



KY Hepatitis Connections

Wishing you and your family a very Happy Labor Day!

Inside our September 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 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. Follow us on Facebook at: KY Viral Hepatitis.

Kathy Sanders, RN MSN

HEPATITIS IN KENTUCKY: IN THE NEWS

Thanks to everyone who stopped by our booth at the Kentucky State Fair!



KY AVHPC- Kathy Sanders at the Kentucky State Fair, with Kentucky Secretary of the Cabinet for Health and Family Services (CHFS): Audrey Tayse Haynes.

Adolescent substance abuse centers receive KY Kids grants

FRANKFORT, Ky. (August 11, 2014) — Attorney General Jack Conway, Gov. Steve Beshear, First Lady Jane Beshear and members of the Substance Abuse Treatment Advisory Committee today announced that 19 substance abuse treatment grant proposals from across the commonwealth have been selected for funding through the KY Kids Recovery program. The grants will fund comprehensive adolescent substance abuse treatment programs, both expanding treatment beds at existing facilities and creating new adolescent treatment programs with the full continuum of care, including intensive outpatient and follow-up care centers.

Kentucky only has about one-tenth of the treatment beds it needs, and according to the most recent report from the Substance Abuse Health and Mental Services Administration, one in eight Kentucky high school students meet the criteria for a substance abuse disorder.

Read More: <http://www.lanereport.com/37157/2014/08/adolescent-substance-abuse-centers-receive-ky-kids-grants/>

Kentucky gets \$1.08 million grant to address prescription drug overdoses

LEXINGTON, Ky. (Aug. 11, 2014) — The Kentucky Injury Prevention and Research Center (KIPRC), housed in the University of Kentucky College of Public Health, is one of just five awardees in the nation to receive a \$1.08 million “Prescription Drug Overdose Prevention Boost” grant from the Centers for Disease Control and Prevention (CDC). KIPRC is a unique partnership between the University of Kentucky’s College of Public Health and the Kentucky State Department for Public Health.

“Prescription drug overdose is a national epidemic and Kentucky is on the front line,” proclaimed CDC Director Dr. Thomas Frieden, during a visit to Eastern Kentucky Tuesday night. “CDC is committed to working with community partners, state health programs to address health disparities and improve the lives of Americans”.

The award, provided over a three-year period, targets states “poised to make immediate progress reducing prescription drug overdose” through activities such as leveraging Prescription Drug Monitoring Programs, and conducting policy evaluation to understand what works.

“Kentucky has been a national leader in several aspects of prescription drug overdose prevention,” said Dr. Terry Bunn, director of KIPRC. “This critical funding gives us the opportunity to highlight, evaluate, and build upon Kentucky’s previous efforts and groundwork in preventing prescription drug overdoses.”

Kentucky had the third highest mortality rate of prescription drug overdoses in 2010 (23.6 per 100,000), with the number of all drug overdose deaths more than quadrupling since 1999 (4.9 per 100,000), according to a 2013 report by Trust for America’s Health. Nationally the rate has doubled.

According to the Kentucky Department for Public Health, Eastern Kentucky Appalachian region has a greater prevalence for heart disease (84 percent higher), diabetes (47 percent higher) and obesity (26 percent higher) than the nation’s average. The state’s lung cancer mortality rates are the nation’s highest, at 67 percent above average.

“Many of Eastern Kentucky’s biggest health challenges could be improved — if not altogether reversed — with a little prevention,” said Dr. Stephanie Mayfield, commissioner of the Kentucky Department for Public Health. “Unhealthy habits, like smoking, are one of the main health concerns facing the people of this region. Many of the associated health concerns could be prevented through healthier choices. <http://www.lanereport.com/37206/2014/08/kentucky-gets-1-08-million-grant-to-address-prescription-drug-overdoses/>

HCV: IN THE NEWS:

Gilead offers Egypt new hepatitis C drug at 99 percent discount

CAIRO/LONDON (Reuters) - Gilead Sciences, facing mounting criticism over the high price of its new hepatitis C pill Sovaldi, has offered to supply the medicine to Egypt at a 99 percent discount to the U.S. price.

While the drug will still cost \$900 for a 12-week course of treatment, that is a fraction of the \$84,000 charged for a course of treatment in the United States. The high price tag in America prompted questions from U.S. lawmakers on Friday, after U.S. health insurers said they were seeking help from state health officials to foot the bill.

