

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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June 6, 2009

Infection Control in Ambulatory Surgery Centers

<http://envisioninc.wordpress.com>

- Lisa M. Venegas, Sr. Writer/Producer, Envision, Inc

Nowadays, it seems that infection control is on everyone's minds, and rightly so. Billions of dollars every year are spent caring for patients who acquire infections during the course of the treatment in a hospital. And recently, it has become obvious that ambulatory healthcare settings may have been underappreciated for their roles in spreading infection. Infusion and dialysis clinics are implicated in outbreaks of HIV, Hepatitis B and Hepatitis C, and surgical site infections may be more prevalent than previously appreciated in Ambulatory Surgery Centers (ASCs).

The ambulatory setting has its own unique sets of challenges when it comes to infection prevention due to the way that care is delivered. In contrast to acute settings, patients are held in common areas for longer periods of time, and they are often in procedures or surgery for shorter periods of time. While at first glance it may seem that this would decrease infection rates, this may in fact increase infections in various ways. For example, there are serious concerns regarding the cleanliness of the waiting room, procedure and post-procedure environments as compared to acute settings. In addition, patients are often not identified with infectious diseases prior to admittance, or tracked for infections after their care.

The education of staff regarding the basics of infection control such as proper hand hygiene, appropriate use of medical equipment, and antibiotic resistant organisms is often infrequent or incomplete in the ambulatory setting. The recent media attention given to outbreaks of HIV, HBV and HCV sheds a spotlight on how a lack of awareness for basic safe injection practices related to saline, medications and other infusates can lead to serious consequences for patients who are already terribly ill. Perhaps equally troubling is the fact that because these patients often do not develop infections for weeks, months or even years afterwards it is often difficult to determine how and when the patient acquired the infectious pathogen, and how many more patients will be identified with infection before mitigation measures can be put into place.

The new CMS Conditions for Coverage implemented May 18, 2009 for ASCs should go a long

way in requiring an Infection Prevention and Control professional to oversee the education of clinicians on best practices for preventing and managing infections and communicable diseases, to track infection rates, and to integrate infection prevention with a quality improvement program. After all, these should be the required basics of infection prevention in any healthcare setting.

IVY Clinic to offer free HIV, Hepatitis C tests

<http://www.steubencourier.com>

ARNOT HEALTH

ELMIRA - Area residents can undergo a FREE Rapid HIV test from 10 a.m. - 3 p.m. Friday, June 26 in observance of National HIV Testing Day. Tests are being offered on a walk-in basis at the Arnot Health Ivy Clinic, 600 Ivy Street, Suite 206, Elmira by the Chemung County Health Department, in cooperation with Arnot Health and the Southern Tier AIDS Program.

The Rapid HIV test gives results in 20 minutes with a painless finger stick and is 99.3% accurate. Also available are free syphilis and Hepatitis C screenings, as well as Hepatitis A and B vaccinations. All tests are confidential. Anonymous testing is available for HIV. Refreshments and giveaways will be provided.

National HIV Testing Day is an annual campaign sponsored by the National Association of People with AIDS to encourage at-risk individuals to take advantage of voluntary HIV counseling and testing. The U.S. Centers for Disease Control and Prevention recommends being tested at least once a year if you do things that can transmit HIV infection, including:

- Injecting drugs or steroids with used injection equipment
- Having sex for money or drugs
- Having sex with an HIV-infected person
- Having more than one sex partner since your last HIV test
- Having a sex partner who has had other sex partners since your last HIV test

According to the U.S. Department of Health and Human Services, approximately 250,000 Americans are living with HIV and are not aware of it. HIV counseling and testing enables people with HIV to take steps to protect their own health and that of their family and sexual partners, and helps those who test negative get the information they need to stay uninfected.

Arnot Health provides diagnostic, ambulatory, secondary and tertiary acute care, as well as rehabilitative and wellness services to the Southern Tier of New York and the Northern Tier of Pennsylvania. Arnot Ogden Medical Center is an independent, not-for-profit, 256-bed tertiary medical facility with more than 300 physicians from over 50 specialties.

June 7, 2009

Needle and syringe programs belong in Canadian prisons: report

<http://rabble.ca>

By John Bonnar

Providing access to sterile injecting equipment to prisoners would reduce the risks of harm associated with injection drug use, including the transmission of HIV and hepatitis C virus (HCV), according to a report released Thursday by the Canadian HIV/AIDS Legal Network.

The report said that harm reduction measures aimed at preventing HIV and HCV transmission in prisons are neither new nor groundbreaking in Canada. “Prison systems have implemented, to varying degrees, forms of harm reduction such as condoms, bleach and methadone maintenance treatment,” said the authors.

“However, as of September 2008, no Canadian jurisdiction had established a prison-based needle and syringe program (PNSP), despite significant evidence that PNSPs reduce risk behaviours associated with HIV and HCV transmission, result in other health benefits for prisoners, do not pose health and safety risks to prisoners or prison staff, and do not increase drug use.”

