On behalf of the KY Adult Viral Hepatitis Prevention and Control Program, Happy New Year! Our wishes are for you and your family to have a healthy and prosperous 2015! Inside our January 2015 Edition of the KY Hepatitis Connections you will find current information about viral hepatitis, opportunities for viral hepatitis continuing professional education and information about educational materials available. See all the exciting things happening here in Kentucky!

Please feel free to forward, copy and/ or 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. We hope you enjoy our newsletter.

Kathy Sanders, RN MSN

"We strongly urge governments, the pharmaceutical industry, clinicians, community organization’s and non-governmental organizations to work together to make global elimination of HCV a realistic target within our lifetimes."

Dr Ranjababu Kulasegaram
REMINDER: HEPATITIS C Voluntary Reporting:

Hepatitis C: Perinatal and Children Aged Five Years or Less. Update on the Project for Voluntary Reporting in Kentucky.

Health care providers are asked to report voluntarily:

- all HCV-positive pregnant women;
- all infants born to HCV-positive women; and
- all HCV-positive infants and children 5 years old and younger seen in birthing hospitals, medical practices and clinics

Routine testing for HCV is not recommended for all pregnant women. Pregnant women with a known risk factor for HCV infection should be offered counseling and testing. Data from the CDC states that approximately 6 out of every 100 infants born to HCV infected woman become infected. The risk is greater, 2 to 3 times, if the woman is co-infected with HIV. There is currently no HCV treatment approved for pregnant women.


Infant born to mothers with HCV

Infants born to HCV-positive mothers should be tested for HCV infection. Children born to HCV-positive mothers can be tested with the HCV RNA tests at 2 months of age or older (at a routine well-child visit) or HCV antibody testing can be done at 18 months of age (wait until 18 months of age to avoid detecting maternal antibody).

http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm

There are no FDA approved HCV treatments for young children. In October, a clinical trial announcement was made to study these young children/adolescents and the treatment of HCV:


Thank you for your continued support of this project and 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 in your communities.

Please continue to report any HCV-positive individuals in the above categories. Complete and fax the reporting form at the end of this newsletter. Please note the new fax number:

Please fax forms to 502-696-3803
Infants of HCV Positive Women:

We are receiving numerous phone calls from all over the state regarding infants born to HCV positive mothers. Many of these infants are being placed into foster care and foster families are seeking guidance and information on HCV. See the links and guidance below concerning HCV in infants/ young children. Please remember:

- HCV antibody testing of infants under the age of 18 months of age is not recommended as they still have their mother’s antibodies present. Diagnosis can be made: Laboratories: liver panel, HCV IgG Antibody (after 18 months of age) and/ or HCV RNA (which can be done after 2 months of age)

- A positive HCV RNA after 2 months of age OR a positive HCV Antibody after 18 months of age means exposure to HCV.

See the links below:

- [http://hcvadvocate.org/Hepatitis/factsheets_pdf/TellChild_HCV.pdf](http://hcvadvocate.org/Hepatitis/factsheets_pdf/TellChild_HCV.pdf)
- [http://www.uky.edu/TRC/CourseDescription](http://www.uky.edu/TRC/CourseDescription)
- [http://www.afpaonline.com/foster-parent-resources](http://www.afpaonline.com/foster-parent-resources)
- [http://www.hennepin.us/childcaremanual](http://www.hennepin.us/childcaremanual)
- [http://www.liverfoundation.org/chapters/rockymountain/doctorsnotes/pediatrichecv/](http://www.liverfoundation.org/chapters/rockymountain/doctorsnotes/pediatrichecv/)
- [http://www.uofmchildrenshospital.org/healthlibrary/Article/88697](http://www.uofmchildrenshospital.org/healthlibrary/Article/88697)
- [http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm](http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm)
HCV: IN THE NEWS:

Few infants tested for HCV after birth, more perinatal testing needed

Very few infants in Philadelphia were tested for hepatitis C virus infection after birth despite mothers who reported being positive for the infection, according to data presented at ID Week 2014.

“Repetitive and conclusive testing of pregnant women and infants in their first 18 months is necessary to identify vertical transmission of HCV and initiate infected infants into care,” the researchers wrote in the abstract.

Researchers from the Philadelphia Department of Public Health, including Danica Kuncio, MPH, hepatitis surveillance epidemiologist, utilized HCV antibody and RNA tests reported since 2002 to identify maternal and infant testing for HCV. Datasets were matched to birth certificates between January 2011 and July 1, 2014 to detect infants born to mothers infected with HCV and to determine if infant testing for the infection occurred. Researchers compared the anticipated rate of 5% for HCV sero-positivity among the infants.

