KY Hepatitis Connections

Spring time weather is finally here! On behalf of the KY AVHPC Program, we wish you and your family a wonderful Easter celebration. We are pleased to share with you the April 2014 issue of *KY Hepatitis Connections*. The *KY Hepatitis Connections* provides current information about viral hepatitis, 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.

Please follow us on Facebook at KY Viral Hepatitis.

Kathy Sanders, RN MSN

Important Update:

Hepatitis C: Perinatal and Children Aged Five Years or Less

Dear Healthcare Provider,

The Kentucky Department for Public Health (KDPH) is requesting your ongoing assistance to report pregnant women and children aged five years and less who are infected with hepatitis C virus (HCV), and seen in birthing hospitals, medical practices, and clinics throughout the Commonwealth.

Since January 1, 2014, KDPH has asked healthcare providers to voluntarily report: 1) all HCV-positive pregnant women; 2) all infants born to HCV-positive women; and 3) all HCV-positive infants and children aged five years or less seen in birthing hospitals, medical practices, and clinics, in addition to the current hepatitis B virus (HBV) infection reporting requirements in these populations (i.e., perinatal HBV-positive reports).

We most appreciate your excellent cooperation with the voluntary reporting about HCV-positive individuals in the above categories (i.e., perinatal HCV-positive reports). In the first 10 weeks of 2014, the number of perinatal HCV-positive reports has exceeded the total number of perinatal HBV-positive reports received for all of 2013.

Please complete the reporting form at the end of this newsletter and fax to the Kentucky Department for Public Health at: 502-564-4760 to continue to report any HCV-positive individuals in the above categories.

We deeply appreciate your time and effort in assisting us with this active surveillance project for perinatal HCV infections. If you have additional questions or concerns, please call Kathy Sanders, RN, MSN at 502-564-3261, ext. 4236 or Julie Miracle, RN, BSN at 502-564-4478, ext. 4260.

Robert L. Brawley, MD, MPH, FSHEA

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Hospital Infection Preventionists: Please distribute to medical providers, nursing staff, and other health-care personnel in Emergence Medicine, Critical Care, Laboratory Medicine, Infectious Diseases, Obstetrics, Newborn Nursery, NICU, Pediatrics, Internal Medicine, Family Medicine, and Primary Care or Ambulatory Care.

LHD staff: Please distribute to community healthcare providers in Infectious Diseases, Obstetrics, Pediatrics, Internal Medicine, Family Medicine, and Primary Care or Ambulatory Care and to FQHCs and RHCs.

HCV genotype 3 is associated with an increased risk of cirrhosis and hepatocellular cancer in a national sample of U.S. veterans with HCV

In a recently published study about hepatitis C (HCV) the authors state that "data show that viral genotype 1 may increase the risk of cirrhosis and hepatocellular carcinoma (HCC) when compared to HCV genotype 2 patients with chronic hepatitis C virus (HCV) infection". But little is known about the rate of disease progression in HCV genotype 3 patients compared to HCV genotype 1 patients.

The aim of the current study was to assess the effect of HCV genotype 3 on HCV disease progression—cirrhosis and liver cancer (HCC). The records of HCV patients obtained from the VA HCV Clinical Registry between 2000 and 2009 were analyzed and adjusted for cirrhosis and liver cancer (HCC) in HCV genotype, patients, age gender, HIV infection, alcohol use, diabetes, body mass index, and HCV treatment (if any) from Veterans for the period of service from World War I and II, Vietnam era, and post-Vietnam.

A total of 110,484 patient record with active HCV RNA or viral load by genotype included:

- 88,348 (79.9%) patients had genotype 1,
- 13,077 (11.8%) patients had genotype 2,
- 8337 (7.5%) patients genotype 3, and
- 1082 (0.9%) patients had genotype 4 infection.

After adjusting for co-founding factors (age, gender, etc.), it was found that patients with HCV genotype 3 had a 31% higher risk of developing cirrhosis and an 80% higher risk of developing liver cancer compared to patients with HCV genotype 1.

The authors concluded that "HCV genotype 3 is associated with a significantly increased risk of developing cirrhosis and HCC compared to HCV genotype 1. This association is independent of patients' age, diabetes, body mass index, or antiviral treatment."

