



KY Hepatitis Connections

Happy Easter! On behalf of the KY Adult Viral Hepatitis Program, we wish you and your family a wonderful Easter holiday. I am pleased to share with you the April issue of *KY Hepatitis Connections*. As the KY Adult Viral Hepatitis Program Coordinator, I believe it is imperative to create a legacy of working with partners and colleagues across the Commonwealth of Kentucky to prevent the transmission of viral hepatitis. The *KY Hepatitis Connections* provides current information, opportunities for viral hepatitis continuing professional education and information about educational materials available. Please feel free to 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.

Kathy Sanders, RN MSN



May is Viral Hepatitis Awareness Month

The month of May is designated as Hepatitis Awareness Month. As you are aware, viral hepatitis is the most common blood-borne illness in the world. Billions of people have been infected with acute hepatitis and hundreds of millions are infected with chronic hepatitis. Chronic viral hepatitis B & C infections are “silent diseases” because frequently, those infected have no obvious symptoms. Without appropriate screening and management of the disease, chronic viral hepatitis carriers frequently die from liver cancer and can pass on the infection to others.

The Kentucky Adult Viral Hepatitis Program urges your organization to plan activities during May for Viral Hepatitis Awareness Month. It is our hope to raise awareness of the health threat of viral hepatitis to communities throughout the Commonwealth, renew support for those living with the disease, and commit to a future free of these illnesses. Please send me information on activities your organization has planned for the May Newsletter. You can email me at Kathyj.sanders@ky.gov.

The CDC has developed tools for Hepatitis Awareness Activities, Videos for Public Service Announcements aimed at testing for Baby Boomers, and on-line Risk Assessments tools for Hepatitis testing and vaccination recommendations. See the links below:

YouTube Video: https://www.youtube.com/watch?feature=player_embedded&v=S_bDKPMsNNY

Risk Assessment: <http://www.cdc.gov/hepatitis/riskassessment/>

Resources for Hepatitis Awareness Month: <http://www.cdc.gov/hepatitis/HepPromoResources.htm> and http://www.cdc.gov/hepatitis/HepAwarenessMonth.htm?s_cid=hepatitis_004.

About Hepatitis Testing Day- May 19, 2013 is the second national Hepatitis Testing Day. It is a day for people at risk to be tested, and for health care providers to educate patients about chronic viral hepatitis and testing. National Hepatitis Testing Day in the United States is part of an educational initiative of CDC's [Division of Viral Hepatitis](#) and the U.S. Department of Health & Human Services' [Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care & Treatment of Viral Hepatitis](#) .



WEBINAR:

May is Hepatitis Awareness Month! Free & Low Cost Opportunities from CDC and local NGOs

Go to www.train.org, sign in or create a valid account, and search for the course ID/ COURSE ID: 1042853

COURSE DESCRIPTION: This is the second Webinar in a series produced by the CT-RI Public Health Training Center in conjunction with the NE ATTC, the CDC and the DHHS. This webinar will review tools available for clinical education, training and communications surrounding Hepatitis B & C. 1 hour and 30 minutes

COURSE OBJECTIVES:

- 1) Understand how May Hepatitis Awareness Month & National Hepatitis Testing day support the Viral Hepatitis Action Plan
- 2) Understand at least 3 available strategies to promote awareness during the May Hepatitis Awareness Month & National Hepatitis Testing Day
- 3) Learn what is effective from others who have implemented May activities

INSTRUCTORS:

Cynthia Jorgensen, DrPH, is the Lead for Education, Training and Communication in CDC's Division of Viral Hepatitis; **Corinna Dan, RN MPH**, is with the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) at the US Department of Health and Human Services and is the Viral Hepatitis Policy Advisor working to implement the National Viral Hepatitis Action Plan and support coordination of viral hepatitis activities across federal agencies and the community; **Chari Cohen** serves as the Director of Public Health for the Hepatitis B Foundation (HBF), in Doylestown, PA; **Philip E. Reichert, MPH**, has been the manager of the Florida Department of Health's hepatitis program since 2005.

Pfizer Stops Developing Hepatitis C Drug (filibuvir), Cites Strategic Review

Pfizer Inc. (PFE) has stopped development of an experimental hepatitis C drug, bowing out of a hotly contested industry race to introduce the next generation of treatments for the infectious liver disease.

The New York-based drug giant decided to discontinue development of PF-00868554, also known as filibuvir, following a strategic review, said spokeswoman Victoria Davis. She said the decision wasn't related to any safety issues.

