



KY Hepatitis Connections

We are pleased to share with you the September 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

Leading Liver and ID Experts to Develop Hepatitis C Practice Recommendations

Recognizing the rapid development of hepatitis C medications coupled with increasing numbers of people being identified with hepatitis C virus (HCV) infection, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) are collaborating to develop clinical recommendations for the management of hepatitis C.

New medications approved by the Food and Drug Administration in recent years have increased HCV cure rates, and several additional medications are expected to be approved in the next three to five years. At the same time, new HCV testing guidelines are expected to increase the number of patients diagnosed with hepatitis C, many of whom currently are HCV-infected but unaware of their status. Ensuring that patients receive the new, effective treatment will be critical in increasing cure rates for hepatitis C. "We can finally say that cure of HCV infection has become a real possibility for the majority of individuals infected with this deadly virus," said Gary Davis, MD, of AASLD.

"Members of AASLD and IDSA are committed to ensuring that patient care keeps pace with rapidly advancing science," said David Relman, MD, president of IDSA. "This effort is an important step toward advancing that goal and comes at an important time as we all work to raise awareness of hepatitis virus infections on World Hepatitis Day on July 28."

Through this collaboration, the societies will review current treatment recommendations and use evidence-based, consensus guidance to develop updated recommendations for managing patients. Recommendations will be updated regularly and made available online. "A web-based system of new recommendations coupled with a published annual update will afford the greatest opportunity for both rapid and comprehensive output," said Donald M. Jensen, MD, of AASLD. Read more:

<http://www.idsociety.org/LeadingLiverandIDExpertsDevelopHepatitisCPracticeRecommendations.aspx>

MMWR: Investigation of Hepatitis E Outbreak Among Refugees - Upper Nile, South Sudan, 2012-2013

As of January 27, 2013, a total of 5,080 acute jaundice syndrome (AJS) cases had been reported from all four Maban County refugee camps (Doro, Gendrassa, Jamam, and Yusuf Batil). Hepatitis E virus (HEV) infection was confirmed in a convenience sample of cases in each camp. A cross-sectional serosurvey conducted in Jamam camp in November 2012 indicated that 54.3% of the population was susceptible to HEV infection. Across all camps, an AJS case-fatality rate (CFR) of 10.4% was observed among pregnant women. The outbreak response has focused on improving safe drinking water availability, improving sanitation and hygiene, conducting active case finding, and optimizing clinical care, especially among pregnant women.

Read more: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6229a2.htm>

Viral Hepatitis Updates from CDC

Hepatitis C Online Course

A new self-study developed by the CDC, an interactive course for medical providers on Hepatitis C infection is now available. At this time, Module 1: Screening and Diagnosis of Hepatitis C Infection and Module 2: Evaluation, Staging, and Monitoring of Chronic Hepatitis C are active. Additional modules will be posted soon. The project is brought to you from the University of Washington and in collaboration with the International Antiviral Society-USA (IAS-USA). Free CME credit is offered throughout the site and free CNE credit will be available soon. These modules are funded by a grant from the Centers for Disease Control and Prevention.

Read more: <http://hepatitisc.uw.edu/index.php>

Patients were exposed to hepatitis B because nurses lacked access to electronic medical records

Because the nurses were unaware of that patient's infection, they failed to properly clean dialysis machines before using them on 13 other patients over a two-week period. Equipment is supposed to be routinely disinfected before being reused on other patients. But extra measures, such as cleaning all internal tubing with bleach and heat, are required when a patient has hepatitis.

Five of the 13 exposed patients lacked immunity to hepatitis B and are being monitored in case they develop the disease. State investigators cited the hospital for violating regulations and issued a so-called statement of deficiencies.

Boston Medical Center contracts with DaVita, a private company, to run its inpatient dialysis unit, and the two nurses involved were not hospital employees. The hospital "failed to ensure" that the nurses "received orientation and read-only access to the hospital's computerized medical record system before being allowed to independently care for hemodialysis patients," state investigators said.

Read more: <http://www.bostonglobe.com/lifestyle/health-wellness/2013/08/01/patients-were-exposed-hepatitis-because-nurses-lacked-access-electronic-medical-records/naCxNH5ZtLZTKIHdw7q2IO/story.html>



Vertex: FDA Puts Partial Hold on Study of Hepatitis C Drug

Vertex Pharmaceuticals Inc. (VRTX) said the U.S. Food and Drug Administration has put a partial clinical hold on a mid-stage study of its experimental hepatitis C treatment VX-135 because of toxicity concerns.

