

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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In This Issue:

- [Liver cancer patients have high diabetes prevalence](#)
- [Nassau County Doctor Rebuilds Practice After Hepatitis Scare](#)
- [Hepatitis C Therapeutic DNA Vaccine Delivered by Inovio Biomedical's Electroporation Technology Reduces Viral Load by Up to 99.7%](#)
- [Needle program could cut 'hep C in jail](#)
- [Woman who got kidney tainted with HIV sues](#)
- [Needles pose threat to housing workers](#)
- [Nurses in fear of needle injuries](#)
- [New hepatitis B guidelines affect some students](#)
- [Man jailed for passing on hepatitis B](#)
- [Liver, thyroid cancer rates increasing in Canada: report](#)
- [How YOU Can Help Save A Hero](#)
- [Phynova to work with Norgine on potential liver disease drugs](#)
- [Working in health care can be risky, study hints](#)
- [Liver Transplantation for Hepatocellular Cancer in Whites, Asians Nearing Parity](#)
- [Policy has changed how organs are allocated](#)
- [Cigarette Smoking, Hepatitis C Virus Synergistic in Raising Liver Cancer Risk](#)
- [Safe injection may save system \\$14-million](#)
- [FDA nixes state appeal to ban multi-dose vials](#)
- [Winnipeg patients may have been exposed to tainted blood](#)
- [Tibotec Begins European Enrollment For Phase 3 Trial Of Telaprevir In HCV Patients Who Failed Prior Treatment](#)

- [Ligand Collaborator GlaxoSmithKline Receives FDA Approval for PROMACTA\(R\)](#)
- [NHS Tayside's £2.7m to fight Hepatitis C](#)
- [Donated organs can give people a new life](#)
- [Excess Body Weight May Be Involved in Course of Hepatitis B](#)

Nov 16, 2008

Liver cancer patients have high diabetes prevalence

www.reuters.com

NEW YORK (Reuters Health) - Patients with hepatocellular carcinoma (HCC) have a significantly higher prevalence of type 2 diabetes mellitus (DM) compared to the general population, according to findings from a case-control study conducted in Italy.

"The association of type (DM2) ... with hepatocellular carcinoma (HCC) has been long suspected," Dr. Valter Donadon, at Pordenone Hospital, and co-authors note in the October 7 issue of the *World Journal of Gastroenterology*. "However, the temporal relationship between onset of diabetes and development of HCC, and the clinical and metabolic characteristics of patients with DM2 and HCC have not been well examined."

Their study included 465 consecutive Caucasian HCC patients and 490 age- and sex-matched controls.

Overall, 145 hepatocellular carcinoma patients (31 percent) and 62 control cases (13 percent) had type 2 diabetes (odds ratio 3.1). Moreover, the authors note, diabetes had been diagnosed at least 6 months prior to the diagnosis of hepatocellular carcinoma in 84 percent of cases, suggesting that diabetes may be a cause rather than a consequence of liver cancer.

Men with DM and HCC were more likely to be treated with insulin than male diabetics in the control group (38 percent vs 18 percent, $p = 0.009$), leading the researchers to recommend "close surveillance for HCC in patients with chronic liver disease and DM2, particularly (among) males and (those) treated with insulin."

They also advise that metabolic control be attempted with insulin-sensitizers, such as metformin and glitazones, in preference to insulin or oral secretagogues.

World J Gastroenterol 2008;14:5695-5700.

Nassau County Doctor Rebuilds Practice After Hepatitis Scare

<http://www.myfoxny.com>

PLAINVIEW, N.Y. (AP) -- A Long Island doctor is rebuilding his practice a year after being accused of spreading hepatitis by using a sloppy injection technique.

Dr. Harvey Finkelstein's lawyer says the Plainview physician's business shrank after state officials told more than 10,000 of his patients last year to get tested for hepatitis and HIV. But attorney Peter Chavkin says Finkelstein's practice has picked up again.

Health officials said in November 2007 that Finkelstein dipped certain syringes multiple times into vials of medicine, contaminating the drugs. Some patients say they got hepatitis from the contaminated medications.

Chavkin says Finkelstein always used a new needle for every injection and now uses only single-dose medicine vials.

Health officials say investigators found no problems in three visits to Finkelstein's office in the past year.

Nov 17, 2008

Hepatitis C Therapeutic DNA Vaccine Delivered by Inovio Biomedical's Electroporation Technology Reduces Viral Load by Up to 99.7%

www.marketwatch.com

Clinical Data Presented at Annual Scientific Meeting of the American Association for the Study of Liver Diseases

SAN DIEGO, Nov 17, 2008 (BUSINESS WIRE) -- Inovio Biomedical Corporation a leader in enabling the development of DNA vaccines using electroporation-based DNA delivery, announced today that its partner, Tripep AB, reported positive additional interim results from its ongoing phase I/II clinical study of its therapeutic DNA vaccine against hepatitis C virus (HCV). This vaccine is being delivered using Inovio's electroporation-based DNA delivery system. In the third and highest dose cohort of the study, two of three subjects demonstrated reductions in viral load of 93% and 99.7%. Previously reported middle dose cohort results demonstrated an 87% and 98% reduction in HCV in two of three subjects, while no anti-viral effect was observed in the low dose cohort. No safety issues have been noted to date in the trial. These data suggest a potential dose response of the vaccine and support the inclusion of three additional subjects in the high dose cohort.

These data were presented by Dr. Matti Sanllberg of Tripep at the recent American Association for the Study of Liver Diseases meeting held in San Francisco.

Avtar Dhillon, MD, Inovio's president and CEO, stated: "We continue to be encouraged by the data flowing out of the ChronVac-C study. This promising DNA vaccine candidate, in which Inovio has an ownership position, is one of the more advanced clinical vaccine candidates in the HCV field. ChronVac-C was designed to play a role as a first-line therapy or as an adjunct to existing therapies."

About ChronVac-C

ChronVac-C(R) is a therapeutic DNA-based vaccine given to individuals already infected with the hepatitis C virus with the aim of clearing the infection from the liver by boosting the body's immune response against the virus. Inovio's electroporation technology is being used to deliver the vaccine and is intended to enhance the potency of the DNA vaccine. This clinical study is being conducted at the Infectious Disease Clinic and Center for Gastroenterology at the Karolinska University Hospital in Huddinge and Solna, respectively, in Sweden. The intended enrollment of 12 patients is being divided into four groups, three with increasing doses of ChronVac-C and the fourth at the maximum tolerable dose. Each patient receives four vaccinations one month apart. After the last vaccination, patients are followed for another six months. The study's main purpose is to assess safety. It is also testing whether the treatment boosts the immune response (immunogenicity) to HCV and its effect on virus replication in the liver.

About Inovio Biomedical Corporation

Inovio Biomedical is focused on developing DNA vaccines for cancers and infectious diseases using its novel method for DNA delivery -- electroporation -- which uses brief, controlled electrical pulses to increase cellular uptake of useful biopharmaceuticals. Initial human data has shown that Inovio's electroporation-based DNA delivery technology can significantly increase gene expression and immune responses from DNA vaccines. Immunotherapy partners include Merck, Wyeth, Vical, University of Southampton, Moffitt Cancer Center, the U.S. Army, National Cancer Institute, and International Aids Vaccine Initiative. Inovio's technology is protected by an extensive patent portfolio covering in vivo electroporation. The company has entered into a definitive merger agreement with VGX Pharmaceuticals. More information is available at www.inovio.com.

