Hepatitis C in Kentucky
Updates on Epidemiology, Testing and Treatment

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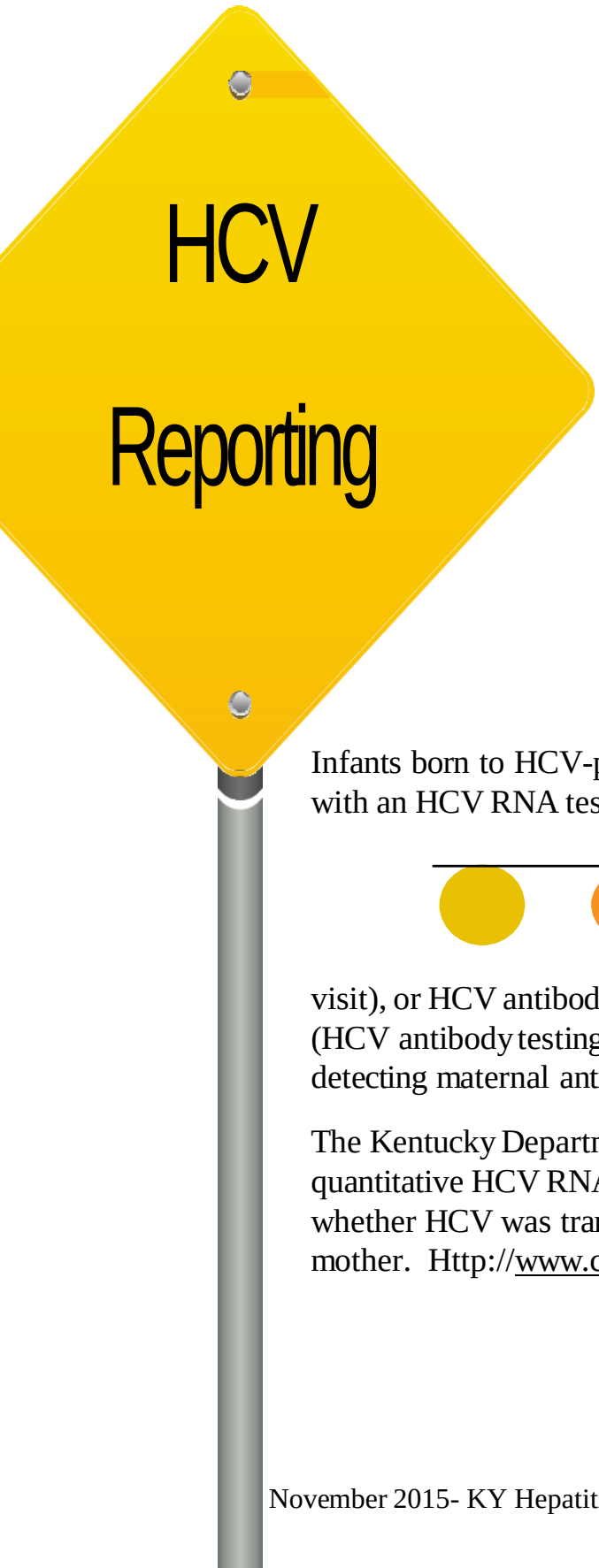
KY Hepatitis Connections

As November has arrived, we wish you and your family a wonderful Thanksgiving Holiday this month! Inside this November 2015 edition of the KY Hepatitis Connections you will find information about hepatitis screening, testing, and treatment, and opportunities for viral hepatitis continuing professional education.

As always, feel free to forward, copy and/or distribute this newsletter to other professionals in your network. Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral hepatitis and its impact on our families throughout the Commonwealth.

Kathy J. Sanders, RN MSN

Reminder: Report Hepatitis C in Pregnant Women, Newborn Infants, and Children Aged Five Years or Less



Health care providers should report:

- **All HCV-positive pregnant women;**
- **All infants born to HCV-positive women;**
- **All HCV-positive infants and children aged 5 years and younger**

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 women 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. http://www.cdc.gov/std/treatment/2010/hepc.htm

Infants born to HCV-positive mothers should be tested for HCV infection with an HCV RNA test 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 (HCV antibody testing should be delayed until 18 months of age to avoid detecting maternal antibody).

