

Hepatitis C in Kentucky Updates on Epidemiology, Testing and Treatment

KY Hepatitis Connections

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Inside this October 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. See all the exciting things happening here in hepatitis!

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. We hope you enjoy the new look to our October newsletter.

Kathy J. Sanders, RN MSN

Reminder:

Hepatitis C: Perinatal 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 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 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>



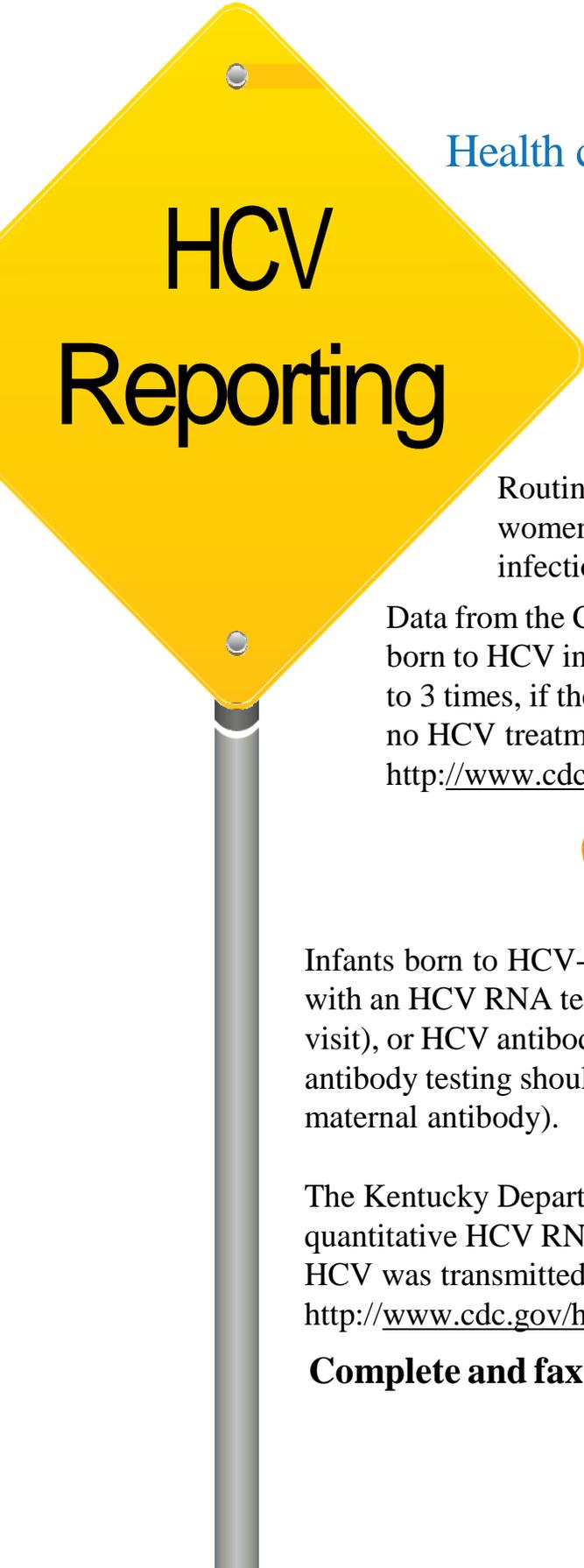
Infants born to HCV-positive mothers should be tested for HCV infection with an HCV RNA test at 2 months of age or older (at a routine well-child visit), or HCV antibody testing can be done at 18 months of age (HCV antibody testing should be delayed until 18 months of age to avoid detecting maternal 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>

Complete and fax the reporting form at the end of this newsletter.

Fax forms to 502-696-3803



HCV
Reporting

Gilead Hep C Drug Found To Work on All Strains

In a new clinical trial, Gilead's new Hepatitis C drug combination has been shown to work against all forms of hepatitis. This, of course, is a major discovery in an increasingly more complicated viral world. An experimental hepatitis C drug combination from Gilead Sciences Inc. wiped out multiple strains of the virus in a large clinical trial, giving the company an advantage against AbbVie Inc. in the race to treat as many patients as possible.