Vertex shares fell 9.1% to \$79.66 in after-hours trading. The drug developer said the hold affects the 200-milligram dose of VX-135, a drug known as a nucleotide polymerase inhibitor, or "nuke," which is designed to combat hepatitis C infection inside liver cells. Vertex joins Bristol-Myers Squibb Co. (BMY) and Idenix Pharmaceuticals Inc. (IDIX) in having to halt certain trials of nuke drugs because of toxicity concerns.

The FDA put a hold on VX-135 after elevated levels of liver enzyme were found in patients involved in a study in Europe examining a 400-milligram dose of the drug in combination with ribavirin, an approved hepatitis C treatment. No serious adverse events have been reported, and no liver or cardiac safety issues have been identified, the company said.

Read more: <http://online.wsj.com/article/BT-CO-20130725-718983.html>

Interferon-Free Combo Controls Hep C Virus

Hepatitis C treatment with a two-drug, interferon-free regimen was effective at maintaining a sustained virologic response in patients deemed unlikely to respond to treatment, researchers found.

A 24-week regimen of sofosbuvir in tandem with weight-based or low-dose ribavirin was associated with a sustained virologic response to treatment of 68% and 48%, respectively, in those with a "high prevalence of unfavorable traditional predictors of treatment response," according to Shyamasundaran Kottlil, MD, PhD, of the National Institute of Allergy and Infectious Diseases in Bethesda, Md., and colleagues. Read more:

http://www.medpagetoday.com/Gastroenterology/Hepatitis/41220?xid=nl_mpt_DHE_2013-08-28&utm_content=&utm_medium=email&utm_campaign=DailyHeadlines&utm_source=WC&eun=g418265d0r&userid=418265&email=kathyj.sanders@ky.gov&mu_id=5517831



Obamacare may give OraSure product a boost Bethlehem company's quick hepatitis C test will be covered under the new law.

World **Hepatitis Day**" — which, in case you missed it, was last month — may not sound like an especially festive occasion. **OraSure Technologies** of Bethlehem, however, did have reason to celebrate: Last month an expert panel issued a ruling that, under **Obamacare**, requires the cost of **hepatitis C** testing to be covered by insurance companies.

For OraSure, which makes the only federally approved rapid hepatitis C test, the ruling is expected to boost sales once it takes effect in July of next year. It certainly will serve as a catalyst to have more people get tested," said OraSure Vice President Ron Ticho.

Nicholas Jansen, a health-care analyst who covers OraSure for Raymond James and Associates, echoed the sentiment: "Long term, it's a positive. It's clearly going to drive more demand. "Specifically, the U.S. Preventive Services Task Force, which is composed of medical professionals, gave hepatitis C screening for at-risk individuals, including virtually all baby boomers, a B grade. Under the Affordable Care Act, also known as Obamacare, a diagnostic test with an A or B grade must be covered by both insurance policies and Medicare.

Read more: <http://www.mcall.com/health/mc-orasure-hepatitis-c-test-20130728,0,1937467.story#ixzz2bCIRDhLQ>

Quest Diagnostics Partners with CDC to Improve Hepatitis C Public Health Research

Quest Diagnostics announces a collaboration with the Centers for Disease Control and Prevention (CDC) to improve public health analysis of hepatitis C screening, diagnosis and treatment, based on analysis of the company's national hepatitis C virus diagnostic information.

The collaboration aims to enhance screening, diagnosis and medical intervention for the approximately 3.2 million Americans infected with hepatitis C, promoting favorable health outcomes. The organizations will primarily focus on individuals born during 1945 through 1965. Individuals in this "baby boomer" generation are five times more likely than other adults to be infected, and one-time testing, as recommended by the CDC in 2012, could prevent more than 120,000 deaths in this age group.

In June 2013, the U.S. Preventive Services Task Force recommended one-time hepatitis C screening for all adults born between 1945 and 1965. "Deaths from hepatitis C infection have nearly doubled over the past decade to now more than 15,000 a year. Early detection and treatment of hepatitis C saves lives, but most people who are infected don't know it or are not being effectively treated," says Jay Wohlgemuth, MD, senior vice president of science and innovation for Quest Diagnostics. "Our collaboration with the CDC underscores the importance of using diagnostic information to derive useful insights enabling effective prevention, detection and management programs for diseases with a significant impact on public health."

