

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Editor-in-Chief*

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October 4, 2009

Vital Therapies Initiates Liver Stabilization Trial

www.medicalnewstoday.com

Vital Therapies, Inc. (VTI), announced that the first subject has been enrolled in a pivotal trial of its ELAD human cell-based liver assist system at California Pacific Medical Center (CPMC) in San Francisco. Todd Frederick, MD, Director of Liver Support Services, is the principal investigator for the trial at CPMC.

It is anticipated that up to 20 leading academic liver centers in the United States and Europe will take part in the SILVER (Stabilization In LiVER disease) study. The SILVER protocol allows for enrollment of patients with chronic liver disease who have recently suffered an acute event leading to moderate to severe liver failure, as measured by the Model for End Stage Liver Disease score (MELD). MELD score is widely accepted as an indicator of liver function.

The SILVER Trial is focusing on stabilization of liver disease so patients can either recover with their own liver intact or live long enough for a liver transplant. Liver transplantation is the only therapy proven to affect survival of liver failure patients. However the shortage of donor livers and the high cost of transplantation create a need either to support regeneration of the patient's own liver or to maintain sufficient liver function until a transplant organ becomes available. This study evaluates whether ELAD can provide this support.

More than 120 patients have so far been treated with ELAD in six clinical trials in the United States, United Kingdom and China. An application for approval to market ELAD in China was filed in September 2007 after a pivotal clinical trial in China. This application is under review by China's SFDA.

VTI is also operating a compassionate use program with cost recovery in the United States, United Kingdom and Singapore.

About Vital Therapies, Inc. and ELAD® (Extracorporeal Liver Assist Device)

Vital Therapies, Inc. (VTI) is a privately held, venture backed company, with cell culture facilities in San Diego, California and a wholly owned subsidiary in Beijing, China. VTI is developing the first human liver cell-based Extracorporeal Liver Assist Device (ELAD) to stabilize liver function in patients with severe liver failure. During ELAD therapy the patient's

plasma flows inside hollow fiber cartridges containing the cells, which process toxins and synthesize proteins and metabolites that are key products of normal human liver function. VTI completed a pivotal trial and filed for market approval of ELAD in China in September 2007. ELAD is in investigational clinical trials in the United States and Europe.

ELAD is a United States trademark of Vital Therapies, Inc.

Source: Vital Therapies, Inc

Provectus Initiates Phase 1 Trial of PV-10 for Liver Cancer

www.medicalnews.today

Provectus Pharmaceuticals, Inc. (OTC BB: PVCT), a development-stage oncology and dermatology biopharmaceutical company, has initiated a Phase 1 study of **PV-10** for liver cancer. The study will enroll up to six subjects with cancer metastatic to the liver or with recurrent liver cancer. PV-10 is the company's lead oncology drug candidate that is also currently undergoing Phase 2 study for metastatic melanoma.

The primary objective of the open-label study is to determine the safety and tolerability of a single intralesional injection of PV-10 in patients with cancer of the liver. Additional objectives are to assess the distribution and retention of PV-10 in the injected lesion, tumor response and viability, and plasma pharmacokinetics of PV-10 following intralesional injection. In each of two planned dose cohorts there will be three subjects. Dose escalation will occur following assessment of safety and tolerability in the first cohort. Dr. Paul Goldfarb, M.D., of Sharp Memorial Hospital in San Diego, will be the Principal Investigator for the study, which is expected to begin enrolling subjects within the next several weeks.

Dr. Craig Dees, PhD, CEO of Provectus said, "Patients with liver cancer currently have very little choice and a terrible prognosis if the cancer cannot be fully removed through surgery, as the disease is usually deadly within months. We hope to demonstrate that PV-10, which has shown excellent selectivity for melanoma, will be a viable therapeutic for liver cancer and cancers metastatic to the liver."

Malignant lesions in the liver arising from primary hepatocellular carcinoma (HCC) or metastases from a wide range of cancers represent an ongoing treatment challenge for oncologists. HCC is one of the most common malignancies worldwide, and its incidence is rapidly increasing in the United States. The liver is a common site of metastases from solid tumors, particularly those arising in the gastrointestinal tract. Other tumors, such as lung and breast cancer and melanoma, also readily spread to the liver.

About PV-10

PV-10 is a proprietary, injectable formulation of Rose Bengal, a compound that has been in use for nearly thirty years by ophthalmologists to assess damage to the eye. It has also been used as an intravenous diagnostic to detect ailments of the liver. Rose Bengal has an established safety history, a short half-life in the bloodstream, and is excreted via the liver and kidneys. Provectus has discovered a novel use for Rose Bengal based on the observation that it is selectively toxic to cancer cells via a process called chemoablation whereby cells undergo a form of cell death that

mimics both features of necrosis and apoptosis.

Source: *Provectus Pharmaceuticals, Inc.*

October 5, 2009

Hepatitis C a Silent Killer on the Rise: Regina Physician

<http://www.leaderpost.com>

By Barb Pacholik, *Leader-Post*

While H1N1 dominates the news these days, another virus is quietly growing at a phenomenal rate to become a "silent epidemic," says a Regina physician.

Dr. Didi Emokpare said rates of hepatitis C have risen 114 per cent among Canadian women between 2006 and 2008, and by 76.6 per cent among men -- and it's believed the numbers could be much greater because the disease is highly underdiagnosed.

"This is a very silent, staggering number," said Emokpare, noting there's been very little attention on the potentially deadly hepatitis C virus (HCV). "It's like it doesn't even exist."

Emokpare is urging more screening for HCV, which can go undetected for decades since it may not lead to illness in its early stages. But detection, through a simple blood test, is important because HCV can be treated and cured, he noted.

"If you don't look for it, you won't find it," Emokpare added. Work is underway to establish hepatitis C clinics in Regina and northern Saskatchewan that will screen, treat and monitor the disease.

Emokpare was speaking in Regina Saturday to those gathered for "The Changing Face of AIDS" conference organized by AIDS Programs South Saskatchewan. Emokpare is executive director of The Lazarus Foundation, a non-profit organization working towards prevention and eradication of HIV/AIDS and its related disease conditions.

Five to 10 years ago, tuberculosis used to be one of the key killers of those infected with HIV; today, they're likely to die of hepatitis C, said Emokpare.

In its later stages, hepatitis C, which is carried in the blood, can lead to liver cirrhosis and cancer.

"This is the new thing that's guaranteed to kill you (those who have HIV/AIDS)," said Emokpare, adding about 30 per cent of the people with HIV are also infected with HCV.

There are about 170 million people infected with HCV worldwide. In Canada, about 300,000 people, mostly between the ages of 25 and 45, have HCV, with about 8,000 new infections per year.

The doctor suggested rates of hepatitis C now are where HIV was in the 1980s. "This is a big deal."

In Saskatchewan the number of carriers has hovered around 600 for the last few years, but Emokpare suspects the actual numbers are higher. Currently working part-time at the Regina jail, Emokpare was surprised at how few inmates had ever been tested for HCV, even though jail and prison populations generally have higher rates of infection.

In Canada, the highest risk comes from sharing needles and other "drug-using" equipment, such as straws for inhaling cocaine. But Emokpare noted that since many people have HCV and don't know it, so aren't taking precautions, the disease is being spread outside of drug use. One of the other risks for contracting HCV is through tattooing in unsanitary conditions.

Emokpare said that while rates of acute hepatitis C are 5.5 times higher for aboriginal people, they are also more likely to respond to treatment because of genetics.

While 30 per cent of those with the disease will recover completely without intervention, among those who don't, about 70 to 80 per cent will get a chronic infection.

About 1,000 to 2,000 people die annually in Canada from hepatitis C and the number is expected to triple in the next 10 to 20 years, said Emokpare.

Jeff Caballero New Vice-Chair of National Hepatitis Roundtable

<http://www.asianweek.com>

NVHR Executive Committee Aims for First-Ever Specific Viral Hepatitis & Liver Cancer Legislation in U.S. History

Oakland, CA - The National Viral Hepatitis Roundtable (NVHR), a coalition of public, private, and voluntary organizations dedicated to the prevention and reduction of viral hepatitis in the U.S., today announced Mr. Jeffrey Caballero as its new Executive Committee Vice-Chair. Mr. Caballero, executive director of the Association of Asian Pacific Community Health Organizations (AAPCHO), plans to aggressively pursue enactment of the first specific viral hepatitis legislation in this nation's history during his yearlong term.

"I am honored to have been elected as the Vice-Chair of NVHR," said Mr. Caballero. "This group has always represented hepatitis B and C advocates, and these election results are a move towards even greater inclusion, collaboration, and participation by all members of the hepatitis community. Concurrently, the new hepatitis legislation and expanded recognition of May as Hepatitis Awareness Month are tremendous opportunities to improve the way we think about and manage viral hepatitis in the US. "

Since forming in 2003, NVHR has worked to develop, implement and maintain a national strategy to eliminate viral hepatitis in the United States. This fall, hepatitis B and C advocates have collaborated to craft a combined bill that represents a first step towards building strong national plan to address viral hepatitis prevention, identification & referral for care. The bill focuses on increasing awareness, prevention, and getting more people tested to identify the overwhelming proportion of people who are unaware of their hepatitis infection (an estimated 6 million Americans have been infected and two-thirds have yet to be diagnosed).

At the helm of these efforts will be newly elected NVHR Chair, Lorren Sandt, executive director of the Caring Ambassadors Program based in Oregon City, Oregon. Members of the National Roundtable include leaders in viral hepatitis advocacy from the Centers for Disease Control and Prevention, the National Medical Association, the Hepatitis B Foundation, among many others. NVHR and the Centers for Disease Control are cosponsoring an Institute of Medicine (IOM) study on prevention and control of viral hepatitis in the United States. A final report of the study's findings is scheduled to be released by the IOM in December this year.

“The meteoric rise in liver cancer is directly connected to the large number of people living with hepatitis B or hepatitis C,” stressed Ms. Sandt. “I am very encouraged and excited to work with Jeff and the NVHR team to pass the Viral Hepatitis and Liver Cancer Prevention and Control Act of 2009 which is essential in preventing unnecessary liver cancer deaths.”

Mr. Caballero participates on numerous national committees that address issues affecting Asian Americans, Native Hawaiians, and other Pacific Islanders, such as tuberculosis, hepatitis B, diabetes, and cancer. Recently, he was a featured speaker on the topic of health care reform at the 2009 California Hepatitis Alliance meeting and also spoke at the US Department of Health and Human Services Office of Minority Health's 2009 World Hepatitis Day in Washington, DC.