“Implementing needle and syringe programs in federal prisons would ensure that the same access provided to people outside prisons is provided to those in custody,” said Anne Marie DiCenso, Executive Director of Prisoners’ HIV/AIDS Support Action Network (PASAN). “Community groups across the country that are working to make prisons healthier and safer, including by preventing the spread of HIV and HCV, see the on-going need for such programs. The lack of such programs is a major contributing factor to the extremely high rates of HIV and HCV in Canadian prisons.”

Senior Policy Analyst Sandra Chu, the lead author of *Clean Switch: The Case for Prison Needle and Syringe Programs in Canada*, said that PNSPs “have operated successfully in over 60 prisons in at least 11 countries around the world since 1992. Evidence shows no negative consequences such as an increase in drug use or injecting, and no reports of syringes used as weapons in any institution with a PNSP.”

Chu added: “Harm reduction measures aimed at preventing HIV transmission in prisons are not new in Canada and the federal government has acknowledged publicly the value of needle exchange programs that have operated for more than 20 years in communities across Canada. But for some reason it has refused so far to let these services operate in prisons, which is at odds with good public health practice and human rights.”

June 8, 2009

Progenics Provides Update on Hepatitis C Program

<http://www.earthtimes.org>

TARRYTOWN, N.Y. - (Business Wire) Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced the discontinuation of development for PRO 206, a pre-clinical compound for the treatment of hepatitis C virus (HCV) infection. The decision was made as part of a portfolio review, and is in line with the Company’s ongoing initiative to allocate resources to the most important programs in order to increase its operating efficiencies. The Company will instead focus on its second-generation HCV-entry inhibitor portfolio and anticipates selection of a new development candidate in 2010.

“Our research and development team has built a robust platform for HCV drug discovery,” said



Paul J. Maddon, M.D., Ph.D., Founder, Chief Executive Officer and Chief Science Officer, Progenics Pharmaceuticals, Inc. "While our review indicated that PRO 206 did not satisfy the criteria for further development, our ongoing research and development efforts have yielded new compounds demonstrating comparable potency to PRO 206. These second-generation compounds also indicate a broader spectrum of activity in laboratory studies against the hepatitis C virus."

Metabasis Therapeutics Inc receives USD2m payment from Roche

<http://www.tradingmarkets.com>

Jun 08, 2009 Metabasis Therapeutics Inc (Nasdaq: MBRX), a biopharmaceutical company, stated on 5 June that biotech company Roche has made a payment of USD2m, recognising the progress made in the research collaboration involving the application of Metabasis' HepDirect liver-targeting technology to Roche's proprietary lead nucleosides for the development of new treatments for hepatitis C viral (HCV) infection.

Roche has also formally accepted MB11362 as a clinical candidate for development.

The collaboration and licensing agreement between Metabasis and Roche was established in August 2008 and included a USD10m upfront payment as well as additional payments upon the achievement of certain preclinical and clinical development events, as well as regulatory and commercialisation events for each product, plus royalties on net sales of products from the collaboration.

Metabasis also said that it has recently carried out a restructuring and is continuing to seek additional capital. If unsuccessful in raising additional capital it may be forced to cease its operations.

Study Finds Noninvasive Blood Test for Liver Fibrosis May Alleviate Need for Liver Biopsies for Some Patients with Chronic Hepatitis C

<http://news.prnewswire.com>

MADISON, N.J., June 8 /PRNewswire-FirstCall/ -- A study in the June issue of *Clinical Gastroenterology and Hepatology*, published by Elsevier, demonstrates that the **Hepascore(TM)** liver fibrosis blood-serum test panel may help physicians more accurately diagnose and stage liver fibrosis in patients with chronic hepatitis C (HCV), potentially alleviating the need for liver biopsy, the standard of care for staging fibrosis, in a particular subset of patients. The Hepascore test panel is provided exclusively by Quest Diagnostics Incorporated (NYSE: DGX), the world's leading provider of diagnostic testing, information and services.

"Hepatologists have long sought a noninvasive technique for assessing fibrosis without conducting a liver biopsy, a painful procedure that can miss cirrhosis in some patients," said Nezam H. Afdhal, M.D., study investigator and director, Hepatology, Beth Israel Deaconess Medical Center and associate professor, Medicine, Harvard Medical School. "While Hepascore is unlikely to entirely replace liver biopsy as a staging test for liver fibrosis, one can envision an

algorithm using Hepascore in the management of chronic HCV. In fact, the present study suggests that a unique Hepascore-based algorithm we developed that incorporates results of FIB-4 and APRI assessments would have spared 103 of the 391 study participants with chronic HCV the need for liver biopsy, with advanced fibrosis missed in one patient. We look forward to longitudinal studies that may prospectively assess the usefulness of Hepascore in clinical strategy for monitoring, treating and possibly alleviating the need for biopsy in a subset of chronic HCV patients."