The Kentucky Department for Public Health recommends the use of quantitative HCV RNA tests at 2 months of age or older to assess whether HCV was transmitted to the infant from the HCV-positive mother. Http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm

Please use the EPID 200 Form for reporting Acute Hepatitis B and Hepatitis C infections.

The EPID 394 form is for reporting of pregnant women, infants born to hepatitis C positive mothers at the time of delivery, and hepatitis C infection in an infant or child aged five years or less

Complete and fax the EPID 394 form at the end of this newsletter. Fax forms to 502-696-3803

Hepatitis: In the News

FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie

The U.S. Food and Drug Administration (FDA) is warning that hepatitis C treatments Viekira Pak and Technivie can cause serious liver injury mostly in patients with underlying advanced liver disease. As a result, we are requiring the manufacturer to add new information about this safety risk to the drug labels. Patients taking these medicines should contact their health care professional immediately if they develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools, as these may be signs of liver injury. Patients should not stop taking these medicines without first talking to their health care professionals. Stopping treatment early could result in drug resistance to other hepatitis C medicines. Health care professionals should closely monitor for signs and symptoms of worsening liver disease, such as ascites, hepatic encephalopathy, variceal hemorrhage, and/or increases in direct bilirubin in the blood.

Viekira Pak and Technivie are used to treat chronic hepatitis C, a viral infection that can last a lifetime and lead to serious liver and other health problems, including cirrhosis, liver cancer, and death. These medicines reduce the amount of hepatitis C virus in the body by preventing it from multiplying and may slow down the disease.

The review of adverse events reported to the FDA Adverse Event Reporting System (FAERS) database and to the manufacturer of these medicines, AbbVie, identified cases of hepatic decompensation and liver failure in patients with underlying liver cirrhosis who were taking these medicines. Some of these events resulted in liver transplantation or death. These serious outcomes were reported mostly in patients taking Viekira Pak who had evidence of advanced cirrhosis even before starting treatment with it. For additional information: http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm

Q&A with AbbVie's Barry Bernstein, MD: Are More FDA Warnings in the Works?

The effectiveness of the new arsenal of hepatitis C antivirals has elated physicians and patients and been a triumph —and lucrative development--for pharmaceutical companies.

The announcement on Oct. 22 that AbbVie, manufacturer of two such drug products was changing labeling to include new warnings dampened the euphoria. Post-marketing reports alerted the company and the US Food and Drug Administration (FDA) of patient deaths and severe liver damage sometimes requiring transplantation in some patients who received AbbVie's treatments.

The company, in consultation with the FDA changed its package inserts and labeling for Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) and Technivie (ombitasvir, paritaprevir, and ritonavir tablets. Patients whose liver disease was staged at the Child Pugh B level (moderate) will now be contraindicated for the drugs. Patients classified as Child-Pugh C (severe) will remain contraindicated as they have been since approval.

Read more at: http://www.hcplive.com/medical-news/q--a-with-abbvies-barry-bernstein-md-are-more-fda-warnings-in-the-works-#sthash.QZJU7Yr3.dpuf

NASTAD Releases White Paper on Drug User Health and ACA Opportunities

NASTAD recently announced the release of a new white paper: Modernizing Public Health to Meet the Needs of People Who Use Drugs: Affordable Care Act Opportunities. This new white paper assesses new financing and delivery models for drug user health services. The project team focused on coverage and financing opportunities for community-based drug user health and harm reduction services typically not covered by insurance. Research focused on eight states, assessing how health departments, community-based organizations, Medicaid programs and plans and hospitals are working together to better address the needs of people who use drugs.

The need to find creative solutions to ensure that broader health care systems and payers are providing prevention, care, and treatment services for people who use drugs comes in the midst of a public health crisis for this population. Rates of HIV infection and viral hepatitis are substantially higher among persons who use drugs than among persons who do not. Opioid use in particular in the United States is at epidemic proportions. This crisis – coupled with limited federal and state resources for drug user health programs and services – has made leveraging the ACA and partnerships with broader health systems and payers even more critical.