NVHR is a coalition of public, private, and voluntary organizations dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis in the United States. For more information on NVHR, please visit www.nvhr.org.

AAPCHO is a national association representing 27 community health organizations dedicated to promoting advocacy, collaboration and leadership that improves the health status and access of Asian Americans, Native Hawaiians, and other Pacific Islanders in the United States. Since 1987, AAPCHO has advocated for policies and programs that improve the provision of health care services that are community driven, financially affordable, linguistically accessible, and culturally appropriate.

For more information on AAPCHO and its Guiding Principles and Values, please visit www.aapcho.org.

Will You B Here? Raising Hepatitis B Awareness

<http://www.8asians.com>

By Kevin

A year or so ago, we had a post about Hepatitis B and how it disproportionately affects Asian Americans. For those who don't already know, Hep B is a disease that attacks the liver without many noticeable symptoms leading many to dub it as the “silent killer” because those who could be infected rarely get tested for it to be diagnosed. Hep B leads to complications with the liver, in forms of liver cancer and liver failure, and could very much lead to death.

Hepb.org claims that over 12 million people in the United States have Hepatitis B and that it has an infection rate of 100,000 a year. An estimated 2 million people have chronic Hepatitis B in the United States and over half of those are of Asian decent. For that very reason, the B Here Campaign is trying to raise awareness on Hep B and its effects on the Asian American

community. Recruiting many Asian American artists and performers, the B Here Campaign is bringing the likes of David Choi, KevJumba, AJ Rafael, Kaba Modern, Paul Datch and others to UC Irvine, UC Davis, and the University of Houston to the spread the word. The performance and exhibit at UC Irvine will actually be tomorrow night, (they'll visit Houston on the 13th and Davis on the 27th) so make sure you head on out! Visit willyouhere.com for more info.

7 Ways to Manage the Stress of Living with Hepatitis C

<http://www.okspanishnews.com>

Expert Physician Offers Coping Strategies and Much More in New Book Edition Hobart, NY –

According to *Science Daily*, three percent of the world's population has been diagnosed with hepatitis C. Very few people with the disease are able to improve their health without medical attention, and such treatment can be both emotionally and physically draining. Add the lack of social understanding of the disease, along with the major financial commitment for treatment, and you have a recipe for legitimate distress.

Leading hepatologist Gregory T. Everson, M.D., explains in the fifth edition of his bestselling book *Living with Hepatitis C*, "Life-challenging illnesses, like hepatitis C, present opportunities for rethinking priorities. We may not always be able to cure the disease, but we can improve the quality of our lives."

Here, Dr. Everson lists seven ways to better cope with hepatitis C (note that specific recommendations regarding diet, nutrition, and exercise may vary and should be evaluated and discussed with your physician):

- Make changes gradually. Adapt an open and curious attitude when exploring areas of coping, and don't try them all at once.
- Put together your medical team with care. Many doctors don't have much experience with hepatitis C, so find a gastroenterologist or hepatologist who does. If you need a mental health professional, make sure they have experience in dealing with issues of chronic illness. Get names from friends you trust and interview a few practitioners.
- Keep abreast of developments in hepatitis research. The more you know, the better your decisions will be. *Living with Hepatitis C*, Fifth Edition offers a "Resources" section in the back of the book.
- Find a support system. Most of us benefit from a network of informal supportive relationships. Formal support groups are useful as well, because they provide a common experience for hepatitis C patients, information-sharing, a sense of not being alone, and a safe place to share feelings.
- Take care of yourself with exercise and good nutrition. Physical movement not only strengthens your body, it helps your emotional state. A normal, healthy diet contains the amounts of essential nutrients and calories you need to prevent either a nutritional deficiency or excess.
- Explore your creative and spiritual sides. Using the mind's capacity for healing includes visualization, relaxation, guided imagery, meditation, journal writing, and creative arts. Help your mind create a quieter atmosphere to improve your quality of life.
- Look at your own beliefs and attitudes about illness. Otherwise, you can't decide what works for you and what doesn't. We don't choose to be sick, but we can choose how we try to

handle the situation.

Living with Hepatitis C, Fifth Edition also includes an overview of the disease; liver facts and liver disease symptoms; tips on taking care of yourself financially; a discussion of co-infection with HIV/AIDS or hepatitis B; and information on research trends and advances in treatment. It is available in paperback and as an e-book wherever books are sold.

About the author:

Gregory T. Everson, M.D., F.A.C.P., one of the country's leading hepatologists, is a Professor of Medicine and Director of Hepatology at the University of Colorado School of Medicine. Dr. Everson is a distinguished Fellow of the American College of Physicians and the American Gastroenterologic Association.

Living with Hepatitis C, Fifth Edition A Survivor's Guide 978-1-57826-305-9, \$15.00, paperback 978-1-57826-350-9, \$9.99, ebook A Hatherleigh Book, Distributed by Random House

October 6, 2009

Expert Panel of Pediatric Liver Specialists Publishes Recommendations for Monitoring and Referral of Children with Chronic Hepatitis B Infections

Improved monitoring for progression of disease in affected children is essential

DOYLESTOWN, PA (October 5, 2009) – An expert panel of nationally recognized pediatric liver specialists convened by the Hepatitis B Foundation is calling for more consistent monitoring and referral of children chronically infected with the hepatitis B virus (HBV). The panel's recommendations for pediatricians and other primary care practitioners stress the need for routine monitoring of children with chronic HBV infections, and timely consultation with a pediatric liver specialist. Their report, published online October 5, 2009 in *Pediatrics*, is the outcome of a meeting hosted on November 11, 2008 at the Foundation's headquarters in Bucks County, PA. "The lack of clear guidance for the care of affected children is a great concern for parents," said Joan Block, RN, BSN, executive director of the Hepatitis B Foundation. To begin to address this gap, the Foundation brought together seven leading pediatric hepatologists for the first-of-its-kind forum, which was facilitated by two thought leaders in hepatitis B research and treatment.

"Because the majority of infants born in the U.S. are now vaccinated against HBV, most pediatricians don't encounter chronic HBV infection very frequently," said lead author Barbara A. Haber, M.D., of the Children's Hospital of Philadelphia. "And often times children at risk, including immigrants from endemic areas, are not screened and remain undiagnosed."

Chronic HBV infection remains a serious health concern in populations who are not vaccinated, or who are exposed prior to being vaccinated. The panel's report discusses the importance of screening children in high-risk groups, such as those born in countries endemic for HBV.

"Most children with chronic HBV infection are asymptomatic, lacking any signs or symptoms of

disease," said Kathleen B. Schwarz, M.D., of Johns Hopkins University School of Medicine, panel member and a co-author of the report. Schwarz stressed, however, that "this is a progressive disease, and children infected chronically with HBV have an increased risk of severe complications as teens or adults, including cirrhosis, and even liver cancer. This is why screening and identification of HBV infection in children is essential."

A challenge facing pediatricians is the lack of clear screening, monitoring and treatment guidelines.

"There are several national and international guidelines available regarding the management of adults with chronic HBV infection," said Brian McMahan, M.D., of the Alaska Native Tribal Health Consortium, panel member and a co-author of the report, "but guidelines for the treatment of children are still evolving, in part because of the limited number of drugs that have been studied in children so far. In the absence of guidelines, the best approach for children is for the primary care physician and a pediatric liver specialist to work in partnership to develop an individualized treatment plan to manage this life-long chronic infection."

"Many children end up at a pediatric liver specialist as a result of parental advocacy," Dr. Haber said. "There needs to be a greater focus on routinely identifying and referring children with chronic HBV."

The panel's report provides recommendations for primary care providers on the initial management of these children, including what tests to conduct to periodically monitor disease progression, and when, based on the test results, a pediatric liver specialist should be consulted. The report includes a flow chart outlining the recommendations, which cover liver function testing, hepatitis B serology and DNA levels, liver ultrasound, alpha-fetoprotein (AFP) testing, and family history. The panel advocates for referral of any child with elevated serum liver enzyme levels, elevated AFP levels, or a family history of liver disease or liver cancer.

"The decision whether or not to treat needs to be evaluated carefully by a pediatrician or specialist familiar with indications for treatment of chronic HBV," Dr. Schwarz said. "The right treatment at the right time can enhance quality and length of life. Inappropriate or unnecessary treatment can result in the emergence of drug-resistant strains of the virus, potentially limiting our treatment options for the future."

Reference

Haber, BA, et al. Recommendations for Screening, Monitoring and Referral of Children with Chronic Hepatitis B in North America: Report of a Workshop. Pediatrics published online Oct 5, 2009. (doi: 10.1542/peds.2009-0567)

About the Hepatitis B Foundation

The Hepatitis B Foundation is the only national nonprofit organization solely dedicated to finding a cure and improving the quality of life for those affected with hepatitis B worldwide through research, education and patient advocacy.

Source: Hepatitis B Foundation

Elevated Lymphotoxin Expression in Liver Leads to Chronic Hepatitis and Causes HCC

www.medicalnewstoday.com

A recent study maps the pathway that leads from infection with Hepatitis B and C virus (HBV and HCV) to chronic hepatitis and liver cancer and proposes a new therapeutic strategy for treating liver diseases with chronic inflammation. The research, published by Cell Press in the October issue of the journal *Cancer Cell*, describes a signaling pathway that can be beneficial during liver regeneration, but can lead to chronic hepatitis and severe liver damage when chronically activated. The research was performed in the Department of Pathology, Institutes of Clinical Pathology and Neuropathology at the University Hospital in Zurich.

HBV and HCV cause chronic hepatitis and can lead to hepatocellular carcinoma (HCC), the most prevalent primary liver cancer in humans. "Although aberrant expression of cytotoxic cytokines is thought to be critically involved in hepatitis-induced liver cancer, the exact mechanisms driving this progression remain elusive," explains senior study author Dr. Mathias Heikenwalder.

The cytokines lymphotoxin (LT) are mainly produced by white blood cells called lymphocytes and play an important role in organ development and control of the immune response. Previous work had shown that, when compared with normal livers, HCV-infected livers exhibit dramatically increased expression of LT. Dr. Heikenwalder's laboratory, in collaboration with the laboratory of Professor Adriano Aguzzi and colleagues investigated a possible causal relationship between aberrant sustained hepatic LT signaling, chronic hepatitis and the development of HCC.