In a trial of 624 patients with any of six strains, or genotypes, of hepatitis C, Gilead's experimental combination of velpatasvir and sofosbuvir was effective at clearing the virus 99 percent of the time after 12 weeks of therapy. Three related trials also showed the drug was successful in treating multiple strains, the company said in a statement in September.

"This is a big step forward to proving they're going to have a pan-genotypic option here," said Asthika Goonewardene, an analyst at Bloomberg Intelligence. In hepatitis C, "you have a very fragmented market," Goonewardene said, because of the genetic diversity of the virus, which causes the liver disease.

Gilead and AbbVie already have drugs on the market for hepatitis C, though they've mostly focused on patients with genotype 1, the most common strain in the U.S. Other strains are more common in different parts of the world. Globally, almost a third of patients suffer from genotype 3, which is more common in India and Southeast Asia.

Read More: <http://www.bloomberg.com/news/articles/2015-09-21/gilead-s-hepatitis-c-drug-works-against-all-strains-in-trial>

Gilead reports positive data on 'universal' hepatitis C regimen

A combination of Gilead Sciences hepatitis C virus (HCV) drug Sovaldi with a new compound can provide high cure rates regardless of the strain of the virus infecting the patient.

The once-daily, fixed-dose combination of Sovaldi (sofosbuvir) with velpatasvir (GS-5816) - described as a 'pan-genotypic' NS5A inhibitor - could eliminate the need for HCV patients to have a genotyping test before starting treatment, said the company.

Four phase III trials of the drug (ASTRAL 1-4) have now been completed, spanning patients with HCV genotypes 1 to 6 and including some with established liver cirrhosis, and showed sustained virologic response (SVR) rates ranging from 80% to 100% after 12 weeks' treatment. Genotype 1 is the most common form worldwide, making up around half of the 185m cases - add in genotypes 2 and 3 and around 60% of HCV infections are accounted for. However, given the huge number of HCV cases the less common genotype infections still affect millions of people, often living in lower-income countries and these are much less served in terms of drug options. Read More:

http://www.pmlive.com/pharma_news/gilead_reports_positive_data_on_universal_hepatitis_c_regimen_826581

Sexual Transmission of HCV Is Increasing Among Gay and Bisexual Men with HIV

Sexual transmission of hepatitis C virus (HCV) is occurring among HIV-positive men who have sex with men, associated with receptive anal sex and non-injection drug use, and a small subset of men may be prone to recurrent infection after being cured of hepatitis C, according to a meta-analysis reported in the August 2015 online edition of AIDS.

"If one thousand HIV-positive MSM were followed for 1 year each, approximately 5 would acquire HCV," lead researcher Holly Hagan from the Center for Drug Use and HIV Research at New York University said in an NYU press release. "This is far lower than the rates among people who inject drugs. However, when we pooled the data across studies and looked at incidence in relation to calendar time, we saw an increase."

Starting in the early 2000s researchers in the U.K. and elsewhere in Europe began reporting clusters of apparently sexually transmitted acute HCV infection among HIV-positive gay and bisexual men in major cities; similar outbreaks followed in the U.S. and Australia. Various risk factors have been implicated -- including condomless anal sex, fisting, group sex, other sexually transmitted infections (STIs), and non-injection recreational drug use -- but these have not been consistent across studies. Some research has found that people who are already HIV-positive when they contract HCV may experience unusually rapid liver disease progression, but here too data are conflicting.

Hagan and her colleagues conducted a systematic review and meta-analysis to better understand sexually transmitted HCV among HIV-positive gay men. They focused on studies that looked at HCV seroconversion or reinfection after successful hepatitis C treatment in HIV-positive men who have sex with men who did not inject drugs. Seroconversion or acute HCV infection was determined according to European AIDS Treatment Network (NEAT) criteria: a positive HCV RNA test following a negative HCV RNA or HCV antibody test in the previous 12 months. Reinfection following treatment was determined by the presence of a different HCV genotype or clade, to distinguish it from relapse.