Infection with HCV most often results in chronic HCV, a liver disease. An estimated 19,000 patients were infected with HCV in the U.S. in 2006 (Source: CDC). Chronic HCV is the most common cause of liver fibrosis, a condition that can progress to liver cirrhosis or cancer. Physicians manage HCV infection based on assessments of the degree of a patient's liver fibrosis. Although liver biopsy is the gold standard for determining the degree of fibrosis in chronic HCV patients, it can cause pain, bleeding and, in rare cases, death. Biopsy also must be performed repeatedly in order to monitor fibrosis' reversal or progression. In addition, an estimated 15 to 30 percent of biopsies miss cirrhosis. Physicians typically give antiviral drug therapy to patients with significant fibrosis and monitor chronic HCV patients at low risk of developing fibrosis.

In recent years, techniques have emerged that calculate a chronic HCV patient's likelihood for fibrosis based on assessments of levels of biomarkers found in blood specimens. Most of these techniques employ an algorithm that incorporates levels of nonspecific biomarkers as well as the patient's age and gender. The Hepascore method combines assessments of hyaluronic acid (HA), a biomarker specific to liver fibrosis, with assessments of the nonspecific biomarkers bilirubin, gamma-glutamyl transferase (GGT), alpha2 macroglobulin (A2M), and age and gender.

Previous studies of Hepascore in populations in France and Australia have showed it is reliable at predicting different degrees of fibrosis in chronic HCV patients. The objective of the present study was to validate the Hepascore test in a U.S. population with chronic HCV infection, and to compare it with two indices that employ nonspecific biomarkers, aspartate aminotransaminase (AST)-platelet ratio index (APRI) and Fibrosis-4 (FIB-4). Three hundred and ninety one patients with chronic HCV infection undergoing liver biopsy were enrolled from the Liver Center at Beth Israel Deaconess Medical Center in Boston. A reference range for a negative Hepascore was also determined from a study of 214 healthy volunteers. The diagnostic performance score for Hepascore by AUROC(1) was 0.81 for significant fibrosis, 0.83 for advanced fibrosis, and 0.88 for cirrhosis.

"While Hepascore is unlikely to entirely replace liver biopsy as a staging test for liver fibrosis, our findings demonstrate the potential value of a Hepascore-based algorithm in managing chronic HCV patients," said Wael A. Salameh, M.D., study investigator and medical director, endocrinology, Quest Diagnostics Nichols Institute. "For a Hepascore value less than or equal to 0.2, significant fibrosis is unlikely and continued observation on an annual basis is sufficient. For individuals with a Hepascore equal to or greater than 0.8 with elevated FIB-4 or APRI values, therapy and cancer screening should be strongly considered."

The study is titled "Validation of Hepascore, Compared With Simple Indices of Fibrosis, in Patients With Chronic Hepatitis C Virus Infection in United States." Beth Israel Deaconess Medical Center and Quest Diagnostics Nichols Institute, the esoteric research and development

testing center of Quest Diagnostics, implemented the study. Quest Diagnostics funded the study. Dr. Afdhal is a consultant who has received grant support from Quest Diagnostics.

{ Visit <http://www.elsevier.com/locate/cgh> for more information on *Clinical Gastroenterology and Hepatology*, published by Elsevier. Members of the media may request copies of the publication by emailing Elsevier at newsroom@elsevier.com. }

Quest Diagnostics is a leader in noninvasive blood-based biomarker testing used by physicians to screen for, diagnose and monitor carcinomas and other tissue-based disease. The company's proprietary Leumeta(TM) portfolio of tests helps physicians identify and analyze genetic components of leukemia and lymphoma tumors using blood plasma instead of bone marrow, which can only be tested after extraction through painful biopsy. In addition, the company is the exclusive national reference laboratory provider of the blood-based HE4 Ovarian Cancer Monitoring test, which is FDA-cleared as an aid in monitoring epithelial ovarian cancer. The company is also developing a molecular blood test based on Epigenomics AG's Septin 9 DNA methylation biomarker that can help physicians detect colorectal cancer based on a patient's blood specimen.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional company information is available at www.questdiagnostics.com.

(1) AUROC is a graphic representation of test results that indicates a test's overall performance based on sensitivity and specificity, with a score up to 1.0. The closer a test scores to 1.0, the more accurate its performance.

SOURCE Quest Diagnostics Incorporated

Dental assistant fails to prove work caused her to contract hepatitis C

<http://www.riskandinsurance.com>

If the claimant has several risk factors for contracting hepatitis C, this is strong evidence against a finding that work caused the claimant's condition.

Case name: Pardue v. Dehudy, 23 MIWCLR 48 (Mich. W.C.A.C. 2009).

Ruling: The Michigan Workers' Compensation Appellate Commission affirmed a magistrate's decision denying benefits to a claimant who alleged she contracted hepatitis C from a patient.

What it means: Evidence indicating that the claimant has several risk factors for contracting hepatitis C is strong evidence against a finding that work caused the claimant's condition.