Read more:

<http://www.foxbusiness.com/news/2013/03/08/pfizer-stops-developing-hepatitis-c-drug-cites-strategic-review/#ixzz2MylAfxXN>

CROI 2013: Sofosbuvir + Ledipasvir + Ribavirin Combo for HCV Produces 100% Sustained Response

An interferon-free regimen of the direct-acting hepatitis C drugs sofosbuvir (formerly GS-7997), ledipasvir (formerly GS-5885), and ribavirin produced a 12-week post-treatment sustained virological response (SVR12) rate of 100% for both treatment-naive patients and prior non-responders with HCV genotype 1, according to data presented today at the 20th Conference on Retroviruses and Opportunistic Infections (CROI 2013) in Atlanta.

Direct-acting antiviral agents that target different steps of the hepatitis C virus (HCV) lifecycle have ushered in a new era of treatment, but many patients and providers are awaiting all-oral therapy that avoids interferon and its difficult side effects. [Read more....](#)

Gilead-Medivir Hepatitis C Drug Clears Virus in Patients

An experimental drug combination from [Gilead Sciences Inc. \(GILD\)](#) and [Medivir AB \(MVRB\)](#) eradicated the virus that causes hepatitis C in 100 percent of patients with the liver disease in an early study.

The 90 patients in the trial, who had tried and failed to respond to other medicines, took a two-drug mixture of Medivir's Simeprevir and Gilead's Sofosbuvir for 12 or 24 weeks, with and without the antiviral ribavirin, researchers said today in Atlanta. The study was presented at the Conference on Retroviruses and Opportunistic Infections.

[Read more...](#)

Spending on HCV, specialty medications rose sharply in 2012

March 11, 2013

Consumer spending on drugs to treat complex illnesses, particularly hepatitis C, increased substantially during 2012, while costs for traditional prescription drugs declined, according to a recent report.

The report, published by Express Scripts, indicated that total spending on prescription drugs decreased by 1.5% during 2012, marking the first such reduction in more than 20 years. Spending on specialty medications for complex illnesses that included [hepatitis C](#), however, increased by 18.4% among commercially insured patients, compared with a 17.1% increase in 2011.

The total spending trend for hepatitis C-related medications grew by 33.7% — the largest increase among drugs for all observed major illnesses for the year. The researchers attributed this surge to the 2011 release of Incivek ([telaprevir](#), Vertex Pharmaceuticals) and Victrelis ([boceprevir](#), Merck). In a [Specialty Quarterly Spotlight](#) within the [report](#), the researchers noted that, “Due to their increased efficacy, both Incivek and Victrelis got off to a quick start in 2011, dramatically increasing the price of treating hepatitis C. Studies have estimated the wholesale acquisition costs of 12 weeks of Incivek therapy at \$49,200 and a 32-week course of Victrelis therapy at \$35,200.”

The estimated average cost for a hepatitis C prescription was \$3,370 in 2011, compared with \$1,389 in 2010. The researchers predicted that spending for hepatitis C-related medications will continue to grow by an estimated 32.3% in 2013 and 56.3% in 2014 as new treatments and screening guidelines emerge.

“Previously untreated patients, some of whom may have recently discovered their infection as a result of the new screening guidelines, along with patients who have failed treatment with one of the other therapies, are said to be awaiting the launch of a new class of interferon-free medications that is expected to hit the market as early as 2014,” the researchers wrote. “Plan sponsors should take steps to prepare for the onslaught of new patients and increased drug costs.”

Meal consumption confounds liver stiffness measurements in patients with chronic HCV

Arena U. *Hepatology*. 2013;doi:10.1002/hep.26343.

March 4, 2013

Liver stiffness varied significantly during a 2-hour period after consumption of a meal, and it impaired detection of fibrosis and esophageal varices in patients with chronic hepatitis C in a recent study.

Researchers measured liver stiffness (LS) via transient elastography (TE) in 125 patients aged 20 to 78 years with [chronic HCV](#) following an overnight fast and 15, 30, 45, 60 and 120 minutes after consumption of a standardized liquid meal. The cohort included 40 patients with [cirrhosis](#), 50 with mild or no fibrosis and 35 with significant or advanced fibrosis. Among patients with cirrhosis, 27 were classified Child-Turcotte-Pugh class A and 13 Child-Turcotte-Pugh class B, and esophageal varices were observed in 20 cases.

