

HCV ADVOCATE WEEKLY NEWS REVIEW

Review of HCV, HBV and HIV/HCV Coinfection Related News and Highlights

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June 22, 2009

Hepatitis C Virus Infection and the Risk of Coronary Disease

<http://infectonews.wordpress.com>

The association between hepatitis C virus (HCV) infection and coronary artery disease (CAD) is controversial. We conducted this study to determine and quantify this association.

We used an established, national, observational cohort of all HCV-infected veterans receiving care at all Veterans Affairs facilities, the Electronically Retrieved Cohort of HCV Infected Veterans, to identify HCV-infected subjects and HCV-uninfected control subjects. We used the Cox proportional-hazards model to determine the risk of CAD among HCV-infected subjects and control subjects.

We identified 82,083 HCV-infected and 89,582 HCV-uninfected subjects. HCV-infected subjects were less likely to have hypertension, hyperlipidemia, and diabetes but were more likely to abuse alcohol and drugs and to have renal failure and anemia. HCV-infected subjects had lower mean (\pm standard deviation) total plasma cholesterol (175 ± 40.8 mg/dL vs. 198 ± 41.0 mg/dL), low-density lipoprotein cholesterol (102 ± 36.8 mg/dL vs. 119 ± 38.2 mg/dL), and triglyceride (144 ± 119 mg/dL vs. 179 ± 151 mg/dL) levels, compared with HCV-uninfected subjects (for all comparisons). In multivariable analysis, HCV infection was associated with a higher risk of CAD (hazard ratio, 1.25; 95% confidence interval, 1.20–1.30). Traditional risk factors (age, hypertension, chronic obstructive pulmonary disease, diabetes, and hyperlipidemia) were associated with a higher risk of CAD in both groups, whereas minority race and female sex were associated with a lower risk of CAD.

Our conclusions are that HCV-infected persons are younger and have lower lipid levels and a lower prevalence of hypertension. Despite a favorable risk profile, HCV infection is associated with a higher risk of CAD after adjustment for traditional risk factors.

Abstract: <http://www.journals.uchicago.edu/doi/abs/10.1086/599371>

Clinical Infectious Diseases 15 July 2009 V.49 N.2 p.225–232

Adeel A. Butt et al.

What I need to know about Liver Transplantation

<http://www.foodconsumer.org>

Steve Jobs, co-founder and CEO of Apple Inc. received a liver transplant in Tennessee about two months ago, Wall Street Journal reported Friday. Jobs has been on medical leave since January to treat a undisclosed medical condition. He has reportedly been recovering well and is expected

to return to work soon.

Cited below is an article on liver transplant from a U.S. government website for those who might be interested in knowing more about the procedure.

What I need to know about Liver Transplantation

http://digestive.niddk.nih.gov/ddiseases/pubs/livertransplant_ez/

Women with Hypothyroidism at Increased Risk of Liver Cancer

<http://patient.cancerconsultants.com>

Long-term hypothyroidism in women significantly increases the risk of developing hepatocellular carcinoma (liver cancer), according to the results of a study published in *Hepatology*.^[1]

The liver is the largest organ in the body and is responsible for over 500 functions, including the secretion of glucose, proteins, vitamins, and fats; the production of bile; the processing of hemoglobin; and detoxification of numerous substances. Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer (cancer that begins in the liver). Factors that increase the risk of developing HCC include long-term, heavy alcohol use and chronic infection with hepatitis B or C viruses.

Hepatocellular carcinoma is the third leading cause of cancer deaths worldwide, and the disease appears to be on the rise, possibly due to an increased incidence of the hepatitis B and C viruses.

The thyroid releases hormones that control the metabolism. Hypothyroidism is a condition in which the thyroid gland fails to produce enough thyroid hormone. Hypothyroidism is more common in women than men and also in individuals over age 50 or those who have been exposed to radiation.

There is some evidence of a link between thyroid disease and hepatitis C virus. In addition, there is evidence that hypothyroidism is related to inflammation of the liver cells. However, no clear link has been established between hypothyroidism and liver cancer.

Researchers at M. D. Anderson Cancer Center in Texas conducted a study to compare the incidence of HCC among patients with and without hypothyroidism. The study included 420 patients with HCC and 1,104 healthy control subjects. The researchers found that a long-term history of hypothyroidism (10 or more years) was associated with a statistically significant high risk of HCC in women—specifically, they were 2.9 times more likely to develop HCC than women without thyroid disease.

Hypothyroidism did not appear to increase the risk of HCC for men. Hyperthyroidism (overactive thyroid) did not increase the risk of HCC in either sex.

The researchers concluded that women with long-term hypothyroidism are at an increased risk of developing HCC. It is unclear whether the weight gain often associated with hypothyroidism plays a role in the development of HCC, as hypothyroidism that did not result in weight gain also

appeared to contribute to the development of HCC. Research will likely be ongoing to continue to evaluate this link.

Reference:

[1] Hassan MM, Kaseb A, Li D, et al. Association between hypothyroidism and hepatocellular carcinoma: A case-control study in the United States. *Hepatology*. 2009; 49: 1563-1570.

June 23, 2009

Providers Often Fail to Inform Patients of Abnormal Test Results

<http://firstwatch.jwatch.org>

Providers frequently fail to inform patients of clinically significant, abnormal test results, reports *Archives of Internal Medicine*.

Researchers retrospectively examined medical records of some 5400 patients (aged 50 to 69) at 23 primary care practices, with a focus on 11 blood tests and 3 screening tests. They also surveyed physicians at the practices about their processes for managing test results.

Among the findings:

- Of some 1900 clinically significant abnormal results, 6% were not communicated to the patient, and 1% were communicated but not documented.
- Practices with the best process scores for test-result management had the lowest rates of failure to inform or document. (Process was scored on several parameters, e.g., whether all results were routinely sent to the responsible physician.)
- Practices with partial electronic medical records had the highest failure rates, while those with either full EMRs or only paper records had similar rates.

The authors point out that most practices did not have "explicit rules" for managing test results.

Health of young offenders is poor

<http://www.upi.com>

ADELAIDE, Australia, June 23 (UPI) -- The physical and mental health needs of juvenile offenders should be a priority if offenders have any hope of rehabilitation, Australian researchers suggest.