Summary: A dental assistant claimed she contracted hepatitis C from her work and sought workers' compensation benefits. Evidence indicated she received a tattoo in high school and worked 21 years as a dental assistant before working for the dentist. The assistant testified she was exposed to blood at work and on occasion was stuck by needles that penetrated her skin even though she wore thick protective gloves. She further claimed she was exposed on numerous occasions to instruments, refuse, needles, and blood from patients that may have contributed to her illness. The commission rejected the assistant's contention that the wrong legal standard was used in evaluating her claim and ruled that she failed to sufficiently prove her hepatitis C was due to the work activities.

The assistant argued that the standard used by the employer's medical expert was applicable in a medical proceeding but not in legal proceedings. The commission nonetheless found the expert's explanation relevant and held his explanation was credible. The commission acknowledged the assistant's failure to report needlesticking incidents and her virus until shortly before she left work due to her illness. Also, medical evidence indicated the assistant had several risk factors, including a tattoo, surgery, body piercing, use of razors and nail clippers, manicures, and unprotected intercourse. The commission found a number of other causes just as likely to transmit hepatitis C and denied an award of benefits to the assistant.

June 9, 2009

HCV Protease Inhibitor Telaprevir Improves Response, Halves Treatment Time For Hepatitis C Patients

<http://www.medicalnewstoday.com>

For patients with the most common form of hepatitis C, the addition of a hepatitis C-specific protease inhibitor called telaprevir to the current standard therapy can significantly improve the chances of being cured, and it does it in half the time of standard therapy alone.

Results of the Phase IIb clinical trial -- led by Duke Clinical Research Institute (DCRI) and 36 other sites, including NewYork-Presbyterian Hospital/Weill Cornell Medical Center -- are published in the April 30th issue of the *New England Journal of Medicine*. The study was funded by Vertex Pharmaceuticals Incorporated, the maker of the drug telaprevir. The drug works by blocking an enzyme that the hepatitis C virus needs in order to replicate itself.

"These findings point the way to a new era in the treatment of hepatitis C," says Dr. Ira M. Jacobson, a co-author of the study and chief of the Division of Gastroenterology and Hepatology at NewYork-Presbyterian Hospital/Weill Cornell Medical Center, and the Vincent Astor Distinguished Professor of Clinical Medicine at Weill Cornell Medical College. "Not only does adding telaprevir make standard hepatitis C treatment more effective, but it makes it work much more quickly. We showed that the duration of therapy can be reduced from 48 weeks to 24 weeks for most patients. This could help reduce the potentially severe side effects of longer regimens with standard therapy."

The randomized, double-blinded trial followed 250 patients with untreated hepatitis C genotype 1. Researchers measured rates of sustained viral response or viral cure -- an undetectable quantity of hepatitis C virus -- 24 weeks after the end of completion of therapy. They compared a 12-week regimen of telaprevir combined with two different durations of the standard therapy --

peginterferon alfa-2a and ribavirin -- to a control group taking 48 weeks of standard therapy alone. Results showed that 67 percent of patients taking telaprevir in combination with standard therapy for 12 weeks followed by standard therapy alone for 36 weeks were cured; and 61 percent of those taking telaprevir in combination with standard therapy for 12 weeks followed by standard therapy alone for 12 weeks were cured. This is compared to 41 percent cure rate in the 48-week control group.

The study also showed that the percentage of patients who relapsed in the 24-week and 48-week telaprevir-based groups (2 percent and 6 percent, respectively) was much lower than the control group (23 percent).

The most common reported side effect in the telaprevir groups was rash, and contributed to some patients discontinuing the therapy.

Peginterferon alfa-2a is an antiviral drug given by injection that is also used to treat HIV and hepatitis B; it works in conjunction with a drug called ribavirin, a nucleoside analogue, to suppress the viral activity of hepatitis C. Side effects can include severe flu-like symptoms, depression, fatigue, insomnia and anemia.

"Treating genotype 1 hepatitis C, the most common form of the infection in the United States, can be challenging because the side effects are difficult for many people to endure, the duration of treatment is long, and traditionally less than half of patients are able to be cured of their disease," says Dr. Andrew Muir, a gastroenterologist at Duke Clinical Research Institute and a senior investigator on the study. "Even though telaprevir does produce side effects of its own, its addition to standard therapy was able to improve response rates and shorten the duration of treatment necessary -- either one alone would have been an advance, and to be able to achieve both is a significant step in the right direction when it comes to treating hepatitis C."

The study's lead author is Dr. John McHutchison, a hepatologist and gastroenterologist and researcher at the Duke Clinical Research Institute. Additional co-authors include Drs. Gregory Everson of the University of Colorado Health Science Center; Stuart Gordon of Henry Ford Hospital; Mark Sulkowski of Johns Hopkins School of Medicine; and Robert Kauffman, Lindsay McNair and John Alam of Vertex Pharmaceuticals.

Drs. Jacobson, McHutchison and Muir have received consulting fees and/or grant support from Vertex, Roche (maker of peginterferon) and Schering-Plough (maker of ribavirin).