SOURCE: Inovio Biomedical Corporation

Needle program could cut 'hep C in jail

<http://news.ninemsn.com.au>

Figures showing nearly half of prison inmates are infected with hepatitis C have sparked renewed calls for needle exchange programs to be trialled in Australian jails.

About 42 per cent of all prisoners and almost 60 per cent of female inmates in the study of South Australian prisoners had hepatitis C when they entered jail.

"This is a startling statistic given that only 1.5 per cent of the Australian population is infected," Deakin University health researcher, Dr Emma Miller said.

The research, to be published in the International Journal of Infectious Diseases, found that inmates who entered prison with the disease were more likely to inject drugs during incarceration.

The study also found needle-sharing was common in jails.

Dr Miller said the findings suggested each needle circulating in South Australian prisons was almost certainly contaminated with the virus.

"It is entirely likely that this would also be the case in prisons around Australia," Dr Miller said.

"This has serious implications for prison staff and also for susceptible prisoners."

Hepatitis C affects the liver and is spread by blood-to-blood contact, often through unsafe injecting practices.

If the virus goes untreated, it can lead to scarring of the liver which may progress to cancer.

Dr Miller said Australian prisons' zero tolerance of needle exchange programs put inmates not infected with the virus at risk.

She said Australian governments needed to consider trialling a needle-exchange program in prisons such as those in Scotland and Germany.

Canada is also considering a trial, Dr Miller said.

"South Australia has a good methadone program in its prison system, but we need to think more pragmatically and also consider a needle exchange program," she said.

Woman who got kidney tainted with HIV sues

<http://www.suntimes.com>

BY KARA SPAK Staff Reporter

NON-EMERGENCY SITUATION / Alleges doctor knew donor was high-risk

A 33-year-old woman who tested positive for HIV and hepatitis C after receiving an infected kidney during an organ transplant at the University of Chicago Medical Center is suing the hospital and a surgeon on the transplant team.

Jane Doe, the plaintiff's alias, was one of four people who received infected organs from the single male donor at Chicago area hospitals in January 2007, said Thomas Demetrio, the woman's attorney. All four were diagnosed with HIV and hepatitis C after the transplants, Demetrio said.

The University of Chicago Medical Center was one of three hospitals officials said last year they were investigating about what they knew and told transplant patients about an infected donor. (AP)

"Emotionally she's pretty devastated, to be honest," he said. "She's just coping with the hand that's been dealt her."

The suit claims Dr. J. Richard Thistlewaite and others at the hospital's transplant team were told by Gift of Hope Organ and Tissue Donor Network that the donor was a homosexual who died in a car collision. The transplant team never told the recipient – whose condition was non-life threatening – the donor was homosexual, which the suit claims is considered "high risk" for organ donation.

A spokesman for the hospital did not have an immediate comment.

Demetrio said the Center for Disease Control's guidelines state that unless the case is life or death, the recipient must be told the background if the donor is a gay man.

Jane Doe previously rejected two kidneys, one from a heavy drinker who had encounters with prostitutes and another who was out on parole for an unknown offense, he said. Had she known the donor was a homosexual, she would have declined the kidney, Demetrio said.

Jane Doe was one of four people infected in January 2007 with HIV and hepatitis C from the donor, who gave both kidneys, his heart and liver. One has since died, Demetrio said.

Jane Doe's body rejected the kidney and she is currently on dialysis in addition to receiving treatment for HIV, he said.

The January 2007 Chicago area transplants were the first time since 1994 that HIV was contracted through a donated organ.

Two blood tests on the donor showed no signs of antibodies for HIV or hepatitis C, the Sun-Times reported in November 2007, when the infections were first publicly revealed. Officials said at the time that there were limitations to the standard tests used to screen organs for the antibodies.

Nov 18, 2008

Needles pose threat to housing workers

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

A construction union is warning housing maintenance workers to watch out for dirty needles when clearing properties.

UCATT members have raised concerns about needlestick injuries when workers enter and work on properties.

Needles – often left by drug addicts – can carry blood borne diseases such as Hepatitis (B or C) or HIV.

Although the risk of infection is rare, UCATT says workers suffer mental anguish and is urging local authorities, housing associations and other maintenance companies to develop training and guidance.

Alan Ritchie, general secretary of UCATT, said: 'Workers who experience needlestick injuries can experience devastating psychological consequences as well as the genuine threat of infections.'

'It is imperative that all companies whose workers could potentially be exposed to dirty needles provide training to minimise potential injuries.'

The needles are sometimes left by accident and can cause injury as workers are clearing rubbish in a flat.

They can also be set up on purpose as a booby-trap for people, including the police or bailiffs, who the occupier does not wish to enter the premises.

They might be attached to light switches and sockets.

The union wants to make workers aware as they could be clearing more homes with increased repossessions and evictions likely during the credit crunch.

Nurses in fear of needle injuries

<http://www.channel4.com>

Half of nurses have been injured by needles used on patients, with many fearing they could be at risk of diseases like HIV and hepatitis C, a report has said.

Nine out of 10 nurses surveyed by the Royal College of Nursing (RCN) said their last injury from a needle drew blood and the head of the union warned of the "potentially lethal consequences" for nurses of being injured by needles.

The RCN's study of almost 5,000 nurses revealed 48% had been injured by a needle that had previously been used on a patient, and a third, 34%, feared they might contract a disease.

While most nurses received information from their employer on the risks of blood-borne diseases, more than one in four, 28%, did not. Only a third of nurses working within the NHS who had suffered an injury, regarded the support offered by their employer as adequate.

Some 94% of employers have a "sharps" policy that covers prevention and reporting, but only 55% of nurses have received any training from their employer on safer needle use, the survey found.

Almost all nurses, 96%, surveyed said they used needles as part of their job. The findings are published in the RCN's Needlestick Injury in 2008 report, which is being presented in the House of Commons.

The RCN's chief executive and general secretary, Dr Peter Carter said: "It is clear that needle injuries are an everyday threat for nurses up and down the country.

"With potentially lethal consequences, being stuck by a needle can be a very traumatic experience, yet too many employers in the NHS fail to provide the necessary support to nurses. It is therefore no surprise that over half of nurses are working in fear of being stuck and injured by a needle.

"Government and employers in the NHS need to start taking this issue seriously by introducing needle policies and investing in safer alternatives to traditional needles so that these accidents don't happen in the first place.

"Nurses should also receive full support from their employers when they sustain an injury because no-one wants to feel isolated and alone when going through such trauma. We look forward to working with the Government, regulators and employers to solve this widespread problem."

New hepatitis B guidelines affect some students

<http://media.www.ntdaily.com/>

Kerry Solan

CDC defines higher-risk category

The new guidelines for hepatitis B testing will extend to some NT students.

The Centers for Disease Control and Prevention issued new guidelines for hepatitis B for those now categorized in a larger risk category.

This includes individuals born in Asia, Africa and other geographic regions with 2 percent or higher prevalence of chronic hepatitis B virus infections.

The category also extends to men who have sex with men, injection drug users, those with unexplained abnormal liver function tests and persons who require immunosuppressive therapy, such as chemotherapy.

With NT's international student population, which makes up about 6 percent of all students, the likelihood of confirmed hepatitis B cases, a liver disease caused by the virus, is not likely, according to the Health and Wellness Center.