LS increased within 15 to 45 minutes of meal consumption, then returned to baseline values by the 120-minute measurement in all cases. Patients with more advanced fibrosis, especially cirrhosis, had significantly greater LS compared with those with a lower fibrosis stage at all evaluated time points. They also had a greater overall change, although the percentage change was significantly greater among those with less severe fibrosis ($P<.001$ for all comparisons).

Investigators noted that the use of LS values collected at any time point following consumption of the meal had a lower probability of accurately detecting fibrosis stage, Child-Turcotte-Pugh class or esophageal varices compared with LS values at baseline.

“During the past decade, TE has been shown to represent an important tool for the assessment of the fibrotic evolution of chronic liver disease, particularly chronic HCV,” the researchers wrote. “The identification of factors negatively affecting the diagnostic accuracy of TE is absolutely crucial.

“The results of the present study provide definitive evidence of the confounding effect of a meal on the accuracy of LS measurements and suggest that a fasting period of 120 minutes should be observed before the performance of TE.”



Chronic HCV linked to hypertension, congestive heart failure

Younossi ZM. *Aliment Pharmacol Ther.* 2013;37:647-652.

February 27, 2013

Patients with chronic hepatitis C are more likely to have hypertension, in addition to insulin resistance and diabetes, and also are at elevated risk for congestive heart failure, according to recent results.

Researchers evaluated data from 19,741 participants in the National Health and Nutrition Examination Survey between 1999 and 2010. The cohort included 173 patients with [chronic HCV](#), with the remaining 19,568 classified as controls.

Participants with chronic HCV were significantly more likely than controls to be male (66.6% of cases vs. 46.1%; $P=.0001$), aged 45 to 55 years (41.9% vs. 20.4%; $P=.0001$) and African-American (23.5% vs. 10.5%; $P<.0001$). Those with HCV also were more likely to have [hypertension](#) (40.1% vs. 28.9%; $P=.0201$), greater insulin resistance (IR) (44.1% vs. 31.1%; $P=.0301$), and a history of tobacco use (76.2% vs. 29.9%; $P<.0001$).

When participants were divided according to age (younger than 65 years or 65 years and older), congestive heart failure was found to be more common among younger patients with HCV compared with controls ($3.84\% \pm 1.50\%$ vs. $0.89\% \pm 0.08\%$; $P=.0467$), but not among older patients. No associations were observed between HCV and cardiovascular disease when the cohort was stratified based on smoking status.

Advanced age, obesity and smoking were predictive of cardiovascular disease development, including congestive heart failure, ischemic heart disease and [stroke](#) ($P<.05$ for all). Multivariate analysis indicated independent associations between chronic HCV and IR (OR=2.06; 95% CI, 1.19-3.57), hypertension (OR=2.06; 95% CI, 1.30-3.24) and [diabetes](#) (DM) (OR=2.31; 95% CI, 1.18-4.54). Investigators also observed an association between chronic HCV and congestive heart failure (OR=2.49; 95% CI, 1.04-5.96), but not stroke or ischemic heart disease.

“Our study shows that [chronic HCV] is independently associated with three important metabolic conditions: IR, DM and hypertension,” the researchers wrote. “The association of HCV with hypertension is a novel finding. ... All of these findings emphasize the importance of assessing the true impact of HCV, not only for its hepatic complications, but also for its extra-hepatic manifestations.”

Confirmed heroin deaths in Lexington increase to 9; task force formed

The number of confirmed heroin overdose deaths in Lexington since Jan. 1 has grown to nine, and local authorities have formed a task force on illegal drugs with an immediate focus on heroin, Fayette County Coroner Gary Ginn said Friday.

Read More: <http://www.kentucky.com/2013/03/08/2548586/confirmed-heroin-deaths-in-lexington.html> . By Valarie Honeycutt Spears

Heroin replacing pain pills as drug of choice in some parts of Kentucky

Heroin has rapidly replaced prescription pain pills as the drug of choice in much of Northern Kentucky and Louisville, raising fears that a heroin scourge will soon ravage the state. In Northern Kentucky, police are finding people passed out in cars at gas stations with needles poking from their arms. In Louisville, initial statistics suggest more than 50 people died of heroin overdoses in 2012. *Read More:* <http://www.kentucky.com/2013/01/25/2490566/heroin-replacing-pain-pills-as.html> . By Beth Musgrave

IMPORTANT NOTIFICATION:

Discontinuation of the RIBA® Product Line, Including CHIRON® RIBA® HCV 3.0 SIA (Product Code 930600)

Dear OCD Customer:

This is a follow up to a previous notification (Ref. CL12-249) that was issued on October 3, 2012 to update you about the inventory shortage of CHIRON® RIBA® HCV 3.0 SIA (RIBA® HCV) (Product Code 930600).