The researchers found that the LT receptor (LT-R) were upregulated in HBV- or HCV-induced hepatitis and HCC and identified both lymphocytes and liver cells called hepatocytes as the main expressing cells. Liver specific expression of LT⁺ and LT⁺ induced chronic liver inflammation and HCC in mice. It was the hepatocytes themselves which were the major LT-responsive liver cells and, importantly, when LT-R signaling was blocked in mice with chronic hepatitis, inflammation was partially attenuated and HCC was prevented.

It appears as if LT-R signaling might be beneficial in some cases and detrimental in others. Previous work has shown that LT- signaling in liver cells supported liver regeneration. However, as is evidenced in this study, there is a causal link between chronic LT⁺R signaling and both chronic hepatitis and HCC development.

Taken together, the findings indicate that sustained LT-R signaling in liver leads to chronic hepatitis-induced HCC. "Our results show that LT signaling is critically involved in the development of chronic hepatitis and subsequent HCC formation and imply that blocking LT-R signaling might become a beneficial therapeutic approach in the context of HBV- or HCV-induced chronic hepatitis and other liver diseases displaying sustained hepatic LT-R signaling," concludes Dr. Heikenwalder.

Source: Cathleen Genova, Cell Press

Nobel Prize-Winning Medical Research Long and Costly

www.reuters.com

By Peter Henderson

SAN FRANCISCO (Reuters) - The Nobel-winning medical science that points the way to a cancer cure was sparked by curiosity, not business sense, a new laureate said on Monday.

Elizabeth Blackburn won the Nobel prize for medicine together with Carol Greider and Jack Szostak for work on the existence and nature of telomerase, an enzyme that helps prevent the fraying of chromosomes and is core to new work on aging and cancer.

Federal research grants made the work possible, and that money is becoming more important as the California public education system which nurtured the science struggles with budget cuts that will probably reduce the wages of Blackburn and her colleagues.

Now a professor of biology and physiology at the University of California, San Francisco, Blackburn's federal grant application had proposed understanding how the ends of the chromosomes worked.

"I was just following my nose," she told a news conference after the announcement of her prize by the Nobel committee in Stockholm. "That would look pretty bad in a business plan," she said, noting that basic research is long and costly.

Blackburn's work in the field dates to the late 1970s, and about three decades later a therapy based on the enzyme is in trials by biotech firms Merck and Geron.

Now the University of California system is chopping salaries and raising the fees that have made it unusually affordable, raising questions over whether Blackburn and her colleagues will face wage cuts for future research.

"Get a Nobel prize, have a pay cut," quipped Blackburn. "It sort of breaks my heart to see it being under attack."

No Quick Profit

Blackburn's San Francisco lab on Monday was filled with fluorescent proteins, cleansing solutions and young scientists asking basic questions that may not cure anything soon, but could be the first step to a drug years away from development.

Her research has federal backing and President Barack Obama last week earmarked \$5 billion from recent stimulus funding for medical research that might not "lend itself to quick profit."

So Blackburn's lab is still full of "crazy" questions, in the words of doctoral student Beth Cimini, 23, who was filling a syringe with a blue liquid. The work is part of a plan to put fluorescent "tags" on a protein and see how it reacts with telomeres, as the ends of the chromosomes are called.

"I went to Liz and said ... 'It might be wacky, but can we try it?'" said Cimini, who added that results suggest her hunch may not be "entirely crazy."

Closer ties between academia and corporations on basic research might provide a way forward in the future.

"The old paradigm needs to be revamped," said Sam Hawgood, dean of the University of California San Francisco School of Medicine, who says star researchers may be able to attract corporate backing even for basic science.

Blackburn may turn to a new source of funding -- herself. Her share of the prize money -- one third of 10 million Swedish crowns (\$1.42 million) -- may go for seed funds for new ideas too small to merit writing a grant, she said.

(Reporting by Peter Henderson; editing by Chris Wilson)

GlobeImmune Announces Late-Breaker Presentation of GI-5005 Treatment Response Data at AASLD 2009 Meeting

<http://www.marketwire.com>

LOUISVILLE, CO--(Marketwire - October 6, 2009) - GlobeImmune Inc. today announced that a late breaking abstract related to GI-5005, its investigational hepatitis C virus (HCV) product candidate, has been accepted for presentation at the 60th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), which will take place Oct. 31 through Nov. 4, 2009, in Boston, Mass.

The abstract, titled "GI-5005 Therapeutic Vaccine Plus PEG-IFN/Ribavirin Improves End of Treatment Response at 48 Weeks Versus PEG-IFN/Ribavirin in Naïve Genotype 1 Chronic HCV Patients," is published online at the AASLD website (www.aasld.org).

At the AASLD meeting, GlobeImmune will present end-of-treatment, 48-week data in interferon-naïve patients from a Phase 2 clinical study investigating the efficacy and safety of GI-5005 plus peg-interferon (peg-IFN) and ribavirin, the current standard of care (SOC), in patients with genotype 1 chronic HCV infection compared to patients receiving only SOC.

Dr. John G. McHutchison, associate director of the Duke Clinical Research Institute at Duke University Medical Center, is the lead author of the abstract that will be presented as part of a late breaking poster session beginning at 8 a.m. EST on Monday, Nov. 2, 2009. The presentation will include complete response rates and ALT data for patients who completed 48 weeks of triple therapy, as well as SOC patients in the control arm of the study.

GI-5005 is a therapeutic vaccine product candidate that contains conserved HCV proteins and is designed to generate HCV specific T-cell responses in both the pre-clinical and clinical setting.

About GlobeImmune

GlobeImmune Inc. is a private company developing targeted molecular immunogens, Tarmogens, intended for the treatment of cancer and infectious diseases. The company's lead product candidate, GI-5005, is a Tarmogen for the treatment of chronic hepatitis C infection (HCV). GI-5005 is designed to complement both the current standard of care and emerging novel therapies for HCV. The company's lead oncology program, GI-4000, targets cancers

caused by mutated versions of the Ras oncoprotein. GI-4000 is being investigated in clinical trials for the treatment of pancreas cancer as well as other cancers that contain mutated Ras, including non-small cell lung cancer and colorectal cancer.

For additional information, please visit the company's Web site at www.globeimmune.com.

Broward General Nurse Possibly Exposed Patients to Risk

<http://www.miamiherald.com>

By John Dorschner

More than 1,800 patients at Broward General may have been exposed to hepatitis and HIV viruses because of a nurse's misuse of tubing for five years.

Broward General Medical Center administrators announced Monday they are taking immediate action to investigate whether a nurse's misuse of saline bags and tubing exposed more than 1,800 cardiac patients over five years to blood-carried diseases such as hepatitis and HIV viruses.

In a news release issued late Monday, the hospital said the nurse, who was not identified, has resigned and the hospital has reported her to the Board of Nursing.

Hospital managers learned of the problem when someone reported seeing the nurse using the same saline bag and tubing more than once when giving intravenous fluids to patients undergoing chemical cardiac stress tests.

Supervisors are now determining whether the practice put patients at risk for exposure through infections carried by blood. The review is for patients handled by the nurse from January 2004 through early September 2009 -- the length of the nurse's employment at the hospital.

The problem is reminiscent of one earlier this year in which more than 10,000 patients of VA hospitals in Miami, Georgia and Tennessee were told they had been given colonoscopies with equipment that had been improperly cleaned. The cases involved several cases of hepatitis and HIV.

James G. Thaw, chief executive of Broward General in Fort Lauderdale, said in a prepared statement: "This is an individual's unacceptable practice that once discovered was immediately corrected. We at Broward General Medical Center understand that this is alarming and may be frightening but want to assure our patients we will assist in every way possible."

The hospital did not offer an explanation on how an employee could have continued a dangerous practice for five years without being noticed or admonished.

The hospital said it has consulted experts from the Centers for Disease Control and Prevention, the Florida Department of Health and the Broward County Health Department.

Broward General said it has identified 1,851 patients who received cardiac chemical stress tests administered by the nurse, sent them letters by certified mail informing them of the situation and is providing a 24-hour hot line for further questions.

The hospital is urging the patients to get tested for hepatitis B and C and for HIV viruses. LabCorp will do the testing at no cost to the patients.

The hospital noted that patients who had undergone regular stress tests, done on a treadmill, are not affected by the nurse's actions.

Concerned patients were invited to call 800-545-5716.

Miami Herald staff writer Fred Tasker contributed to this article.

Hep C on the Outside: Universal Screening Sought

<http://www.citylimits.org>

City Limits Weekly #703

By Nekoro Gomes

The Hepatitis C virus often shows no signs for decades - and then might destroy your liver. Advocates are sounding the alarm for greater education and testing.

When Betty Vega first learned that she had Hepatitis C eight years ago, she remembers being stunned. Vega, 58, had been aware of having elevated liver enzymes in her blood, but doctors had assured her they came from benign sources. After all, says Vega – a music promoter in Park Slope – there was no apparent cause, with more than 20 years past since any college-era sampling of drugs, a primary risk factor that doctors often say necessitate a test for the disease.

Upon learning of her positive diagnosis after a perceptive doctor suggested she get additional testing, Vega was fearful and confused. “From what I had read [about hepatitis C], I was convinced I was going to die. I thought it was something that had to be much worse than HIV,” she recalls. In fact, a subsequent liver function test would show that Vega was in the second stage of hepatitis C infection, a point at which the liver has become inflamed and mild scarring, or fibrosis, had begun to form.

Vega began to educate herself and after finding a doctor who specializes in hepatitis C treatment, she was able to clear the virus from her body in 2007, six years after first being diagnosed. That positive outcome is “on the rarer side,” she says. According to the Centers for Disease Control, up to 70 percent of people with the virus will contract chronic liver disease, and up to 20 percent will develop cirrhosis.

Today Vega considers herself lucky that the disease was caught at a treatable stage, but her work as a patient advocate and support group facilitator for chronic hepatitis C victims has prompted her to get involved in both the politics and policy surrounding the disease. And, even as she’s getting a new support group going at Long Island College Hospital in downtown Brooklyn, she believes not nearly enough is being done to educate people about the disease. Vega does not appear to be alone in that – this past July, the state’s health department announced the launch of a \$270,000 public awareness campaign that will use billboards, subway and bus shelter advertisements to promote early testing and treatment for the disease. “Over 200,000 New Yorkers have hepatitis C. Are you one of them?” the campaign asks.