"The health of young offenders is commonly poorer in comparison with the general youth population," lead author Dr. Anne Wilson said in a statement.

The review, published in the *Australian Journal of Primary Health*, and co-authored by doctoral student Phillip Tully found:

- Mental health, grief and trauma are among the most common issues affecting both male and female young offenders.
- Youth who are detained in secure care show significantly higher rates of mental health issues than young offenders who are not detained.

- Young offenders in secure care generally have a poor level of physical health because of issues such as frequent substance abuse, head injury, exposure to direct trauma injuries or exposure to violence, hepatitis C infection and liver disease, and exposure to sexually transmissible diseases.
- Young offenders have a higher death rate than similar aged non-offenders, with as many as 70 percent of deaths attributable to drugs and suicide.
- High-risk sexual behavior leads to higher rates of pregnancy among young female offenders.

CDC Researchers Release Latest Hepatitis A, B, and C Statistics

www.hivandhepatitis.com

By Liz Highleyman

The Centers for Disease Control and Prevention (CDC) Division of Viral Hepatitis recently updated its web site with new estimates of the disease burden for viral hepatitis in the U.S. in 2007, including estimates of chronic hepatitis B and chronic hepatitis C prevalence and hepatitis-related deaths.

[The latest statistics are available online.](#)

In related news, CDC researchers published updated epidemiological data on acute viral hepatitis in the May 22, 2009 Morbidity and Mortality Weekly Report Surveillance Summaries.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5803a1.htm>

In the U.S., acute viral hepatitis is most frequently caused by hepatitis A virus (HAV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection, the report authors noted as background. Safe and effective vaccines are available for hepatitis A and B, but there is currently no vaccine for against hepatitis C.

While acute hepatitis A resolves spontaneously, a proportion of people with acute hepatitis B or C will go on to develop chronic infection (lasting longer than 6 months), which over years or decades can progress to advanced liver disease including cirrhosis and hepatocellular carcinoma.

Cases of acute viral hepatitis are reported voluntarily to the CDC by state and territorial health departments via the agency's National Notifiable Disease Surveillance System (NNDSS). Reports are received electronically via the CDC's National Electronic Telecommunications System for Surveillance (NETSS).

The MMWR report covers information collected during 2007, the most recent year for which data are available; these data were compared with those from previous years.

Findings:

- Acute hepatitis A incidence (new cases) has declined by 92% over the past decade, from 12.0 cases per 100,000 persons in 1995 to 1.0 per 100,000 persons in 2007 -- the lowest rate ever recorded.
- Declines in hepatitis A were greatest among children and in states where routine HAV vaccination of children has been recommended since 1999.
- Acute hepatitis B incidence has declined by 82%, from 8.5 cases per 100,000 persons in 1990 to 1.5 per 100,000 persons in 2007, also the lowest rate ever recorded.

- Declines occurred in all age groups, but were greatest among children younger than 15 years of age.
- Acute hepatitis C incidence declined steadily after a peak in 1992, but incidence rates have plateaued since 2003.
- In 2007 -- as in previous years -- the majority of acute hepatitis C cases occurred among adults, with injection drug use being the most common risk factor.

"The results documented in this report suggest that implementation of the 1999 recommendations for routine childhood hepatitis A vaccination in areas of the United States with consistently elevated hepatitis A rates has reduced rates of infection," the authors wrote. "In addition, universal vaccination of children against hepatitis B beginning in 1991 has reduced disease incidence substantially among younger age groups."

However, they continued, "Higher rates of hepatitis B continue among adults, particularly among males aged 30-44 years, reflecting the need to vaccinate adults at risk for HBV infection."

The decline in hepatitis C incidence after 1992, the authors noted, was primarily attributable to a decrease in incidence among injection drug users. "The reasons for this decrease were unknown," they wrote, "but probably reflected changes in behavior and practices among injection drug users" -- and may also reflect public interventions such as education and needle exchange programs.

Translating these findings into public health guidelines, the authors stated that the 2006 expansion of routine hepatitis A vaccination recommendations to include all children aged 12-23 months is expected to reduce hepatitis A rates even further.

Ongoing hepatitis B vaccination programs, they wrote, "ultimately will eliminate domestic HBV transmission, and increased vaccination of adults with risk factors will accelerate progress toward elimination."

Prevention of hepatitis C, they said, "relies on identifying and counseling uninfected persons at risk for hepatitis C (e.g., injection drug users) regarding ways they can protect themselves from infection."

"Further prevention of hepatitis B and hepatitis C," they added, "relies on identifying and preventing transmission of HBV or HCV in hospital and non-hospital health-care associated settings." In recent years there have been several reported outbreaks of viral hepatitis due to improper cleaning or reuse of medical equipment.

HBeAg-Positive Pregnant Women With HBV DNA Warrant Further Assessment to Prevent Transmission to Infant: Presented at ICC

<http://www.docguide.com>

By Louise Gagnon

TORONTO -- June 23, 2009 -- Pregnant women who are at elevated risk of transmitting hepatitis B virus (HBV) to their unborn children should be referred to a specialist who can evaluate whether steps can be taken to reduce the potential for mother-to-child transmission, according to



a study presented here at the 26th International Congress of Chemotherapy and Infection (ICC).

Ameeta Singh, Division of Infectious Diseases, University of Alberta, Edmonton, Alberta, and colleagues retrospectively analysed factors linked to the transmission of HBV in infants born to mothers who tested positive for hepatitis B surface antigen (HBsAg) between 2000 and 2005 in Alberta, to determine which mothers were at greater risk of transmitting the virus to their children.

Current intervention programs in Alberta offer postexposure prophylaxis to infants whose mothers have tested positive for HBV infection, explained Singh on June 20.

"To prevent passage from the mother to the infant, the infants receive passive prophylaxis with hepatitis B immunoglobulin and 3 doses of vaccine given over several months to help them develop antibodies," said Singh. "[The treatment] is highly effective, but we do still see some failures.

"The trouble is that, if we fail, 90% of those infants will go on to develop chronic hepatitis B, so they have it for life and are at much higher risk of developing cirrhosis and liver cancer," she continued.