The study's results match those of a similar study conducted in Europe that was reported on in the same issue of the *New England Journal of Medicine*. An accompanying editorial recounts the history of hepatitis C treatments, beginning 25 years ago with the discovery of interferon. It comments on the two studies: "Telaprevir appears to be a material advance in the therapy of hepatitis C, beginning a new era of treatment -- an era of antiviral agents developed specifically to target this virus."

Two Phase III studies currently under way at NewYork-Presbyterian/Weill Cornell and centers worldwide will attempt to confirm the results, potentially leading to FDA approval of telaprevir. One study is looking at 12 weeks of telaprevir in combination with standard therapy (peginterferon alfa-2a and ribavirin) followed by either 12 or 36 weeks of standard therapy alone

depending on patients' response to therapy. A second study is comparing 8-week and 12-week regimens of telaprevir in combination with standard therapies followed by at least 12 weeks of standard therapy, depending on patients' response to therapy, to a placebo group taking 48 weeks of standard therapy alone. Both studies are currently closed to recruitment.

Film aims to expose dangers in U.S. food industry

www.reuters.com

Christine Kearney

NEW YORK (Reuters) - Bigger-breasted chickens fattened artificially. New strains of deadly E. coli bacteria. A food supply controlled by a handful of corporations.

The documentary "Food, Inc." opens in the United States on Friday and portrays these purported dangers and changes in the U.S. food industry, asserting harmful effects on public health, the environment, and worker and animal rights.

Big corporations such as biotech food producer Monsanto Co., U.S. meat companies Tyson Food Inc. and Smithfield Foods, and poultry producer Perdue Farms all declined to be interviewed for the film.

But the industry has not stood silent. Trade associations across the \$142-billion-a-year U.S. meat industry have banded together to counter the claims. Led by the American Meat Institute, they have created a number of websites, including one called SafeFoodInc.com.

"Each sector of the industry that's named is doing its part to counter a lot of the misinformation in the movie," said Lisa Katic, a dietitian and consultant with an unnamed coalition of trade associations representing the food industry.

Their campaign promotes the U.S. food supply as safe, abundant and affordable, whereas the film asserts that images of animals grazing on grassy farms emblazoned on U.S. food product labels are misleading.

"Food, Inc." explores the argument that food comes not from friendly farms but from industrial factories that put profit ahead of human health.

"The film pulls back the curtain on the way food is produced," said Michael Pollan, who appears in the film and is the best-selling author of several books including "In Defense of Food: An Eater's Manifesto.

"Products with farm labels attached -- this stuff comes from factories now," he said.

But an industry spokesman said 98 percent of U.S. farms were family owned and operated and they accounted for 82 percent of farm production.

Mace Thornton of the American Farm Bureau, the nation's largest farm group, said the industry was interested in the well-being of farm animals.

"If a farmer or rancher is not the kind of person to take care of their animals, they're not going to be in business long," he said.

A Peek Inside

The film shows footage inside cattle, pork and chicken production plants, some secretly recorded by immigrant workers under cramped conditions for both workers and the animals.

Maryland farmer Carole Morison let cameras in to show chickens collapsing and dying before they are put on the market because, she said, of fast weight gain caused in part by antibiotics in the feed. Morison said she lost her contract with Perdue.

The film says U.S. food corporations now widely use industrial techniques linked to growing problems like obesity, diabetes, salmonella, toxic strains of common E. coli bacteria and environmental pollution.

"Confined animal agriculture is so unsustainable in so many ways. It depends on using antibiotics in the feed that lead to antibiotic-resistant diseases. It produces more pollution than any other industry," Pollan said.

"It costs treasury, costs the public health system," he said. "The film vividly shows it costs the people who do the work and of course it is brutal to the animal."

Barbara Kowalcyk, whose 2-year-old son Kevin died from an infection of E. coli, appears in the film trying to persuade Congress to pass "Kevin's law," which would give the U.S. Department of Agriculture the power to shut down plants that produce contaminated meats. It has not passed.

Consumers can effect change, the film says, pointing to Stonyfield Farm's Gary Hirshberg, who now offers his line of organic products at giant chain Wal-Mart due to demand.

"You vote for what you eat by what you buy at the supermarket," Pollan said.

(Additional reporting by Daniel Trotta; Editing by Michelle Nichols and Philip Barbara)

Senate Democrats unveil healthcare bill

www.reuters.com

By Donna Smith

WASHINGTON (Reuters) - Leading Senate Democrats unveiled on Tuesday a plan to reshape U.S. healthcare that calls for sweeping insurance market reforms and prohibits insurers from denying coverage or charging more due to medical history.

The measure also would require individuals to buy insurance, provide subsidies to help make coverage affordable and set up a new government plan to help provide medical coverage for the uninsured.

The Senate Health, Education, Labor and Pensions Committee's bill is one of at least three healthcare proposals brewing in Congress, which Democrats hope will lead to legislation that

President Barack Obama can sign into law by October.

"Our goal is to strengthen what works and fix what doesn't," Senator Edward Kennedy, chairman of the committee, said in a statement that accompanied the bill's unveiling.