The campaign is a continuation of an earlier educational effort for viral hepatitis diseases that was first started in 2004 after many health care providers and hepatitis C advocacy groups called for the addition of a toll-free hotline in both Spanish and English. So far, more than 400 people have called in from throughout the state to get basic information on the disease since the campaign was re-launched in mid-July.

Under the radar

A health bulletin from the Department of Health and Mental Hygiene (DOHMH) released several years ago says that 200,000 to 300,000 New York City residents are infected with the virus and most are currently unaware of their status. The most conservative estimate labels 2.2 percent of the city's [non-homeless, outside-prison] adults infected, higher than the nationwide average of 1.8 percent.

Yet, some advocates say, the amount of funding currently available for hepatitis C education and awareness is not nearly proportional to the number of people at risk of contracting the disease.

Part of the reason that advocates for hepatitis C say education about the disease is needed is because of hepatitis C's elusive nature. Unlike other viral hepatitis strains, there is no vaccine against the disease and it has to be tested for specifically: victims often exhibit no visible symptoms for decades after infection. As a result, there is no way to tell exactly when a person may have become infected or even pinpoint the exact number of infections that exist throughout the city.

And although the sharing of needles with an infected person, most often through intravenous drug use, is thought to be the most common way the disease is contracted in New York City, someone can become infected in any circumstance where they come in contact with an infected person's blood. In fact, among the many task force committees that provide resources for sufferers is one that targets how to control infection among the city's many tattoo and piercing parlors, nail salons and barber shops as well.

According to the latest data on newly reported people in New York City living with chronic hepatitis C, the most common age for new diagnoses is between 50 and 59, which adds another challenge to the city's effort to get people to properly screen themselves for the disease.

"A lot of people who may have done drugs [in the past] have stopped," says Eric Rude, director of the Office of Viral Hepatitis Coordination at DOHMH. "So they're probably not going to be perceived to be at-risk...a general [education] campaign would be appropriate."

Rude says a significant portion of the money the department receives through the state's health budget goes towards public awareness efforts around the need for early screening, in addition to helping to fund several comprehensive hepatitis C treatment centers throughout the city.

In order to reach populations most at risk for contracting and spreading the disease, DOHMH has worked to better coordinate testing and treatment resources through its support of several interconnected task forces made up of providers, local health clinics and support groups that meet several times a year. Rude adds that free testing for hepatitis C is done in many of the city's STD clinics, as well as through community-based organizations that are part of the city's task forces.

Although the \$1.19 million in state funding that went towards hepatitis C programs in New York State for the 2009-10 fiscal year is a reduction from the \$1.58 million allocated the year before, Shari Newman-Foster of the statewide hepatitis C advocacy group, Status C Unknown, says the inclusion of funding is still a hard-won gain for hepatitis C advocates in the state.

“Governor Paterson cut funding for all new programs by 50 percent,” explains Newman-Foster. “But [the state] kept the line item for hepatitis C [programs].” That’s one of several signs she sees of the state taking more action around the disease.

Grassroots efforts

Mireya Delgado, a senior patient care manager with the Latino Organization for Liver Awareness (LOLA), a Bronx-based nonprofit that works primarily with Spanish-speaking clients dealing with chronic hepatitis C, also points to the toll-free hotline in both Spanish and English as an improvement in the state’s efforts.

Delgado says that prior to her nonprofit’s founding in 1994, there was little information on severe liver disease and the effects of chronic hepatitis C in Spanish. The organization also operates its own bilingual hotline.

When City Council restored \$480,000 to a hepatitis C public education campaign, it noted that of the 200,000 to 300,000 New York residents estimated to be infected with hepatitis C, approximately 40 percent are Latino.

Through the grant from the city council, along with matching funds from the state, LOLA was able to use \$750,000 in funding for hepatitis C education for fiscal years 2006-2008.

“Media is very costly,” explains Delgado. “We do a lot of community outreach, presentations at rehab centers, clinics, comprehensive medical centers and health fairs. With the grant we were able to conduct trainings and at one point we were able to train more than 200 trainers who were in turn able to go back to their agencies.”

But while Delgado acknowledges that the type of support needed to do community education for hepatitis C programs can be expensive, she says it pales in comparison to the cost of doing nothing for the largely Latino population she works with, which she says is often unable to access health insurance due to their immigration status.

“We’re seeing cases that are often diagnosed too late and they’re not a candidate for treatment ... much more awareness is needed [for people] who are still not aware and who are walking around with it.”

October 7, 2009

Scientific Paper Supports Micro-Bland Embolization Technique for Liver Cancer with Embozene(TM) Microspheres

www.medicalnewstoday.com

The authors of a newly published paper in the September/October journal Vascular Disease Management conclude that the micro-bland embolization technique possible with

Embozene(TM) Color-Advanced Microspheres leads to better clinical outcomes. Franco Orsi, MD, PhD, and colleagues at the European Institute of Oncology (EIO) in Rome conclude that small, tightly calibrated Embozene(TM) Microspheres are better than other products for the treatment of liver cancer and metastases. The group at EIO has developed a technique to cut off the blood supply deep within the tumor bed of primary and metastatic liver tumors that leads to effective tumor control and reduced recurrence of tumors without the use of chemotherapy drugs. As the authors say, "The dimension and shape of embolic particles seem to be the most important characteristics for this aim."

"We are pleased that Dr. Orsi has pioneered this embolization technique which we call Micro-Bland(TM) embolization made possible due to the unique and very precise calibration of Embozene(TM) Microspheres. We are gratified that he has demonstrated that this technique using CeloNova's Embozene(TM) leads to superior clinical findings in the treatment of liver cancer," said Thomas A. Gordy, President and Chief Executive Officer, CeloNova Biosciences. Embozene(TM) Microspheres, unlike other embolics, are precision shaped and sized so that larger spheres allow the deepest possible penetration of tumors. Patients with liver cancer treated in this new way can experience a longer life and a better quality of life.

"Embolic particles should be size-calibrated with a small bandwidth in diameter variations because during administration, larger particles within the same vial or syringe may occlude micro-vessels more proximally and prevent a deeper penetration of the smaller ones," reports Professor Orsi.

About Embozene(TM) Microspheres

Embozene(TM) Microspheres are the first and only microspheres to be color-enhanced with a different color for each size for increased procedural safety, efficiency, and visibility. They are also available in a wider range of sizes than any other spherical embolic on the market. CeloNova's Embozene(TM) Microspheres consist of a hydrogel core and an exterior shell made from Polyzene®-F, CeloNova's proprietary, anti-inflammatory, and bacterial-resistant polymer. Four design features distinguish Embozene(TM) Microspheres from other spherical embolics: biocompatibility, precise calibration, stable suspension, and structural stability.

About CeloNova BioSciences, Inc.

Headquartered in Newnan, Georgia, CeloNova BioSciences, Inc., is a developer of novel medical devices that are enhanced by one of the Company's proprietary materials, Polyzene®-F, a highly lubricious, anti-thrombotic, anti-inflammatory, and bacterial-resistant making it an ideal surface treatment for implanted medical devices. The Company's current products include Embozene(TM) Color-Advanced Microspheres and the CATANIA(TM) Coronary Stent System with NanoThin Polyzene®-F.

Source: CeloNova BioSciences, Inc

Idera Pharmaceuticals Initiates Phase 1 Clinical Trial of IMO-2125, a TLR9 Agonist, in Combination with Ribavirin for Chronic Hepatitis C Virus Infection

<http://www.businesswire.com>

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today announced that patient treatment has been initiated in a phase 1 clinical trial evaluating **IMO-2125** in combination with ribavirin in treatment-naïve patients with chronic hepatitis C virus (HCV) infection. IMO-2125 is a novel agonist of Toll-like Receptor (TLR) 9.

“We expect that the IMO-2125 trial with ribavirin in treatment-naïve HCV patients and our ongoing IMO-2125 monotherapy trial in HCV patients who failed to respond to previous standard of care therapy will provide us with data in two HCV patient populations on safety, immunological activity, and effect on HCV RNA levels,” said Tim Sullivan, Ph.D., Vice President of Development Programs. “We plan to use the data from these ongoing trials to guide us in further clinical development of IMO-2125 in the treatment of chronic HCV infection.”

About the Trial

The phase 1 randomized, placebo-controlled clinical trial evaluating IMO-2125 in combination with ribavirin is being conducted in treatment-naïve patients with genotype 1 chronic HCV infection. IMO-2125 is administered subcutaneously once a week for four weeks in combination with daily oral administration of standard doses of ribavirin. The target enrollment is 15 patients per cohort, with 12 randomized to receive IMO-2125 plus ribavirin treatment and three randomized to receive placebo plus ribavirin treatment. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 over an escalating range of dosages in combination with standard doses of ribavirin. In addition, the effect of treatment on HCV RNA levels will be monitored. The clinical trial is expected to be conducted at five or more sites in France and Russia.

Upcoming Presentations on IMO-2125 at the 60th Annual Meeting of the American Association for the Study of Liver Diseases

The Company’s two abstracts have been published and can be accessed on the AASLD website. The abstracts are:

- Abstract 1593: “IMO-2125, a TLR9 agonist, induces Th-1 type cytokines and interferons with potent anti-HCV activity in human peripheral blood mononuclear cells and plasmacytoid dendritic cells”
- Abstract 1597: “Gene expression profiles induced by IMO-2125, an agonist of Toll-like receptor 9, in human peripheral blood mononuclear cells”

The posters will be presented on Tuesday, November 3, at 8:00AM ET.

About IMO-2125

IMO-2125 is a novel DNA-based TLR9 agonist being evaluated for the treatment of chronic HCV infection. IMO-2125 was designed to induce endogenous interferon-alpha along with other immune response factors to treat hepatitis C. In preclinical studies, the immune response factors induced by IMO-2125 have potent activity alone and in combination with ribavirin in HCV replicon assays. In addition to the announced trial, IMO-2125 is also being evaluated as a monotherapy in an ongoing phase 1 randomized, placebo-controlled clinical trial for the treatment of patients with chronic HCV infection who have failed to respond to previous standard of care combination therapy of ribavirin and pegylated interferon-alpha.