A total of 6,259 females between the ages of 12 and 44 were reported as positive for HCV infection. Of those females, there were 1,065 infants born in Philadelphia during the study period to women positive for HCV. Only 1,017 infants survived and 66 were tested for HCV. There were 41 children in the registry that matched to the birth certificates for the study period, but their mothers were not in the registry. Overall, 10% of all infants (n=107) born to HCV positive women were tested for HCV. Twelve percent of 18 month-old infants underwent HCV testing. Six infants tested positive for HCV RNA.

“This data shows that an insufficient number of infants are being tested for HCV after birth, likely resulting in a pool of chronically infected children whose disease remains unmonitored.” the researchers wrote in the abstract.

If a 5% rate of HCV sero-positivity among infants born to mothers positive for HCV was assumed, 47 more infants would be expected to develop HCV infection.

“Efforts need to be made to bridge the gap in testing for these infants born to HCV positive mothers,” Kuncio told Healio.com/Hepatology. “[The Philadelphia Department of Public Health] intends on launching a pilot program to better ensure screening for perinatal HCV in Philadelphia.” – by Melinda Stevens

http://www.healio.com/hepatology/hepatitis-c/news/online/%7Ba2855634-0df1-430f-a8d1-8a80a9318c00%7D/few-infants-tested-for-hcv-after-birth-more-perinatal-testing-needed?ecp=5FF3B6D7-4120-4789-B533-70B7305523EF
Increase in hep C, B and HIV exposure from sharps injuries

Nursing staff continue to be at risk of exposure to blood borne viruses from sharps injuries, with figures showing a rise in staff reporting these incidents. This is despite the availability of safety-engineered devices and new rules promoting their use, noted Public Health England in its Eye of the Needle report.

It found the number of staff exposed to blood borne viruses via sharps injuries increased by a third from 373 in 2004 to 496 in 2013. Around 80% of the 4,830 incidents reported over the period involved doctors, nurses, and healthcare assistants.

“All healthcare employers [should] provide safety devices to healthcare workers”. More than half of these exposures were to patients with hepatitis C, while around a third involved HIV and 9% hepatitis B. The increase comes in spite of the introduction of UK Sharps Regulations in 2013, which legally requires employers to ensure safe working conditions that reduce the risk of sharps injury.

These conditions include shift patterns that reduce tiredness for healthcare workers, providing safety devices to minimize the risk of a needle stick injury before, during, or after use, and appropriate training. The report was presented yesterday at this year’s Prevention of Occupational Infections, Treatment, and Reporting Strategies conference in Cardiff. It found that from 2004 to 2013, nine workers in England, Wales, and Northern Ireland became infected with hepatitis C following exposure at work. Eight of these staff members received therapy, with seven achieving viral clearance.

Almost all (97%) of those exposed to HIV who commenced post-exposure prophylaxis treatment did so within 72 hours and no workers reported contracting HIV infections. Of those exposed to hepatitis B, none reported contracting the virus. Of the 313 staff who reported their immunization status, 96% had had the hepatitis B vaccine.

Fortune Ncube, head of the blood borne virus department at PHE, said it was disappointing that workers continued to experience “entirely preventable” sharps injuries. “We want to remind all healthcare employers to comply with the regulations regarding safer working conditions and to provide safety devices to healthcare workers in an effort to reduce sharps injuries and protect them from infection,” he said.

“Despite this, we are encouraged that there have been no new HIV infections in healthcare workers and that the immunization program for hepatitis B is effective,” he added. Jill Holmes, an infection prevention control nurse specialist and member of the Safer Needles Network, warned that safety-engineered devices were not “fool proof” and urged healthcare providers to train staff in their use.

“It is also essential for all staff to remember the importance of basic sharps safety, such as never, ever re-sheathing a used needle, always taking the sharps bin to the point of use, and never filling above the fill line,” she said. Safe use and handling of sharps must be embedded into everyday practice,” said Ms. Holmes.

Many hepatitis C patients with cirrhosis or advanced fibrosis face liver failure and liver cancer

Nearly one-third of chronic hepatitis C patients with liver cirrhosis and 12% with advanced fibrosis progressed to decompensation within five years, and 23% and 11%, respectively, died, according to a study presented at the American Association for the Study of Liver Diseases (AASLD) Liver Meeting last month in Boston. These findings underscore the urgent need for treatment for such individuals.

Over years or decades chronic hepatitis C virus (HCV) infection can progress to serious liver disease including cirrhosis, hepatocellular carcinoma (HCC), liver decompensation -- when the liver can no longer carry out its vital functions -- and liver-related death.