The VA study is important because the analysis was conducted using a large number of patient records. The results the study should prompt medical providers and patients to step up their efforts to increase medical monitoring and treatment. In addition, even with the current standard of care to treat HCV genotype 3 (Sovaldi and ribavirin) that can cure the majority of people with HCV genotype 3, more therapies are needed to treat the more difficult patients with HCV genotype 3.

Read More: http://www.mdlinx.com/infectious-disease/news-article.cfm/5125143/cohort-longitudinal-veterans-administration-viral-factors

Brief Overview of HCV Drug Data (DAA's) Released at CROI 2014—March 4, 2014, by Alan Franciscus, Editor-in-Chief

CROI (Conference on Retroviruses and Opportunistic Infections) is an annual conference that focuses on research information about HIV. In the last few years, more and more coverage has been presented on HCV mono-infection and HIV/HCV co-infection. The table below is a brief overview of some of the data that was released.

HCV Drugs	HCV Genotype	Treatment Duration	Cure Rate	Date Posted
Sovaldi/ledipasvir	1	12 weeks	100%	3/3/2014
Sovaldi/ledipasvir plus GS-9669	1	6 weeks	95%	3/3/2014
Sovaldi/ledipasvir plus GS-9451	1	6 weeks	100%	3/3/2014
Comments: A total of 60 HCV genotype 1 patients were enrolled in the study. The study was conducted in Washington D.C. by the National Institutes of Allergy and Infectious Diseases. The patients in the study were mostly low-income and many of the patients had negative predictors of treatment response—70% male, 90% African Americans, 70% genotype 1a. About a quarter of the patients had severe fibrosis or cirrhosis. There were no serious side effects or treatment discontinuations. The most common side effects reported were headache, fatigue and diarrhea. Update: 3/4/2014 There will also be 3-drug combination arms that will explore treating people with cirrhosis and the investigators will also be enrolling people in a 4-week trial.				
Daclatasvir, Asunaprevir, BMS-791325	1	12 weeks	92%	3/3/2014
Comments: There was a total of 168 HCV genotype 1 a/b patients (84% 1a) in two arms (BMS-791325 dose was different in the arms). About 18% had biopsy confirmed cirrhosis. The most common side effects reported were headache, diarrhea, fatigue, nausea.				
ABT-450/r, ABT-267, ABT-333 with ribavirin	1b	12 weeks	99%	3/3/2014
ABT-450/r, ABT-2687 ABT-333 without ribavirin	1b	12 weeks	99%	3/3/2014
Comments: A total of 419 patients were enrolled and treated with Abbvie's HCV inhibitors with and with ribavirin. The cure rates were high even among those patients with the usual negative predictors of treatment response. The most common side effects were headache, fatigue, pruritus (itching), nausea, and weakness with itching and rash higher in the ribavirin containing groups.				

Hepatitis C Drug Price Limiting State Medicaid Approvals

The price of Gilead Sciences Inc. (GILD)'s $1,000-a-day hepatitis C pill is keeping state-run Medicaid programs from making it available to many of the people who are most likely to be infected with the disease.

People in Medicaid, the government health plan for the poor, are prime candidates for Gilead's Sovaldi, which works better and carries fewer side effects than existing therapies. The $84,000 cost for the cure over 12 weeks, the most expensive medicine for the disease, has states from Pennsylvania to Colorado limiting its use to only the sickest patients, according to health officials and private insurers that manage care for Medicaid programs. Hepatitis C, a virus infecting about 2.7 million in the U.S., is transmitted through blood, with those getting transfusions before 1992 and intravenous drug users most at risk. It can be symptomless for decades before it begins to scar the liver, leading to liver cancer in some cases, organ failure and the need for a transplant.

Read More: http://www.bloomberg.com/news/2014-03-05/hepatitis-c-drug-price-limiting-state-medicaid-approvals.html

FDA Opioid Rulings Slammed

FDA decisions about prescription opioid painkillers have been inconsistent, and the agency should make future decisions with greater transparency, according to drug safety researchers.