About the IMO-2125 Monotherapy Trial

In this trial, IMO-2125 is administered subcutaneously once a week with four weeks of treatment. The target enrollment is ten patients per cohort, with eight randomized to receive IMO-2125 treatment and two randomized to receive placebo treatment. The trial is designed to assess the safety and tolerability of IMO-2125 over an escalating range of dose levels and to determine the effect of IMO-2125 on HCV RNA levels and parameters of immune system activation. The trial is being conducted at six U.S. sites.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals develops drug candidates to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants. Our proprietary drug candidates are designed to modulate specific Toll-like Receptors (TLRs), which are a family of immune system receptors that direct immune system responses. Our pioneering DNA and RNA chemistry expertise enables us to create drug candidates for our internal development programs and our partnered programs, and generates opportunities for additional collaborative alliances. For more information, visit www.iderapharma.com.

Greg Dunbar's Story of Tragedy, Moxie, Miracles and Triumph: Part 1

<http://www.willitsnews.com>

By Maureen Moore/TWN Staff Writer

The Dunbar family has been a part of the Willits community for 32 years. Judy works at the Mendocino County jail as an administrative assistant, her youngest son Josh owns AccelaDry Carpet Cleaning in Willits, his son Brent attends Baechtel Grove Middle School. Her eldest son, Eric, is a dentist and lives with wife Alanna and daughters Logan and Shaylee in Lake Almanor. Husband Greg, a contractor, has worked building and remodeling homes through Dunbar Construction. He also plays in rock bands with friends for fun.

Things were going smoothly for the Dunbar family until Greg and Judy were returning home after visiting family in Fresno in May 2007. Greg had been experiencing extreme discomfort in his abdomen, and his belly had started to swell.

When they returned home, they went to the Howard Memorial Hospital emergency room. Doctors ran a magnetic resonance imaging (MRI) test, which ruled out a tumor as the cause of the swelling. Blood tests enabled them to diagnose him with esophageal varices, a problem that occurs when normal blood flow to the liver is blocked, causing blood to back up into smaller, more fragile blood vessels, resulting in the vessels' swelling.

The danger was a vessel could burst, causing life-threatening internal bleeding.

Doctors were able to band some of the vessels, allowing Greg to feel better for the time being.

Greg was suffering from ascites, the accumulation of fluid in parts of the abdomen.

He also was diagnosed with hepatitis C, a disease he had unknowingly contracted more than 40 years ago. During those years, Greg displayed no symptoms of the disease, which now manifested suddenly and definitively as ascites.

The Hepatitis Foundation International notes "a national survey found 1.8 percent of Americans about 3.9 million have been infected with hepatitis C. Most about 2.7 million are chronically infected with the disease, but many show no signs or symptoms.

"Hepatitis C is a slow-progressing disease that may take 10 to 40 years to cause serious liver damage in some people," the HFI says.

For Greg the news was grim; he would need a liver transplant, and that meant being placed on a transplant list and waiting until a liver became available.

The catastrophe insurance the Dunbar family carried at that time only covered emergency room and hospital visits; none of the diagnosis, prescriptions or lab work was covered.

At the beginning of the following month, the Dunbar family tried to get Greg on an additional group policy to help cover his looming medical bills. They were told he could not be accepted until December 2007, an almost six-month wait.

And with Greg's now "pre-existing condition" he would have to wait until July 1, 2008, before the insurance would cover the blood tests, prescriptions, diagnostic tests and other medical expenses.

With no other choice, the family decided to wait and hope for the best.

Though Greg was sick during fall and winter 2007 and spring 2008, he was able to work and function fairly well, although family members noticed deterioration in his overall health.

Greg's health crisis occurred after the June 21 lightning fires ignited the county, filling the air with choking, hot smoke.

Like many area residents, Greg and Judy were filled with concern for the safety of their property, homes and belongings, which were close to the raging fires burning all over Northern California.

Wanting to prepare for the worst, Greg and Judy spent Friday, June 27, frantically cutting weeds and scrapping dirt fire breaks, exhausting themselves in the smoky humid air. Greg continued to look relatively healthy, except for his swollen belly, which made him look nine months pregnant. Judy humorously noted that allowed Greg to get in touch with his "feminine self."

But being a hard worker, Greg overexerted himself, initiating a fast downward spiral in his health. Greg had lain down on the couch in the family's downtown office to recuperate after the exhausting work, and Judy was unable to wake him Saturday morning.

Taken first to Howard Memorial Hospital, Greg was later transferred to Ukiah Valley Medical Center where he spent the night in the intensive care unit.

Judy had meticulously chronicled the results of Greg's lab tests and paperwork in a notebook she carried from hospital to hospital. Because of Judy's medical background, she was able to accurately and quickly relay information, dosages, medicines, results and other information to UVMC doctors, enabling the hospital to quickly and efficiently make necessary decisions they

said saved Greg's life.

The records of Greg's lab test values proved vitally important, forming a large portion of the information doctors used to determine how sick Greg was. They determined Greg could wait for his insurance to kick in on July 1. He would have to wait until then for a required three-day evaluation to become a transplant candidate.

In the meantime, UVMC doctors contacted the California Pacific Medical Center in San Francisco, where the transplant would take place. CPMC's Dr. Maurizio Bonacini told them to bring Greg down to the hospital, even before group insurance was going to become active. He arrived at the center on June 30.

At CPMC, Greg had to undergo a three-day evaluation to determine if he was too sick to be placed on the transplant list. All potential transplant recipients must undergo the evaluation, which includes psychological testing of the recipient and his family. Potential transplant recipients also must demonstrate a determination to stay clean and sober.

In addition, the hospital had to determine if Greg's insurance would cover a reasonable amount of the cost of hospitalization and surgery, and had to examine the family's finances.

However, without insurance coverage, the Dunbars were unable to afford the \$15,000 to \$20,000 evaluation, let alone the transplant surgery and a month-long stay in the hospital, which would have driven the cost up to about \$800,000.

By July 3, doctors decided to tap Greg's belly to relieve increased swelling, removing 11 liters or 24.2 pounds of fluid.

Greg says felt "excellent" after the fluid had been removed, and joked with hospital staff about going home right away. But by early the following morning, Greg had slipped into a coma.

EDITOR'S NOTE: This is part one of a two-part article.

Organ Transplants for Patients with HIV on the Rise

<http://host.madison.com>

By David Wahlberg

Tony Cunning, infected with HIV for at least 20 years, has lived long enough to encounter another serious medical problem: kidney failure.

Now the 48-year-old Milwaukee man is showing how much many doctors consider HIV, the AIDS virus, a chronic disease and no longer a death sentence.

He received a kidney transplant last month at University of Wisconsin Hospital, becoming one of the state's first HIV-positive patients to get a life-saving resource once thought too scarce for them.

"I was a sick puppy," Cunning said last week while recovering at the hospital, where the

transplant made him excited about his future. "The adrenaline has me going."

A nationwide organ donor shortage remains, and more than 6,000 people die while waiting for transplants each year. But antiviral HIV medications, first available in the mid-1990s, are keeping many patients alive for decades.

The average life expectancy after an HIV diagnosis was 23 years in 2005, up from 11 years in 1996, according to a study in September by the Centers for Disease Control and Prevention. Patients who manage their infections well with drugs are expected to live considerably longer, and doctors say they are as deserving of transplants as anyone else.

The immune-suppression drugs that transplant recipients must take to prevent organ rejection were initially considered too risky for patients with HIV because the virus compromises their immune systems. But researchers have found that the drugs don't make well-managed HIV infections any worse.

"Patients with HIV who meet the transplant criteria should be considered for transplant," said Dr. Tony D'Alessandro, liver transplant director at UW Hospital. "The HIV stigma should be melting away."

Study results mixed

UW Hospital performed a liver transplant on another patient with HIV last month. Froedtert Hospital did the state's first transplant on an HIV-positive patient last December; that person received a kidney.

Wisconsin has had just the three cases. Nationwide, more than 500 transplants have been done in patients known to have HIV since 1989, according to the United Network for Organ Sharing, which oversees the country's transplant system. The HIV status of about 13 percent of transplant patients isn't publicly known.

The vast majority of the procedures in patients with HIV have been within the past five years. Almost all involve kidneys and livers. Four hearts, one lung and one pancreas have been placed in HIV-positive patients, according to UNOS.

"We transplant kidneys into people in their 70s with Type 2 diabetes, so why not patients with HIV?" asked Dr. Peter Stock, of the University of California-San Francisco.

Stock heads up the main study of HIV-positive transplant recipients, sponsored by the National Institutes of Health. Up to 275 patients with HIV are undergoing transplants at 20 medical centers around the country and being followed for five years.

Early results show that 94 percent of the HIV-positive kidney recipients were alive three years after their transplants, and the kidneys were still functioning in 83 percent of recipients (some had to go back on dialysis). The figures mirror the outcomes for patients without HIV, Stock said.

Despite having faulty immune systems, the HIV-positive kidney recipients have had more rejection problems with their organs than those without HIV. "It's not the absence of an immune

system; it's the presence of a very disregulated immune system," Stock explained.

HIV-positive liver recipients haven't fared as well as their HIV-negative counterparts, especially those whose liver disease is caused by infection with hepatitis C. Those with hepatitis B, another liver infection, are doing as well, Stock said.

HIV status doesn't affect where a patient is placed on the organ waiting list. To shorten the wait, many patients in the study have agreed to receive "marginal" donor organs - those from high-risk donors, which are frequently turned down by hospitals, doctors or patients, Stock said.

All study patients must be on antiviral HIV drugs, have an undetectable level of HIV and harbor a substantial reserve of immune-boosting T-cells.

Fighting for life

The same requirements apply at UW Hospital, which isn't part of the study, D'Alessandro said.

He said the surgery teams conducting the transplants in Madison took the same "universal precautions" they take during any surgery, such as wearing gloves, washing hands and handling sharp instruments carefully.

The liver transplant patient, who has hepatitis B and has not been identified, is doing well, D'Alessandro said.

Cunning, the kidney recipient, has experienced "delayed graft function," which affects about a quarter of kidney recipients, D'Alessandro said. He has to continue dialysis while waiting for his transplanted kidney to function, a problem that is usually resolved after about two weeks, D'Alessandro said.

Cunning must now follow strict regimens of anti-rejection drugs and antiviral HIV drugs. But he said he is grateful for the transplant after eight years of dialysis.