NASTAD has been awarded another year of Elton John AIDS Foundation funding to support a learning collaborative that builds off of the findings of the white paper and supports health departments to partner with broader health care systems and payers to increase access to drug user health services. To see more of NASTAD's drug user health work, including the Statement of Urgency: Addressing the Opioid Epidemic in the United States and Minimizing Harm, Maximizing Health: The Role of Public Health Programs in Drug User Health, please visit: https://www.nastad.org/domestic/viral-hepatitis/drug-user-health

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Hepatitis C May Increase Risk of Heart Disease

Positive hepatitis C infection may increase risk for liver damage as well as future heart problems, according to findings published in *The Journal of Infectious Diseases*.

Researchers from Johns Hopkins Medicine evaluated almost 1,000 men aged 40 to 70 years with or without human immunodeficiency virus (HIV), of which 87 also had hepatitis C in order to measure associations between hepatitis C with coronary atherosclerosis. About 750 men participating in the study also underwent CT angiography. The participants, who did not have overt existing heart disease, were recruited from the Multicenter AIDS Cohort Study, a larger study focused on men who have sex with men.

Prior research demonstrated that people with HIV already have an elevated risk for heart disease, but the researchers believe their findings here offer strong support for hepatitis C also contributing to cardiovascular damage independent of HIV status.

The investigators found that patients infected with hepatitis C are more likely to have atherosclerosis, which they cite as a common signal of future heart attacks or strokes. After adjusting for various demographic characteristics, HIV serostatus, behaviors, and cardiovascular risk factors, chronic hepatitis C infection was what the researchers called "significantly associated" with a higher prevalence of both coronary artery calcium and noncalcified plaque . See more at: http://www.hcplive.com/medical-news/hepatitis-c-may-increase-risk-of-heart-disease-

Gilead Submits New Drug Application to U.S. Food and Drug Administration for Fixed-Dose Combination of Sofosbuvir/ Velpatasvir for Treatment of All Six Genotypes of Hepatitis C

*If Approved, Combination Would Be First All-Oral, Pan-Genotypic Single-Tablet Regimen for Chronic HCV Infection * Filing is Company's Third in Three Years for a New HCV Medicine*

Gilead Sciences, Inc. (Nasdaq:GILD) announced on October 28th that it had submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for an investigational, once-daily fixed-dose combination of the nucleotide analog polymerase inhibitor sofosbuvir (SOF), approved as Sovaldi® in December 2013, and velpatasvir (VEL), an investigational pan-genotypic NS5A inhibitor, for the treatment of chronic genotype 1-6 hepatitis C virus (HCV) infection. The NDA is supported by clinical studies exploring the use of 12 weeks of SOF/VEL for patients with genotype 1-6 HCV infection, including patients with compensated cirrhosis and 12 weeks of SOF/VEL with ribavirin for patients with decompensated cirrhosis.

"As the first fixed-dose combination of two pan-genotypic, direct-acting antivirals, SOF/VEL represents an important step forward in the treatment of patients with hepatitis C," said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. "Genotype 1 is the most prevalent form of HCV in the United States, but worldwide, more than half of people living with HCV are infected with other genotypes. SOF/VEL complements our current HCV portfolio of Sovaldi and Harvoni, offering high cure rates and the potential to simplify treatment and eliminate the need for HCV genotype testing."

The FDA has assigned SOF/VEL a Breakthrough Therapy designation, which is granted to investigational medicines that may offer major advances in treatment over existing options. The NDA for SOF/VEL is supported by data from four Phase 3 ASTRAL trials, which evaluated the fixed-dose combination in hepatitis C genotypes 1.
Of the 1,035 patients treated with SOF/VEL for 12 weeks in the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies, 1,015 (98 percent) achieved the primary efficacy endpoint of SVR12. The ASTRAL-4 study randomized 267 patients with decompensated cirrhosis (Child-Pugh class B) to receive 12 weeks of SOF/VEL with or without ribavirin (RBV), or 24 weeks of SOF/VEL. Those who received SOF/VEL plus RBV for 12 weeks achieved an SVR12 rate of 94 percent, while those who received SOF/VEL for 12 weeks and 24 weeks achieved SVR12 rates of 83 percent and 86 percent, respectively.

Read More: http://biotech-365.com/gilead-submits-new-drug-application-to-u-s-food-and-drug-administration-for-fixed-dose-combination-of-sofosbuvirvelpatasvir-for-treatment-of-all-six-genotypes-of-hepatitis-c/

Learn the Effects of Hepatitis C on the Body

Hepatitis C is a viral disease that primarily causes inflammation of the liver, but the effects can be felt throughout the body.