Read More: <http://www.infectioncontroltoday.com/news/2013/07/quest-diagnostics-partners-with-cdc-to-improve-hepatitis-c-public-health-research.aspx>

FDA Approves ViiV HIV Integrase Inhibitor Dolutegravir (Tivicay)

The U.S. Food and Drug Administration (FDA) today (August 12, 2013) approved the second HIV integrase inhibitor, dolutegravir, which will be marketed under the brand name Tivicay by ViiV Healthcare. Phase 3 studies showed that dolutegravir works as well as raltegravir (Isentress) or Atripla and is generally safe and well-tolerated.

Integrase inhibitors work by preventing HIV from inserting its genetic material into host cell chromosomes. This class of drugs does not interfere with known human cellular processes and has few toxicities. Dolutegravir is taken once-daily (the first approved integrase inhibitor, raltegravir, is twice-daily) and does not require a pharmacokinetic boosting (unlike elvitegravir, a component of the Stribild single-tablet regimen but not yet approved as a single agent). Read More:

<http://www.hivandhepatitis.com/hiv-aids/hiv-aids-topics/hiv-treatment/4246-fda-approves-viiv-hiv-integrase-inhibitor-dolutegravir-tivicay>

Medivir- Interim Results Simeprevir and Sofosbuvir in HCV Patients with METAVIR Scores F3-F4

In Hepatitis C patients with advanced liver fibrosis or cirrhosis (METAVIR F3 or F4) 12 weeks all oral treatment with simeprevir and sofosbuvir with or without ribavirin led to SVR4 rates of 96% and 100%, respectively once-daily simeprevir and sofosbuvir with or without ribavirin was generally safe and well tolerated. Read more: <http://hepatitisnewdrugs.blogspot.com/2013/08/medivir-interim-results-simeprevir-and.html?sref=fb>

Medivir Discontinues NS5A Inhibitor Program

Medivir Makes Strategic Decision to Focus Proprietary Hepatitis C R&D Efforts Exclusively on Nucleotide-Based Polymerase Inhibitors

Medivir AB (STO:MVIR-B) (OMX: MVIR) today announced that it will focus its proprietary hepatitis C (HCV) research and development efforts exclusively on nucleotide-based polymerase inhibitors.

Medivir had been working on the discovery and development of new HCV nucleotide-based inhibitors and NS5A inhibitors (NS5A replication complex inhibitor) to enable additional potential interferon-free combinations. However, based on an evaluation of the competitive landscape and the expected evolution of therapies for HCV infection, Medivir has decided to focus exclusively on nucleotide-based polymerase inhibitors and to discontinue its NS5A inhibitor program.

Read more: <http://online.wsj.com/article/PR-CO-20130815-903829.html>

Magnetic resonance laparoscopy: A new non-invasive technique for the assessment of chronic viral liver disease

Hepatol Res. 2013 Aug;43(8):836-45. doi: 10.1111/hepr.12025. Epub 2013 Feb 28.

Ogura S, Saitoh S, Kawamura Y, Sezaki H, Hosaka T, Akuta N, Kobayashi M, Suzuki F, Suzuki Y, Arase Y, Ikeda K, Kumada H.

AIM: Laparoscopy-guided liver biopsy is the most accurate method for assessing liver fibrosis but have several limitations. We designed a non-invasive method, called magnetic resonance laparoscopy (MRL), based on gadolinium-ethoxybenzyl-diethylenetriamine pentaacetic acid-enhanced magnetic resonance imaging, to assess liver fibrosis in patients with chronic hepatitis B and C virus.

METHODS: We prospectively analyzed 49 patients with normal liver and 353 patients with chronic viral hepatitis, laparoscopic liver biopsy was performed on 109 patients and 244 patients were diagnosed as having liver cirrhosis clinically. The MRL findings of the liver surface were classified into three categories: (i) smooth (essentially smooth surface of the entire liver or with limited areas of depression); (ii) partially irregular (several interconnected depressions on the surface mainly in the left lobe of the liver); and (iii) diffusely irregular (nodules present on the liver surface). Patients with diffusely irregular liver surface was diagnosed as liver cirrhosis.

RESULTS: The liver surface changed with the progression of liver fibrosis from smooth, partially irregular to diffusely irregular, irrespective of viral type. The sensitivity, specificity, positive and negative predictive values for the diagnosis of cirrhosis according to the surface findings on MRL were 96%, 100%, 95% and 95%, respectively. The cirrhotic liver showed: (i) disappearance of impression of the right ribs; (ii) enlargement of the lateral segment; and (iii) atrophy of the right lobe according to Child-Pugh classification.