Democrats in the U.S. House of Representatives and a second group of U.S. senators led by Senate Finance Committee Chairman Max Baucus are developing similar proposals. Baucus has been working with Kennedy's panel and is expected to unveil his version of the bill in the coming days.

Meanwhile Democratic members of the House Ways and Means Committee, one of three panels writing the House version of the bill, met with Obama to discuss the legislation. The White House issued a statement saying the group agreed that the cost of the overhaul, which some estimates put at about \$1.2 trillion, should not add to budget deficits.

The White House said Obama -- under pressure from critics over his huge spending and deficit plans -- would soon spell out more cost savings for the Medicare and Medicaid health programs for the elderly and poor.

More Work Needed

The Kennedy panel will hold a public hearing on its bill on Thursday and will begin considering amendments in public sessions beginning on June 16, the committee said.

"Much work remains, and the coming days and weeks won't be easy. But we have a unique opportunity to give the American people, at long last, the health care they need and deserve," said Kennedy, who is in his second year of fighting brain cancer.

Obama has called on Congress to pass legislation this year to overhaul the \$2.5 trillion healthcare system, aiming to cut costs and ensure that millions of Americans now without health insurance get coverage.

But many congressional Republicans have criticized Democratic proposals for including a public insurance program that would compete with private insurers.

In a bow to Republican concerns, Kennedy's committee bill leaves open the details of how such a plan would operate. Panel Democrats and Republicans are set to meet this week to try to work out differences over the public plan.

Also still to be worked out are details on whether employers would be required to offer insurance to workers.

The House and Senate bills would establish an exchange, a kind of clearinghouse, where people and small businesses could shop for insurance. Lawmakers want the proposed new public plan to be an option offered in that exchange.

Democrats say a public plan that competes with private insurers is the only way to contain costs and keep premiums low. Republicans and insurers argue that it would drive insurance companies out of business and lead to an entirely government-run U.S. healthcare system.

"If you don't have a public option, who is going to keep the insurance companies honest?" said Senator Charles Schumer, a member of the Senate Democratic leadership. "Most of us don't believe that government regulation will be sufficient because they have the profit motive."

(Writing by Donna Smith; Editing by Xavier Briand)

MMIRF: CDC Selects Multiplo HIV/Hepatitis C (HCV) Rapid Test for Program

<http://www.tradingmarkets.com>

By Fain Hughes, fhughes@knobias.com

MedMira Inc. (MMIRF) announced that the Centers for Disease Control and Prevention (CDC) in the United States has selected the Company's **Multiplo HIV/Hepatitis C (HCV) Rapid Test** to be a part of a program entitled "Opportunity to Collaborate in the Evaluation of Rapid Diagnostic Tests for HIV and HCV".

This program of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (DHHS) will see evaluations done in laboratories and in the field to determine the viability of rapid tests for use in screening and/or diagnosis of HIV and HCV in the United States. A number of rapid tests will be evaluated as part of the program however Multiplo HIV/HCV will be the only combination rapid flow-through test with the ability to deliver simultaneous results for HIV and HCV.

About Knobias:

Knobias is a premier financial information provider of trading and investing data covering all U.S. equities for investors and security professionals. Knobias is best described by its three major components: Real-time desktop applications providing quotes, charts, level 2, analysis etc.; Knobias RAiDAR providing thousands of real-time news stories, alerts and documents daily; Knobias fundamentals providing a comprehensive database of fundamental research information.

Pharmasset Initiates Phase 1b Multiple Ascending Dose Clinical Trial of PSI-7851 in Chronic Hepatitis C Patients

<http://news.prnewswire.com>

- PSI-7851 was generally safe and well tolerated in Phase 1a single ascending dose trial

- Further results from single ascending and multiple ascending dose trials are expected in second half 2009

PRINCETON, N.J., June 9 /PRNewswire-FirstCall/ -- Pharmasset, Inc. (Nasdaq: VRUS) announced today that it had completed the single ascending dose study and begun dosing in a multiple ascending dose trial with **PSI-7851**, a nucleotide analog polymerase inhibitor for the treatment of chronic hepatitis C virus (HCV) infection. This study is designed to assess the



safety, tolerability and antiviral activity of PSI-7851 over 3 days in HCV-infected individuals.

"We are encouraged by the safety and pharmacokinetics of PSI-7851 thus far," stated Michelle Berrey, MD, MPH, Pharmasset's Chief Medical Officer. "We believe PSI-7851, Pharmasset's lead second generation nucleotide, has the potential to be administered once a day at low milligram doses, while also continuing to demonstrate the many benefits nucleos(t)ides have over other classes of HCV direct acting antivirals, including a high barrier to resistance, pan-genotype potency, and ability to combine with other classes of compounds."

PSI-7851 Phase 1 Program Overview

The Phase 1 program is investigating the safety, tolerability and pharmacokinetics of PSI-7851 in healthy subjects following single doses (Phase 1a) and in patients chronically infected with HCV genotype 1 following repeat dosing for 3 days (Phase 1b). The Phase 1b study will additionally investigate hepatitis C viral dynamics and monitor for the development of drug resistance.