Successful treatment that leads to sustained viral response (SVR) can slow or halt liver disease progression and may allow for some degree of recovery. When the standard of care was interferon-based therapy -- which lasted up to a year, caused difficult side effects and cured only about half of patients -- treatment was recommended only for people with evidence of progressive liver damage.

Now that highly effective and well-tolerated interferon-free direct-acting antiviral regimens are available, some experts have called for universal treatment. But given the drugs' high cost, current guidelines state that people with advanced liver disease should be prioritized, and many national health systems and private insurers are limiting treatment to the sickest patients.


One million people with hepatitis C in the US at high priority for treatment

An estimated 813,000 people with diagnosed hepatitis C in the US have undergone liver disease staging and meet the 'highest' or 'high' priority criteria for immediate treatment, according to an analysis presented at the American Association for the Study of Liver Diseases (AASLD) Liver Meeting last month in Boston. The number would be even higher if taking into account undiagnosed individuals and prisoners and others excluded from household surveys.

Over years or decades chronic hepatitis C virus (HCV) infection can progress to serious liver disease including cirrhosis, hepatocellular carcinoma, and liver failure. Successful treatment can slow or halt liver disease progression, and may even allow for some degree of recovery.

When the standard of care was interferon-based therapy -- which lasted up to a year, caused difficult side-effects and cured only about half of patients - treatment was recommended only for people with moderate or worse liver damage (Metavir stage F2 or higher).

Rheumatic hand manifestations observed in chronic HCV

Hepatitis C virus infection prompted hand manifestations among Egyptian patients, according to study data. “Patients infected with HCV might develop at least one extra hepatic manifestation in 40% to 74% of cases during the course of the disease; rheumatologic manifestations are among the most frequent,” the researchers wrote. “Hand manifestations in the form of arthralgia and arthritis are the main extra hepatic manifestations in patients with HCV affecting mainly the metacarpophalangeal joints, wrists and proximal interphalangeal joints. However, the decision of treatment may be difficult and hazardous as patients with [rheumatoid arthritis] require more aggressive therapy.”

Researchers recruited 297 patients (54.2% male) with HCV from the National Hepatology and Tropical Medicine Research Institute in Egypt who underwent testing for erythrocytic sedimentation rate, C-reactive protein, rheumatoid factor, antinuclear antibody and anti-cyclic citrullinated peptide, as well as a plain X-ray, for hands and wrists.

Overall, 46.1% of patients (n=137) experienced hand abnormalities during the study. The most frequent hand manifestations observed among the cohort were arthralgia (28.6%), tenosynovitis in the flexor tendons of the hands (10.1%), Raynaud’s phenomenon (9.1%) and arthritis (5.1%). Rheumatoid factor was observed in 114 patients, cryoglobulins were found in 28, four patients had anti-cyclic citrullinated peptide, but were negative in HCV-related polyarthritis and cryoglobulinemia, and 19 had antinuclear antibody. Four percent of patients had abnormal X-rays due to hand erosions and narrow joint spaces. Hand erosions were found to be related to arthritis (P<.001), as well as arthralgia (P<.01).


Preventing hepatitis C patients from being lost in the health-care system

A new study shows that many patients infected with the hepatitis C virus (HCV) are lost during different stages of health care to manage the disease. This real-life' view of the HCV patient care continuum in a major U.S. urban area is published in Hepatology, a journal of the American Association for the Study of Liver Diseases, and highlights the importance of generating awareness among clinicians and at-risk groups about appropriate HCV testing, referral, support and care.

Despite efforts to manage HCV, it is one of the most prevalent diseases with up to 150 million individuals worldwide living with chronic infection according to the World Health Organization (WHO). In the U.S. about 3.2 million people are infected with HCV, making it the main cause of chronic hepatitis disease. Up to 70% of those with acute infection have no symptoms and are typically unaware they
have HCV until years later after the disease has progressed to cirrhosis, liver cancer (hepatocellular carcinoma [HCC]), or liver failure.

Medical evidence emphasizes HCV screening of at-risk individuals such as injection drug users, blood transfusion recipients, children born to mothers with chronic infection, or adults born between 1945 and 1965 in order to improve diagnosis of the disease. Yet some programs are not comprehensive and one prior study estimates that 50% to 75% of chronic HCV patients remain unaware of their infection.

"The inadequacy of screening programs has made it difficult for state health departments to accurately determine the extent of HCV and the rate of transmission within the community," explains Kendra Viner, Ph.D., MPH, from the Philadelphia Department of Public Health. "Our study examines the management of HCV care at a population level to determine which patients tend to fall out of the medical system and why this might occur."