From provincial surveillance records, the researchers identified 12 cases of HBsAg-positive mothers (median age 30 years) with infants who were infected with HBV and 48 control subjects (median age 32 years) whose infants were not infected. The participants were tested for hepatitis e-antigen (HBeAg) and anti-hepatitis B core antigen (anti-HBc), and HBV DNA PCR sequencing was performed.

HBeAg was positive in 7 of 9 cases (78%) and 12 control subjects (25%; $P < .05$). Anti-HBc was negative in 1 of 11 cases and positive in all control subjects. HBV DNA PCR was positive in all cases and 41 control subjects. No mothers tested positive for HIV or hepatitis C (HCV).

Investigators found HBV vertical transmission was more common in HBeAg-positive mothers and in mothers who had higher HBV DNA levels.

"The minimum recommendation should be that any mother who is HBeAg positive and who has any level of HBV DNA should be referred to a specialist for further assessment," said Singh. "We would ask mothers who are HBsAg positive to submit for DNA. The specialist would [decide] if they are suitable candidates for therapy."

Funding for this study was provided by the Stollery Children's Hospital Foundation.

[Presentation title: Factors Associated With Vaccine Failure and Vertical Transmission of Hepatitis B Among a Cohort of Canadian Mothers and Infants. Abstract O55]

June 24, 2009

Did Steve Jobs' money buy him a faster liver transplant?

www.cnn.com

By Ray Hainer

- *Apple cofounder Steve Jobs is recovering from transplant surgery in Tennessee*
- *His surgery raises questions about preferential treatment*
- *Current system results in regions with much shorter wait times than others*
- *16,000 people on the liver waiting list; in any one year only one-third get liver*

This week it was reported that Steve Jobs, the CEO and cofounder of Apple, underwent a liver transplant two months ago. One detail concerning Jobs's transplant seemed odd: The surgery took place at a hospital in Tennessee, some 2,000 miles from Jobs' home in northern California. Why Tennessee?

The answer sheds light on the intricacies of the organ transplant system, as well as why it's sometimes easier for people with significant financial resources to get an organ transplant. (Jobs' estimated net worth: \$5.7 billion.)

Livers are a scarce resource. In any given year, only about one-third of the people on the national transplant waiting list receive one, and as of late June, more than 16,000 people were on the list.

Yet it sometimes seems that celebrities in need end up at the front of the line when they need a transplants, and people often assume they get preferential treatment. (Rumors about special treatment circulated after baseball player Mickey Mantle's liver transplant in 1995, for example.) [Health.com: The real gift of life: How medical donations help](#)

The truth is more complicated. No one can actually buy an organ in the United States (legally, that is). But getting a liver transplant, it turns out, is a lot like getting into college. Once you're on the waiting list, your chances of getting off it depend largely on your personal circumstances -- how sick you are and whether you are a good donor match. But getting on the list in the first place -- or on more than one list, as the case may be -- requires resources and know-how that most people don't have.

Can some people 'cut the line'?

There are 127 centers in the U.S. that perform liver transplants. If you need an organ transplant, your doctor will refer you to one of these centers, where you will be evaluated, given a score based on the severity of illness, and placed on the center's waiting list, if you are indeed a candidate for transplant.

The center's waiting list feeds into a national database managed by the United Network for Organ Sharing (UNOS), a nonprofit organization that contracts with the federal government to manage the nation's organ transplant system.

UNOS works with 58 organ procurement organizations (OPOs) that coordinate organ distribution in their region of the country. When an organ becomes available, the OPO in that region searches the UNOS database for a local match using blood type (and other biological considerations), the patient's severity score, and the time spent on the waiting list. If a match can't be made within that region, the organization expands its search to neighboring regions.

The problem -- or the advantage for some patients -- is that not all OPOs are created equal. Some regions contain nearly 15 times as many people as others, and their waiting list times vary widely. Patients in the smaller OPOs tend to be less sick and experience shorter wait times

before getting an organ. In the Tennessee OPO where Jobs received his transplant, the median wait for a liver between 2002 and 2007 was just over four months. The national average was just over a year, and in some OPOs it was more than three years.

Though there is always the possibility of preferential treatment once a patient is on a waiting list -- UNOS conducts periodic audits of transplant centers for exactly this reason -- it is unlikely that someone like Steve Jobs can "cut the line" of the transplant waiting list. Health.com: Three sisters find kidney donor for dad using craigslist

The reason that some people might be able to get transplants more quickly is that they're standing in more lines. Nothing prevents someone from being evaluated and listed at multiple transplant centers. As long as a patient has the wherewithal to fly around the country -- and be available at the drop of a hat if a liver becomes available (this is where the private jet comes in handy) -- a patient can, in theory, be evaluated by all the transplant centers in the country.

"The system works at two levels," explains Arthur Caplan, Ph.D., the chair of the department of medical ethics at the University of Pennsylvania. "One, who gets in to a center. Two, who gets transplanted off a particular center's list when an organ becomes available. Most of the attention goes to stage two, but the biggest ethical challenges are really at stage one."

Jobs underwent surgery for pancreatic cancer in 2004. (He reportedly had a type that grows more slowly -- and has a better prognosis -- than others.) He was said to have recovered, but last year he appeared in public looking thin and sick. He took a leave of absence in January and underwent a liver transplant a few months later. However, it's not clear how long he was on the transplant waiting list, or whether he was on the waiting list for a center other than the one in Tennessee.

Insurance matters too

Since 2003, UNOS has required that transplant centers inform all candidates that they can be evaluated and listed at more than one center, and that they can also transfer their care from one center to another without losing the time they have accrued on the waiting list. However, not everyone can afford to fly around the country and be evaluated at more than one transplant center. In fact, many people can't afford a liver transplant, period.

According to the most recent estimates, the cost of a liver transplant is \$519,600 -- a price tag that excludes roughly one-third of Americans because they don't have sufficient insurance (or any insurance), Caplan estimates. According to data collected for UNOS, only about 5 percent of liver transplants are paid for out of pocket. Health.com: Where the money goes: A breast cancer donation guide

"What your insurance covers is very different from everyone else's," says Anne Paschke, a spokesperson for UNOS. Some insurance companies won't cover evaluations at multiple transplant centers, Paschke explains, and in at least one case, an insurance company has restricted its coverage to a single transplant center that the company itself owned.