Subjects in the phase 1a single ascending dose study received single doses of PSI-7851 ranging from 25mg to 800mg or a matching placebo. Preliminary data from the phase 1a single ascending dose study demonstrated:

- No serious adverse events or discontinuations;
- No dose-related adverse events;
- No grade III / IV lab abnormalities;
- No clinically significant changes in vital signs or ECGs.

A Phase 1b multiple ascending dose trial has now been initiated in patients with chronic HCV genotype 1 infection. Subjects will be enrolled at multiple centers and randomized to PSI-7851 (8 per cohort) or placebo (2 per cohort). Based upon the results from the SAD study, the first dose of PSI-7851 to be tested will be 50mg once daily. The primary objective is to assess the safety, tolerability and pharmacokinetics of PSI-7851 after repeat dosing over 3 days. The secondary objective is to evaluate the decrease in HCV RNA.

Results from both studies are expected in the second half of 2009.

About PSI-7851

PSI-7851 is a uridine nucleotide analog currently in development for the treatment of chronic HCV infection. PSI-7851 has demonstrated potent in vitro anti-HCV activity with EC₅₀ values of 90 +/- 60 nM, which is approximately 15- to 20-fold more potent than Pharmasset's first generation nucleoside polymerase inhibitor, R7128. In vitro studies of PSI-7851 have not shown evidence of any mitochondrial or other cellular toxicities that may be associated with some nucleoside analogs. The half-life of the triphosphate in primary human hepatocytes is approximately 38 hours, which suggests the possibility for once-daily dosing. Like R7128, PSI-7851 has demonstrated in vitro activity against all of the most common HCV genotypes.

About Pharmasset

Pharmasset is a clinical-stage pharmaceutical company committed to discovering, developing, and commercializing novel drugs to treat viral infections. Pharmasset's primary focus is on the development of oral therapeutics for the treatment of hepatitis C virus (HCV) and, secondarily, on the development of Racivir(R) for the treatment of human immunodeficiency virus (HIV). Our research and development efforts focus on nucleos(t)ide analogs, a class of compounds

which act to inhibit the enzymes required for viral replication. We currently have three clinical-stage product candidates: R7128, a nucleoside analog for chronic HCV infections, has initiated a Phase 2b clinical trial in combination with Pegasys plus Copegus through a strategic collaboration with Roche; PSI-7851, an unpartnered, next generation HCV nucleotide analog, which recently began Phase 1 clinical studies and Racivir, for the treatment of HIV that has completed a Phase 2 clinical trial.

Hepatitis B hasn't gone away – and may come back

Gus Cairns

www.aidsmap.com

People with HIV who have been vaccinated for hepatitis B may still become infected, the fifth Annual Workshop on HIV and Hepatitis Co-infection in Lisbon heard this week. The conference also heard of a case where starting interferon-based hepatitis C therapy in a person with HIV apparently caused a reactivation of a dormant hepatitis B infection.

The conference also heard that HIV/hepatitis B co-infected people have considerably faster CD4 declines than people co-infected with HIV and hepatitis C or HIV alone, that rates of hepatitis B co-infection in HIV positive African immigrants are as high as they are in gay men and often go undetected, and that hepatitis B patients with high viral loads have a very high rate of liver cancer.

The good news is that at least two-thirds of patients treated with tenofovir and FTC or 3TC develop undetectable hepatitis B viral loads. However the 10-30% of patients who fail to respond are not always the same as those who fail HIV therapy, showing that transmitted drug resistance is becoming important in people with hepatitis B too.

One presentation from Toronto (Wong) discussed four cases of people with HIV who developed new hepatitis B infections despite previous hepatitis B vaccination. In two cases they developed chronic hepatitis B infection – an unusually high rate given that only about 10-15% of people with HIV who acquire hepatitis B normally go on to develop the chronic disease.

In one case the patient had had three full courses of hepatitis B vaccination, one before he acquired HIV, but had failed to develop immunity. Three years after being diagnosed with HIV he developed acute hepatitis with high liver enzymes, but was able to get rid of the infection. In the second case, the patient acquired hepatitis B in 2007 despite having been vaccinated and having immunity to hepatitis B in 2004 when he was diagnosed with HIV. He also resolved his infection.

In the other two cases, however, the patients developed chronic infections. In both cases the patients had had hepatitis B vaccination but their immunity status was unknown. The third case was vaccinated in 2004 at the time of his HIV diagnosis but presented with hepatitis symptoms a year later. He refused antiretroviral drugs and went on to develop chronic hepatitis B.

In the final case a long-term survivor of HIV (diagnosed in the 1980s) was vaccinated for hepatitis B in 2005 but presented with hepatitis symptoms in 2009. It was thought these were due to his HIV therapy (he was multi-drug-resistant and was on etravirine, darunavir and raltegravir,

none of which work against hepatitis B), so this was stopped. However it later turned out he had had acute hepatitis B and went on to develop the chronic disease. He is now taking tenofovir/FTC (Truvada) for his hepatitis B but remains off HIV therapy.