He contracted HIV, he said, by having unprotected sex with multiple partners, a risk fueled by drug and alcohol use. He suspected he had HIV for a while but delayed testing because of the stigma.

Cunning, a father of two, said he hopes the transplant will allow him to see more of his three grandchildren's football games and other activities.

He's determined to do well, despite the early problem with his transplanted kidney.

"It's going to be a fight," he said. "But there's nothing about this HIV for the last 20 years that hasn't been a challenge."

Transplants by the Numbers

- Patients on the national organ waiting list: 104,065
- Patients on Wisconsin's waiting list: about 1,600
- Transplants last year in U.S.: 27,964
- Transplants last year in Wisconsin: 734

- Patients who died waiting for transplants last year in U.S.: 6,640
- Patients who died waiting last year in Wisconsin: 99
- Patients with HIV who have received transplants in U.S. (through June 30 this year): 506
- Patients with HIV who have had transplants in Wisconsin: 3

Sources: *United Network for Organ Sharing, Donate Life Wisconsin*

October 8, 2009

Q+A: How Do You Know You Have the Flu?

www.reuters.com

By David Morgan

WASHINGTON (Reuters) - Vaccination programs against H1N1 swine flu are under way in the United States, China and Australia and will begin soon in parts of Europe.

As people await their chance for immunization, here are some questions and answers about flu symptoms and what to do if they arrive before the vaccine does.

What Is Influenza and What Are the Symptoms of H1n1 Swine Flu?

Influenza is a virus that infects the nose, throat and lungs. Seasonal flu typically kills 250,000 to 500,000 people globally, mostly the elderly but also very young children, pregnant women and people with chronic diseases.

H1N1 swine flu is a new strain that appeared in March and became pandemic in June. Like seasonal flu, H1N1 is usually mild and requires no medical care. But H1N1 also differs from seasonal flu because it is more likely to infect children and young people than the elderly.

Most H1N1 symptoms are the same as seasonal flu: fever, coughing or sore throat, runny or stuffy nose, headaches, body aches, chills and fatigue. But swine flu also can cause vomiting and diarrhea.

Dozens of other viruses cause similar symptoms but one hallmark of influenza is a sudden onset of symptoms. An illness that develops gradually is likely to be from another virus.

What if Someone Gets Sick?

People who get infected by the H1N1 virus may be contagious as early as one day before they show symptoms.

Because H1N1 is now the overwhelming flu strain circulating globally, health authorities say anyone with influenza should assume it is the swine flu.

Quick flu tests may not detect H1N1 so doctors are advised not to even bother testing people with flu-like symptoms.

The U.S. Centers for Disease Control and Prevention recommends that people with H1N1 stay home from work, school, travel, shopping, social events and public gatherings until at least 24 hours after the fever has disappeared.

Officials also urge the sick to avoid contact with anyone in a high risk group, including pregnant women, children and infants and people with chronic medical conditions including asthma, diabetes or heart disease.

In the meantime, officials recommend frequent hand-washing, covering coughs and sneezes, and in some cases use of face masks to avoid spreading infection.

The main remedies for mild illness are rest and ample fluids such as water, broth, sports drinks or electrolyte beverages made to prevent dehydration in small children.

What if Someone Gets Really Sick?

Medical attention is recommended if the sick person has difficulty breathing or chest pain, appears blue or purple around the lips, vomits and cannot keep liquids down or shows signs of dehydration including dizziness.

The government recommends that people with chronic conditions who come into contact with an H1N1 patient seek treatment with antiviral drugs such as oseltamivir, which Roche AG and Gilead Science sell under the Tamiflu brand name, or zanamivir, an inhaled medicine produced as Relenza by GlaxoSmithKline.

Pregnant women are urged to take special care, as they are always at heightened risk from flu and especially H1N1. More than 100 pregnant women have been admitted to intensive care with H1N1 in the United States this year and 28 have died.

Parents should especially seek treatment for children with flu-like symptoms who cannot be awakened easily, who appear blue or gray, or who become ill again after getting better -- as this last symptom may indicate they have a secondary bacterial infection that can be more serious after a bout of flu.

(Editing by Maggie Fox and Vicki Allen)

Cheryl Brunton Is Public Health Champion 2009

<http://www.scoop.co.nz>

Paying tribute to Dr Brunton at the Public Health Association conference dinner in Dunedin, the president Richard Egan said despite quite personal attacks, including the bullet in the letterbox, she was a courageous advocate of gun control on both a local and national level.

“She used the same determination to bring the issue of hepatitis C to national awareness, and it has driven her work, over the last 20 years, with injecting drug users (IDU) and the needle exchange programme. This is a public health practitioner who takes on unpopular issues and never gives up doing everything she can to improve the health of those affected by them,” Mr Egan told the delegates.

Apart from her role as a Medical Officer of Health for the West Coast and Canterbury, Dr Brunton is also a senior lecturer in public health at the University of Otago in Christchurch.

“Many students, in particular those in the Masters of Public Health programme are indebted to her inspiring, expert guidance and her encouragement as their supervisor and mentor,” Mr Egan said.

Dr Brunton’s work with hepatitis C began when she investigated an outbreak at Christchurch Prison in 1991. This led to an on-going interest in hepatitis C research and advocacy. She helped establish the Auckland and Christchurch Hep C support groups, was instrumental in founding the Christchurch Hepatitis C Resource Centre and was the inaugural chair of its trust board. She also took part in the development of the first national Hepatitis C Action plan.

“She continues to arrange conferences, workshops and training on Hep C, played a part in the establishment of the Hepatitis C community clinic in Christchurch, and is part of its advisory group.

“Stemming from her work in Hep C, Cheryl has also worked with injecting drug user groups and the needle exchange programme for almost 20 years. She helps to conduct national needle exchange serosurveys and has led and encouraged research into blood-borne viruses among IDU. She’s advocated for needle exchange as a public health measure and worked to counter the stigma and discrimination towards Hep C, injecting drug use and needle exchange.”

Dr Brunton’s other recent research interests have included the impact of the reform of prostitution law, influenza in travellers, a survey of vaccine-preventable disease and a hand sanitiser study.

“If this did not make her busy enough, she’s also been an active member of the Public Health Association’s Canterbury branch since it began. She’s made an invaluable contribution to the priorities and aims of the organisation and to public health throughout New Zealand.”

Hepatitis C Tests Turned up Surprises

<http://www.denverpost.com>

By Lauren Lollini

I am one of those patients who was infected with the Hepatitis C virus during a routine surgical procedure at Rose Medical Center because a drug addict was allowed to switch a needle on my surgical tray, a needle filled with saline instead of the pain medication I was prescribed.

Look at my hospital bill and you will see that I paid \$89.25 for that vial of fentanyl — which wasn't fentanyl at all.

Ask people on the street about Hepatitis C and they can't tell you much about the disease. Odd, since Hepatitis C infects millions more people in the United States than does HIV.

But not unlike HIV, many people are infected with Hepatitis C and they do not even know it. Take a look at Rose Medical Center statistics: About 4,700 patients were urged to be tested after possibly coming in contact with Kristen Parker. Seventy of them were found to have Hepatitis C. The Department of Justice said that 35 cases were traced to Parker. That means 35 others who tested positive for the virus were not connected to Parker.

Think about it: About half of the people found to have Hepatitis C because of this case may have had no idea they had the virus.

Hepatitis C accounts for nearly 12,000 deaths each year and can lead to years of debilitating symptoms and costly treatments with harsh side effects.

How do we change these atrocities? How do we ensure patient safety? How do we save thousands of people from having to struggle with this disease and its long-term effects of liver disease, cirrhosis and the need for a transplant and worse?

Something needs to be done. More testing, stricter oversight and procedures, single-use syringes, education and the ability to lift the stigma of the disease. We have to spread the word faster than the virus. We have to educate as we have with HIV and make people aware.

What have we learned from this outbreak and what changes have been made? If Rose Medical Center supposedly had all the policies and procedures in place to keep us safe, how did this happen? How was it so easy for a surgical scrub tech to not only divert drugs but also infect so many unsuspecting surgery patients?

The system was broken and failed not only me, but everyone with whom Kristen Parker came into contact, including fellow hospital employees and several thousand patients.

I wish this were an isolated incident. I wish I could say that with some tightening up of hospital and clinic protocols we can all be safe. Unfortunately, it is not so simple. Over the past 10 years, there have been more than 40 such incidents.

Join the cause by speaking out if you are infected, ask questions if you are unaware, donate so more people can be tested, seek the support you may need from others who understand what you are going through.

For more information, go to www.hepc-connection.org .

Lauren Lollini (lauren@openskywilderness.com) is a licensed therapist in Denver.

Liver Cells Grown from Patients' Skin Cells; Treatment of Liver Diseases Possible

<http://www.sciencedaily.com>

ScienceDaily (Oct. 9, 2009) — Scientists at The Medical College of Wisconsin in Milwaukee have successfully produced liver cells from patients' skin cells opening the possibility of treating a wide range of diseases that affect liver function.

The study, published in the journal *Hepatology*, was led by Stephen A. Duncan, D. Phil., Marcus Professor in Human and Molecular Genetics, and professor of cell biology, neurobiology and anatomy, along with postdoctoral fellow Karim Si-Tayeb, Ph.D., and graduate student Ms. Fallon Noto.

"This is a crucial step forward towards developing therapies that can potentially replace the need for scarce liver transplants, currently the only treatment for most advanced liver disease," says Dr. Duncan.

Liver disease is the fourth leading cause of death among middle aged adults in the United States. Loss of liver function can be caused by several factors, including genetic mutations, infections with hepatitis viruses, by excessive alcohol consumption, or chronic use of some prescription drugs. When liver function goes awry it can result in a wide variety of disorders including diabetes and atherosclerosis and in many cases is fatal.

The Medical College research team generated patient-specific liver cells by first repeating the work of James Thomson and colleagues at University of Wisconsin-Madison who showed that skin cells can be reprogrammed to become cells that resemble embryonic stem cells. They then tricked the skin-derived pluripotent stem cells into forming liver cells by mimicking the normal processes through which liver cells are made during embryonic development. Pluripotent stem cells are so named because of their capacity to develop into any one of the more than 200 cell types in the human body.

At the end of this process, the researchers found that they were able to very easily produce large numbers of relatively pure liver cells in laboratory culture dishes. "We were excited to discover that the liver cells produced from human skin cells were able to perform many of the activities associated with healthy adult liver function and that the cells could be injected into mouse livers where they integrated and were capable of making human liver proteins," says Dr. Duncan.