Moreover, your insurance continues to be important during the evaluation process. The decision to accept a transplant candidate takes place before UNOS enters the picture, and the committees that determine whether a patient is added to the transplant center's waiting list have access to a

patient's full medical and financial history.

"There's a huge triage involved in getting in," says Caplan. "If you're a homeless alcoholic sleeping on the streets of L.A., and you're going toe-to-toe with Steve Jobs, you're going to lose."

For most people, the ability to pay is a precondition for acceptance at more than one transplant center. Wealthy people who are, in effect, financially "pre-approved" for a liver transplant, can shop around and identify the transplant centers that will give them the best chance of receiving a new organ.

Reforming the system

Despite the apparent problems with the transplant system, past efforts at reform have generally failed. Health.com: Could painkillers be hurting your heart?

In the late 1990s, the U.S. Department of Health and Human Services issued new regulations that would have given priority to the sickest patients, regardless of region. This would have eliminated the geographic disparities that make approval at multiple transplant centers advantageous, but Congress blocked the regulations and instead asked the Institute of Medicine, an advisory organization that belongs to the National Academy of Sciences, to consider the issue.

The IOM's proposal was less far-reaching, but it did recommend standardizing the size of the organ donor pool for the sickest patients. Congress failed to implement this measure as well, however.

Some transplant centers advocated the shift away from the OPO system, but others vigorously lobbied Congress to oppose the new policy. The smaller transplant centers were concerned that in a national organ allocation system, they would receive fewer transplants and be driven out of business. The larger transplant centers, meanwhile, wanted to maintain the size and geographical reach of the OPOs in their areas.

"There was a huge split in the transplant community," says Paschke. "It was very territorial at the time, and there was a lot of maneuvering going on. There were a lot of business interests on the part of the transplant centers."

UNOS itself has been split on the issue of multiple listing. The organization's board of directors has voted on whether to restrict multiple listing three times in the past 15 years; the first vote resulted in a tie, and in the others the proposal was rejected by a divided vote.

The inequity revealed in the liver transplant process is symptomatic of the larger inequalities in the American health-care system, says Caplan, who also cochairs a United Nations task force on organ trafficking. In countries such as Canada or Switzerland that have national health-care systems, a patient's finances don't influence access to organs to the same extent, he says.

"Money doesn't play such a big role in entry into the system," he says. "Steve Jobs' transplant is relevant to why we need some health reform."

U.S. pursues crackdown on healthcare fraud

www.reuters.com

WASHINGTON (Reuters) - U.S. authorities on Wednesday announced they had charged 53 people with Medicare fraud and vowed to pursue a crackdown on schemes that cost taxpayers billions of dollars a year.

Attorney General Eric Holder said Medicare fraud charges this week demonstrate "we will strike back against those fraudulent schemes" that undermine the health insurance program for the elderly and contribute to rising health costs.

The Justice Department said indictments unsealed in Detroit charged the 53 people -- doctors, business owners, employees and patients -- with more than \$50 million in Medicare offenses.

That followed separate indictments in Miami charging eight people of defrauding the healthcare system by creating phony clinics that produced fraudulent bills of about \$100 million.

President Barack Obama has pledged to get healthcare reform through Congress this year. The administration was talking with lawmakers about allowing better data-sharing and other strategies to battle fraud, Health and Human Services Secretary Kathleen Sebelius said.

"As we work on health reform legislation, we're working to ensure that the final legislation includes new policies to help prevent fraud and abuse," she said.

"This is not a victimless crime," FBI Director Robert Mueller said. "We in the FBI now have more than 2,400 pending healthcare fraud investigations."

Investigators are using techniques such as undercover operations and wiretaps in these types of cases, Mueller said.

"By pursuing these methods we can reduce the long-term damage to the American economy and to the citizens we serve," he said.

(Reporting by Tabassum Zakaria; Editing by Xavier Briand)

Groups urge FDA to release info on rejected drugs

www.reuters.com

By Susan Heavey

WASHINGTON (Reuters) - The U.S. Food and Drug Administration should make more information available to the public, even on drugs and devices that never make it to the U.S. market, consumer advocates told the health agency on Wednesday.

But industry representatives cautioned that findings or data containing confidential company information could harm competition if made widely available.

While the FDA often provides public details on products that win its approval, doctors and consumers could benefit from similar disclosure on those it rejects, several advocates and former FDA staff reviewers said at a public meeting to discuss ways the agency can make its regulatory decisions clearer.

Details on why it declines a new use for a drug already on the market could help protect patients from possible side effects if doctors are already prescribing it for so-called "off-label" use or as rival drugs are developed, said the Pew Prescription Project's Allan Coukell.

"Lives might have been saved," Coukell, director of the nonpartisan consumer safety group, told the panel of eight top FDA officials.

The FDA, which regulates a wide-range of foods, drugs and devices that make up about 25 percent of the U.S. economy, has ultimate say on whether medications can be sold or whether certain foods must be recalled. It also monitors manufacturing sites and monitors drug risks, among other duties.

But it has come under fire amid a number of scandals involving a variety of products including painkillers, contaminated peppers and peanut butter.

Some critics said the agency, which gets much of its funding from company fees, is too cozy with the industries it regulates.

FDA has adopted a "corporate culture" and focuses too much on company interests instead of science, said Public Citizen Health Research Group Deputy Director Peter Lurie, whose advocacy group has long-challenged many FDA decisions.

Dr. Joshua Sharfstein, deputy commissioner of the FDA and head of the panel, defended the fees earlier this year, saying agency staff make decisions based on evidence.

U.S. lawmakers only recently boosted the FDA's budget.

Industry groups said the FDA could do a better helping consumers understand its actions but warned that too much public detail on products or manufacturing may tip off rivals.

"To provide that type of information before approval would provide competitors with insights ... those types of insights come at a cost, a competitive cost," said Pharmaceutical Research and Manufacturers of America lawyer Jeffrey Francer.

Mark Leahey, president of the Medical Device Manufacturers Association, said it could also scare off potential venture capitalists crucial to many smaller companies.

"Investments ... will dry up," he told the panel.

The panel is set to meet again this autumn and will deliver its recommendations to FDA Commissioner Margaret Hamburg in six months.