Read More: <http://news.yahoo.com/gilead-offers-egypt-hepatitis-c-drug-99-percent-201030356--finance.html>

'Stop drinking alcohol' isn't always helpful advice for people with hepatitis C

The World Health Organization estimates that 130 to 150 million people are chronically infected with hepatitis C virus (HCV) and that deaths related to HCV claim 350,000 to 500,000 people yearly. Unfortunately, there is no vaccine to protect against getting hepatitis C, but there are effective medications to cure it in up to 90 per cent of those infected.

The medications, however, are expensive and out of the reach of many people, especially in resource poor nations. These are many of the same countries that have the highest rates of HCV infection. It isn't likely that everyone will have access to these life-saving drugs in the near future. So it's important that there are strategies developed to keep people healthy until the time that there are affordable medications to cure everyone infected with the hepatitis C virus. Hepatitis C mainly causes damage to the liver, although it can affect almost every other organ of the body. There are many ways that people can protect the health of the liver, and 'Stop drinking alcohol' is probably the first piece of advice issued to people with HCV.

Alcohol is processed by the liver and in large quantities can cause damage to an HCV infected individual. But people with hepatitis C face many challenges in dealing with this life-threatening disease and the stigma associated with it. They are told to make major lifestyle changes – to stop drinking, smoking,

drug-taking; the list goes on and on. Read More: <http://doctorsoftheworld.org.uk/blog/entry/stop-drinking-alcohol-isnt-always-helpful-advice-for-people-with-hepatitis>

HEPATITIS GUIDANCE:

You are probably familiar with <http://www.hcvguidelines.org/>, a web-based guidance developed by the Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD) for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for hepatitis C management to provide healthcare professionals with timely guidance as new therapies are available and integrated into HCV regimens.

These guidelines are a "living document" with new sections to be added and updated frequently as new information and treatments become available. In August, AASLD and IDSA, in collaboration with the International Antiviral Society-USA (IAS-USA), released the latest section titled, **"When and in Whom to Initiate HCV Therapy."** (<http://www.hcvguidelines.org/node/91>)

With the addition of the new section, www.hcvguidance.org offers clinicians information on how to prioritize treatment for those patients who will derive the most benefit or will have the greatest impact on limiting further HCV transmission. Highest priority should be given to patients with advanced fibrosis with compensated cirrhosis and liver transplant recipients and high priority given to patients at high risk for liver-related complications and severe extra-hepatic HCV complications. The guidance provides further detailed information on additional conditions that warrant prioritization of treatment

Read More: <http://www.hcvguidelines.org/node/91>

HEPATITIS TREATMENT

Vertex removing Telaprevir from US market

Vertex Pharmaceuticals Incorporated will discontinue the sale and distribution of INCIVEK® (telaprevir) in the United States by October 2014.

Patients should talk to their health care providers if they are currently receiving INCIVEK or were planning to start INCIVEK soon. Patients should not stop taking INCIVEK unless they have been instructed by their health care provider. Vertex will continue to provide financial support to eligible patients currently prescribed INCIVEK.

For INCIVEK product support information, contact 1-877-824-4281.

Practice Guideline: Hepatic Encephalopathy in Chronic Liver Disease

In August, AASLD announced the release of a new practice guideline on Hepatic Encephalopathy. This practice guideline was developed in collaboration with EASL.

Read More: <http://onlinelibrary.wiley.com/doi/10.1002/hep.27210/abstract>

Achillion Achieves 100 Percent Sustained Virologic Response Rate (SVR4) From an Eight Week Phase 2 Trial Evaluating a Ribavirin-Free Regimen of ACH-3102 and Sofosbuvir for Genotype 1 HCV ("Proxy Study")

Achillion Pharmaceuticals, Inc. today announced interim results from an ongoing Phase 2 proxy study evaluating ACH-3102, Achillion's second-generation NS5A inhibitor, in combination with sofosbuvir, without ribavirin, for eight weeks of treatment in patients with treatment-naïve genotype 1 chronic hepatitis C virus (HCV) infection. Of the 12 patients treated, 100 percent (n=12/12) remained HCV RNA undetectable four weeks after completing therapy (SVR4). Based upon these results, 12 additional patients will begin treatment with six weeks of once daily ACH-3102 and sofosbuvir.