Out of 779 potentially relevant abstracts, the researchers fully assessed 173 reports and identified 25 to be included in the meta-analysis -- 21 that looked at initial HCV seroconversion and 4 on post-treatment reinfection. Half the studies were from Europe, 4 from the U.S. 3 from Asia, and 2 from Australia -- all looking at men in urban settings in high- income countries.

Of these, 17 reports included HCV incidence density numbers that could be used to calculate pooled rates; there were 2 reports each from the Amsterdam Cohort Study and Swiss HIV Cohort, both of which were included only once in the pooled calculation. Of the 4 reinfection studies, 2 included incidence density. Only 4 of the 21 selected seroconversion studies reported risk factors in an adjusted analysis that included only MSM who were not injection drug users.

Read More:

<http://hivandhepatitis.com/hcv-prevention/hcv-sexual-transmission/5384-sexual-transmission-of-hcv-is-increasing-among-gay-and-bi-men>

Recent HCV patients show more complications than decades prior

According to data from a retrospective study, researchers from the University of Michigan Health System found that patients with hepatitis C virus infection treated in 2011 and 2012 had more advanced liver disease vs. patients seen in 1998 and 1999.

“To prepare for the launch of interferon-free regimens, we examined the characteristics of hepatitis C patients newly referred to our liver clinics in 2011/2012 and compared them with patients seen in 1998/1999,” the researcher wrote. “We hypothesized that compared to the 1990s, HCV patients seen in recent years are older, have more advanced liver disease, are more likely to be treatment experienced and are enriched for HCV genotypes and sub genotypes that are more refractory to treatment.”

Data from 1,348 adult patients with HCV seen at the University of Michigan Health System in 1998/1999 (Era 1) and 2011/2012 (Era 2) were collected and analyzed via ICD-9 codes. Overall, 538 patients were included for analysis in Era 1 and 810 were seen in Era 2.

Analyses showed that compared to patients in Era 1, patients in Era 2 were older ($P < .001$) and of other races than Caucasian ($P = .003$). In addition, the median interval between diagnosis and evaluation was 4 years in Era 1 compared with 2 years in Era 2 ($P < .001$). More patients diagnosed with advanced liver disease, such as compensated or decompensated cirrhosis or hepatocellular carcinoma, were found in Era 2 compared with patients in the Era 1 group (61.6% vs. 51.5%; $P < .001$). More patients in Era 2 were treatment experienced compared with Era 1.

“There were few unexpected findings,” the researchers wrote.

Researchers also found HCV genotype 1 to be prevalent in 43.7% of patients in Era 2 compared with 21.7% in Era 1.

“Our finding is important because while some direct-acting antivirals have pan-genotype activity, others have lower barrier to resistance with genotype 1a HCV and lower sustained virologic response rate, and some DAA combination therapies are developed for patients with genotype 1b infection only,” the researchers wrote.

The researchers concluded: “Reduction in HCV disease burden will require development of treatment regimens targeted towards patients in the current Era ..., improvement in early diagnosis and referral of infected patients to appropriate centers for treatment, and reduction in costs of newly approved DAAs; otherwise, implementation of screening programs and availability of highly efficacious treatment regimens will have little impact on disease burden.” –*Melinda Stevens*

<http://www.healio.com/hepatology/hepatitis-c/news/online/%7B24f9c363-faea-4ae1-9c9f-ec9a202c0142%7D/recent-hcv-patients-show-more-complications-than-decades-prior>

Liver disease persists in HIV/HCV co-infected patients despite ART

Patients co-infected with HIV and hepatitis C have higher rates of liver decompensation compared with patients with hepatitis C mono-infection, despite the use of antiretroviral therapy, according to new study results.

HCV occurs in 10% to 30% of HIV-infected patients, according to researchers. Studies have suggested that ART slows the progression of HCV-related liver fibrosis, but rates of hepatic decompensation and other severe liver events among co-infected patients receiving ART have so far remained unclear.

“Our results suggest that serious consideration should be given to initiating hepatitis C treatment in patients co-infected with HIV and hepatitis C — particularly among those with advanced liver fibrosis or cirrhosis — in order to try to reduce the risk of serious, potentially life-threatening liver complications,” Vincent Lo Re III, MD, of the Penn Center for AIDS Research at the University of Pennsylvania, said in a press release. “By taking action sooner, we may be able to reduce the risk of advanced liver disease in co-infected patients.”