(Reporting by Susan Heavey, editing by Leslie

Should you get tested for hepatitis C?

<http://www.14wfie.com>

By Ellie Rodgers,
Contributing Writer, myOptumHealth

Millions of Americans have the hepatitis C virus (HCV), and many of them don't know it. This infection can cause liver damage over time, but it usually doesn't cause symptoms right away. Many people are diagnosed only through routine blood work or when they try to donate blood.

But should everyone be tested for hepatitis C? The Centers for Disease Control and Prevention (CDC) says no. The CDC recommends testing people who have a high risk for the infection. This includes anyone who:

- Has injected illegal drugs. This includes people who may have only done it a few times, and it was years ago.
- Had a blood transfusion or organ transplant before July, 1992.
- Had a blood transfusion from someone who later tested positive for hepatitis C.
- Received blood clotting factors made prior to 1987.
- Has ever had long-term kidney dialysis.
- Has signs of liver damage, such as abnormal liver function tests (blood tests).

How is hepatitis C spread?

Hepatitis C is spread through infected blood, usually by people who share needles while injecting illegal drugs. Health care workers can get it by being stuck with a needle that has contaminated blood on it. An infected mother may pass the virus to her baby during birth.

The virus can also enter the body through minor cuts or scrapes by razors or toothbrushes. It can also be on needles used for tattooing or body piercing, or on materials used to snort cocaine.

Sometimes hepatitis C virus is spread during sexual contact, but this is not thought to occur very often.

How can I get tested?

A blood test is used to check for HCV antibodies in the blood. Your doctor can order the test, or you can call your local health department and ask where to get tested.

If a test shows you have the virus, your doctor may do other tests, including one to confirm the results and others to check for liver damage. Once your doctor has all the results, he or she may prescribe medicines to fight the virus and stop or slow liver damage.

Hepatitis C Cases on the Rise in Langlade County

<http://www.wsaw.com>

Reporter: Liz Hayes

Hepatitis C is a virus that attacks the liver, and it's on the rise in Langlade County (WI).

According to the health department, the number of new infections in the last three months, six, is

what is usually recorded in a year.

Some are connecting the rise in cases to the so-called heroin epidemic in the area.

Though Karen Hegranes, the assistant director of the health department, isn't making that connection.

"I think there could be several different things that might be happening in the community," Hegranes said.

She does say there may be even more undiagnosed cases, and most of the time there are no symptoms.

"There may be more people that are infected in Langlade county. I just don't know because they haven't been tested, so the only way I'm aware is if a physician has tested," Hegranes said.

Hepatitis C is contracted through blood to blood contact, sexual intercourse, and sometimes from an infected mother to her child.

3.2 million Americans are affected.

Hegranes urges everyone involved in risky behavior to get tested.

In rare cases, some diagnosed with the virus can overcome it.

Insulin Resistance Among Chronic Hepatitis C

<http://www.hghblen.com>

A recent article in *Clinical Gastroenterology and Hepatology* 8-08 by Stephen A Harrison at Brooke Army Medical Center points out the co-existence of insulin resistance and chronic hepatitis C which occurs more often than predicted by chance. Recent estimates that 30 to 70 % of patients with chronic hepatitis C display some evidence of insulin resistance and this insulin resistance often has a negative impact on treatment outcomes for viral hepatitis C.

Successful managing insulin resistance or diabetes mellitus in these patients may improve patients' likelihoods of successful antiviral therapy. Studies are underway to determine whether improving insulin sensitivity results in better outcomes in patients receiving pegylated interferon / ribavirin therapy for chronic hepatitis C such as statin therapy, ursodeoxycholic acid or vitamin E which in small studies showed promise. Other studies are investigating the effect of pioglitazone or rosiglitazone on insulin sensitivity, hepatic fat and sustained viral response from the pegylated interferon and ribavirin therapy.

For the present, encouraging weight loss and exercise to reduce insulin resistance and fatty liver (steatosis) may improve the response to interferon therapies.

Conatus Pharmaceuticals Initiates A Second Phase 2 Clinical Trial For The Treatment Of Hepatitis

<http://www.medicalnewstoday.com>

Conatus Pharmaceuticals Inc. announced the initiation of a second Phase 2 clinical trial with a novel drug candidate for the treatment of liver disease associated with Hepatitis C Virus (HCV) infection. The trial will enroll patients for whom treatment with approved standard of care treatments is not currently advised. Results from an earlier clinical trial in HCV patients who failed standard of care treatment are expected to be reported later this year.

CTS-1027 is an oral, small molecule compound that inhibits the activity of key members of a class of protease enzymes, the matrix metalloproteinases or MMPs. CTS-1027 had previously been shown to be effective in multiple preclinical models of inflammatory liver disease and HCV infection.

The clinical trial is a double-blind, placebo-controlled trial testing an optimized dose of CTS-1027 alone or in combination with ribavirin. Dosing will last for up to twenty four weeks. The Company expects approximately 70 patients to be enrolled. The clinical trial will be conducted at up to twenty five medical centers in the U.S. Additional information

"Our recent preclinical studies suggest that CTS-1027 treatment has the potential to impact the second phase of HCV virus inhibitory kinetics in patients. This phase is associated with the gradual reduction and replacement of HCV infected cells by uninfected liver cells. Interestingly, ribavirin is also postulated to have the greatest impact on HCV second phase inhibition, leading us to evaluate CTS-1027 in combination with ribavirin," said Steven J. Mento, President and CEO of Conatus. "We believe that CTS-1027 represents a novel approach to treating HCV disease and look forward to developing this drug candidate to fill an important medical need in HCV-infected patients."

Conatus Pharmaceuticals Inc. is a privately-held specialty pharmaceutical company engaged in the development of innovative human therapeutics to treat liver disease. Chronic liver disease affects millions of people worldwide and can be caused by many different conditions or "insults" to the liver including Hepatitis C and other viral infections, obesity, chronic alcohol abuse or autoimmune diseases. Conatus was founded by the executive management team of Idun Pharmaceuticals in July 2005 following the successful sale of Idun to Pfizer.