"Testing isn't required because of circumstances," said Dr. Herschel Voorhees, medical director at the Center. "It would require more contact with a patient."

Overall, college students may be at higher risk for hepatitis B because living in close quarters like a dorm may increase the risk of exposure.

Students may travel abroad to areas where the disease is common, said Soraya Fletcher, a Denton-area nurse practitioner who specializes in gastroenterology.

"It can be dangerous because you can live out your day-to-day lifestyle, and there's often no symptoms because the immune system can suppress those signs," Fletcher said.

For now, no change is necessary at the Health and Wellness Center under the new guidelines.

"We look at it from a clinical staff group and see how that will affect the way we practice and if it's applicable to what we do for students," Voorhees said. "We're inundated with guidelines, so we take our cue from other organizations, such as the American Medical Association."

Most NT students will have had the hepatitis B series of vaccinations if they adhered to a normal vaccine schedule, which is now part of the standard immunization series for infants. The vaccine is more than 90 percent effective.

"It's very effective," said Voorhees, who also said the clinical staff will perform blood tests if there is a high risk for exposure.

Hepatitis B is extremely common worldwide, though it is limited to about 2 percent in Europe and the United States.

It ranges in severity from a mild acute illness lasting a few weeks, to a serious long-term chronic illness that can lead to liver disease or cancer.

The virus can be spread through unprotected sex or sharing items like toothbrushes, razors and dirty tattoo needles. According to the CDC, one of every 20 people in the United States will become infected with hepatitis B virus at some point during their lives.

About 1.25 million Americans already have chronic hepatitis B, and approximately 5,000 people die every year as a result of illness caused by the virus.

Though the guidelines may increase awareness and diagnoses, Voorhees said that by avoiding usual high-risk behaviors, students are not at an increased risk for contracting it.

"Students have to be careful. Try not to engage in risky behavior, regardless of this or any other sexually-transmitted diseases we see," he said.

Man jailed for passing on hepatitis B

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

Gloucester A man who had unprotected sex and knowingly gave a woman potentially life-threatening hepatitis B was jailed for two years.

Ercan Yasar, 29, a Turkish restaurant worker from Cheltenham, Gloucester, knew that he had the disease and had been warned that he should always practise safe sex.

The woman fell ill a week after a one-night stand with him. Detective Constable Paul Day, of Gloucestershire police, said the use of DNA to prove the source of the infection made it the first case of its kind in Britain.

Yasar, who admitted inflicting grievous bodily harm on the woman, faces deportation on his release.

Liver, thyroid cancer rates increasing in Canada: report

<http://www.cbc.ca>

Doctors should consider the possibility of cancer in young people and be particularly vigilant about thyroid and liver cancers, say researchers who reviewed the latest Canadian cancer statistics.

Loraine Marrett of Cancer Care Ontario and her colleagues reviewed the 2008 edition of *Canadian Cancer Statistics*. The results of their review are published in Monday's online issue of the *Canadian Medical Association Journal*.

"Given the rising rates of thyroid cancer in men and women, as well as liver cancer in men, clinicians should be vigilant for these cancers," the researchers said in their recommendations to health care providers.

After standardizing for age, the average incidence of liver cancer increased by 2.7 per cent a year for men between 1995 and 2004. The incidence of thyroid cancer went up by 5.5 per cent a year among men in that time and 10.1 per cent among women, the researchers reported.

The report's authors suggested that although the risk of cancer is low, it is increasing among younger adults.

"It is becoming increasingly important to be vigilant about cancer in women, especially among those aged 20–59 years, as the incidence of breast, cervical, lung and thyroid cancers and melanoma continues to drive cancer rates in this group," the researchers wrote.

"Early detection of cancer through regular screening, along with effective treatment, can help reduce the severity of disease and mortality from cancers such as colorectal, cervical, prostate and breast."

Early detection stressed

Improvements in early diagnosis and treatment have led to declining mortality rates for all cancers combined as well as for certain types of cancer, after accounting for age.

The mortality rate for breast cancer for example has fallen by more than 25 per cent since 1986, likely the result of a combination of more mammography screenings and the use of better therapies after surgery, the researchers said.

The authors of the study also called on doctors to promote healthy lifestyles and recommended cancer screenings.

The change in the incidence rate of thyroid cancer is probably largely due to better detection of small cancers. Survival for thyroid cancer is excellent, the team said, likely because treatments are highly effective when it is detected early.

Thyroid cancer is one of the few cancers that occurs more frequently in women than in men, at a ratio of nearly four to one, the researchers said. It is also one of the most common cancers in young women, ranking second after breast cancer in women age 20 to 49.

The relatively low but increasing rates of liver cancer and mortality for that type of cancer, particularly among men, are likely related to the prevalence of hepatitis B and C infections, the researchers said.

"This may, in part, be because of changing patterns of immigration, whereby an increasing proportion of the population was born in countries where hepatitis B is endemic or where exposure to liver toxins, such as aflatoxin, are common," the study's authors wrote.

In Europe and the United States, it is estimated that about 22 per cent of primary liver cancers are attributable to hepatitis B infection and 60 per cent to hepatitis C infection, the researchers said. Alcohol-related cirrhosis and obesity accounted for other cases.

Clinicians also need to be aware of the late appearance of side-effects from treatment, second and recurrent cancers and issues related to surviving cancer, given that nearly three per cent of Canadians have received a cancer diagnosis in the last 15 years, the study's authors said.

How YOU Can Help Save A Hero

<http://www.wtkr.com>

"They don't come any better than that." Smithfield Police Chief Mark Marshall is talking about his friend and co-worker for 25 years, Lt. Kurt Beach.

"A man of the highest caliber a man that's committed to his family, his country and most especially to his community," Chief Marshall said.

Lt. Beach is also a man who's dying of Hepatitis C, a disease he contracted while trying to save a baby's life on the job back in 1988.

"I couldn't get breaths into her, so the only thing I could think to do was to clear the airway," Lt. Beach said. "So, I did what I thought I needed to do which was suck out the mucus and blood that was clogging her up."

Because of that night the hero, father and husband now needs a liver transplant to survive. But, for years he didn't even know he was slowly dying. In fact, he didn't find out until he was trying to donate blood seven years after being infected.

"It was actually discovered accidentally. It wasn't because he was feeling bad or had any symptoms. He was feeling great," Chief Marshall said.

The Smithfield Lt's lack of symptoms turned out to be a bad thing, because when he finally found out he'd contracted the disease on the job and tried to file a worker's compensation claim he was denied.

"I couldn't understand the reasoning," Lt. Beach said.

So, he appealed, again and again and was shut down by The Virginia Worker's Compensation Commission every time.

"We often see results that we wish didn't with workers compensation laws," Judd Mendelson, a worker's compensation lawyer said.

Mendelson and his law partner Ira Steingold didn't represent the Lt., but agreed to explain why he lost his fight.

"You have two years from the date that you're diagnosed with the occupational disease or five years from the last exposure or whichever occurs first," Mendelson said.

In short, the Lt's years of good health cost him compensation.

"He didn't know. He wasn't tested. He didn't have any reason to believe he'd contracted something that was deadly," Chief Marshall said.

That's why the chief and his town fought on behalf of the Lt. in the case, actually disagreeing with the insurance company to try and get Lt. Beach coverage, but got no where.

So, the Lt. and his wife were stuck.