Lo Re and colleagues used patient health records to compare the incidence of hepatic decompensation between 4,280 co-infected patients who recently initiated ART and 6,079 HCV-mono-infected patients receiving care between 1997 and 2010. All patients in the study had detectable HCV RNA and were HCV treatment-naive. Hepatic decompensation was determined through diagnoses of ascites, spontaneous bacterial peritonitis or esophageal variceal hemorrhage. The researchers also examined factors associated with developing decompensation.

Read More: <http://www.healio.com/infectious-disease/hepatitis-c/news/online/%7B29e54e5b-9fa0-41ac-aedc-187d84067d16%7D/liver-disease-persists-in-hivhcv-coinfected-patients-despite-art>

AbbVie Demonstrates Commitment to Hepatitis C Patients with New Data on VIEKIRA PAK™ (ombitasvir, paritaprevir, ritonavir tablets; dasabuvir tablets) and Ongoing Clinical Development Program at The Liver Meeting® 2015

NORTH CHICAGO, Ill., Oct. 1, 2015 /PRNewswire/ -- AbbVie a global research-based biopharmaceutical company, today announced that 34 abstracts from its chronic hepatitis C clinical development program have been accepted for presentation at The Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco from November 13-17, further demonstrating AbbVie's strong leadership and ongoing commitment to patients with chronic hepatitis C virus (HCV) infection.

Read More: <http://www.prnewswire.com/news-releases/abbvie-demonstrates-commitment-to-hepatitis-c-patients-with-new-data-on-viekira-pak-ombitasvir-paritaprevir-ritonavir-tablets-dasabuvir-tablets-and-ongoing-clinical-development-program-at-the-liver-meeting-2015-300152779.html>

HCV Current Initiative: Addressing the National Epidemics of Prescription Opioid misuse and Hepatitis C through Unique Partnerships

Recently, there has been a spotlight on America's prescription opioid misuse and overdose epidemics. However, too often, people remain unaware of the related hepatitis C virus (HCV) epidemic. The Centers for Disease Control and Prevention (CDC) reported an estimated 150% increase in new HCV infections from 2010 to 2013 and, further, that most of the new infections were associated with injection drug use. An analysis of state and national data indicate that a large proportion of new HCV infections are occurring in young people (<30 years of age) in rural and suburban areas who use oral prescription opioid analgesics before transitioning to injecting.

At the same time, recent years have seen advances that have revolutionized the field of hepatitis C. Groundbreaking treatments with cure rates as high as 90-100% is now available. Preventive screenings without cost-sharing under the Affordable Care Act make HCV screening more accessible for many people. And the national Viral Hepatitis Action Plan increases coordination across federal programs and includes among its priorities the urgent need to reduce viral hepatitis associated with drug use behaviors.

However, reaching health professionals with information about these important changes in the evolving hepatitis C arena can be challenging. Because of the prevalence of HCV among people who inject drugs, addictions treatment, and recovery professionals are a key group to engage in efforts to address HCV. Additionally, both primary care and behavioral health settings are becoming increasingly important providers of HCV screening and care, creating the need for more effective means for timely HCV information dissemination.

As a result, the HCV Current initiative was launched in March 2015. HCV Current provides free HCV informational resources for health professionals, including online and in-person curriculum and training, downloadable provider tools, and region-specific resources. As new HCV research emerges, these products are updated. The tools available on HCV Current can help empower health care professionals to better educate patients about what to expect along each stage of the HCV continuum of care, including screening and understanding treatment options. Providers can also download patient education resources, including fact sheets.