The Effects of Hepatitis C on the Body Hepatitis C is caused by a virus that is passed through contact with the blood of an infected person. The infection leads to inflammation of the liver. The liver processes blood and filter toxins so they don't cause damage to your body. The liver also produces bile, which helps you to digest food and stores glucose and vitamins. Inflammation makes it difficult for the liver to perform these vital functions. In time, the hepatitis C infection can affect the entire body. Early symptoms, including yellowing skin and fatigue, may be mild and easily dismissed. Chronic infection can cause scarring of the liver (cirrhosis). As the disease progresses, symptoms such as skin problems, blood disorders, and fever may appear. In the long term, hepatitis C can lead to severe liver damage, liver cancer, and liver failure. Early treatment can help delay or prevent serious damage.

See more at: http://www.healthline.com/health/hepatitis-c/effects-on-the-body

Paying for Hepatitis C Treatment

In recent years, the Fair Pricing Coalition (FPC) has been working closely with the pharmaceutical industry to streamline access to co-pay programs and PAPs for people living with viral hepatitis. The FPC has negotiated co- pay programs with virtually every major hepatitis drug manufacturer. Below is a list of co-pay and patient assistance programs for hepatitis B and C, including contact information for these programs. Different pharmaceutical company programs have different eligibility criteria based on the federal poverty level (FPL). Eligibility for this year is based on last year's income. The figure is adjusted based on family or household size. Unless otherwise stated, companies ask for verification of income, usually in the form of a federal income tax return. Companies also generally consider household income, meaning that a married couple filing joint taxes will be judged on their combined income. People who file individual tax returns will only have their individual income considered.

If you are told you are ineligible for assistance, this does not mean there is no chance for you; you can always appeal to have the decision reversed or see if you are eligible for alternative financial assistance.

CO-PAY PROGRAMS and PAP PROGRAMS

Co-pay programs offer assistance to people with private insurance, reducing the co-payments or coinsurance costs required to obtain hepatitis B or hepatitis C drugs at the pharmacy. Many of these programs are not available for those enrolled in Medicare, Medicaid, or other government-based prescription plan.

Patient assistance programs (PAPs) offer free hepatitis B or C drugs to lower-income people who are uninsured or underinsured, and who do not qualify for insurance programs such as Medicaid or Medicare.

If you are ineligible for co-pay or patient assistance funds because you have Medicare, Medicaid or another government-based prescription plan, and cannot afford your prescription(s), ask the pharmaceutical company to refer you to a patient advocacy organization (some in the link below).

For HBV and HCV Patient Assistant Programs, see:
http://www.hepmag.com/articles/2512_20506.shtml?
utm_source=mpnews&utm_medium=include&utm_campaign=l esson

Enzo Biochem Demonstrates Greater Sensitivity of Its AmpiProbe™Platform for Molecular Diagnostics

Enzo Biochem, Inc. ENZ, announced on October 29, 2015 it had demonstrated new thresholds of sensitivity and breadth for its assay for the measurement of Hepatitis C virus (HCV) viral load. The data was generated from clinical samples tested at Enzo Clinical Labs and analyzed by its Translational Diagnostics Group. The assay is based on the proprietary AmpiProbe™ real-time amplification / detection technology platform developed by Enzo Life Sciences, and was reported in a presentation at a conference of the prestigious American Society for Clinical Pathology (ASCP) in Long Beach, CA.

The data show that AmpiProbe HCV™ Assay could detect as low as 5.5 IU (International Units) per mL of serum with a positive rate greater than 95%, while the limit of quantification (LOQ) was observed to be 10 IU/mL. The AmpiProbe HCV™ Assay was also able to detect the six main genotypes and subtypes of HCV at concentrations of 15 IU/ml with a hit rate of over 95%. The study was designed to further evaluate the extent of sensitivity of products emanating from the AmpiProbe™ platform.

"The limit of detection (LOD) that we observed was greater than a 50% improvement in analytic sensitivity than leading commercially available HCV viral load assays," said Dieter Schapfel, MD, Enzo's Medical Director and lead author of the study. This can be an important development as therapies to treat this wide- spread disease continue to improve."

A similar presentation was made previously at the meeting of the College of American Pathologists (CAP) earlier this month in Knoxville, TN.

