreventiveservicestaskforce.org/uspstf12/hepc/hepcfact.pdf>



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