"ACH-3102 continues to demonstrate good safety and tolerability through three Phase 2 studies. We believe these studies also confirm a differentiated efficacy profile for an NS5A inhibitor. Achieving 100% SVR4 with eight weeks of treatment with sofosbuvir serving as a nucleotide proxy indicate that dosing 50 mg once daily of ACH-3102 plus a nucleotide inhibitor has the potential to achieve commercially competitive results for curing HCV in a short duration, ribavirin-free doublet," commented David Apelian, M.D., Ph.D., Executive Vice President and Chief Medical Officer at Achillion. "In addition, understanding how ACH-3102 performs with sofosbuvir provides valuable insight for the design of our proprietary combination trial with ACH-3102 and ACH-3422, a uridine-analog nucleotide that continues to advance through its Phase 1 clinical development program."

Read More: <http://www.marketwatch.com/story/achillion-achieves-100-percent-sustained-virologic-response-rate-svr4-from-an-eight-week-phase-2-trial-evaluating-a-ribavirin-free-regimen-of-ach-3102-and-sofosbuvir-for-genotype-1-hcv-proxy-study-2014-08-15>

The New Health Care: Why the Price of Sovaldi Is a Shock to the System, AUG. 6, 2014

The outcry about the new hepatitis C drug Sovaldi has focused a lot on its price tags — \$1,000 a pill and \$84,000 total for a typical patient. But just how high is that price compared with other drugs on the market? Gilead Sciences, its manufacturer, says its price is comparable to existing treatments for hepatitis C, a viral disease that causes liver damage, including cirrhosis and cancer in some cases. The

company also describes it as a breakthrough drug, and essentially in a class of its own. Because it is more effective than existing therapies and has many fewer side effects, it is much more popular. A Gilead executive described it as a “new price to the system.”

To help put Sovaldi’s price in context for The Upshot, the health care consulting firm Visante prepared a set of other high-earning “breakthrough” drugs from the past 15 years. The comparison drugs were all, like Sovaldi, the first in their class. To avoid comparisons to niche drugs that treat only a handful of patients, the list is limited to drugs that have sold at least \$1 billion over their lifetimes.

Read More: <http://www.nytimes.com/2014/08/29/upshot/should-i-buy-a-warranty.html?rref=upshot&module=ArrowsNav&contentCollection=The%20Upshot&action=click®ion=FixedRight&pgtype=article>

\$1,000 Hepatitis Pill Shows Why Fixing Health Costs Is So Hard

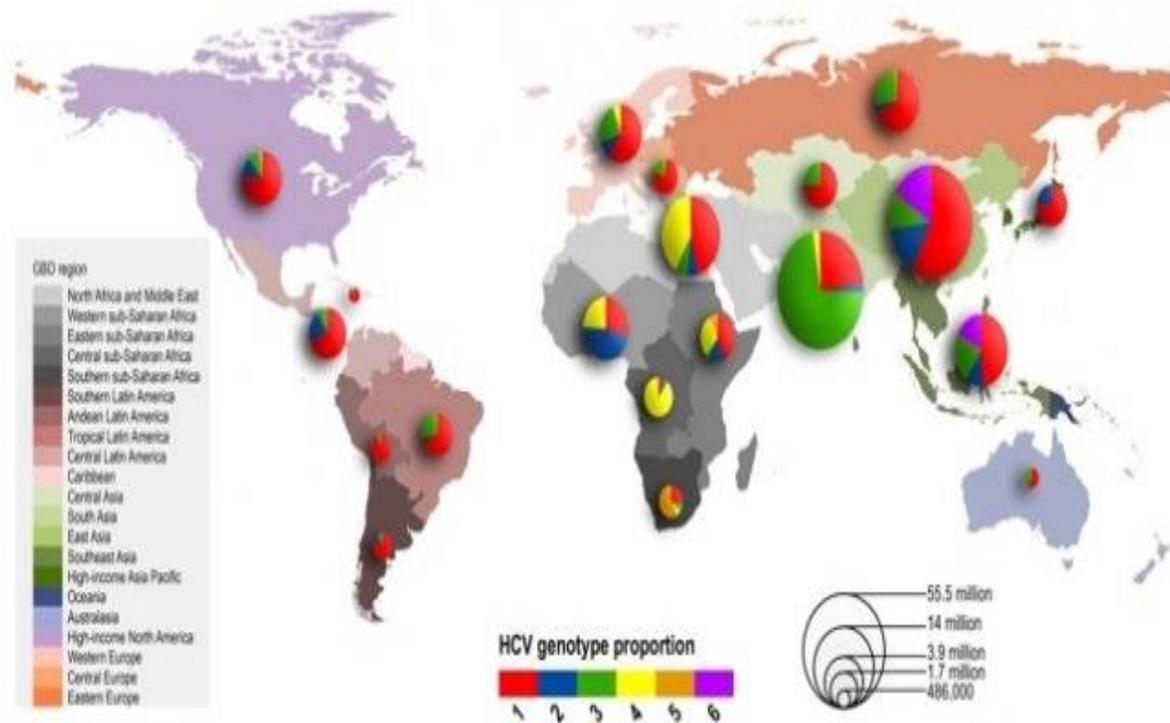
A new drug for the liver disease hepatitis C is scaring people. Not because the drug is dangerous — it’s generally heralded as a genuine medical breakthrough — but because it costs \$1,000 a pill and about \$84,000 for a typical person’s total treatment.