"The insurance companies had denied it because there was a workers compensation claim involved, so those bills were stacking up, so it was rough for us," Lt. Beach said.

Prescriptions, treatments and more had to be paid by a hero who risked his life to save someone else; all because he missed a deadline.

"I believe in my heart of hearts that that law should be changed," Lt. Beach said.

Mr. Mendelson also admits the law has its faults.

"Sometimes some very good people lose out because of how it's written," Mendelson said.

That's why the chief believes lawmakers need to take action!

"That time requirement is not fair. It's not just," Chief Marshall said. "The law needs to be changed."

Lt. Beach is hoping for the same thing, but says even if the law remained the same, he'd risk his life all over again.

"I wouldn't hesitate," Lt. Beach said.

If you want to show your support for Lt. Kurt Beach, give your local Delegate a call! To find a Delegate in your area, [CLICK HERE](#).

Phynova to work with Norgine on potential liver disease drugs

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

Botanical drug developer Phynova has signed an agreement with pan-European pharma company Norgine that will allow Norgine access to some of Phynova's drug candidates.

Under the terms of the agreement Norgine will assess some of Phynova's candidates to measure their potential effectiveness in treating liver disease.

Dr Tony Mills, Phynova's chief executive described Norgine's interest in Phynova's drug candidates as very encouraging. He added that the agreement represented an important step in the commercial validation of the company's approach to botanical drug development.

The two companies could work together again in the future if this first collaborative phase is successful.

Elsewhere, Phynova has got the green light for a European patent with a notice of allowance covering its lead drug candidate **PYN17**, for symptomatic relief in chronic hepatitis C. A notice of allowance is a written notification that a patent application has cleared an internal review and is nearing issuance.

Nov 19, 2008

Working in health care can be risky, study hints

www.reuters.com

By Anne Harding

NEW YORK (Reuters Health) - A new study from the Centers for Disease Control and Prevention shows that health care workers are more likely to die from bloodborne infections and related illnesses than people working in other occupations.

"There is evidence that over the past 20 to 25 years health care workers have been more likely to die of these kinds of infections than other workers are," Dr. Sara E. Luckhaupt of the CDC's National Institute for Occupational Safety and Health (NIOSH) in Cincinnati told Reuters Health.

"What we can't say is how much of this is occupational exposure and how much is non-occupational exposure, so it's important to think about both," she added. Past investigations have suggested that most of these infections were not contracted on the job.

Needlesticks and other accidents on the job expose nurses, doctors and other health care workers to infection with HIV (the virus that causes AIDS), hepatitis B, and hepatitis C, Luckhaupt and her NIOSH colleague Dr. Geoffrey M. Calvert note in a report in the *American Journal of Industrial Medicine*.

The researchers had previously found that male health care workers are at increased risk of HIV and viral hepatitis. They conducted the current study to examine whether death from these infections is also higher among workers in the field.

Luckhaupt and Calvert looked at data from the National Occupational Mortality Surveillance system for 1984 to 2004 on 248,550 deaths from HIV, hepatitis B, hepatitis C, and liver cancer and cirrhosis, both of which can be consequences of viral hepatitis.

For men, they found, working in health care more than doubled the likelihood of dying from HIV, while it nearly doubled mortality from hepatitis B. Deaths due to hepatitis C and cirrhosis were also somewhat more likely among men who worked in health care. But for women, only death from hepatitis C was more frequent in health care workers.

Based on occupation, male nurses were at the highest risk of HIV and hepatitis B mortality, while female nurses were actually 31 percent less likely to die of HIV than women working outside the health care industry.

"The greatest limitation to our study was that information was not available on possible confounding factors such as sexual risk behaviors, history of blood transfusions, intravenous drug use, and alcohol use," the researchers write. However, they add, past studies suggest that most bloodborne infections among health care workers are not job-related. Work in the health care industry could be a stand-in for other risk factors, they suggest.

"Research is needed to understand why, despite their probably high degree of knowledge about the transmission of HIV and hepatitis, male health-care workers still engage in these risk behaviors," Luckhaupt and Calvert write. "Targeted interventions to decrease the risk of bloodborne pathogens among health-care workers may need to be gender-specific."

SOURCE: American Journal of Industrial Medicine, November 2008.

Liver Transplantation for Hepatocellular Cancer in Whites, Asians Nearing Parity

www.medscape.com

NEW YORK (Reuters Health) Nov 07 - In recent years, the disparity in liver transplantation rates for hepatocellular carcinoma (HCC) favoring whites over Asians has decreased to near parity, at least in California, according to a report in the October 15th issue of Cancer.

Dr. Anthony S. Robbins from the California Cancer Registry, Sacramento, and colleagues examined whether differences in liver transplantation rates between whites and Asian/Pacific Islanders (APIs) with HCC were changing over time.

A preliminary study in 2002 showed that whites were 1.5 times more likely than APIs to undergo liver transplantation in the prior 4 years, the authors explain.

During the current study period running from 1998 to 2005, they found that transplantation rates were higher for whites (19.8%) than for APIs (14.1%).

The odds of undergoing transplantation were 2.56 times higher for whites than for APIs between 1998 and 2003, the researchers note, but in the last 2 years studied, there were no significant racial differences in the odds of transplantation.

Five-year survival rates were higher for patients who underwent liver transplantation (68.2%) than for those who did not (23.4%).

In 2002, the investigators say, the Unified Network for Organ Sharing (UNOS) started assigning additional Model of End-stage Liver Disease (MELD) points to patients with HCC awaiting liver transplantation. "Our analyses may be among the first to document the particularly favorable outcomes observed among APIs after the implementation of these policy changes," they write.

"The UNOS policy changes have provided a rational means for increasing liver transplantations among groups with historically lower use of this life-saving treatment," the authors conclude.

Cancer 2008;113:2173-2179.

Nov 20, 2008

Policy has changed how organs are allocated

www.reuters.com

NEW YORK (Reuters Health) - An organ allocation policy that puts the sickest patients first in line to receive available donor livers for transplantation has created some unintended consequences for those patients low on the organ wait list, research suggests.

Since the new donor organ allocation system was implemented in early 2002, there has been a shift toward using poorer quality organs in patients least in need of a transplant, the University of Michigan, Ann Arbor-based research team has found.

This has reduced post-transplant survival in recent years among these patients.

"What's striking," Dr. Michael L. Volk noted in a university-issued press statement, is that these patients typically have a low risk of dying before the transplant, "and ultimately derive limited benefit, in terms of survival, from liver transplantation. In some cases, these patients may actually be harmed by a transplant, even with an organ of average quality."

The allocation system is dubbed MELD, for Model for End-Stage Liver Disease (MELD).

Although priority for liver transplantation is determined by the MELD score - a formula that uses several factors to gauge the risk of death from liver disease - the quality of organs used and the patients to whom they are given is subject to physician discretion, Volk and colleagues explain in a report in the journal *Gastroenterology*.

Volk and colleagues set out to determine whether implementation of the new MELD system has affected the quality of organs transplanted, the type of patients that receive the higher-risk organs, and the impact of these changes on post-transplant survival.

To accomplish this, they analyzed data from the United Network for Organ Sharing (UNOS) for adults who underwent a deceased donor liver transplant between January 1, 1997 and August 1, 2007.

The team found that the overall quality of transplanted livers has gotten worse since the implementation of the MELD-based priority system.