CONCLUSION: Our data indicated that MRL is a potentially useful non-invasive examination for evaluation of liver fibrosis associated with viral hepatitis.

New Findings May Open Doors for HCV Research: Cure for hepatitis C virus comes closer to reality

Washington, Aug 3 (ANI): Researchers from the Icahn School of Medicine at Mount Sinai have shown for the first time that the hepatitis C virus (HCV) can replicate in monkeys, by differentiating monkey stem cells into liver cells and inducing successful infection.

The new findings may lead to the first new animal model and provide new avenues for developing treatments and vaccines for this disease, which impacts more than three million people in the United States. Read more:

<http://www.newstrackindia.com/newsdetails/2013/08/03/129-Cure-for-hepatitis-C-virus-comes-closer-to-reality.html>



EDUCATIONAL MATERIALS

Recent KY Hepatitis Connection newsletters have addressed the heroin epidemic and crisis many communities throughout the Commonwealth are facing. As this problem continues, the HCV, HIV and HBV rates will continue to rise as recent data suggests. Recently, the Louisville Courier Journal addressed the issue and the implications for the Louisville- Southern Indiana communities. Read More:

<http://www.courier-journal.com/article/20130810/NEWS01/308030036/Heroin-problem-exploding-Louisville-Southern-Indiana>

The following articles were recently published online in Clinical Infectious Diseases entitled "Prevention and Management of Hepatitis C Virus Infection Among People Who Inject Drugs: Moving the Agenda Forward." Read More: http://cid.oxfordjournals.org/content/57/suppl_2.toc

Clinical Trials

To learn more about Hepatitis C virus clinical trials or to find out if a study is currently enrolling patients, Read more: <http://www.clinicaltrials.gov/ct2/results?term=hepatitis+c+phase+2&recr=Open>

Hepatitis C Training Workshop- Midway College

Lucinda K. Porter, RN (pictured below with Kathy Sanders, RN MSN, KY Adult Viral Hepatitis Prevention Coordinator [left] and Tonia Carr, RN, University of Kentucky Hepatology Nurse Case Manager [right]), Author and Speaker with the HCV Advocate presented the Hepatitis C Training Workshop to a large group of healthcare professionals and providers at Midway College on August 22nd.



NKY physicians will soon prescribe meds to treat opiate overdoses

St. Elizabeth Physicians will help distribute naloxone

DAYTON, Ky. —A northern Kentucky medical team expects to receive a pharmaceutical in the coming weeks that can be prescribed to treat opiate overdoses.

Dr. Jeremy Engel told The Kentucky Enquirer that his team at St. Elizabeth Physicians of Bellevue will prescribe naloxone to "individuals at high risk." He said they will begin by administering it to heroin addicts in treatment.

The newspaper reports the state Office of Drug Control Policy wants to use Engel's team to create a model to distribute naloxone in the rest of the state.

Read more: <http://www.wlwt.com/news/local-news/news-northern-kentucky/nky-physicians-will-soon-prescribe-meds-to-treat-opiate-overdoses/-/13608792/20633882/-/5vmlp/-/index.html#ixzz2dCEj4Ade>

Legislative Update:

SECTION 10. A NEW SECTION OF KRS 217.005 TO 217.215 IS CREATED TO READ AS FOLLOWS:

- (1) A licensed health-care provider who, acting in good faith, directly or by standing order, prescribes or dispenses the drug naloxone to a patient who, in the judgment of the health-care provider, is capable of administering the drug for an emergency opioid overdose, shall not, as a result of his or her acts or omissions, be subject to disciplinary or other adverse action under KRS Chapter 311, 311A, 314, or 315 or any other professional licensing statute.
- (2) A prescription for naloxone may include authorization for administration of the drug to the person for whom it is prescribed by a third party if the prescribing instructions indicate the need for the third party upon administering the drug to immediately notify a local public safety answering point of the situation necessitating the administration. A person acting in good faith who administers naloxone as the third party under this section shall be immune from criminal and civil liability for the administration, unless personal injury results from the gross negligence or willful or wanton misconduct of the person administering the drug.



Adult Viral Hepatitis Prevention Program Staff:

Robert Brawley, MD, MPH, FSHEA
Chief, Infectious Disease Branch
502-564-3261
Ext. 4235
Robert.Brawley@ky.gov

Kathy Sanders, RN, MSN
Adult Viral Hepatitis Prevention Program Manager
502-564-3261
Ext. 4236
KathyJ.Sanders@ky.gov