The latest results regarding AmpiProbe's extended capabilities have been submitted in support of Enzo's application for regulatory approval.

"The clinical data presented at these highly regarded meetings underscore the continued applications we have been making in this key enabling platform technology," said Dr. Elazar Rabbani, Chairman and CEO of Enzo. "Over the last year, we have been expanding the reach of the AmpiProbe™ platform to such areas as Hepatitis B virus and HIV viral loads, as well as in our development of a comprehensive panel of assays designed to identify a number of infectious diseases related to women's health, one of the fastest growing segments of that market.

"Moreover, the results we have shown are even more exciting given the difficulty of using this virus as our first application of AmpiProbe™. Hepatitis C virus is a single stranded RNA virus and, as such, is inherently more unstable and thus more challenging to work with than DNA viruses. Additionally, we needed to demonstrate the applicability of AmpiProbe™ across a wide spectrum of genotypes while simultaneously producing both high levels of sensitivity and linearity of results."

Read More: http://www.marketwatch.com/story/enzo-biochem-demonstrates-greater-sensitivity-of-its-ampiprobetmplatform-for-molecular-diagnostics-2015-10-29

HCV Guideline Update: Treat All Patients with New Drugs

The American Association for the Study for Liver Diseases and the Infectious Disease Society of America (IDSA) have updated HCVguidelines.org so that it reflects the current understanding that virtually all individuals who are positive for the hepatitis C virus (HCV) should receive the newer HCV treatment. The site emphasizes that new sections have been added and that the recommendations are updated regularly as new information becomes available.

The guidelines begin by explaining that new direct-acting oral agents that can cure HCV infection have been approved in the United States. "We've been accumulating understanding of the value and safety of the medications," David L. Thomas, MD, MPH, spokesperson for IDSA, explained to Medscape Medical News. He described the change in position as an "evolution."

When the newer HCV drugs were first introduced, physicians had to rely entirely on data from clinical trials. The new guidelines reflect the addition of real-world physician experience.

The new guidance explains that the sustained virologic response that is characteristic of a successful HCV treatment would benefit almost everyone who is infected with HCV. Moreover, many of the highest-risk patients have already had the opportunity to receive treatment with the new medications.

The IDSA notes that the cost of the new drugs and regional availability of the appropriate healthcare provider may still translate into a need to prioritize patients for treatment

Some general practitioners will feel comfortable treating their HCV-positive patients, and others will feel more comfortable referring their patients to a specialist for treatment. "A good relationship between physician and patient is crucial to achieving the best outcomes with direct-acting therapies. The physician needs to make an assessment of a patient's understanding of the treatment goals and provide education on the importance of adherence to the therapy and follow-up care," said IDSA panel co-chair Gary Davis, MD, in a press release.

Dr Thomas said that although the guidelines are meant to demystify treatment, the most severely affected patients should probably be referred to a specialist. "For hepatitis C, the patients who are often in need of referral are those with severe liver disease and cirrhosis," he explained.

Unfortunately, it is hard for physicians to predict reimbursement from insurance companies. "Our focus is on the physicians and the patients," explained Dr. Thomas, calling the world of insurance companies "challenging" and "vexing."

According to HCVguidelines.org, approximately 3 to 4 million individuals in the United States are chronically infected with HCV, and half of them are unaware of their status

Read More: http://www.medscape.com/viewarticle/853416

Retroviral RNA May Play a Part in Liver Cancer

An international group led by RIKEN in Japan and INSERM in France have found that retroviral long-terminal-repeat (LTR) promoters—a type of repetitive element that are widely distributed in the human genome—are highly activated in hepatocellular carcinomas, the most common type of liver cancer. Intriguingly, these areas—which are particularly activated in HCCs associated with viral hepatitis, are not normally activated in the liver but are in reproductive tissues such as testis and placenta. The study, published in Genome Research, suggests that the activation of LTR promoters might contribute to the development of cancer in the liver.

Retroviral LTRs are widely believed to be the remnants of retroviruses—like the HIV virus—which lost the ability to exit from cells and became parasitic elements in the genome. "Since these viral elements contain elements that are capable of functions such as transcription" says Piero Carninci of the RIKEN Center for Life Science Technologies, one of the corresponding authors, "it seems that organisms have sometimes made use of these LTRs for their own purposes, and in fact they are highly activated in reproductive tissues and, as we discovered earlier, in ES and iPS cells."