Source: Conatus Pharmaceuticals

OraSure says FDA seeks more study on hepatitis C test

www.reuters.com

By Anand Basu

- * Says to conduct additional testing, trial of HCV test
- * Sees \$3 mln charge

- * Says facing problems in manufacturing rapid HIV test
- * Says advisory committee to review OTC HIV test study
- * Shares down about 27 pct (Adds analysts' comments, updates share movement)

BANGALORE, June 25 (Reuters) - OraSure Technologies Inc (OSUR.O) said U.S. health regulators asked it to conduct an additional study of its hepatitis C virus (HCV) test on concerns of potential bias in data interpretation, delaying the test's marketing approval.

OraSure also said it is facing difficulty in resuming full-scale production of its rapid HIV test and that it would require an advisory committee to review results related to its over-the-counter (OTC) HIV test.

Shares of the company were down 24 percent at \$2.49 in midday trade Thursday, making them one of the top percentage losers on Nasdaq. They touched a low of \$2.41 earlier in the session.

"I think that the most disappointing part is hepatitis C (test delay) as that was the near-term catalyst for the stock," Wm Smith Securities analyst Aaron Lindberg said by phone.

The U.S. Food and Drug Administration indicated that clinical data related to the HCV test could have been biased because the same operators performed the test and interpreted results on multiple specimen types derived from the same patient, the company said.

In October, OraSure filed a premarket approval application (PMA) for its OraQuick HCV test for use with multiple specimen types, including venous whole blood, fingerstick whole blood, oral fluid and other sample types.

"The FDA has changed the rules in the middle of the PMA process, requiring new studies that will likely delay approval of the device for at least another year," Susquehanna Financial Group analyst David Turkaly wrote in a note to clients.

Turkaly downgraded OraSure to "neutral" from "positive."

OraSure had expected to address the FDA's concerns without material impact to the clinical program.

However, the FDA recently concluded that additional clinical testing will be required to obtain approval of the PMA for a venous whole blood claim, the company said.

A new clinical study will also be required for approval of claims for oral fluid and other sample types, it added.

Wm Smith Securities' Lindberg, who was expecting the HCV test to get approval by the next two months, now sees an initial approval for whole-blood samples early next year.

However, a meaningful approval for oral fluid and fingerstick sample tests would be further delayed as a new clinical study would be required, Lindberg said.

Oral fluid and fingerstick samples are going to be the most commonly used HCV tests, he added.

Needham & Co analyst Sameer Harish said, "It's clearly a negative for the company, we were expecting delays and now we are starting to see that."

The exact timing and costs tied to the HCV test will not be fully determined till protocols are submitted and reviewed by the FDA, which should occur in the next several weeks, the company said.

The company expects to record a non-cash impairment charge of \$3 million related to a portion of the milestone payments previously made under a license for certain HCV patents.

Manufacturing Issues

OraSure said it is facing an intermittent difficulty in manufacturing a component required for its rapid HIV test and its second-quarter revenue would be hurt if it is unable to resume full-scale production of the test this week.

The OraQuick Advance Rapid test, which detects antibodies to HIV-1 and HIV-2 in 20 minutes, is approved by the FDA for use with oral fluid, fingerstick or venous whole blood and plasma specimens.

The company also expects second-quarter gross margins to be hurt by higher unabsorbed production costs and scrap expenses.

OTC Test Review

OraSure said the FDA indicated that an advisory committee should review and approve the results of an observed-use study and the remaining clinical activities related to its OTC HIV test.

"With the delays, they potentially lose the first mover advantage (in the HIV space). It depends on how long it takes for competitors to catch up," Needham & Co's Harish said.

Wm Smith's Lindberg said the delay in the OTC HIV test was expected as it was a new territory for the FDA.

In August, the company submitted the results of its observed-use study to the FDA to obtain approval for an OTC version of its OraQuick test.

The study was designed to assess an individual's ability to interact with the product packaging, comprehend the instructions for use, take the test and interpret the results.

(Editing by Aradhana Aravindan, Ratul Ray Chaudhuri)

Hepatitis C warning for cocaine snorters

<http://www.thisisjersey.com>

Michael Gafoor,
Director of the Alcohol and Drugs Service.

SOME cocaine users in Jersey have contracted Hepatitis C from sharing bank notes and straws to snort the class A drug.

Health officials have confirmed that there have been cases to suggest that people who snort cocaine have contracted Hepatitis C but would not reveal how many people have been infected.

At the moment Health officials have no idea of the prevalence of Hepatitis C in the Island.

The news comes as Customs and Immigration reveal that seizures of cocaine have significantly increased compared to this time last year.

Michael Gafoor, director of the Alcohol and Drugs Service, is warning people who snort drugs like cocaine that they are putting themselves at risk of getting Hepatitis C.

June 26, 2009

Liver Lines

<http://www.antonnews.com>

Dr. David Bernstein

The international community recognized the importance of liver disease on May 19, World Hepatitis Day. One in 12 people worldwide have chronic hepatitis, including roughly 350 million with HCV and 170 million with HBV. Morbidity and mortality from these conditions are high with the world's health authorities estimating that at least one million people die each year of hepatitis, especially in Asia, sub-Saharan Africa and Latin America where it is endemic.

Where do we stand in the war against hepatitis? The battles are being fought on three fronts: screening, treatment and prevention. Screening programs are becoming more widespread and are essential in identifying and tracking sufferers; they are determined by country and governmental priorities. The effectiveness and scope of these programs are directly related to a nation's economic resources. Progress in treatments over the past decade has been dramatic. Hepatitis B has three highly potent compounds available for treatment: interferon-alpha, entecavir and tenofovir. Prior to 1992, there were none. Several worldwide societies have published cutting edge clinical practice guidelines that are highly innovative in their use of virology orientated endpoints and their recommendations of choice of therapy. Despite this progress, hepatitis B is still a chronic incurable condition.

The treatments available for hepatitis C are not as advanced as those available for hepatitis B. Standard interferon and ribavirin therapy can cure about half of patients. There remains no good treatments for those who fail initial therapy. The good news is that newer agents in combination with standard hepatitis C therapies appear to increase the sustained response rates to more than 75 percent and this should help reshape the course of this disease for the better.

There is no vaccine for hepatitis C while the hepatitis B vaccine has been extremely effective in limiting new infections. If the world were to adopt universal vaccination, it is conceivable that the next generation could expect to be free of hepatitis B altogether.

