On behalf of the KY Viral Hepatitis Program, we wish you and your loved ones a prosperous, healthy and Happy NEW YEAR! We are pleased to share with you the January 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.

Join us on Facebook at KY Viral Hepatitis.

Kathy Sanders, RN MSN
Hepatitis C: Perinatal and Children Aged Five Years or Less

The Kentucky Department for Public Health is requesting the assistance of Kentucky Healthcare Providers with an active surveillance project to help us estimate the number of 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 Kentucky, only acute hepatitis C cases are normally required to be reported. **Starting January 1, 2014 through March 31, 2014, we are asking for 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 infection reporting requirements in these populations. To report any HCV-positive individuals in the above categories during this time period, please complete the reporting form at the end of this newsletter and fax to the Kentucky Department for Public Health at: 502-564-4760. This letter and reporting form was distributed to KY healthcare providers in December 2013.

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.

**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.
Hepatitis C virus dried on inanimate surfaces can remain infectious for up to six weeks

Dried spots of blood contaminated with hepatitis C virus (HCV) can remain infectious for up to six weeks at normal room temperatures, research published in the online edition of the Journal of Infectious Diseases shows. Commercially available antiseptics reduced the infectivity of the blood spots, but only when used at recommended concentrations.

“We observed that HCVcc [cell culture] could maintain infectivity for up to 6 weeks at 4°C and 22°C,” write the authors. “Commercially available antiseptics reduced the infectivity of HCV on surfaces only when used at the recommended concentrations, but not when further diluted.”

The investigators believe their findings could explain hospital-acquired HCV infections in individuals who have not undergone surgery or received blood products, and also the ongoing HCV epidemic among injecting drug users.

HCV is a blood-borne virus. Injecting drug use is a well-known risk factor, and a large number of individuals were infected with HCV after receiving blood or blood products. But research suggests that hospital-acquired infections are occurring among patients who did not receive blood/blood products or undergo an invasive procedure. Investigators from Yale University hypothesised that this was due to contact with infectious quantities of HCV in minute dried blood spots on inanimate surfaces and objects.

http://www.aidsmap.com/Hepatitis-C-virus-dried-on-inanimate-surfaces-can-remain-infectious-for-up-to-six-weeks/page/2808006/

Protein Analysis Could Lead To Hepatitis C Vaccine

A hepatitis C vaccine is one step closer thanks to the efforts of scientists at The Scripps Research Institute (TSRI), who have managed to discover unexpected structural features of a protein used by the virus to infect liver cells.

The study authors, whose work appears in Friday’s edition of the journal Science, state any successful hepatitis C vaccine would most likely target this protein, which is known as E2 envelope glycoprotein. Rare antibodies capable of binding E2 in ways that can neutralize a vast array of different viral strains have already been isolated in patients by scientists, they added.

Read More:
Randomized Trial Of Daclatasvir And Asunaprevir With Or Without Peginterferon/Ribavirin For Hepatitis C Virus Genotype 1 Null Responders

Patients with chronic hepatitis C virus (HCV) infection and prior null response (<2 log HCV RNA decline after ≥12 weeks of peginterferon/ribavirin) have limited options. We evaluated daclatasvir plus once- or twice-daily asunaprevir in non-cirrhotic genotype 1 null responders.

Methods

In this randomized, phase 2a, open-label, 24-week treatment study, 101 patients received daclatasvir (60 mg) once-daily. In addition, 38 genotype 1b patients received asunaprevir (200 mg) twice- (DUAL A1) or once-daily (DUAL A2); 36 genotype 1a and 5 genotype 1b patients received asunaprevir twice- (QUAD B1) or once-daily (QUAD B2) plus peginterferon/ribavirin; and 18 genotype 1a and 4 genotype 1b patients received asunaprevir twice-daily plus ribavirin (TRIPLE B3). The primary endpoint was undetectable HCV RNA 12 weeks post-treatment (sustained virologic response, SVR12).

Results

Across all groups, mean HCV RNA was ≥6 log IU/mL, and 99% of patients had a non-CC IL28B genotype. SVR12 rates were 78% (A1), 65% (A2), 95% (B1), and 95% (B2). In B3, most genotype 1a patients experienced virologic breakthrough. The most common adverse events were headache, diarrhea, and asthenia. Grade 3-4 aminotransferase elevations were infrequent and not treatment-limiting.