While all extended-release oxycodone products (OxyContin and generics) are required to have abuse-deterrent properties, that's not the case for long-acting oxymorphone (Opana and generics) or hydrocodone (Zohydro), according to Lewis Nelson, MD, of NYU School of Medicine, and colleagues.

That's just one of a flood of recent decisions that will "confuse clinicians and disgruntle both constituencies," they wrote in *Expert Opinion on Drug Safety*, referencing the highly polarized debate between those who believe the drugs are too widely prescribed and those who are concerned about limiting access to patients who are genuinely in pain

Read More:
http://www.medpagetoday.com/PainManagement/PainManagement/44698?utm_source=rss&utm_medium=rss&utm_campaign=fda-opioid-rulings-slammed

CROI 2014: Hepatitis C Treatment in the Real World

The opening day of the 21st Conference on Retroviruses and Opportunistic Infections (CROI 2014) featured a press conference on advances in the treatment of hepatitis C, with a focus on how new drugs may be used in the real world, given barriers such as high cost and a shortage of experienced medical providers.

The panel of hepatitis C experts included Douglas Dieterich from Mt. Sinai's Ichan School of Medicine, Trevor Hawkins from the Southwest CARE Center, Anita Kohli from the National Institutes of Health, Daniel Cohen from AbbVie, and Marion Peters form the University of California at San Francisco.

Read More: http://hepatitisresearchandnewsupdates.blogspot.com/2014/03/croi-2014-hepatitis-c-treatment-in-real.html

Medical groups question price of new hep C drug

WASHINGTON (AP) — An innovative hepatitis C drug that was only recently hailed as a breakthrough treatment is facing skepticism from some health care providers, as they consider whether it is worth the $1,000-a-pill price set by manufacturer Gilead Sciences Inc.

A panel of California medical experts voted Monday that Gilead's Sovaldi represents a "low value" treatment, considering its cost compared with older drugs for the blood-borne virus.

The vote was part of a broader review of new hepatitis C drugs by the California Technology Assessment Forum, an insurance industry-affiliated group that assesses the costs and effectiveness of new medical treatments. The group is expected to issue a final report next month on Sovaldi and another new hepatitis C drug, Olysio from Johnson & Johnson.

Read More: http://bigstory.ap.org/article/medical-groups-question-price-new-hep-c-drug

HCV in Women – Long Term Follow-up

There are very few long-term studies of people with HCV that we can use to track the true percentage of people who have serious HCV disease progression. This is due to the fact that it is very difficult to diagnose acute HCV. Another reason is that the test to identify HCV wasn't developed until 1989. There are, however, a couple of long term studies available that provide vital information to help us understand this important issue.

One such study is of East German women who were infected with contaminated batches of anti-D immunoglobulin between August 1978 and March 1979. There were total of 2,867 East German women who were given the HCV contaminated anti-D immunoglobulin—anti-D immunoglobulin is given to

rhesus negative pregnant women if their unborn baby was rhesus positive to prevent serious health complications to the baby.

The study examined the records of 718 women from the original group of 2867 who were identified 35 years ago who were currently available. In this group who were available for evaluation, 189 women had self-limited infection (resolved or natural clearance of HCV) and 529 women developed chronic infection. Of these 529 women, 197 were treatment naïve, 149 were treated and achieved a cure and 183 women were treated, but did not achieve a cure. The 3 groups were evaluated for HCV disease progression.

After the 35 year period, 9.3% of the women had clinical signs of cirrhosis. The highest percentage of women who had end-stage liver disease (15.3%) was the women in the group who were not cured or HCV positive. In the group that had self-limited or resolved HCV infection the disease progression to cirrhosis was only 6%, which is higher than one would suspect.

The authors concluded that "The present study provides further evidence for a mild, but significant, disease progression at 35 years after infection in the German HCV (1b)-contaminated anti-D cohort. Patients with self-limited HCV infection or SVR after antiviral treatment were protected from progressive liver disease and showed the best clinical long-term outcome."