**New Report: Decades of Drug Research Failures and Successes Transform Hepatitis C from Incurable to Curable Disease**

The Pharmaceutical Research and Manufacturers of America (PhRMA) released a new report in December 2014, "Twenty-Five Years of Progress Against Hepatitis C: Setbacks and Stepping Stones," that examines the scientific challenges and setbacks researchers have faced on the path to developing new medicines with the potential to transform treatment for hepatitis C patients and how these so-called "failures" are an integral part of the drug discovery process.

The new report found between 1998 and 2014, 77 investigational medicines failed in clinical trials, laying the groundwork for 12 approved medicines over the same period.

The learnings from these setbacks inform the continuous innovation in treatment leading to new advances in treating the hepatitis C virus. The evolution of treatment from interferon-based therapy to direct-acting antiviral agents has helped transform hepatitis C from a chronic and often fatal illness to an infection that with new and forthcoming treatments may one day be considered a rare disease. While the trajectory of hepatitis C is changing thanks to America’s biopharmaceutical companies, substantial unmet medical need for patients remains, which is why the industry continues to research further treatment advances for patients. According to the report, there are 75 new hepatitis C medicines either in clinical trials or awaiting review by the U.S. Food and Drug Administration (FDA).

"New and forthcoming hepatitis C treatments represent a remarkable advance against a very serious disease," said PhRMA President and CEO John J. Castellani. "These treatments are often curing more than 90 percent of patients – transforming lives and helping to avert billions of dollars in unnecessary hospitalizations and other costly medical services. Forthcoming treatments are projected to provide even greater cure rates and shorter duration of treatment, vastly improving patients’ health and quality of life."

Hepatitis C is the leading cause of liver transplants and the primary driver of increases in liver cancer. The costs of treating hepatitis C can be daunting with average health care costs per patient battling liver
cancer estimated at $112,000 per year and the cost of a liver transplant ranging as high as $500,000 per patient. These costs underscore the importance of new therapies in treating and potentially curing the disease for both patients and the health care system.


**The American Journal of Medicine Launches Hepatitis C Resource Center**

The American Journal of Medicine (AJM) announced the availability of an original, comprehensive, online Hepatitis C Resource Center dedicated to providing primary care providers and specialists with the latest information on the screening, diagnosis, treatment, and management of Hepatitis C (HCV). Elsevier, a world-leading provider of scientific, technical, and medical information products and services, publishes AJM.

In a survey of primary care physicians (PCPs) who had screened and/or cared for HCV patients within the last six months, 60 percent confirmed they were not very confident or only somewhat confident when screening patients for chronic HCV infection. AJM and Elsevier Multimedia Publishing commissioned the survey, which was conducted by Metrics for Learning, LLC.

"The mandate for population-based screening and the lack of confidence of PCPs to screen highlights an opportunity that can be addressed in our healthcare system by appropriate education," said Edward Lebovics, MD, FACP, AGAF, FACG, FAASLD, Division of Gastroenterology and Hepato-biliary Diseases at New York Medical College. Dr. Lebovics is guest editor of the Resource Center.

The survey found that PCPs have misconceptions about who to screen, the risk of progression of liver disease and available therapies. Dr. Lebovics emphasized the shortage of educational resources to provide healthcare practitioners with the latest information on the screening, diagnosis, treatment, and management of HCV.


**Gilead: Support Path for Sovaldi:**

Gilead’s Support Path assists eligible hepatitis C patients in the US access to Sovaldi. The Support Path program assists individuals with or without insurance with co-pays and the cost of Harvoni and Sovaldi. Practitioners can refer patients to call 1-855-7-MYPATH (1-855-769-7284) to register over the phone or visit:  http://www.mysupportpath.com
STATEMENT BY THE HEPATITIS FOUNDATION INTERNATIONAL REGARDING FDA’S APPROVAL OF NEW TREATMENT FOR HEPATITIS C PATIENTS

SILVER SPRING, MD | December 22, 2014 --- The Hepatitis Foundation International (HFI) on behalf the hepatitis community commends the U.S. Food and Drug Administration’s (FDA) approval of a new interferon-free treatment regimen available to hepatitis C (HCV) patients. HCV is an infectious disease caused by the hepatitis C virus, primarily affecting the liver and spread by blood to blood transmission. HCV is a serious and life threatening illness that significantly impacts families, patients, caregivers, and communities globally.

AbbVie’s all oral drug Viekira PakTM makes an interferon-free treatment available to 3 million Americans infected with genotype 1 of the hepatitis C virus HCV, representing 75 percent of the total number of Americans affected with HCV.