Read More: <https://blog.aids.gov/2015/09/hcv-current-initiative-addressing-the-national-epidemics-of-prescription-opioid-misuse-and-hepatitis-c-through-unique-partnerships.html>

HEPATITIS C: WHAT YOU NEED TO KNOW



5-7 Million*

Americans are living with hepatitis C

At least half of infected individuals are unaware of their status.²

1 IN 3
young adults



3 IN 4
older adults



who have used or now use intravenous drugs are HCV-infected.⁴

DEPRESSION

is highly prevalent among HCV-infected persons.⁶



ALMOST HALF

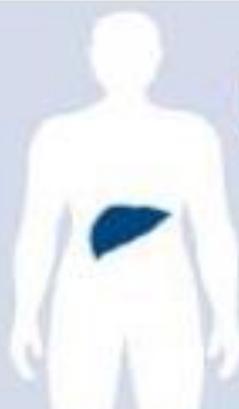
of new hepatitis C cases in the U.S. are associated with injection drug use.³



Up to **85%** of people infected with HCV will develop chronic infection.⁴



Up to **70%** of people infected with HCV will develop chronic liver disease.⁴



Baby boomers (born 1945-1965) and persons with mental health and substance use disorders face **INCREASED RISK OF INFECTION.**

EMERGING EPIDEMIC

of hepatitis C infection among young people who use intravenous drugs, both male and female, primarily white, found in suburban and rural settings.⁵

WITHOUT SIGNIFICANT INTERVENTION,

the HCV epidemic will cost the American public more than \$85 billion in the next few years.²

DRAMATIC MEDICAL ADVANCES IN THE PAST YEAR

have revolutionized the course of HCV treatment, increasing the role of primary care and behavioral health settings in addressing this public health concern.

See reverse side for additional details about this new initiative.

HCVCurrent

Initiative to Increase HCV Knowledge among Medical and Behavioral Health Professionals



ATTC

Addiction Technology Transfer Center Network

¹ <http://www.hepatitis-c.org/publications/epidemiology-and-prevalence-of-hepatitis-c-in-the-us>
² <http://hepcchallenge.org/hcv-facts>
³ <http://www.drugabuse.gov/publications/factsheets/hcv-infection-which-populations-are-most-affected>

⁴ <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm>
⁵ <http://www.aids.gov/athc-and-young-pw-id-consultation-report.pdf>
⁶ http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a1.htm?h_q=hd%20a1_e

HCVCurrent

RESOURCES FOR MEDICAL AND BEHAVIORAL HEALTH PROFESSIONALS



HCV Current is a national Addiction Technology Transfer Center (ATTC) initiative to increase HCV knowledge among medical and behavioral health

HCV Education Snapshot:

An Introduction to Hepatitis C for Health Care Professionals

HCV Snapshot is a **free, 90-minute online course**. It is designed to briefly familiarize medical and behavioral health professionals with hepatitis C.

The course's four self-paced modules cover:

1. **Populations at risk:** Describe populations at increased risk for hepatitis C.
2. **Hepatitis C, the disease:** Differentiate hepatitis C from A and B, and review transmission, symptoms, testing, and curability.
3. **Screening processes:** Describe the screening process and the importance of your role in addressing patient concerns and improving outcomes.
4. **Treatment options:** Review factors influencing treatment, current and emerging treatment options, and patients' treatment concerns.

Register now for the course at healthknowledge.org.

Providers' Clinical Support System for Medication Assisted Treatment

PCSS-MAT (or Providers' Clinical Support System for Medication Assisted Treatment) is a national training and mentoring project developed in response to the prescription opioid misuse epidemic and the availability of newer pharmacotherapies to address opioid use disorder. The overarching goal of PCSS-MAT is to make available the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.

Webinar Description:

People with opioid use disorder are commonly infected with Hepatitis C virus (HCV) and/or HIV. It is important that all providers delivering treatment to individuals with opioid use disorder understand appropriate prevention, screening and treatment strategies of HCV and HIV and specific considerations for people receiving opioid agonist therapy. This includes an understanding of the latest technology used for detection of HCV and HIV, appropriate use of highly effective antiviral therapy, and recognition of potential interactions with methadone, buprenorphine and naltrexone. A strong foundation in understanding HCV and HIV prevention and treatment strategies is important for all providers treating individuals with opioid use disorder.

<http://pcssmat.org/event/hep-c-and-hiv-and-opioid-addiction/>

Baby Boomers and HCV Testing

An estimated 75% of the 3 to 4 million people HCV-infected persons, living in the U.S. are baby boomers and approximately half are unaware of their infection. HCV screening needs to be implemented in clinical settings that serve low income populations because the prevalence of HCV is significantly higher in these groups.