Hepatitis is only the start of a continuum of diseases that can affect the liver, creating a long-term health concern with huge mortality concerns. Fatty liver caused by either non-alcoholic steatohepatitis secondary to diabetes or obesity, alcoholic liver disease, autoimmune diseases such as primary biliary cirrhosis and hereditary liver diseases continue to pose long-term

concerns for the overall health of our populations. Of these conditions, fatty liver is the most common and most concerning as its incidence is rapidly on the rise and it is associated with the metabolic syndrome and is a risk factor for heart disease. All of these conditions can lead to cirrhosis and recent evidence suggests these conditions can directly cause liver cancer. Liver cancer is often the terminal endpoint of the continuum of liver diseases. As we look towards the future, especially in the Western World, even if hepatitis is brought under control, chronic disease will almost certainly progress through cirrhosis to liver cancer, and the current peak in hepatitis cases will see a peak in liver cancer 20 years from now. This relationship has already been seen in Japan.

Dr. Bernstein is the director of Hepatology for the North Shore-Long Island Jewish Health System.

Teenager Jazzy de Lisser's award-winning film about living with killer disease hepatitis C

<http://www.mirror.co.uk>

Exclusive: By Hannah Wood 26/06/2009

Jazzy de Lisser was born with hepatitis C and just six months ago heard she was too ill to continue treatment. Here, Jazzy, whose film of her life has won a Daily Mirror competition, tells how she coped.

When Jazzy de Lisser was just 13, doctors told her she had the liver of a middle-aged alcoholic.

The schoolgirl had known for 10 years that her mum passed chronic liver disease hepatitis C to her at birth.

“Mum thinks she got it from intravenous drug use in her early 20s, years before I was born,” explains Jazzy, now 17. “She’s been clean for 25 years.”

Jazzy was three when mum Serena Bute began to worry something wasn’t quite right. The tot’s stomach was painfully bloated and tests showed she had been born with the chronic disease.

It was only then that fashion designer Serena realised she had hep C, too.

At the age of six Jazzy and her family moved to London from Jamaica to begin treatment with Interferon – then the most common drug used to combat the virus.

“I had to just get on with my life,” says Jazzy, who has just won a film competition backed by the Daily Mirror with a documentary about her long battle with the disease.

Watch it [here](#):

“I didn’t really feel the effects of hep C other than being more prone to illness than my school friends and I didn’t tell many people because I didn’t want them to react differently to me.

“But when I was about 13 I started researching websites and found them so unfriendly and

negative. I couldn't get my head around all the ways they described hep C attacks and damages the liver. I began to really worry about what I had."

Jazzy went to King's College Hospital in London for an update on her condition where doctors said the scarring on her liver was getting worse.

"The doctor said Jazzy had the liver of a 50-year-old man who had been drinking and taking drugs his whole life," says mum Serena.

Jazzy tried alternative therapies and even flew to Austria to see a specialist. But at 14 she got sick of restricting her diet and taking dozens of homeopathic pills every day.

So in September 2007, Jazzy switched her treatment back to Interferon but this time combined with another drug, Ribavirin. Together, they have a 48 per cent success rate in curing hep C in children.

Jazzy, whose stepdad is the former Grand Prix driver Johnny Dumfries, was inspired by documentary-maker Mel Agace to record a video diary of her treatment over 15 months.

Then she heard about the launch of the Daily Mirror, MediaBox and Bebo Your Film09 competition. It aimed to find young film-makers to make a documentary about something important in their lives.

Ten people were selected to take part in special workshops with Bafta mentors to transform their ideas into films.

Jazzy turned the diary into her award-winning short film My Story of C, which captures the highs and lows of her treatment – from promising test results, lying in bed in agony, to blazing rows with her mum.

"I'd never met anyone my age going through this and thought I could show people what it's like," she says.

The documentary captures Jazzy's suffering caused by the drugs, as well as her mum's guilt as she watches her daughter beg for it all to stop.

"The drugs were so invasive," says Serena, whose own condition is stable. "It was horrifying to watch her suffer knowing I was the reason."

Jazzy battled with the side-effects of the drugs as she studied for her A-levels.

"They made me exhausted and moody," she explains. "I had blinding headaches and no energy. I got mouth ulcers and eczema and loads of my hair fell out."

Jazzy initially responded well to the latest treatment but then tests showed the disease was back – in another form.

In January this year, after 15 months on the dual-drug regime, Jazzy heard the terrible news that the virus had become so bad treatment had to stop.

“I was really angry and upset,” she says. “I felt totally helpless.”

But she wasn't about to give up and vowed to help others in her situation. Jazzy has built a website (www.livergoodlife.com) with the British Liver Trust to explain the disease to teenagers like her in a more positive way than the sites she'd seen.

She has also raised cash to pay Oscar-winning animation company Passion Pictures to create a cartoon explaining how hep C damages the liver.

Her next move is to raise money for equipment to help find new treatments. “I'm not going to try another treatment until there's something with a very high success rate,” she says.

“A liver transplant would be the very last option and my aim is to get rid of this by the time I'm 21.

“One day I want to be able to say I have had hepatitis C and I've beaten it.”

HEP C: THE FACTS

- Hepatitis C is a contagious viral disease that leads to serious liver damage. It can cause death.
- It can take months for someone exposed to the virus to realise it because there is an incubation period.
- The disease is spread through contact with infected blood and is commonly transmitted through the sharing and reusing of dirty needles.

Fury as heroin addicts get "one hit kits" from Boots

<http://www.dailyrecord.co.uk>

By Steven Stewart

HEROIN addicts are getting free "one hit kits" packed with syringes, spoons and drug taking equipment from chemists Boots.

The move has triggered fury from anti-drug campaigners.

But health chiefs say the packs will ease the spread of hepatitis C in the west of Scotland.

The One Hit Kits, available at 85 sites in Greater Glasgow and Clyde, contain dozens of needles, "cooking-up" spoons, swabs and citric acid to prepare heroin.

But Helen Mackenzie, secretary of the Families United Support Group, said it was, "like giving 200 cigarettes to someone who was trying to give up smoking".

Helen, 59, added: "These kits are a disgrace. I couldn't believe my eyes when I first saw them.