Conclusion

In genotype 1 null responders, daclatasvir plus twice-daily asunaprevir DUAL therapy is effective for most genotype 1b patients, and daclatasvir, asunaprevir, and peginterferon/ribavirin QUAD therapy is effective for nearly all genotype 1a and 1b patients; but neither DUAL nor TRIPLE therapy is effective for genotype 1a patients. Interferon-free regimens including daclatasvir and twice-daily asunaprevir for genotype 1 null responders should be tailored to subtype.

Hepatitis C - Changes to Incivek (telaprevir) product labeling

FDA approved changes to the Incivek (telaprevir) product labeling to include results from trial C211 (OPTIMIZE) to support a twice daily dosing regimen. In addition new contraindications were added for anticonvulsant medications (carbamazepine, phenobarbital and phenytoin) and other revisions to the section 7 Drug Interactions.

Below is a summary of the changes

- Section 2: Dosage and Administration of telaprevir were updated throughout the label: from 750 mg three times a day to 1125 mg twice daily.
- The anticonvulsant medications carbamazepine, phenobarbital, and phenytoin were moved from the Drug Interaction section (Section 7, Table 5) to the Contraindications section (Section 4, Table 3)
- Section 6: Adverse Reactions was updated as follows:

Additional Data from Clinical Trials

In the analysis of an additional study (Trial C211), the safety profile of combination treatment with INCIVEK 1125 mg twice daily was similar to the safety profile for patients receiving combination treatment with INCIVEK 750 mg every 8 hours (q8h) [see Clinical Studies (14.2)]. No new safety findings were identified.

The New Paradigm of Hepatitis C Therapy - Integration of Oral Therapies Into Best Practices

Emerging data indicate that all-oral antiviral treatments for chronic hepatitis C virus (HCV) will become a reality in the near future. In replacing interferon-based therapies, all-oral regimens are expected to be more tolerable, more effective, shorter in duration and simpler to administer. Coinciding with new treatment options are novel methodologies for disease screening and staging, which create the possibility of more timely care and treatment. Assessments of histologic damage typically are performed using liver biopsy, yet noninvasive assessments of histologic damage have become the norm in some European countries and are becoming more widespread in the United States. Also in place are new Centers for Disease Control and Prevention (CDC) initiatives to simplify testing, improve provider and patient awareness and expand recommendations for HCV screening beyond risk-based strategies. Issued in 2012, the CDC recommendations aim to increase HCV testing among those with the greatest HCV burden in the United States by recommending one-time testing for all persons born during 1945–1965. In 2013, the United States Preventive Services Task Force adopted similar recommendations for risk-based and birth-cohort-based testing. Taken together, the developments in screening, diagnosis and treatment will likely increase demand for therapy and stimulate a shift in delivery of care related to chronic HCV, with increased involvement of primary care and infectious disease specialists. Yet even in this new era of therapy, barriers to curing patients of HCV will exist. Overcoming such barriers will require novel, integrative strategies and investment of resources at local, regional and national levels.


N.H. hospital worker gets 39 years in hepatitis case

CONCORD, N.H. (AP) A traveling medical technician was sentenced Monday to 39 years in prison for stealing painkillers and infecting dozens of patients in four states with hepatitis C through tainted syringes.

“I don’t blame the families for hating me,” David Kwiatkowski said after hearing about 20 statements from people he infected and their relatives. “I hate myself.”

Kwiatkowski, 34, was a cardiac technologist in 18 hospitals in seven states before being hired at New Hampshire’s Exeter Hospital in 2011. He had moved from job to job despite being fired at least four times over allegations of drug use and theft. Since his arrest last year, 46 people have been diagnosed with the same strain of hepatitis C he carries.
Kwiatkowski admitted stealing painkillers and replacing them with saline-filled syringes tainted with his blood. He pleaded guilty in August to 16 federal drug charges.

Before he was sentenced by Judge Joseph LaPlante, Kwiatkowski said he was very sorry what he had done. He said that his crime was caused by an addiction to painkillers and alcohol.

The victims spoke angrily and tearfully of the pain that Kwiatkowski had inflicted upon them.

Linda Ficken, 71, of Andover, Kan., was one of two Kansas victims to attend the sentencing hearing. She underwent a cardiac catheterization at Hays Medical Center in 2010, and said she is haunted by the memory of Kwiatkowski standing at her bedside for more than an hour, applying pressure to the catheter’s entry site in her leg to control a bleeding problem.