"This was accompanied by a shift from using the higher-risk organs in the more urgent patients (in the pre-MELD era) to using the higher-risk organs in the less urgent patients (in the post-MELD era)," according to the investigators.

As a result, post-transplant survival has worsened over time in patients least in need of a transplant

"The most striking finding of this study was the complete reversal from the pre- to post-MELD eras in which organs were deemed acceptable for use in which patients," the investigators write. "This demonstrates how strongly changes in national policy can affect individual medical decisions."

Despite the physician being the one to make the final call on an available donor organ, Volk thinks transplant patients should be informed about the quality of a potential donor organ. They also need to have an understanding of the transplant process and the MELD system.

"Few would dispute that patients have the right to know the quality of organ they receive, but it's unclear how much patients are truly informed," Volk said. "This is a complex subject, and physicians say that they find it difficult to communicate all the various risks without scaring the patient."

Although Volk and his colleagues do not advocate for changing the MELD system, they do recommend increased patient involvement in decisions about organ quality; better education of doctors about the harm caused by allocating high-risk organs to less sick patients; and changes in the reimbursement system so that managing and transplanting sicker patients are reimbursed at higher rates to remove any incentive to transplant the more stable patients with lower quality organs.

SOURCE: Gastroenterology, November 2008.

Cigarette Smoking, Hepatitis C Virus Synergistic in Raising Liver Cancer Risk

www.medscape.com

NEW YORK (Reuters Health) Nov 19 - There appears to be a synergistic link between smoking and hepatitis C virus (HCV) infection, leading to a more than 136-fold increased risk of hepatocellular carcinoma (HCC) in men, according to a team at The University of Texas MD Anderson Cancer Center.

Dr. Manal M. Hassan and colleagues in Houston also found a link between HCV, heavy alcohol consumption and HCC in women.

Dr. Hassan's team conducted a case-control study of 319 HCC patients and 1,061 healthy controls to evaluate the effects of active and passive smoking on risk factors for HCC in men and women.

The use of smokeless tobacco, cigars and pipes, and passive smoking exposure were not related to HCC among noncigarette smokers.

However, regular cigarette smoking was associated with HCC in men, with an adjusted odds ratio (AOR) of 1.9. Heavy alcohol consumption was associated with HCC in women, with an AOR of 7.7.

Co-infection with HCV increased risk of HCC exponentially. "Cigarette smoking interacted synergistically with chronic infection of hepatitis C virus in men," Dr. Hassan's team reports in the October 15 *International Journal of Cancer*. They found an AOR of 136.3 for HCC for male smokers with HCV infection.

Women chronically infected with HCV who were heavy drinkers had an AOR of 13.7 for HCC.

"We conclude that sex differences were observed in HCC's relationship with cigarette smoking and alcohol consumption," the authors write. "Controlling smoking exposure might be a prudent approach to the prevention of HCC, especially in patients with chronic viral hepatitis infections."

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Safe injection may save system \$14-million

<http://www.theglobeandmail.com>

Carly Weeks

Vancouver's safe-injection site will save the health-care system at least \$14-million and prevent more than 1,000 HIV infections over a 10-year period, according to a new study about the controversial program.

The study, published today in the *Canadian Medical Association Journal*, is the latest piece of research to suggest the potential social benefit of Insite in helping curb substance abuse, and reducing the spread of hepatitis C, HIV and other infectious diseases.

"We were a bit surprised. The model really suggests that there are very considerable benefits," said Ahmed Bayoumi, lead author and scientist at the Centre for Research on Inner City Health in Toronto. .

Vancouver's drug scene is considered to be worsening, and many government and non-profit programs aim to curb the problems associated with it. Yesterday, the federal government announced \$200,000 in new funding to help Vancouver's Drug Treatment Court, which uses treatment programs to help drug users charged with crimes to stop using illicit substances.

But the safe-injection site, where drug users are given clean needles in order to reduce needle sharing and subsequent spread of disease, has been riddled with controversy since it opened in

2003. Critics of the program say that it enables drug use and that there is no credible proof it helps curb drug addiction or the spread of infectious diseases.

The federal government is in the process of appealing a decision by a B.C. court this year that allowed Insite to remain open. The court had ruled that it would violate a drug user's Charter rights to be denied access to Insite's health-care services.

But a growing amount of scientific evidence indicates the program helps reduce public disorder, overdoses and disease as well as providing users with an avenue for treatment. The World Health Organization has also endorsed the site.

In the analysis, researchers used sophisticated computer models to try to forecast what effect Insite would have in Vancouver over a 10-year period. They also used a model to determine what would happen if Insite didn't exist.

The models were created using current data in a range of categories, such as the number of people with HIV and hepatitis C, the number of drug users, and the number users seeking treatment in Vancouver. If Vancouver-specific data were unavailable, researchers used information from medical literature, giving particular emphasis to North American studies.

"We put all of those things together in a fairly sophisticated computer model," Dr. Bayoumi said.

They found that Insite has the potential to save \$14-million in health-care dollars and 920 life years over the next decade, while averting 1,191 cases of HIV and 54 cases of hepatitis C.

Those savings were calculated by taking into account how much the decreased incidence of needle sharing could curb the spread of infectious disease and the associated costs of treatment.

When researchers ran the model again considering the effect of decreased needle sharing, as well as the increased use of safer practices during shared injections such as using bleach to sterilize needles, the savings rose to \$20-million, with 1,070 life years saved.

"I think the most important message is that, compared to other health-care interventions, investing in the supervised injection facility represents very good value for money," Dr. Bayoumi said. "Even though the facility itself has operating costs that are considerable, the potential health benefits and potential savings down the line are considerable and that all has to be taken into account."

It's impossible to predict the future with 100-per-cent accuracy, Dr. Bayoumi said. But the researchers used current information on the population of intravenous drug users in Vancouver, and the rate of disease among that population, to forecast what would happen over a long period of time.

The researchers also ran models in which they changed the data - such as lowering the number of intravenous drug users in the city - to see whether it would have an impact on Insite's estimated benefits.

They found that the safe-injection site remained a viable use of health-care dollars in nearly all circumstances. The only scenario in which the cost of Insite outweighed its benefits was when researchers assumed there was very little needle sharing in Vancouver and low HIV rates in the city.

"The finding that investing in the facility was a good use of health-care resources didn't change," Dr. Bayoumi said. "Only in very extreme circumstances did we start to find it wasn't good value for money."

Dr. Bayoumi's work is supported by an award from the Ontario HIV Treatment Network. Gregory Zaric, second study author and associate professor of epidemiology and biostatistics at the University of Western Ontario's Richard Ivey School of Business, received a grant from the National Institute on Drug Abuse. No other external funding was received for the study and the authors didn't accept any financial compensation for the research.

FDA nixes state appeal to ban multi-dose vials

<http://www.newsday.com>

By Ridgely Ochs and Michael Amon

The head of the U.S. Food and Drug Administration has rejected an appeal from New York State's health commissioner to ban the manufacture of multi-dose vials, saying they are an important option for hospitals.

In January, state Health Commissioner Dr. Richard Daines and New York City's health commissioner, Dr. Thomas Frieden, sent FDA Commissioner Dr. Andrew von Eschenbach a letter calling on the FDA to eliminate the manufacture and distribution of multi-dose vials.

Although there are state and federal guidelines against the practice, reusing syringes in multi-dose vials was the source of at least one hepatitis C transmission by Plainview pain management physician Dr. Harvey Finkelstein. The state health department was criticized last November when it was revealed that because of legal delays and complicated lab tests, it had waited three years before telling the public of Finkelstein's improper practice.