"The people who decided to introduce this initiative obviously have no idea what it is like to see

their son or daughter dying from heroin addiction.

"How can they have a health warning on a pack of cigarettes but not on this - full of syringes and drug taking material? These kits have every single thing an addict needs except the heroin.

"They are making it too easy for these addicts. The pack has the jazzy name 'One Hit Kit' and some of the packaging suggests this is aimed at younger people.

"This type of thing encourages a new generation of drug addicts. It is capitalising on pain and addiction. I am disgusted that this kind of thing could be available free to people."

Last night, NHS Greater Glasgow defended the kits, which were introduced in February.

Carole Hunter, lead pharmacist in the Addictions Partnership, said: "There are more than 50,000 people with hepatitis C across Scotland and 95 per cent became infected through injecting drug use.

"Needle exchange has been hugely effective in reducing HIV cross-infection and the One Hit Kits are designed to deliver similar reductions in the spread of hepatitis C."

Paul Bennet, standards director for Boots, added: "This service takes a harm reduction approach to drug use and aims to reduce the transmission of blood-borne viruses."

Three-Year Data Support Peginterferon Alfa-2a for HBeAg-Negative Chronic Hepatitis B

www.medscape.com

NEW YORK (Reuters Health) Jun 25 - In patients with hepatitis B e antigen (HBeAg)-negative chronic hepatitis B, a late-phase form of the disease with a poor prognosis, biochemical and virologic responses are sustained for up to 3 years in about 25% of patients given a 48-week course of peginterferon alfa-2a with or without lamivudine.

The results are from a 3-year post-treatment observational study involving 315 patients reported by Dr. Patrick Marcellin, from Hopital Beaujon in Clichy, France, and colleagues in the June issue of *Gastroenterology*.

Patients were treated with peginterferon alfa-2a only (180 µg once weekly; n = 116), in combination with lamivudine (100 mg daily; n = 114), or lamivudine alone (n = 85) for 48 weeks.

Three years after treatment, a higher percentage of patients treated with peginterferon alfa-2a than with lamivudine had normal alanine aminotransferase (ALT) levels (31% versus 18%; p = 0.032), Dr. Marcellin and colleagues report.

Treatment with peginterferon alfa-2a and high baseline ALT level were independent baseline predictors of long-term virologic response (p = 0.04 and p = 0.01, respectively).

Similarly, more patients treated with peginterferon alfa-2a than with lamivudine monotherapy had HBV DNA levels of 10,000 copies/mL or less (28% versus 15%; $p = 0.039$). "This is an HBV DNA level accepted by the latest treatment guidelines as an approximate marker of response," the study team notes.

In addition, a high proportion (44%) of patients treated with peginterferon alfa-2a with undetectable HBV DNA 3 years after treatment had also cleared hepatitis B surface antigen (HBsAg), compared with none of those treated with lamivudine alone.

"The ability to induce HBsAg clearance -- an outcome associated with long-term complication-free survival -- supports the use of peginterferon alfa-2a as a first-line treatment of HBeAg-negative disease, avoiding the need for long-term therapy and the associated risks of developing drug resistance in those patients who achieve and maintain their response," the investigators conclude.

They also note that, until now, the long-term response of peginterferon alfa-2a beyond 6 months of follow up has not been described.

Gastroenterology 2009;136:2169-2179.

HIV Coinfection Has Little Effect on Response to Chronic Hepatitis B Treatment

www.hivandhepatitis.com

By Liz Highleyman

Antiviral therapy for chronic hepatitis B virus (HBV) infection is similarly effective in HIV negative and HIV positive patients, according to a study published in the April 2009 issue of *Hepatology*.

Studies have consistently shown that HIV-HCV coinfecting patients do not respond as well to interferon-based therapy as those with HCV mono-infection. While interferon stimulates the natural immune response, and therefore its effectiveness may be impaired by HIV-related immune deficiency, antiviral therapy for HBV directly targets the virus. Furthermore, some nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) -- including lamivudine (3TC, Epivir), emtricitabine (Emtriva), and tenofovir (Viread, also in the Truvada and Atripla combination pills) -- have dual activity against both HBV and HIV.

After starting antiviral treatment for hepatitis B, there is a biphasic clearance of HBV, similar to that seen with HIV and HCV therapy, Sharon Lewin from Alfred Hospital in Melbourne, Australia, and colleagues noted as background. However, little is known about the effect of combination NRTIs and the influence of HIV coinfection on HBV viral kinetics following the initiation of dually active HAART.

In the current study, 21 treatment-naive HIV-HBV coinfecting patients in Thailand were enrolled in a viral kinetics sub-study of the TICO (Tenofovir in HIV-1-HBV Coinfection) study, a randomized trial comparing 300 mg tenofovir versus 300 mg lamivudine versus tenofovir plus lamivudine, as part of an efavirenz (Sustiva)-based HAART regimen.

The researchers measured HBV DNA frequently over the first 56 days of treatment. To fit the viral load data, they used a model of HBV kinetics that allows for the estimation of treatment effectiveness, viral clearance, and infected cell loss.

Results

- A biphasic decline in HBV DNA was observed in almost all patients.
- There were no significant differences in HBV viral dynamic parameters between the 3 treatments groups.
- Overall HBV treatment effectiveness was 98%.
- The median HBV virion (single virus particle) half-life was 1.2 days.
- The median half-life of an HBV-infected cell was 7.9 days.
- Hepatitis B "e" antigen (HBeAg) positive individuals had a significantly longer infected-cell half-life than HBeAg negative patients (9.0 vs 6.2 days; $P = 0.02$).

"HBV viral dynamic parameters are similar following anti-HBV NRTI monotherapy and dual combination therapy in the setting of HIV-1-HBV coinfection," the study authors concluded. "HIV-1 coinfection has minimal effect on HBV viral dynamics, even in the setting of advanced HIV-1-related immunosuppression."

Reference

SR Lewin, RM Ribeiro, A Avihingsanon, and others. Viral dynamics of hepatitis B virus DNA in human immunodeficiency virus-1-hepatitis B virus coinfecting individuals: Similar effectiveness of lamivudine, tenofovir, or combination therapy. *Hepatology* 49(4): 1113-1121. April 2009.