Please note that Novartis Diagnostics, the legal manufacturer of the RIBA® line of products, has informed Ortho-Clinical Diagnostics, Inc. (OCD) that it has decided to discontinue the manufacturing of the entire RIBA® product line effective immediately. This product line includes RIBA® HCV.

For customers in the United States, alternative testing methods for RIBA® HCV were established and approved by the U.S. FDA in late 2012. For more information on these methods, you can access the following link on the FDA website:

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm322704.htm>

Our priority is to ensure the highest quality blood supply in the United States and worldwide. We apologize for any inconvenience this may have caused your laboratory and are fully committed to supporting our customers through this transition to alternative testing methods for the discontinued RIBA® line of products.

Thank you for your business and ongoing partnership. If you have additional questions or would like to discuss further, please contact Customer Technical Services at 1-800-421-3311.

Sincerely,

Tony Hardiman
WW Marketing Director, Donor Screening
Ortho Clinical Diagnostics

TRAINING INFORMATION:



March 21, 2013

TO: NASTAD Members

FR: Julie Scofield and Oscar Mairena

RE: Release of NASTAD Primer on ACA and Viral Hepatitis

Action Items:

- **Read** NASTAD's [primer](#) on the ACA and viral hepatitis
- **Go to** NASTAD's [blog](#) on the release of the primer
- **Share** the primer with staff, community and advocates
- **Save-the-date** for our primer webinar – March 26, 2013 at 1:00 PM EST

This weekend marks the third anniversary of the passage of the Patient Protection and Affordable Care Act (ACA). In light of the ACA's anniversary, NASTAD released a primer today on viral hepatitis and the ACA, [*The Affordable Care Act and the Silent Epidemic: Increasing the Viral Hepatitis Response through Health Reform.*](#)

The first of its kind for viral hepatitis, this primer provides an overview of some of the most significant pieces of reform for viral hepatitis prevention, screening, linkage to and retention in care, and treatment. To find out more about the ACA and viral hepatitis, read NASTAD's [blog post](#) on the release.

NASTAD's Viral Hepatitis Work Group will host an overview webinar on **March 26, 2013 at 1:00 PM EST**. If you are not a member of this work group, but would like to join this webinar, **please save this email** and [click this link](#) on March 26 at 1:00 PM. The call-in number is **866-740-1260** and the access code is **9377556**.

The release of this primer is part of NASTAD's ongoing technical assistance on ACA implementation and the impact on HIV and viral hepatitis programs. NASTAD's Viral Hepatitis Technical Assistance Meeting this October will also provide information on ACA implementation.

If you have any questions about NASTAD's work on viral hepatitis and the ACA please contact [Chris Taylor](#) or [Oscar Mairena](#). For more information on NASTAD's work on health reform implementation and technical assistance, please contact [Amy Killelea](#) or [visit our website](#).

INTERNATIONAL: "High Viral Load, HBeAg Positivity Increased Risk for Mother-to-Infant HBV Transmission"

Healio (03.08.13)

Babies born to women who have a high hepatitis B viral load—especially if the mothers also test positive for hepatitis B e antigen (HBeAg)—are more likely to contract hepatitis B, even when vaccinated against the disease.

The study focused on 303 hepatitis B-infected mothers and their babies' risk of contracting the virus during the first three years of life. Researchers first established the maternal viral load and HBeAg status—81 women were HBeAg-positive—then gave initial and follow-up hepatitis B tests to all of the babies. All babies received complete doses of hepatitis B immunization, and the babies born to HBeAg-positive mothers also received hepatitis B immunoglobulin within the first 24 hours of life. The study results controlled for confounding factors, including age, birth type, gender, weight, gestational age, and feeding practices.

Ten children in the study, all of whom were born to HBeAg-positive mothers, developed chronic hepatitis B, in spite of prophylactic measures. To lower risk of hepatitis B infection, researchers recommended that future screening and treatment interventions incorporate the study results.

The full report, "Mother-to-Infant Transmission of Hepatitis B Virus Infection: Significance of Maternal Viral Load and Strategies for Intervention," was published online in the *Journal of Hepatology* (February 2013; [doi:10.1016/j.jhep.2013.02.015](https://doi.org/10.1016/j.jhep.2013.02.015)).

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