The group used CAGE technology, a technique developed at RIKEN, to examine RNA expression in liver cancer tumors and non-tumor tissue taken from the same patients. They found 4,756 non-coding promoters that were more highly activated in the tumor tissue than the non-tumor tissue, and remarkably, 935 of these were located in retroviral LTRs.

Read More: http://www.dddmag.com/news/2015/10/retroviral-rna-may-play-part-liver-cancer

Hepatitis C Clinical Trials

ClinicalTrials.gov is a registry of clinical trials. It is run by the United States National Library of Medicine (NLM) at the National Institutes of Health, and is the largest clinical trials database, currently holding registrations from about 200,000 trials from more than 170 countries in the world.

To view hepatitis C completed and recruiting clinical trials, visit: https://clinicaltrials.gov/ct2/results?term=hepatitis+c

NASTAD Conference

The Kentucky AVHPC, Kathy Sanders, RN MSN, recently attended NASTAD's 5th National Hepatitis Technical Assistance Meeting in Washington, DC. The only gathering of its kind, the meeting is a venue for Viral Hepatitis Prevention Coordinators (VHPC), other health department staff and Federal and Industry partners to share promising program strategies, hear from Federal partners and other thought leaders, and to network and build relationships across jurisdictions.

This year's meeting included participants from 48 states, 4 cities, the District of Columbia, Guam, and Puerto Rico. This meeting allows health department staff to continue to strategize to meet collective goals of eliminating hepatitis B and C in the U.S. Kathy Sanders presented on "Perinatal HCV in Kentucky". Participants were interested in the perinatal HCV, Kentucky is the only state reporting and analyzing this data.

The peer-to-peer technical assistance allows for increasing health department expertise and capacity. Participation in this meeting brings participants up to date on the most recent trends, promising prevention strategies and opportunities for additional support and technical assistance.

Dr. John Ward, Director of Viral Hepatitis at the CDC, with Kathy Sanders, in Washington DC discussing The Silent Epidemic HCV in the PWID populations. Bridging Science, Policy, and Public Health. Kathy Sanders

Chris Taylor, Director- Viral Hepatitis National Alliance of State £ Territorial AIDS Directors with Kathy Sanders in Washington, DC discussing Eliminating Hepatitis in the US!

Women's Policy, Inc. Luncheon

While in Washington, DC, Kathy Sanders was invited to attend the Women's Policy, Inc. luncheon on The Silent Epidemic: Hepatitis C and its Impact on Women.

Speakers were:
John Ward, MD, Director, Division of Viral Hepatitis, National Center for HIV/ AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control.

Dr. Wilson Compton, Deputy Director, National Institute on Drug Abuse

Natasha Martin, DPhil, Associate Professor of Global Public Health, Department of Medicine, University of California San Diego

Dr. Virginia Caine (shown top left speaking), Director, Marion County Public Health Department, Associate Professor of Medicine, Division of Infectious Diseases, Indiana University School of Medicine.

Top Left: Dr. Caine presenting on Indiana HCV/ HIV Co-infection. L to R: Dr. Martin, Dr. Compton, and Dr. Ward.

Middle: Kathy Sanders with Dr. Compton and Dr. Ward.

Bottom Left: L to R: Katherine Lewis, Senator Assistant with Kathy Sanders

EPID 394(Rev August 2014)

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

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

Kentucky UNBRIDLED SPIRIT

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

EPID 200 – 9/2014

Disease Name_____

Mail Form to Local Health Department

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

Disease/Organism	Date of Onset / /	Date of Diagnosis / /
List Symptoms/Comments	Highest Temperature Days of Diarrhea	

Hospitalized? ☐ Yes ☐ No	Admission Date / /	Discharge Date / /	Died? ☐ Yes ☐ No ☐ Unk	Date of Death / /

Hospital Name: Is Patient Pregnant? ☐ Yes ☐ No If yes, # wks_____

School/Daycare Associated? ☐ Yes ☐ No
Name of School/Daycare:

Outbreak Associated? ☐ Yes ☐ No
Food Handler? ☐ Yes ☐ No

Person or Agency Completing form: Name: Agency:	Attending Physician: Name:
Address:	Address:
Phone: Date of Report: / /	Phone:

LABORATORY INFORMATION

Date	Name or Type of Test	Name of Laboratory	Specimen Source	Results

ADDITIONAL INFORMATION FOR SEXUALLY TRANSMITTED DISEASES ONLY

Method of case detection: ☐ Prenatal ☐ Community & Screening ☐ Delivery ☐ Instit. Screening ☐ Reactor ☐ Provider Report ☐ Volunteer

Disease: Stage
☐ Syphilis ☐ Primary (lesion) ☐ Secondary (symptoms) ☐ Early Latent ☐ Late Latent ☐ Congenital ☐ Other

Disease: Site: (Check all that apply) Resistance:
☐ Gonorrhea ☐ Genital, uncomplicated ☐ Ophthalmic ☐ Penicillin
☐ Chlamydia ☐ Pharyngeal ☐ PID/Acute Salpingitis ☐ Tetracycline
☐ Chancroid ☐ Anorectal ☐ Other _____
☐ Other_____

Date of spec. Collection	Laboratory Name	Type of Test	Results	Treatment Date	Medication	Dose

If syphilis, was previous treatment given for this infection? ☐Yes ☐No
If yes, give approximate date and place_____

902 KAR 2:020 requires health professionals to report the following diseases to the local health departments serving the jurisdiction in which the patient resides or to the Kentucky Department for Public Health (KDPH).
(Copies of 902 KAR 2:020 available upon request)

REPORT IMMEDIATELY by TELEPHONE to the Local Health Department or the KY Department for Public Health:

- **Unexpected pattern of cases, suspected cases or deaths which may indicate a newly recognized infectious agent**
- **An outbreak, epidemic, related public health hazard or act of bioterrorism, such as SMALLPOX**

Kentucky Department for Public Health in Frankfort
Telephone 502-564-3418 or 1-888-9REPORT (973-7678)
SECURED FAX 502-696-3803

REPORT WITHIN 24 HOURS

Anthrax
Arboviral Disease*
Neuroinvasive
Non-Neuroinvasive
Botulism
Brucellosis
Campylobacteriosis
Cholera
Cryptosporidiosis
Diphtheria
***E. coli* shiga toxin positive (STEC)**
Haemophilus influenzae
invasive disease
Hansen's disease
Hantavirus infection
Hepatitis A
Listeriosis
Measles
Meningococcal infections
Pertussis
Plague
Poliomyelitis
Psittacosis
Q Fever
Rabies, animal
Rabies, human
Rubella
Rubella syndrome, congenital
Salmonellosis
Shigellosis
Syphilis, primary, secondary, early latent or congenital
Tetanus
Tularemia
Typhoid Fever
Vibrio parahaemolyticus
Vibrio vulnificus
Yellow Fever

REPORT WITHIN ONE (1) BUSINESS DAY

Foodborne outbreak
Hepatitis B infection in a pregnant woman or child born in or after 1992
Hepatitis B, acute
Mumps
Streptococcal disease invasive, Group A
Toxic Shock Syndrome
Tuberculosis
Waterborne outbreak

REPORT WITHIN FIVE (5) BUSINESS DAYS

AIDS
Chancroid
***Chlamydia trachomatis* infection**
Ehrlichiosis
Gonorrhea
Granuloma inguinale
Hepatitis C, acute
Histoplasmosis
HIV infection
Lead poisoning
Legionellosis
Lyme disease
Lymphogranuloma venereum
Malaria
Rabies, post exposure prophylaxis
Rocky Mountain spotted fever
***Streptococcus pneumoniae,* drug-resistant invasive disease**
Syphilis, other than primary, secondary, early latent or congenital
Toxoplasmosis

***** Includes Eastern Equine, Western Equine, California group, St. Louis, Venezuelan and West Nile Viruses
Influenza virus isolates are to be reported weekly by laboratories.
902 KAR 02:065 requires long term care facilities to report an outbreak (2 or more cases) of influenza-like illnesses (ILI) within 24 hours to the local health department or the KDPH.

All cases of HIV infections/AIDS are reportable to a separate surveillance system in accordance with KRS 211.180(1)b. To report a HIV/AIDS case call 866-510-0008.

DO NOT REPORT HIV/AIDS CASES ON THIS FORM.