Comments: This is a very interesting study and it does provide important and reassuring information that HCV disease progression is generally slow for many people. It also reinforces the benefit of HCV treatment. But, it is also important to know that this information can't be 100% applied to the general population of people with hepatitis C. The reasons that the information can't be translated to everyone with HCV include:

- After being infected the women were diagnosed with non-A/non-B hepatitis based on symptoms and elevated liver enzymes—most people with hepatitis C are not diagnosed until many years later—if diagnosed at all.
- The women were counseled after diagnosis to avoid alcohol and were given self-help counselling messages.
- The women were medically monitored on a regular basis.
- Generally, women have a slower disease progress than men, especially women who are pre-menopausal.

Still, the study is important for the obvious reasons and should reassure patients and medical providers. But it should also encourage people to seriously consider treatment. And it also should help with the overall message that a diagnosis with hepatitis C can help save lives, including all those undiagnosed baby boomers and people who have other risk factors for HCV infection—*Alan Franciscus*

Evaluation of liver disease progression in the German hepatitis C virus (1b)-contaminated anti-D cohort at 35 years after infection

Manfred Wiese et al. *Hepatology*, Volume 59, Issue 1, pages 49–57, January 2014. The article was first published online: 18 NOV 2013 DOI: 10.1002/hep.26644

NKY health officials concerned about hepatitis C linked to heroin use

FLORENCE, Ky. —The heroin epidemic is expanding in new dimensions and it has Northern Kentucky health officials concerned about what it brings with it.

- The 25 heroin facts in this slideshow are provided by the National Institute on Drug Abuse.

  http://www.wlwt.com/health/20464864

"As we hear of more (heroin) in the community, we're seeing a rise of the hepatitis C along with it," NKY Health Department epidemiologist Joyce Rice said.

In 2009, there were three cases reported. By 2011 the number climbed to 42 and last year there were 55 cases.

Watch this story: http://www.wlwt.com/news/heroin-epidemic-brings-rise-in-hepatitis-c-cases/24966504

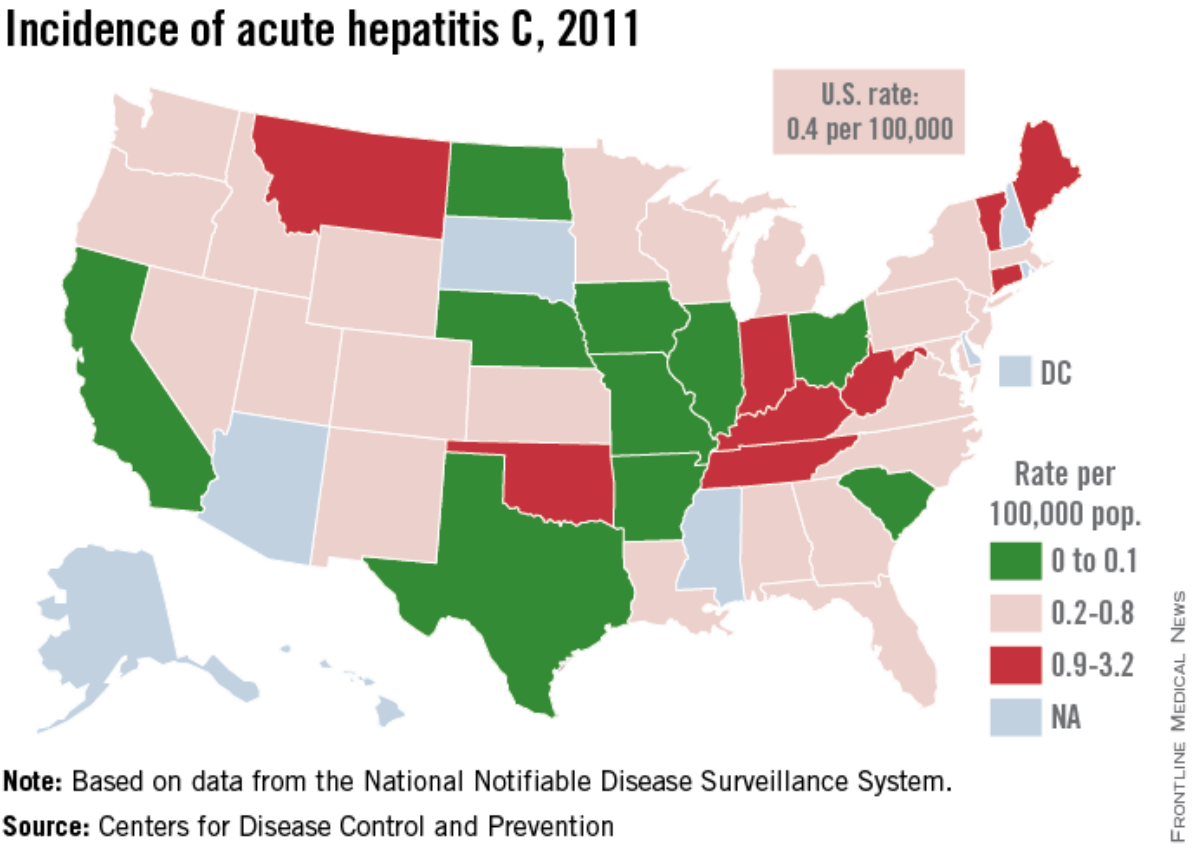
Incidence of acute hep C highest in Kentucky