“All innovations that increase treatment options for patients are applauded. Therapeutic options, like AbbVie’s new product, will prevent suffering and death for many families, as well as avoid costly and serious medical interventions, such as liver transplantation,” said Ivonne Fuller Cameron, CEO, and Hepatitis Foundation International.

Karen Wirth, Board Chair said, “As healthcare costs continue to escalate, access and affordability are also major concerns for our patient population.” Cameron continued, “Patients and payers are looking for viable solutions to cover and cure diseases like HCV. Access to these treatments for all patients necessitates creative strategies and solutions.”

“It is an exciting time for the hepatitis community, hopefully one that will continue to improve health outcomes for hepatitis patients. Patients should utilize which ever therapy their doctor believes is most appropriate. Two oral interferon-free treatments for HCV patients have been released months apart from each other. AbbVie’s Viekira Pak™ and Gilead’s Harvoni™, can only result in more patients being treated for HCV and being cured,” said Dane Christiansen, Vice Chair, HFI Board of Directors.

Mr. Christiansen concluded, “As HFI works to support patients through the full continuum of care, we are pleased that yet another miraculous tool has been developed to help affected individuals regain their quality of life. "We all win,” added Wirth.

About HFI
The Hepatitis Foundation International HFI is a 501(c) 3 non-profit organization established in 1994 working to eradicate chronic hepatitis for 400 million people globally. HFI is dedicated to increasing and promoting health and wellness; reducing the incidence of preventable liver-related chronic diseases, and lifestyles that negatively impacts the liver. Some of these diseases include: obesity, diabetes, hepatitis, substance abuse, HIV/AIDS, cardiovascular disease, and fatty/liver cancer. The HFI reaches well over 5 million patients and health care professionals annually through our public and private partnerships (www.HepatitisFoundation.org).

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January 2015
AbbVie - Vikiera Pak Patient Assistance program:

AbbVie has launched a patient support program, called proCeed™, which is intended to provide a broad range of patient support options. The proCeed™ program can be accessed at [www.viekira.com](http://www.viekira.com) or by calling 1-844-2-PROCEED.

HCV: Clinical Trials:

For the latest hepatitis C drug studies, recruitment, and evaluations:

Patient Assistance and Co-Pay Programs for Viral Hepatitis Drugs

Pharmaceutical companies offer Patient Assisted programs and co-pay programs to help offset costs and save money on hep C treatment.


Hepatitis in Corrections:

Behind Bars, Hep C Takes A Toll On Inmates, And Budgets

Rhode Island’s prisons are grappling with a dilemma. Hundreds of inmates have hepatitis C. New drugs can cure it. But they’re so expensive the department of corrections can’t afford them for every inmate who’s sick.

Every week for the past 20 years, Rich has peddled to Cranston to see patients behind bars. On this day he’s in his cluttered office in Providence, between meetings and phone calls. Rich advocates for treating hepatitis C behind bars as a way to make a real dent in the epidemic. That’s because the disease is far more prevalent in corrections than in the general population – by some estimates as many as 30 percent of the nation’s prison population has hepatitis C.

Viral Hepatitis Prevention Program Staff:

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Adult Viral Hepatitis Prevention Program Coordinator  
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You may have more patients with **Hepatitis B and C** than you know.

Learn how to screen, what to do about positive serologies, and who and how to treat with **ACT-First**.

More than 3 million people in the U.S. have hepatitis C (HCV), and three in four don't know they are infected.

Take the first step in helping your patients with liver disease. Visit [aasld.org/ACTFirst](http://aasld.org/ACTFirst) for complete information about HBV and HCV patient care.

That is why the Centers for Disease Control and Prevention (CDC) recommends screening for everyone in the demographic group that is most likely to be infected—people born between 1945 and 1965.

In addition, the U.S. Preventative Services Task Force recently upgraded to B its recommendation for hepatitis B (HBV) screening of persons at high risk of infection.

You are on the front lines of testing, diagnosing, and treating these potentially deadly diseases. The American Association for the Study of Liver Diseases (AASLD) has developed ACT-First, a **free, online CME course** for primary care providers to help you stay updated. Two units—on HCV and HBV—are available now, with additional units on other liver diseases to be released soon. Each teaching unit includes seven to eight short (20-minute) presentations addressing every aspect of the disease state.
# 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 502-696-3803

## DEMOGRAPHIC DATA

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<th>Gender</th>
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<th>City</th>
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## 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

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## SERUM AMINOTRANSFERASE LEVELS

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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