Several studies have shown that liver cells generated from embryonic stem cells could potentially be used for therapy. However, the possible use of such cells is limited by ethical considerations associated with the generation of embryonic stem cells from preimplantation embryos and the fact that embryonic stem cells do not have the same genetic make-up as the patient.

Although the investigations are still at an early stage the researchers believe that the reprogrammed skin cells could be used to investigate and potentially treat metabolic liver disease. The liver may be particularly suitable for stem-cell based therapies because it has a remarkable capacity to regenerate. It is interesting to note that the regenerative nature of the liver was referenced in the ancient Greek tale of Prometheus. When Prometheus was caught stealing the gift of fire from Zeus, he was punished by having his liver eaten daily by an eagle. This provided the eagle with an everlasting meal because each night the liver of Prometheus would re-grow.

The liver is a central regulator of the body's metabolism and is responsible for controlling sugar and cholesterol levels, secretion of a variety of hormones, production of blood clotting factors, and has an essential role in preventing toxins from damaging other organs in the body.

It is possible that in the future a small piece of skin from a patient with loss of liver function could be used to produce healthy liver cells, replacing the diseased liver with normal tissue.

Recently, the National Institutes of Health's National Institute of Diabetes and Digestive and Kidney Diseases through the American Recovery and Reinvestment Act have provided the

MCW researchers, in collaboration with Markus Grompe, M.D., at the Oregon Health and Science University, a \$1 million research grant to pursue the possibility of using reprogrammed skin cells to study and treat metabolic liver disease. Using this support, as well as donations from individuals throughout Milwaukee, the Medical College researchers are currently producing reprogrammed cells from patients suffering from diabetes, hyperlipidemia, and hypercholesterolemia in an effort to identify new treatments for these diseases.

Journal reference:

Karim Si-Tayeb, Fallon K. Noto, Masato Nagaoka, Jixuan Li, Michele A. Battle, Christine Duris, Paula E. North, Stephen Dalton, Stephen A. Duncan. Highly efficient generation of human hepatocyte-like cells from induced pluripotent stem cells. *Hepatology*, 2009; NA DOI: 10.1002/hep.23354

Adapted from materials provided by Medical College of Wisconsin, via EurekAlert!, a service of AAAS.

Study Isolates Virus in Chronic Fatigue Sufferers

www.reuters.com

By David Morgan

WASHINGTON (Reuters) - A virus linked to prostate cancer also appears to play a role in chronic fatigue syndrome, according to research that could lead to the first drug treatments for a mysterious disorder that affects 17 million people worldwide.

Researchers found the virus, known as XMRV, in the blood of 68 out of 101 chronic fatigue syndrome patients. The same virus showed up in only 8 of 218 healthy people, they reported on Thursday in the journal *Science*.

Judy Mikovits of the Whittemore Peterson Institute in Nevada and colleagues at the National Cancer Institute and the Cleveland Clinic emphasized that the finding only shows a link between the virus and chronic fatigue syndrome, or CFS, and does not prove that the pathogen causes the disorder.

Much more study would be necessary to show a direct link, but Mikovits said the study offers hope that CFS sufferers might gain relief from a cocktail of drugs designed to fight AIDS, cancer and inflammation.

"You can imagine a number of combination therapies that could be quite effective and could at least be used in clinical trials right away," Mikovits said in a telephone interview.

She said AIDS drugs such as reverse transcriptase inhibitors and integrase inhibitors as well as nonsteroidal anti-inflammatory drugs and cancer-fighting proteasome inhibitors could be tested as potential treatments for CFS.

Takeda Pharmaceutical Co Ltd makes a cancer drug called Velcade that is a proteasome inhibitor, although there are no reports that it has been tested against XMRV.

Biochemist Stuart Le Grice of the National Cancer Institute, who also worked on the study, said some AIDS drugs may be ineffective against XMRV because many are tailor-made for HIV.

"But we've learned a lot from HIV, and if XMRV does become a serious issue, we can bring that to bear very quickly," La Grice said.

Incapacitating Fatigue

CFS impairs the immune system and causes incapacitating fatigue, according to the U.S. Centers for Disease Control and Prevention. Sufferers can also experience memory loss, problems with concentration, joint and muscle pain, headaches, tender lymph nodes and sore throats.

Symptoms last at least six months and can be as disabling as multiple sclerosis or rheumatoid arthritis, the CDC said.

But Mikovits said there is currently no treatment for CFS aside from cognitive behavioral therapy to help patients cope with the disorder's crippling effects.

The XMRV virus is a retrovirus, like the HIV virus that causes AIDS. As with all viruses, a retrovirus copies its genetic code into the DNA of its host but uses RNA -- a working form of DNA -- instead of using DNA to do so.

Known formally as xenotropic murine leukemia virus-related virus, XMRV has also been found in some prostate tumors and is also known to cause leukemia and tumors in animals.

Mikovits' team said further research must now determine whether XMRV directly causes CFS, is just a passenger virus in the suppressed immune systems of sufferers or a pathogen that acts in concert with other viruses that have been implicated in the disorder by previous research.

"Conceivably these viruses could be co-factors in pathogenesis, as is the case for HIV-mediated disease, where co-infecting pathogens play an important role," the report said.

Because 3.7 percent of the healthy test population tested positive for XMRV, the researchers said several million otherwise healthy people in the United States could be infected with it.

(Editing by Maggie Fox)

October 9, 2009

MicroRNA Expression Might Predict Outcomes from Liver Cancer Therapy

www.medscape.com

Roxanne Nelson

October 8, 2009 — Micro (mi)RNAs are small noncoding RNA molecules that have been shown to be up- or downregulated in specific cell types and disease states. They regulate the translation of many genes and appear to hold promise as biomarkers for cancer diagnosis and prognosis.

A new analysis shows that the expression status of 1 miRNA, miR-26, is associated with both

survival and response to adjuvant therapy with interferon alfa among patients with hepatocellular carcinoma.

In addition, the analysis, which appears in the October 8 issue of the *New England Journal of Medicine*, showed that the expression patterns of miRNAs in hepatic tissue appear to differ between the sexes in hepatocellular carcinoma.

One of the primary attributes of hepatocellular carcinoma is that it has a higher incidence in men than in women, the study authors note, and women who have the disease tend to live longer. This suggests that there may be sex-specific differences in the biologic features of the tumor and the host microenvironment, and that sex-related factors might be associated with prognosis.

Therapeutic strategies based on modulation of these small molecules hold promise because of their ability to influence cellular behavior, say the authors, headed by Junfang Ji, MD, PhD, a visiting postdoctoral fellow at the Center for Cancer Research at the National Cancer Institute in Bethesda, Maryland.

Expression Lower in Tumor Samples

The researchers analyzed 3 independent patient cohorts (n = 455) in which individuals had undergone radical tumor resection, between 1999 and 2003, for hepatocellular carcinoma. In all 3 cohorts, the majority of patients were male (85.1%), were long-term carriers of hepatitis B virus (90.5%), and had cirrhosis (88.0%). In addition, more than half had an elevated serum level of alpha-fetoprotein (62.2%).

Cohort 1 consisted of 241 patients for whom miRNA microarray data were available, and the researchers were able to analyze miR-26 expression in 224 patients and survival in 217 patients.

Cohorts 2 and 3 consisted of 214 patients drawn from prospective randomized controlled trials of adjuvant therapy with interferon alfa.

In cohort 2, data from 135 patients were evaluated in an independent validation analysis to measure miRNA expression. Evaluation of both miR-26 expression and survival was conducted in 118 patients. In cohort 3, data from 79 patients (40 control subjects and 39 receiving interferon alfa) were assessed to validate the association between miR-26 expression and response to interferon alfa therapy.

To examine differences in expression of miRNAs between the sexes, a global analysis was conducted using samples from patients in cohort 1 in which both tumor and nontumor miRNA microarray data were available.

"We found that the expression of miR-26a and miR-26b in nontumor hepatic tissues was higher in women than in men, but the expression was significantly downregulated in tumor samples, as compared with paired samples of noncancerous tissues, regardless of sex," write the authors.

More Likely to Respond to Adjuvant Therapy

The researchers observed that tumors with reduced miR-26 expression had a distinct gene-expression profile and were biologically distinct from those with high expression. Patients whose tumors had low miR-26 expression had poorer survival, but were more likely to respond to

adjuvant treatment with interferon alfa than patients whose tumors had high miR-26 expression.

In both univariate and multivariate analyses, interferon alfa was associated with significantly improved survival in patients with low miR-26 expression, and the researchers observed a "significant interaction" between miR-26 expression and interferon alfa therapy in regard to its effect on survival (miR-26a, $P = .004$ for interaction; miR-26b, $P = .02$ for interaction). Thus, the authors note, the expression of miR-26 "emerged as an independent predictor of the response to interferon alfa."

There is the "potential promise" of manipulating miRNA expression in cancer therapy, writes Judy Lieberman, MD, PhD, from Harvard Medical School in Boston, Massachusetts, in an accompanying editorial.

"Since miR-26 is expressed by most normal cells, such replacement therapy is unlikely to be toxic to normal cells," writes Dr. Lieberman. "The major obstacle to therapies that are based on RNA interference is delivering these oligonucleotides inside cells. Because of its filtering role, the liver traps and internalizes both small RNA drugs and gene-therapy viruses, making it an ideal testing ground for this new approach to treating cancer."

The study was supported in part by grants from the Intramural Research Program of the Center for Cancer Research of the National Cancer Institute. Coauthor Hui-Chuan Sun, MD, PhD, from Fudan University in Shanghai, China, reports receiving lecture fees from Bayer. None of the other authors have disclosed any relevant financial relationships. Dr. Lieberman reports serving on an advisory board for, receiving consulting fees from, and having an equity interest in Alnylam and Cequent; receiving consulting fees from Baxter; receiving lecture fees from Asuragen, Genentech, Merck, Wyeth, Pfizer, Baxter, and MedImmune; receiving grant support from an alliance between GlaxoSmithKline and the Immune Disease Institute; and holding a patent and being named on patent applications for delivery of small interfering RNA molecules and the treatment of viral infections.

N Engl J Med. 2009;361:1437-1447, 1500-1501.