In a letter dated Jan. 18, Daines and Frieden said that despite "numerous guidelines and recommendations," some doctors continue to misuse needles and syringes, leading to contamination of multi-dose vials. Daines said he believed it was better to "engineer out" human error by getting rid of multi-dose vials.

But in a letter dated Oct. 20, von Eschenbach said multi-dose vials "are an important dosage option for hospital pharmacies," are less expensive and require less storage space.

Instead, the commissioner said, the FDA was looking at including warning statements on multi-dose vials and posting instructions on the FDA Web site on the vials' correct use.

Daines said he was frustrated by the FDA's response: "I don't think they understood the problem," which he said was not misuse by hospitals but by individual doctors. "I would like

safety engineered into the product," said Daines, who said he would pursue the matter when a new presidential administration is in place.

Meanwhile, the state can't be sued for the Department of Health's slow response to the Finkelstein case, a Court of Claims judge said in a ruling made public last week. Attorneys for Susan Lewis of North Massapequa, who claimed the department's tardy notification delayed treatment of her hepatitis C, said they will appeal.

Winnipeg patients may have been exposed to tainted blood

<http://www.canada.com>

Winnipeg Free Press

WINNIPEG - Seventeen city residents will be tested for hepatitis C, hepatitis, B and HIV because they may have been exposed to tainted blood.

Winnipeg Regional Health Authority medical officer Dr. Pierre Plourde said Thursday a nurse at Centre de sante in the city's St. Boniface General Hospital reused a finger-stick blood sampling device on patients between May 2007 and October 2008.

The nurse received the device from a pharmaceutical company representative, and did not ask her supervisor if it was safe to use. The device is not approved for use on multiple patients.

Winnipeg Regional Health Authority medical officer Dr. Pierre Plourde said Thursday a nurse at Centre de sante in the city's St. Boniface General Hospital reused a finger-stick blood sampling device on patients between May 2007 and October 2008.

Plourde said the odds that any patient contracted a blood-borne infection is "one in a million."

He said it's unclear whether the nurse will be disciplined.

It's not the first time patients in the West risked exposure to tainted blood through the reuse of medical devices.

Between 2001 and 2002, 33 Winnipeg children with diabetes were tested for hepatitis C and HIV after a lancet was reused at a clinic. The children were learning how to test their own blood. The sharp point on the lancet was not reused, but the device and its cap were.

The practice was stopped when an employee questioned whether it was safe. All the children tested negative for blood-borne infections.

Last month, health officials in northern Alberta said up to 2,700 former patients would be tested for HIV and hepatitis after it was discovered some staff were routinely reusing syringes in intravenous lines.

Some of the incidents involved patients from 18 years ago.

The reused needles had medication vials attached to them that were filled with enough medication to treat several people undergoing endoscopy or dental procedures in a given day.

The syringes weren't placed directly into patients' arms, but into intravenous lines.

When the needle was withdrawn, there was a chance that some blood and contaminated medication could come up the IV line into the syringe, possibly infecting the next patient.

The practice was immediately stopped after a manager at the health centre saw syringes being reused during training of a new employee.

Just days after the Alberta case went public, a doctor who works in both Alberta and Saskatchewan reported he'd also been reusing syringes. Both Alberta and Saskatchewan announced investigations into how widespread the practice might be.

Dr. Gerry Predy, Alberta's acting chief medical officer of health, last month asked his counterparts in other provinces to make certain the practice isn't being followed in their own medical facilities.

Tibotec Begins European Enrollment For Phase 3 Trial Of Telaprevir In HCV Patients Who Failed Prior Treatment

<http://www.medicalnewstoday.com>

Tibotec BVBA today announced that it has begun enrolling patients in its **phase III** study of **telaprevir (VX-950)**, an investigational protease inhibitor (PI), in patients with chronic genotype 1 hepatitis C virus (HCV) for whom the current standard treatment has not been successful. Tibotec is managing the global trial, which is being conducted at more than 50 sites in Europe. In addition, nine presentations on telaprevir were presented recently at the American Association for the Study of Liver Disease's (AASLD) Liver Meeting 2008 in San Francisco, California, 31 October - 4 November, 2008. Tibotec presented interim findings from its exploratory phase II study, VX950-C208, evaluating telaprevir administered every eight hours or every 12 hours, in genotype 1 treatment-naïve HCV patients. Data showed that the majority of patients in four telaprevir-based treatment arms achieved an undetectable viral load by week four and week 12 of treatment. Telaprevir is being co-developed by Vertex Pharmaceuticals, Inc. and Tibotec.(i)

The current standard of care for HCV, pegylated interferon (Peg-IFN) combined with ribavirin (RBV), is effective in thirty to fifty percent of patients with genotype 1 HCV, demonstrating a significant need for new therapeutic approaches.(ii)Currently, there are no effective treatment regimens for patients who have failed standard treatment.(iii) The REALIZE study (Re-treatment of Patients with Telaprevir-based Regimen to Optimize Outcomes), which compares the efficacy, safety, and tolerability of telaprevir combined with Peg-IFN alfa-2a plus RBV, versus Peg-IFN alfa-2a and RBV alone, is the first phase III trial to study a direct antiviral treatment for HCV in patients who do not respond to standard of care therapy.(i)

"The phase III trial will give us essential information about the safety and efficacy of a telaprevir-based regimen in patients who otherwise would have no recourse when standard treatment fails," said Roger Pomerantz, M.D., president of Tibotec Research and Development.

"We also are proud to present phase II data that show a strong therapeutic response in treatment-naïve patients. We look forward to continuing to develop telaprevir and working with health authorities to make it available to patients."

About Telaprevir Phase II Data in Treatment-Naïve Patients

Interim data from Tibotec's exploratory phase II study, VX950-C208, of telaprevir in treatment-naïve patients with HCV genotype 1 were presented recently at AASLD. The ongoing, open-label, randomized study evaluated telaprevir administered every eight hours or every 12 hours in combination with Peg-IFN alfa-2a or -2b and RBV in treatment-naïve patients with genotype 1 HCV.(i) An interim analysis showed that the majority of patients in all four treatment arms achieved an undetectable viral load by week four and week 12.(i)

Week four results(i):

- Sixty-nine percent taking telaprevir 750 mg every eight hours with alfa-2b and RBV
- Eighty percent taking telaprevir 750 mg every eight hours with alfa-2a and RBV
- Sixty-seven percent taking telaprevir 1125 mg every 12 hours with alfa-2b and RBV
- Eighty-three percent taking telaprevir 1125 mg every 12 hours with alfa-2a and RBV

Week 12 results(i):

- Ninety-three percent taking telaprevir 750 mg every eight hours with alfa-2b and RBV
- Ninety-three percent taking telaprevir 750 mg every eight hours with alfa-2a and RBV
- Eighty-five percent taking telaprevir 1125 mg every 12 hours with alfa-2b and RBV
- Eighty-three percent taking telaprevir 1125 mg every 12 hours with alfa-2a and RBV

When the study reached week 12, patients on telaprevir-based therapy received either 12 or 36 additional weeks of Peg-IFN with RBV, depending on the patients' virological response.(i)

Adverse events (AEs) reported in this trial were consistent with those observed in earlier studies.(i) Overall, the incidence of any AE reported in greater than 25 percent of subjects in any group (regardless of severity and causality) was comparable between the four treatment arms.(i) Serious AEs leading to permanent treatment discontinuation were mainly due to rash- and anemia-related events.(i) Rash and anemia events were reversible upon cessation of treatment.(i)

Additionally, recent telaprevir data from studies led by Vertex were also presented at AASLD, including the final results of the PROVE 2 study. PROVE 2 is a phase 2b clinical trial that examined telaprevir in combination with Peg-INF-alfa-2a with or without RBV in treatment-naïve genotype 1 HCV patients at 28 clinical centers throughout Europe.