Hepatitis C is most often spread through contact with the blood of an infected person, but it can also be spread through sexual contact.

According to the Centers for Disease Control and Prevention, an estimated 3 to 4 million people in the United States are living with the virus, whether they know it or not. About two-thirds of those people are baby boomers. The virus itself is not lethal, but its effects can be serious.

Why baby boomers are at risk

Here are some of the reasons this population is more at risk:

Blood transfusions and risky behaviors

“Blood transfusions were not screened before July 1992,” says Dr. Adhami a gastroenterologist and hepatologist with Cleveland Clinic. “There was also a sexual revolution in the 1960s, which not only encouraged risky sexual behaviors, but also drug experimentation.” People who have had unprotected sex and those who have taken drugs, particularly who have injected or snorted, are also at an increased risk for hepatitis C, he says.

Use of blood products

Dr. Adhami believes that all baby boomers should be tested, but there are some risk factors that make testing even more imperative. “Anyone in this age group who has received blood products is at risk,” says Dr. Adhami. “Chronic dialysis and HIV patients also need to be tested.”

The CDC recommends: One-time HCV testing for persons born between 1945 and 1965* without prior ascertainment of risk.

Other persons should be screened for risk factors for HCV infection, and testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection.

HCV-testing is recommended for those who:

- Have current injecting or intranasal drug use
- Ever injected drugs, including those who injected/ intranasal once or a few times many years ago
- Unregulated body piercing and/ or tattoos
- Household contact with a known HCV positive person
- History of high risk sexual behavior
- History of sexually transmitted infection
- History of incarceration

Have certain medical conditions, including persons:

- who received clotting factor concentrates produced before 1987
- who were ever on long-term hemodialysis
- who have HIV infection
- who have Hepatitis B infection
- Were prior recipients of transfusions or organ transplants, including persons who:
 - were notified that they received blood from a donor who later tested positive for HCV infection
 - received a transfusion of blood, blood components or an organ transplant before 1992
- HCV- testing based on a **recognized exposure** is recommended for:
 - Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
 - Children born to HCV-positive women

Note: For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended.

Annual HCV testing is recommended for persons who inject drugs and for HIV- seropositive men who have unprotected sex with men. Periodic testing should be offered to other persons with ongoing risk factors for exposure to HCV.



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 <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Unk
Address		City	State	Zip	County of Residence
Phone Number	Patient ID Number	Ethnic Origin <input type="checkbox"/> His. <input type="checkbox"/> Non-His.		Race <input type="checkbox"/> W <input type="checkbox"/> B <input type="checkbox"/> A/PI <input type="checkbox"/> Am.Ind. <input type="checkbox"/> Other	

DISEASE INFORMATION			
Describe Clinical Symptoms:	Date of Onset: / /	Jaundice: <input type="checkbox"/> Yes <input type="checkbox"/> No	Date of Diagnosis: / /
Is Patient Pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /		
IgM anti-HBc	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /		
HBeAg	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /		
IgM anti-HAV	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /		
HCV Antibody	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /		
HCV RNA Confirmation	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /		

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

<p>Mother: Hepatitis Risk Factors <input type="checkbox"/> IDU <input type="checkbox"/> Multiple Sexual Partners <input type="checkbox"/> Tattoos <input type="checkbox"/> STD <input type="checkbox"/> HIV <input type="checkbox"/> Foreign Born/ Country _____ <input type="checkbox"/> Exposure to known HBV/HCV Pos contact</p>	<p>Child: Hepatitis Risk Factors <input type="checkbox"/> Mother HBV Pos <input type="checkbox"/> Household member exposure HBV Pos <input type="checkbox"/> Mother HCV Pos <input type="checkbox"/> Household member exposure HCV Pos <input type="checkbox"/> Foreign Born / Country _____</p>
<p>Mother: Hepatitis A vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / / Hepatitis B Vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused If yes, how many doses <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Year completed: / /</p>	
<p>Child: Hepatitis A vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / / Hepatitis B Vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / / Was PEP Infant of Positive HBV mother given at birth? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