Medication Effective for Acute Liver Failure in Early Stages of Disease

www.medicalnewstoday.com

The antidote for acute liver failure caused by acetaminophen poisoning also can treat acute liver failure due to most other causes if given before severe injury occurs, UT Southwestern Medical Center researchers and their colleagues at 21 other institutions have found.

Acute liver failure occurs when cells in the liver die quickly, resulting in toxins being released into the bloodstream and brain. Patients often end up in a hepatic coma as a result of toxins not being cleared by the failing liver. Known causes of acute liver failure include autoimmune hepatitis, drug-induced liver injury, hepatitis A and B, and acetaminophen poisoning.

In a study published in the September issue of *Gastroenterology*, researchers found that acute liver failure patients in early stages of hepatic comas, when treated with the medicine N-acetylcysteine (NAC), were nearly 2.5 times more likely to survive than those treated only with a

placebo.

"NAC is safe, easy to administer, doesn't require intensive care and can be given in community hospitals," said Dr. William M. Lee, professor of internal medicine at UT Southwestern and lead author of the study. "NAC is an excellent treatment for non-acetaminophen acute liver failure if the disease is caught early."

Acute liver failure affects about 2,000 people annually in the U.S., and 50 percent of those cases are caused by acetaminophen poisoning. Until this study, liver transplantation was the only treatment if the failure was from non-acetaminophen causes.

To test NAC's use in non-acetaminophen cases, researchers at 22 sites randomly assigned non-acetaminophen acute liver failure patients by the level of their coma, with those with mild to moderate coma in one group, and patients with more severe coma in the other group. Beginning in 1999 and continuing for eight years, 173 patients received either NAC or a placebo for 72 hours. Doctors recorded patient survival three weeks after they were placed on treatment.

Researchers found that 52 percent of acute liver failure patients in mild to moderate comas survived when treated with NAC, compared to just 30 percent of those treated with only a placebo. In patients experiencing more severe coma, treatment with NAC did not result in a significant difference in survival rates.

"That makes sense because patients with advanced comas typically die or get a transplant within a few days," said Dr. Lee, principal investigator of the Acute Liver Failure Study Group, a national consortium of liver centers formed in 1997 to increase research into the rare disease.

"This study establishes NAC as a treatment for non-acetaminophen acute liver failure patients in mild to moderate coma and provides the first glimmer of hope that something can help these direly ill patients," Dr. Lee said.

He said he will continue to study NAC as a therapy for acute liver failure not caused by acetaminophen poisoning to determine optimal dosing and duration.

Other UT Southwestern researchers involved in the study included Dr. Linda Hynan, professor of clinical sciences and psychiatry; Dr. Anne Larson, associate professor of internal medicine; and Dr. Joan Reisch, professor of clinical sciences and family and community medicine. Other Acute Liver Failure Group investigators involved in the study were from the University of California, Davis; the University of Michigan; Virginia Commonwealth University; University of California, San Francisco; Baylor University Medical Center; University of Nebraska; and the National Institute of Diabetes and Digestive and Kidney Diseases.

The study was funded in part by the National Institutes of Health, the Food and Drug Administration, and the Northwestern Medical Foundation. The N-acetylcysteine used was supplied by Apothecon/Geneva Pharmaceuticals, a division of Bristol Myers Squibb and Cumberland Pharmaceuticals.

Visit <http://www.utsouthwestern.org/digestive> to learn more about UT Southwestern's clinical services for digestive disorders and liver disease.

Greg Dunbar's Story of Tragedy, Moxie, Miracles and Triumph: Part 2

<http://www.willitsnews.com>

By Maureen Moore/TWN Staff Writer

Editor's Note: This is the second part of a two-part article:

By July 3, doctors at San Francisco's California Pacific Medical Center decided to tap Greg Dunbar's abdomen to relieve increased swelling caused by Dunbar's failing liver, removing 24.2 pounds of fluid.

Dunbar, who had been diagnosed with hepatitis C, said he felt "excellent" after the fluid had been removed, and joked with hospital staff about going home. But in the early morning hours of July 4, Dunbar slipped into a coma. Hospital staff found him slumped halfway out of his hospital bed.

Dunbar was intubated and taken to CPMC's intensive care unit, where he was treated for a severe electrolyte imbalance, the result of the massive fluid removal from his abdomen the previous day.

Two days later, doctors placed a transjugular intrahepatic portosystemic shunt, or TIPS, in a vein in his liver to permit blood flow to bypass the organ. Although the procedure raised many potential problems, doctors told the family it would buy Greg time until a liver transplant became an option.

Three days after the procedure, Greg was back in the ICU in a coma. He bounced back and forth between his hospital room and the ICU four times between July 1 and July 19 before becoming a permanent ICU patient while doctors waited for his Model for End-Stage Liver Disease (MELD) score to reach a nominal range so his name could be returned to the transplant list.

The MELD score evaluates the ability of patients awaiting transplants to withstand the procedure, and the post-surgery outcome. A score of 25 to 27 will place a patient in the "let's actively look for a liver" category. A patient with a score of 35 is in the "really ready right now" category.

At one point, Greg's MELD score reached 43, and he was taken off the list. Doctors didn't believe he would survive the surgery. Instead, Greg was placed on 24-hour dialysis.

Once he was taken off the list, doctors encouraged the family to say their good-byes and be with Greg during his final moments. Asked if there was anything he wanted, Greg's only response was to hold his wife. Judy and Greg embraced and touched one another for the first time in 28 days.

Awake most of the nights during his ICU, Greg went through a mental inventory of his life and the possibility of his approaching death, finally deciding he was no longer going to struggle with the concept of dying, that he and his family would be okay.

Still on dialysis, Greg's condition unexpectedly began to improve. His potassium levels and other vitals signs were better, and he was returned to the transplant list.

Judy was invited to listen in and become part of the circle of professionals during the presentations doctors would give while making their morning rounds. Six-weeks of being in a hospital environment really enabled her to understand what was being said, she remembers.

True to Dunbar humor and good-heartedness in hard times, the family would joke that Greg's uncontrollable shaking had turned his regular toothbrush into an electric one. At one point Greg had decided to use an electric razor to shave his beard; due to his shakes, he caught an eyebrow, leaving a stylish bare patch that provided everyone a much-needed laugh.

On July 31, doctors told Judy that they were moving Greg from the ICU to a room with a view. The news was tinged with an air of good-hearted mischief, as nurses spent the morning giving Greg a "Spa Day," washing his hair, and giving him a foot bath and a shave.

Greg's surgeon, Dr. Robert Osorio, stopped by to see the Dunbars in their new digs and, smiling, asked if anyone who had told them the news. Greg, Judy and their family members held their breaths as Osorio told them a liver had been found and Greg was scheduled for a midnight transplant.

Phone trees spread the news to concerned family and friends at home and across the state that a very healthy, young male donor had been matched to Greg, and Dunbar would soon undergo transplant surgery.

Surgery was expected to last 10 to 12 hours, but only needed seven. Doctors noted everything went well, and on August 1, Greg woke up with a new liver.

Greg calls August 1 his new birthday, claiming to now be a Leo. He celebrated his first year of good health with a Leo party at Recreation Grove Park, attended by family and friends, who played music, shared stories and celebrated the miracle of the past two years.

The Dunbars expressed their gratitude and appreciation to the teams at all the hospitals, noting a team effort was the keystone of success in Greg's case.

After Dunbar's checkups showed the transplant has been successful, he was asked to join a study, enabling doctors to track the effects of Greg's hepatitis C on his new liver. His blood tests, tissue samples and biopsy samples are submitted to the study to help physicians gain new understanding of the disease.

With his six-month, and one-year biopsies showing him continuing to remain healthy, Dunbar is on his way to returning to a healthy, happy life. He has regained muscle mass and filled back out into an almost more healthy-looking version of himself than before the whole process started.

The Dunbars hope Greg's story will heighten peoples' awareness of what can happen to your liver, not just from the stereotypical consumption of alcohol, but from getting a fatty liver due to a high-fat diet, genetics, and a range of other problems that can go unnoticed until it is too late.

They encourage north county residents to get a checkup and a blood test because many people infected with Hepatitis C remain asymptomatic. The blood test for hepatitis C is expensive, but a CBC blood panel will show if ALT and AST values are elevated. This is often the first clue there is something wrong with the liver.

The Dunbars urge area residents to become informed and be proactive to catch diseases before they spin out of control.

"Allow yourself to have a chance at making a change, and living the rest of your life with family and friends for years to come," the Dunbars say.

Information: the Hepatitis Foundation International website, www.hepfi.org, or speak with your physician.

Doctors and Nurses on Alert for Hep C

<http://www.nursinginpractice.com>

The Department of Health is calling on GPs and practice nurses to be on the alert for the 100,000 patients who don't know they've got hepatitis C as part of a new awareness campaign.

The "Get Tested. Get Treated" campaign will get underway in October with radio and online advertising to remind people of life experiences that could have exposed them to infection.

Evidence suggests around 100,000 individuals in England are unaware that they are infected. GPs and practice nurses are key to identifying patients at risk and encouraging them to be tested and treated.

The campaign encourages doctors to support the campaign by offering information and testing for patients in at risk groups like former injecting drug users and those from South Asian communities who may have been exposed to hepatitis C infection abroad.

Recent research indicates that the number of hepatitis C referrals from GPs and practice nurses to specialists is increasing, but awareness could be improved around the effectiveness of treatment. On average, drug therapy successfully clears the virus in more than half of patients treated, with success rates of around 80% for some strains.

National Director for Primary Care and Medical Adviser, David Colin-Thome said: "GPs and practice nurses play a vital role in the detection and diagnosis of hepatitis C. Around 100,000 people in England are estimated to have long-term hepatitis C but don't know they are infected. It can take years or even decades for symptoms to appear, if at all, and if left untreated can lead to liver damage and premature death.

"Fortunately, effective treatment is available. GPs and practice nurses, as the key clinical carer for their patients, will need to be alert to risk factors and symptoms and ensure they get tested and treated."

Dr Kosh Agarwal, Consultant Hepatologist at King's College Hospital, London, said:

“Increasing awareness of hepatitis C amongst healthcare professionals is leading to more patients being diagnosed and referred for treatment. We need to sustain this progress so that we continue to reduce the level of undiagnosed infection, prevent serious liver disease and also help stop the spread of infection.”

Primary healthcare care professionals are advised to visit www.orderline.dh.gov.uk or call 0300 123 1002 to request printed copies of the literature