“On one hand, you were saving my life, and on the other hand, your acts are a death sentence for me,” she told him Monday. “Do I thank you for what you did to help me? Do I despise you for what your actions did and will continue to do for the rest of my life? Or do I simply just feel sorry for you being the pathetic individual you are?”

Lynwood Nelson, who was infected when he went in for a procedure at the Baltimore VA Medical Center in 2012, said Kwiatkowski “should receive the same punishment he gave us: the death penalty.”

Prosecutors had pushed for a 40-year prison sentence, saying Kwiatkowski created a “national public health crisis,” put a significant number of people at risk and caused substantial physical and emotional harm to a large number of victims.

Defense lawyers argued that a 30-year sentence would better balance the seriousness of the crimes against Kwiatkowski’s mental and emotional problems and his addiction to drugs and alcohol, which they said clouded his judgment.

In all, 32 patients were infected in New Hampshire, seven in Maryland, six in Kansas and one in Pennsylvania. Kwiatkowski, 34, also worked in Michigan, New York, Arizona and Georgia.

Two of the 16 charges stem from the case of a Kansas patient who has since died. Authorities say hepatitis C, a blood-borne virus that can cause liver disease and chronic health problems, played a contributing role.

Ficken told The Associated Press last week that while she has struggled with fatigue since her diagnosis, a bigger blow came last month when her brother was diagnosed with leukemia and was told he needs a stem cell transplant. While siblings often are the closest match, she can’t donate because of her hepatitis C status.

http://www.bostonglobe.com/metro/2013/12/02/hospital-worker-gets-years-hepatitis-case/oC1dMK4IPFFWoxxyRNZvQ2M/story.html
FDA approves OLYSIO (simeprevir) for treatment of chronic hepatitis C infection

Janssen Therapeutics, Division of Janssen Products, LP (Janssen), announced today the U.S. Food and Drug Administration (FDA) has approved OLYSIO™ (simeprevir), an NS3/4A protease inhibitor, for the treatment of chronic hepatitis C infection as part of an antiviral treatment regimen in combination with pegylated interferon and ribavirin in genotype 1 infected adults with compensated liver disease, including cirrhosis. OLYSIO™ may benefit patients with chronic hepatitis C, including those who are treatment naive or who have failed prior interferon-based therapy.

Chronic hepatitis C is a blood-borne infectious disease of the liver that affects approximately 3.2 million people in the United States.


AbbVie Cites Positives In Hepatitis C Treatment

AbbVie Inc. said its oral treatment for hepatitis C showed about 96 percent of patients had no detectable levels of the virus after 12 weeks.

The late-stage trial was designed to evaluate a regimen that fuses two experimental drugs developed by AbbVie with an antiviral drug that has been used a hepatitis C treatment for decades. The 631 patients enrolled in the trial were diagnosed with the genotype 1 variant of the infection, which accounts for some 70 percent of hepatitis C cases.

Read More: http://www.wbjournal.com/article/20131121/NEWS01/131129991/1002
2013: HCV Year in Review

The Big Story Of 2013?

The biggest story thus far is the FDA approval of Olysio (simeprevir) and Solvadi (sofosbuvir), two new oral drugs to treat hepatitis C, or is it?

In 2013 we found ourselves with a prolific HCV pipeline of direct-acting anti-viral agents which have improved: 1. Efficacy - overall 90% cure rates, 2. Tolerability - less side effects and 3. Convenience - shorter treatment duration, less pill burden. Wow.

In this short 2013 review we count down twelve months of news, research and breakthroughs that made a significant difference in the lives of people living with hepatitis C.

Hepatitis B Corner

Perinatal Hepatitis B Prevention Program- Julie Miracle, RN BSN

Mother to child transmission, also known as perinatal transmission, of hepatitis B is still a public health issue in the U.S. Approximately 800 newborns in the U.S. are chronically infected each year through perinatal exposure. Half of all hepatitis B-infected individuals are from Asian American and Pacific Islander (AAPI) populations, and the most common form of transmission is from mother to child.