In addition to the REALIZE trial currently underway, telaprevir is now being studied in treatment-naïve patients in a phase III trial program called ADVANCE, led by Vertex.

About the REALIZE Phase III Study

REALIZE is a randomized, placebo-controlled, double-blind study that will compare the efficacy, safety, and tolerability of two regimens of 750 mg telaprevir every eight hours (with and without a delayed start) combined with Peg-IFN alfa-2a plus RBV, versus Peg-IFN alfa-2a and RBV alone. Six hundred fifty patients with genotype 1 HCV who have failed prior treatment with Peg-INF and RBV are enrolled in REALIZE, which will be conducted over 72 weeks. Patients belong to one of the three following groups:

- Null responders (achieved less than a 2 log reduction in RNA at week 12 of prior therapy)
- Partial responders (achieved at least a 2 log reduction at week 12, but failed to achieve undetectable HCV RNA by week 24 of prior therapy)
- Relapsers (achieved an undetectable HCV RNA at the completion of at least 42 weeks of prior treatment, but relapsed during follow-up)

The primary endpoint is sustained virologic response (SVR), defined as undetectable HCV genotype 1 RNA (<10 IU/mL) 24 weeks after the completion of treatment. SVR is considered a cure for people with HCV.

For additional information on the inclusion and exclusion criteria for this study, please see <http://www.clinicaltrials.gov>.

Tibotec has the right to develop and commercialize telaprevir in Europe, South America, the Middle East, Africa, India, Australia and New Zealand. Vertex will commercialize telaprevir in the U.S., Canada and Mexico.

(i) Phase 2 Study of Telaprevir Administered q8h or q12h with Peginterferon Alfa-2a or Alfa-2b and Ribavirin in Treatment-naïve Subjects with Genotype 1 Hepatitis C: Week 12 Interim Results. Xavier Forns, Patrick Marcellin, Tobias Goesser, Peter Ferenci, Frederik Nevens, Giampiero Carosi, Joost P Drenth, Koen De Backer Rolf van Heeswijk, Tony Vangeneugden, Gaston Picchio, Maria Beumont-Mauviel. AASLD, Oct. 31-Nov. 4, 2008.

(ii) World Health Organization (WHO). Fact sheet No. 164. Revised October 2000. <http://www.who.int/mediacentre/factsheets/fs164/en/>.

(iii) Using Pegylated Interferon and Ribavirin to Treat Patients with Chronic Hepatitis C. American Family Physician. 2005 Aug. Volume 72, Number 4. Raymond P. Ward, M.D., PH.D., Marcelo Kugelmas, M.D.

(iv) Risk factors for hepatitis C recurrence after liver transplantation. J Viral Hepat. 2007 Nov;14 Suppl 1:89-96. Roche B, Samuel D. Assistance Publique-Hopitaux de Paris, Hôpital Paul Brousse, Centre Hépatobiliaire; and INSERM, Unité 785; and Université Paris-Sud, UMR-S 785, Villejuif, France.

Tibotec BVBA

Nov 21, 2008

Ligand Collaborator GlaxoSmithKline Receives FDA Approval for PROMACTA(R)

<http://www.marketwatch.com>

SAN DIEGO, Nov 20, 2008 (BUSINESS WIRE) -- Ligand Pharmaceuticals Incorporated (LGND) announced today that the U.S. Food and Drug Administration (FDA) has granted accelerated approval of GlaxoSmithKline's (GSK) **PROMACTA(R) (eltrombopag)** for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or

splenectomy. PROMACTA is the first oral thrombopoietin (TPO) receptor agonist therapy for the treatment of adult patients with chronic ITP.

Chronic ITP is a disorder marked by increased platelet destruction and/or inadequate platelet production in the blood, which causes an increased risk of bruising and bleeding. PROMACTA has been shown in pre-clinical research and clinical trials to stimulate the proliferation and differentiation of cells in the bone marrow to produce platelets.

"Today marks an important milestone for Ligand as this is the first NDA approval stemming from one of our collaborator programs," said John L. Higgins, President and Chief Executive Officer of Ligand Pharmaceuticals. "We are very pleased with the FDA approval of PROMACTA as it validates Ligand's success contributing to the discovery of novel, innovative therapies, and demonstrates our ability to create valuable financial assets and potential cash flows by entering into collaborations with pharmaceutical companies. I commend GSK for its dedication and commitment to creating a new treatment option for this potentially life-threatening disease."

As a result of the FDA's approval of PROMACTA, Ligand will be entitled to receive a \$2 million milestone payment from GSK. In addition, Ligand will earn tiered royalties in the range of 5%-10% on annual net sales of PROMACTA.

In addition to ITP, GSK reported positive Phase II data in patients with thrombocytopenia associated with hepatitis C and initiated two Phase III trials in patients with hepatitis C in the fourth quarter of 2007. A Phase II study in patients with chemotherapy-induced thrombocytopenia has been completed, a Phase III study is ongoing in chronic liver disease and a Phase I study is ongoing in patients with sarcoma receiving the adriamycin and ifosfamide regimen. GSK also expects an MAA submission for the long-term treatment of ITP by year-end.

About Ligand Pharmaceuticals

Ligand discovers and develops new drugs that address critical unmet medical needs of patients with thrombocytopenia, hepatitis C, hormone-related diseases, osteoporosis, inflammatory diseases and anemia. Ligand's proprietary drug discovery and development programs are based on its leadership position in gene transcription technology.

SOURCE: Ligand Pharmaceuticals Incorporated
www.ligand.com

NHS Tayside's £2.7m to fight Hepatitis C

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

NHS Tayside will spend £2.7 million over the next three years tracking down and treating people with Hepatitis C (writes Marjory Inglis, medical reporter).

Most will be drug addicts who contracted the potentially serious blood-borne infection through sharing contaminated needles.

Without screening many would be unaware they have the virus until they develop chronic liver disease or cancer. The majority of people infected with the virus have no symptoms and do not know they are infected.

Health bosses, meeting in Dundee today, heard there are an estimated 3000 people in Tayside with the condition, but not diagnosed. At the moment an average of 44 people a year are treated, but NHS Tayside plans to step up activity in treating the disease and preventing spread of infection.

Ann Eriksen, NHS Tayside's commissioner for sexual health and blood-borne virus, told members of the health authority's strategic policy and resources committee, that long-term consequences of Hep C are significant.

"The overwhelming majority of people go on to develop chronic liver disease," said Mrs Eriksen. "The Hepatitis C virus is responsible for between a half and three quarters of all liver cancer cases."

The commissioner said the Scottish Government is investing £43 million over three years to tackle Hep C.

NHS Tayside has been allocated £2.7 million and Mrs Eriksen outlined plans to spend the cash on increased screening for the virus and treating more people with the infection.