Kentucky has the highest rate of acute hepatitis C infection – 3.2 cases per 100,000 population – in the United States, according to the Centers for Disease Control and Prevention.

Based on reports from 2011, the last year for which data are available, there were 142 cases of hepatitis C virus (HCV) infection in Kentucky, which was 58 more than Indiana, the state with the second-highest number of cases, and 96 more than West Virginia, the state with the second-highest rate, the CDC reported.

Among the 42 states that submitted reports to the CDC's National Notifiable Disease Surveillance System, the average rate of acute HCV infection was 0.4 cases per 100,000. The U.S. total of 1,229 cases represents a 44% increase over 2010. Three states – Arkansas, Iowa, and North Dakota – reported zero cases for 2011, the report said.

The CDC also noted that most cases of hepatitis are not reported, and after adjusting for asymptomatic infections and underreporting, the agency estimated that 16,500 new HCV infections occurred in 2011.



Read More: http://www.obgynnews.com/single-view/incidence-of-acute-hep-c-highest-in-kentucky/1addc8b3e2b14002735efa99e095a01e.html

Will The New Hepatitis C Drugs Trigger A Battle Over Cost?

As excitement mounts among physicians and investors over a new batch of drugs for treating hepatitis C, there is also concern that patients in developing countries may not have sufficient access due to high prices. But a recent poster presentation at a medical conference suggests that drug makers can produce these new medicines for relatively little cost and should be compelled to do so.

The analysis, which was displayed at the American Association for the Study of Liver Diseases gathering last week in Washington, DC, concluded that large-scale production of direct acting antivirals may be possible for as little as $100 to $200 for 12 weeks of treatment. The estimate cited HIV drugs, which initially cost tens of thousands of dollar per patient but have since dropped significantly in price in developing nations, as a model framework.

Read More: http://www.forbes.com/sites/edsilverman/2013/11/11/will-the-new-hepatitis-c-drugs-trigger-a-battle-over-cost/

How Much Should Hepatitis C Treatment Cost?

"A new pill to treat hepatitis C raises difficult questions about fair pricing, not only in the United States and other affluent nations but in developing countries around the world. Hepatitis C, which afflicts some 150 million people globally, often without symptoms for years, can cause fatigue and fever, cirrhosis or liver cancer.

The pill, known as Sovaldi, or generically as sofosbuvir, costs $84,000 for a standard 12-week course of treatment. That breaks down to $1,000 for each pill, taken daily. T he manufacturer, California-based Gilead Sciences, says private insurers are already covering Sovaldi. The question is whether insurers and public programs like Medicare and Medicaid should have to pay so much for this drug, driving up costs for taxpayers and private policyholders."

Read More: http://www.nytimes.com/2014/03/16/opinion/sunday/how-much-should-hepatitis-c-treatment-cost.html?_r=0

Should Prisoners Get Expensive Hepatitis C Drugs?

If used widely, a new generation of antiviral drugs has the potential to wipe out the deadly hepatitis C virus in the United States. But the high price of the drugs might prevent their use in prisons, which house as many as one-third of those who are infected.