Kentucky has had an increase in acute hepatitis B cases compared to most other states. The Kentucky prevalence rate is 5.1/100,000 compared to the US rate of 1.0 per 100,000. With this increase, the Kentucky Department for Public Health has seen an increase in reports of Hepatitis B positive pregnant women. The Kentucky Immunization Program follows all infants born to mothers that are Hepatitis B surface antigen-positive in the Perinatal Hepatitis B Prevention Program (PHBPP) to ensure that the infants are protected from infection. The graph below shows the number of infants followed up after delivery by the PHBPP for the last 5 years.
Kentucky law (KRS 214.160) mandates that all pregnant women must be screened for hepatitis B surface antigen (HBsAg) during each and every pregnancy. Those pregnant women with HBsAg-positive results must be reported to the Local Health Department in the woman’s county of residence or to the Kentucky Department for Public Health. High risk mothers, previously tested and found to be HBsAg-negative, and mothers with unknown HBsAg status must be tested at the time of admission to the hospital for delivery. All infants born to HBsAg-positive women must receive Hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG) within 12 hours of birth for protection against hepatitis B infection, including such infants weighing less than 2,000 grams. NICU staff need to obtain the mother’s HBsAg results for all infants to assure that proper hepatitis B immunoprophylaxis is given. All infants born to HBsAg-positive women must also complete a valid hepatitis B vaccine series and receive post vaccination serology testing.

**The Birth Dose of Hepatitis B Vaccine**

The Advisory Committee on Immunization Practices recommends that all newborns should receive the birth dose of hepatitis B vaccine prior to discharge. The Immunization Action Coalition is recognizing hospitals and birthing centers that have attained 90% or greater coverage rates for administering hepatitis B vaccine at birth. Since July 2013, four Kentucky birthing hospitals are meeting this standard. They are Ephraim McDowell Regional Medical Center
in Danville (98%); Georgetown Community Hospital, Georgetown (98%); Harrison Memorial Hospital, Cynthiana (99%); and Paul B. Hall Regional Center, Paintsville (97%). Congratulations!

To apply; Ggo to [http://www.immunize.org/honor-roll/birthdose](http://www.immunize.org/honor-roll/birthdose).

**Hepatitis B Updates from CDC**

**MMWR - CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Post exposure Management**

This report is an extension of the 2011 ACIP recommendations for evaluating hepatitis B protection among health-care personnel (HCP) and administering post-exposure prophylaxis. The MMWR emphasizes the importance of administering Hepatitis B vaccination for all health-care personnel and provides explicit guidance for evaluating hepatitis B protection among previously vaccinated health-care personnel (particularly those who were vaccinated in infancy or adolescence), and it clarifies recommendations for post exposure management of health-care personnel exposed to blood or body fluids. This new guidance can assist clinicians, occupational health and student health providers, infection-control specialists, hospital and health-care training program administrators, and others in selection of an approach for assessing Hepatitis B protection for vaccinated health-care personnel.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm)

**Testing Asian Americans & Pacific Islanders for Hepatitis B – Clinical Summary**

Studies have shown that while Asian Americans and Pacific Islanders (AAPI) represent 5% of the total U.S. population, they make up 50% of hepatitis B cases. Nearly 2 in 3 people living with chronic hepatitis B do not know they are infected. Testing for chronic hepatitis B plays an important role in the detection, classification, management and medical care for patients with hepatitis B. This fact sheet outlines who should be tested for Hepatitis B with an HBsAg test, the geographic distribution of chronic hepatitis B infection worldwide, recommended follow-up for a positive HBsAg, and interpretation of serologic tests.


**Know Hepatitis B Campaign Materials**

Know Hepatitis B is a national communications campaign promoting Hepatitis B testing among Asian Americans and Pacific Islanders (AAPIs). Four languages (Burmese, Hmong, Khmer, and Lao) have been added to campaign materials already available in Chinese, Vietnamese, Korean, and English. English, Chinese, Korean, Vietnamese and multi-lingual posters are also now available for [ordering](http://www.immunize.org/honor-roll/birthdose).
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Dear Healthcare Provider,

The Kentucky Department for Public Health is requesting your assistance to help us estimate the number of 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. The Kentucky Adult Viral Hepatitis Prevention Program has been conducting a pilot test of HCV laboratory testing at selected local health departments for the last two years. The pilot testing sites have reported an increase in confirmed HCV-positive tests among individuals aged 20 through 29 years. A concern is that this age group includes women of child bearing ages where potential HCV transmission to the infant/child could occur if the pregnant woman was HCV infected.

In Kentucky, only acute hepatitis C cases are normally required to be reported. Starting January 1, 2014 through March 31, 2014, we are asking for 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 infection reporting requirements in these populations. To report any HCV-positive individuals in the above categories during this time period, please complete the attached reporting form and fax to the Kentucky Department for Public Health at: 502-564-4760.

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.

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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 a Pregnant Woman, Infant, or Child (aged five years or less)  
Fax Form to 502-564-4760

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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:  
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