A Washington advocacy effort has sprung up overnight, largely devoted to objecting to the cost of this one medication, Sovaldi. Members of Congress have started a joint investigation into how its maker, Gilead Sciences, settled on its price. “Clearly, \$1,000 a pill strikes people as completely unreasonable,” said John Rother, president of the National Coalition on Health Care, an advocacy group that has been raising an outcry about the drug’s price as “unsustainable.” Gilead “stepped in it when they decided to go for that cost per pill, because people can’t imagine why that could be justified.” But maybe we are looking at the costs of Sovaldi in the wrong way. One reason it is causing such angst among insurers and state Medicaid officials is that treatment costs are coming all at once

First of all, there is pent-up demand. There are a lot of people with hepatitis C — an estimated 3.2 million in the United States — many of whom have been waiting for a good treatment. Second, unlike drugs for most chronic diseases, like diabetes or H.I.V./AIDS, for which treatment continues over many years, Sovaldi can cure most patients’ hepatitis in just a few weeks, with the bill soon to follow. The lifetime cost of treating someone with an H.I.V. infection is around \$380,000, according to estimates from the federal Centers for Disease Control and Prevention, but the annual bill is much smaller.

<http://www.nytimes.com/2014/08/03/upshot/is-a-1000-pill-really-too-much.html?action=click&contentCollection=The%20Upshot&module=RelatedCoverage®ion=Margin&pgtype=article>

Map of hepatitis C strains should help eradication efforts



The researchers produced a map showing which strains of hepatitis C were most prevalent in different regions. Researchers have for the first time mapped the global distribution of hepatitis C strains, creating a crucial resource in the fight to eradicate it.

An estimated 185 million people are infected with the hepatitis C virus (HCV) worldwide. A significant number of those who become infected will go on to develop liver cirrhosis or liver cancer, and up to 500,000 people die each year from liver diseases related to the virus. Hepatitis C can be cured, and a number of new, dramatically more affordable drug therapies with minimal side effects are set to become available over the next decade. With efforts to create a vaccine also showing promise, the prospect of eradicating the disease is now within sight.

However, the virus has six common strains, or genotypes, which respond differently to different treatments and vaccines. Knowing which strains are common in which areas is essential for planning eradication campaigns. In a paper published today in *Hepatology*, researchers from the Oxford Martin School, University of Oxford and Imperial College London provide the first comprehensive survey of hepatitis C genotypes across the world.

Read More:

http://www3.imperial.ac.uk/newsandeventspggrp/imperialcollege/newssummary/news_29-7-2014-10-27-41

Researchers discover how Hepatitis C virus persists for years

Hepatitis C virus (HCV) lingers in the human body for years, slowly damaging the liver and leading to liver diseases such as hepatitis, cirrhosis and liver cancer, which is often fatal. Research conducted at the University of North Carolina at Chapel Hill has discovered a mechanism that facilitates the virus achieving this life-long persistence. Chronic HCV infection is the leading cause of liver cancer in the United States.

"Liver cancer is one of the most important causes of cancer mortality worldwide. It's also increasing in rapidly incidence within the United States, due largely to the spread of HCV among Americans in the 60s and 70s," said Stanley M. Lemon, MD, Professor of Medicine at the UNC School of Medicine and a member of the UNC Lineberger Comprehensive Cancer Center.

In a paper published online by *Nature Medicine* this week, a team led by Dr. Lemon and colleague Daisuke Yamane, DVM, PhD, found that HCV has a sensor function that allows it to be regulated by the oxidative damage to cell membranes that occurs as a byproduct of its replication and the body's response to it. This slows down virus growth when oxidative membrane damage becomes too high, but allows it to resume when the membrane damage is reduced. By auto-regulating its replication in this way, the virus maintains a low profile, helping it escape detection by the immune system.