While not all people with the virus are injecting drug users or have been so in the past, that is where the most significant problem lies. Up to half of injecting and former drug users have the infection, falling to less than 0.4% of the general population.

Mrs Eriksen said treatment will be offered in both the specialist Hep C and drug treatment services. She explained that the drug treatment service offered the best opportunity to "engage" the most-at-risk group — those using drugs — because they are already in contact.

Treatment would be provided by existing staff in the drug treatment service with an additional two nurses. Staff in the treatment service would receive additional training to allow them to carry out a testing programme to identify people with the virus.

Part of the cash will be used to provide injecting equipment and further develop Tayside's needle exchange service, which seeks to reduce harm by ensuring drug addicts have ready access to clean needles and safe disposal of used needles.

Donated organs can give people a new life

<http://www.pasadenastarnews.com>

By Rebecca Kimitch

San Gabriel resident Stanley Gray has had a lot of new starts in his life: getting off drugs, getting out of prison, writing an award-winning screenplay, starting his own business.

But nothing compares to the new start he got one year ago when he was the recipient of a donated liver to replace his own cancer-ridden one.

"This last year has been the happiest year of my life," said the 70-year-old Gray.

The cancer in Gray's liver was a result of cirrhosis, which in turn was a result of the hepatitis C Gray had contracted decades earlier from intravenous drug use.

His battle with cancer began in 2003, when doctors found a tumor on his liver. They removed it, along with one-third of the organ.

The liver is the only internal organ that can fully regenerate itself; two-thirds of the liver can be removed, and it will grow back to its original size. Gray's liver did just that, and for three years he was cancer-free.

But last year, doctors found another spot, and removal was not an option. Once a liver with cirrhosis is operated on, it is difficult to do again, explained Gray's surgeon, Dr. Rick Selby, the director of the University of Southern California's Liver Transplant Program.

A transplant became the only solution.

The liver is the largest organ in the body. It cleans poisons, germs and bacteria from the blood and produces agents to control infection. It also stores vitamins, sugars, fats, and other nutrients.

In cirrhosis, scar tissue replaces healthy tissue, which blocks blood flow and prevents the liver from working normally.

Cirrhosis is the 12th leading cause of death by disease, killing about 26,000 people each year, according to the National Institutes of Health.

More than 19,000 new cases of liver cancer were diagnosed in 2007, an increase of 6,000 compared to the number of cases a decade earlier, according to the American Liver Foundation. The majority of liver cancer can be linked to cirrhosis of the liver. Cirrhosis is a general term for scarring of the organ that can be caused by various liver diseases. The leading causes of cirrhosis in the United States are chronic hepatitis C and alcoholic liver disease, according to the ALF.

Hepatitis C is the No. 1 reason for liver transplantation in the country, according to the ALF.

And the need for liver transplants is on the rise. While the overall incidence of hepatitis C - a common cause of liver disease - is decreasing, doctors are seeing more patients with mature and end-stage liver disease, Dr. Selby said. This is because people who contracted hepatitis C in the 1970s and 1980s from blood banks or drug use, before the disease was well understood, are now aging, Selby said.

So though the number of donors have increased, the need has increased even faster.

Unlike waiting for a kidney transplant, which is a time-based wait list, the liver transplant list is based on how sick a patient is, Selby explained. Cancer patients are moved to the top of the list.

Gray waited three months and in October 2007 he received his new organ.

"It was a success, everything that could go right, did go right," Gray said.

It helped that Gray is in good shape. He plays basketball regularly.

And he has stayed in good shape. Last week Gray ran in the San Gabriel Turkey Trot 5K race.

"I won second place in my age group," he said. "But there were only two people in that category," he added with a chuckle.

In July, Gray also participated in the U.S. Transplant Games, in his native Pittsburgh, Pa. He won gold and silver medals.

Since the transplant, he has also driven a race car, seen a game at Yankee Stadium before it is torn down, and shot a 20-foot jump shot at the legendary street basketball locale Rutgers Park in New York.

"I'm sort of showing off," he admitted. "I mean, I want to show people its worthwhile donating your organs. I want to show people that as an organ recipient, you have a whole new life."

Above all, Gray is spending time with his two grandchildren. To have grandchildren, he said, is the reason people have children.

Many of the cultural blocks to becoming an organ donor have faded, and donating organs is "fairly well accepted," according to Selby. Still, medical advancements have produced more potential uses for donated organs and tissues.

Drugs known as immunosuppressants, which inhibit immune system activity, have helped reduce the body's rejection of transplanted organs and tissues.

Improvements to these drugs have allowed doctors to conduct at least one face transplant, Selby said.

"As immunosuppressants get better, it may stretch the ability for more face transplants or hand transplants; it is not inconceivable that we could talk about replacing appendages through transplants," he said.

Livers and kidneys are the two most common types of organ transplants. About 15,000 kidney transplants are conducted in the United States every year, and about 7,000 livers are transplanted.

Heart, lung and pancreas transplants are less common.

Kidney transplants can last approximately 15 years. Gray's new liver could last the rest of his life.

Gray is on a mission to share with people what being an organ donor means. He is perpetually armed with pocket full of donor cards and a list of facts: 100,000 people are waiting for donated

organs; 18 people die every day for lack of an organ; theoretically one donor can save seven lives and benefit 50 others with his or her kidney, heart, lungs, liver, pancreas, intestines, cornea, skin, bone, and bone marrow.

"Kids don't know these things," he said. "We don't talk about death. We are afraid of death.

"I tell them, 'look, if I was working the pearly gates, and you showed up missing some organs, I am going to move you up to the front of the line.'"

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Excess Body Weight May Be Involved in Course of Hepatitis B

www.medscape.com

NEW YORK (Reuters Health) Nov 20 - A report in the *Journal of Clinical Oncology* suggests a role for excess body weight in the transition from healthy hepatitis B virus (HBV) carrier state to hepatoma and liver-related death.

In the issue published online on October 27 in advance of print, Dr. Ming-Whei Yu, of National Taiwan University, Taipei, and colleagues describe a prospective study in 2903 male HBV surface antigen (HBsAg)-positive government employees enrolled between August 1989 and June 1992.

Over a mean follow-up period of 14.7 years, 134 patients developed hepatocellular carcinoma (HCC). Of 218 deaths that occurred during follow-up, 92 (42.2% of total deaths) were attributable to liver-related disease, with deaths due to HCC in 71 patients and to cirrhosis in 21.

Hazard ratios for incident HCC were 1.48 in overweight men (those with body mass index of 25.0 to 29.9 kg/m) and 1.96 in obese men (at least 30.0 kg/m), compared with normal-weight men. Hazard ratios for liver-related mortality were 1.74 in overweight men and 1.50 in obese men.

Excess body weight was associated with elevated serum levels of ALT and gamma-glutamyltransferase (GGT) and reduced AST:ALT ratios.

In 257 subjects, cirrhosis was detected by ultrasonography during follow-up. According to the article, the risk of cirrhosis increased with increasing quartiles of BMI (p trend = 0.0005). The adjusted odds ratio for cirrhosis was 2.37 among obese HBsAg carriers compared with those of normal weight.

"The association of higher BMI with increased risk of HCC or death resulting from liver disease is independent of diabetes," the authors note. "The spectrum of liver diseases in relation to excess weight among HBsAg carriers extends from simple fatty liver at the most benign end to chronic hepatitis, cirrhosis and HCC at the opposite end."

J Clin Oncol 2008.