The drugs cost anywhere from about $65,000 to $170,000 for a single course of treatment—between three and nine times more than earlier treatments. Ronald Shansky, former medical director of the Illinois prison system and founder of the Society of Correctional Physicians, described that price as "extortionarily high, criminal."

Read More: http://www.pewstates.org/projects/stateline/headlines/should-prisoners-get-expensive-hepatitis-c-drugs-85899542574

Adelaide researchers claim breakthrough in tackling HIV and hepatitis C with DNA vaccine

South Australian researchers claim they have made a significant breakthrough in tackling HIV and hepatitis C, using a new type of DNA vaccine which protects against the viruses and could possibly provide a cure in five years.

Adelaide University's Professor Eric Gowans says the vaccine has already had positive results in animals, with human trials to start next year.

"DNA vaccines in general have enormous potential, but haven't worked very well in large animals and in patients," he said.

Read More: http://www.abc.net.au/news/2014-03-25/adelaide-researchers-develop-dna-vaccine-to-tackle-hiv-and-hep-c/5345068?section=sa

Interview with John Ward, CDC's Viral Hepatitis Division Director

How a Simple Test Can Save 120,000 Lives

Hepatitis C, the "silent epidemic" afflicting baby boomers, is twice as prevalent among African-Americans, but preventive measures may save $2.5 billion in health care costs, a CDC official says.

Read More: http://www.nationaljournal.com/next-america/health/how-a-simple-test-can-save-120-000-lives-20140227

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EPID 394(Rev NOV 2013)

Kentucky Reportable Disease Form

Department for Public Health
Division of Epidemiology and Health Planning
275 East Main St., Mailstop HS2E-A
Frankfort, KY 40621-0001

Hepatitis Infection in Pregnant Women or Child (under the age of five)
Fax Form to 502-564-4760

DEMOGRAPHIC DATA

Patient's Last Name	First	M.I.	Date of Birth	Age	Gender ☐ M ☐F ☐ Unk

Address	City	State	Zip	County of Residence

Phone Number	Patient ID Number	Ethnic Origin ☐ His. ☐ Non-His.	Race ☐W ☐B ☐A/PI ☐Am.Ind. ☐Other

DISEASE INFORMATION

Describe Clinical Symptoms:	Date of Onset: / /	Jaundice: ☐Yes ☐No	Date of Diagnosis: / /

Is Patient Pregnant? ☐Yes ☐No If yes, # wks_____	Expected Date of Delivery: / /	Name of Hospital for Delivery:

Physician Provider Name: Address: Phone:		

LABORATORY INFORMATION

Hepatitis Markers	Results	Date of test	Viral Load *if applicable	Name of Laboratory
HBsAg	☐ Pos ☐ Neg	/ /		
IgM anti-HBc	☐ Pos ☐ Neg	/ /		
HBeAg	☐ Pos ☐ Neg	/ /		
IgM anti-HAV	☐ Pos ☐ Neg	/ /		
HCV Antibody	☐ Pos ☐ Neg	/ /		
HCV RNA Confirmation	☐ Pos ☐ Neg	/ /		

SERUM AMINOTRANSFERASE LEVELS

Patient	Reference	Date of test	Name of Laboratory
AST (SGOT) U/L	U/L	/ /	
ALT (SGPT) U/L	U/L	/ /	

Mother: Hepatitis Risk Factors
☐IDU ☐Multiple Sexual Partners ☐Tattoos ☐STD
☐HIV ☐Foreign Born/ Country _____
☐Exposure to known HBV/HCV Pos contact

Child: Hepatitis Risk Factors
☐Mother HBV Pos ☐Household member exposure HBV Pos
☐ Mother HCV Pos ☐Household member exposure HCV Pos
☐Foreign Born / Country_____

Mother: Hepatitis A vaccination history: ☐Yes ☐No ☐Refused Dates Given: / /
Hepatitis B Vaccination history: ☐Yes ☐No ☐Refused
If yes, how many doses ☐1 ☐2 ☐3 Year completed: / /
Child: Hepatitis A vaccination history: ☐Yes ☐No ☐Refused Dates Given: / /
Hepatitis B Vaccination history: ☐Yes ☐No ☐Refused Dates Given: / /
Was PEP Infant of Positive HBV mother given at birth? ☐Yes ☐No