"You might consider it like a thermostat," said Dr. Lemon, "one that regulates the growth of the virus like your thermostat regulates the temperature of your house."

Read More: <http://medicalxpress.com/news/2014-07-hepatitis-virus-persists-years.html>

Montgomery County Ohio Coroner: 17 Heroin Overdose Deaths This Week

MONTGOMERY COUNTY OHIO-- Alarming numbers from the Montgomery County Coroner's office about the Miami Valley's heroin epidemic. Officials say they've had 17 drug overdose deaths in just the last seven days.

Eight people died from overdosed last weekend, and another nine people succumbed to the deadly drug. The coroner's office believes these latest deaths are due to heroin being mixed with fentanyl, which is a very lethal combination.

"It's something that this staff has never seen in the careers and history we've been here", Ken Betz from the Montgomery County Coroner's Officer told us, and "it's just an incredible number of deaths that should not occur."

The coroner's office says they've seen an uptick in heroin overdoses since last November, with most of the victims being white and between the ages 18 and 44. Police say the drug is cheap and accessible.

http://www.abc22now.com/shared/news/top-stories/stories/wkef_vid_21666.shtml

HEPATITIS IN CORRECTIONS

New Hep C Meds Could Spell Disaster for U.S. Prison Budgets

Prisoners, unlike most Americans, have a constitutional right to medical care. That is why the introduction of an expensive new drug to treat hepatitis C is forcing prison administrators to begin wrestling with a big dilemma — save their budgets or treat their inmates. The drug, Sovaldi, which sells for \$1,000 a pill, is also a source of consternation for health insurers and state Medicaid directors. But the problem will be felt most intensely in the prison system because it has a disproportionate share of hepatitis C patients, and most systems will end up paying full price.

The blood-borne disease is most frequently transmitted through needles shared by intravenous drug users. Estimates vary, but a recent study finds that more than 17 percent of all inmates have the infection, which can cause liver damage, cirrhosis and cancer. And nearly a third of American residents with the virus find themselves in jail or prison at some point.

Read More: http://www.nytimes.com/2014/08/07/upshot/why-the-hepatitis-cure-sovaldi-is-a-budgetary-disaster-for-prisons.html?_r=2&abt=0002&abg=1

HEPATITIS B Corner

Model of viral lifecycle could help in finding a cure for hepatitis B

In a paper published August 2014 in the journal *Proceedings of the National Academy of Sciences*, Sangeeta Bhatia of MIT and Charles Rice of Rockefeller University describe using micro fabricated cell cultures to sustain hepatitis B virus in human liver cells, allowing them to study immune responses and drug treatments.

Around 400 million people worldwide are infected with the hepatitis B virus (HBV); of those, one-third will go on to develop life-threatening complications, such as cirrhosis and liver cancer.

Although there is an effective HBV vaccine, only around 50 percent of people in some countries where the disease is endemic are vaccinated. A complete cure for the disease is very rare, once someone has been chronically infected.

"Once a liver cell is infected, the viral genome persists inside the nucleus, and that can reactivate later," says Bhatia, the John and Dorothy Wilson Professor of Health Sciences and Technology and Electrical Engineering and Computer Science. "So although we have a vaccine, it's important to find a way to study this persistent form of the virus to try to identify treatments that could efficiently clear it."

'Finicky' Hepatocytes

To develop a treatment for HBV, researchers need to be able to study infected liver cells, known as hepatocytes, so they can understand how the virus interacts with them.

But while researchers have previously been able to infect cultures of human hepatocytes with HBV, the cells' limited lifespan has made it difficult to study the virus, says Bhatia, who is also a Howard Hughes Medical Institute investigator and a member of MIT's Koch Institute for Integrative Cancer Research and Institute for Medical Engineering and Science. "That's because the hepatocyte—the main cell in the liver—is unstable," she says. "It's a very finicky cell, and when you isolate it from the liver and try to culture it under conventional conditions, it rapidly loses its repertoire of liver functions."

Read More: <http://medicalxpress.com/news/2014-08-viral-lifecycle-hepatitis.html>

"The hepatitis B virus, one of the smallest human pathogens is one of the largest public health problems in the world. As many as 360 million people have chronic hepatitis B, with about two million of those in the U.S. Chronic infection can lead to cancer and other serious liver diseases, contributing to the estimated 600,000 deaths associated with hepatitis B annually." Adam Zlotnick

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

NEW FAX NUMBER for submitting report

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 to 502-696-3803

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 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	/ /	

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	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 _____
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: / /	
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	