Emma Page from London's Chelsea and Westminster Hospital presented a case where hepatitis C therapy apparently caused a flare-up of hepatitis B infection in a patient, despite their having been vaccinated for hepatitis B (and hepatitis A) at the time of HIV diagnosis. It was known he had had hepatitis B infection many years previously but his immunity to it had waned, though there was no sign of chronic infection. He developed acute hepatitis C just a few months after his HIV diagnosis and was put on pegylated interferon and ribavirin for hepatitis C, but not on HIV therapy as he had a high CD4 count.

A couple of months into his treatment he developed hepatitis symptoms and very high liver enzyme levels (and also anaemia) and was found to have an acute hepatitis B infection. It was concluded that this was not a new infection but a resurgence of his original infection from years back. Dr Page hypothesised that the interferon therapy had caused a form of IRIS. In hepatitis C and A the liver damage is caused directly by the virus but in hepatitis B the damage is caused by the immune response to the virus, so what suppresses hepatitis C may, it appears, sometimes reactivate hepatitis B.

Dr Vincent Soriano of Carlos III Hospital in Madrid outlined some of the serious consequences of unchecked hepatitis B infection. In a cohort of 3500 HIV/hepatitis B co-infected patients, 10% developed liver cancer in 11 years and 5% (184 patients) liver cancer.

In America, David Thomas of Johns Hopkins University told the conference that patients co-infected with HIV and hepatitis B had an annual mortality rate due to liver disease of 1.4%; in contrast in people with HIV alone annual liver-related mortality was 0.17% and in people with hepatitis B alone 0.08%.

Evidence has also been accumulating that hepatitis B infection exacerbates CD4 decline in patients with HIV. Soriano said that in the SMART Trial, patients in the 'Drug Conservation' arm who stopped therapy at 350 CD4 cells/ml³ and resumed it at 250 were much more likely to resume therapy if they had hepatitis B: after 18 months, nearly 80% of HIV/hepatitis B co-infected patients had resumed therapy compared with 45% with HIV alone and 48% co-infected with hepatitis C.

However Thomas told the conference that patients with HIV and hepatitis B who started HIV therapy had exactly the same increases in CD4 count.

Worldwide, hepatitis B is most prevalent in sub-Saharan African and central and east Asia. A substantial proportion of Africans with HIV also have hepatitis B, though the majority of them get hepatitis B through mother-to-child transmission and then HIV through sex in adult life, whereas in the developed world both viruses are acquired most often sexually.

A team from London's Royal Free Hospital surveyed its patients with chronic hepatitis B and found that 38% were African; a third were women compared with only 4% of the non-African group. African patients were three times less likely to have the hepatitis B e antigen, an indicator of current liver inflammation, than non-African patients but seven times more likely to have liver

cirrhosis, an indicator of their long infection.

The authors commented that the high prevalence of chronic hepatitis B and the advanced nature of liver disease in African patients had implications for antiretroviral rollout in Africa, with the most commonly-available drugs either inactive against hepatitis B or, in the case of 3TC, causing resistance when given as monotherapy.

All patients in the Royal Free were on HIV regimens that contained drugs active against hepatitis B (tenofovir plus either FTC or 3TC) and seven out of every eight patients (87.5%) had an undetectable hepatitis B viral load (under 1000 copies/ml³).

There is however no standard definition of ‘undetectable’ and a study from the Chelsea and Westminster Hospital found that only 66% of patients were undetectable according to the stricter definition of below 34 copies/ml³, with another 23% partially suppressed (between 34 and 10,000 copies/ml³) and 11% over 10,000. However 74% of patients on tenofovir/FTC or tenofovir/3TC had fully suppressed viral loads; the lower average figure was due to less suppressive regimens.

While some hepatitis B treatment failures are due to poor adherence to what for most patients is essentially two-thirds of their HIV drug regimen, some is due to drug-resistant hepatitis B. A study of 119 HIV/hepatitis B co-infected patients in Portuguese clinics of whom 87% were on tenofovir/FTC, 9% on 3TC monotherapy and 4% on solo tenofovir found that 18% had detectable hepatitis B. Eight of these (38% of failures) had poor adherence. But two patients taking solo 3TC and 10 patients on tenofovir/FTC had one to three drug resistance mutations (57% of failures), mainly due to previous 3TC monotherapy.

Can chronic hepatitis B infection be cured? In the Portuguese cohort just three patients developed antibodies to the surface antigen of hepatitis B, which would indicate immunity if they were vaccinated. One Italian case achieved hepatitis B immunity and no sign of hepatitis B DNA sustained for over a year by adding a year’s course of interferon to antiviral drugs.

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Coffee May Reduce Risk of Liver Cancer

<http://www.naturalproductsmarketplace.com>

TOKYO—Coffee consumption may reduce the risk of liver cancer regardless of hepatitis C (HCV) and B virus (HBV) infection status, whereas green tea may not reduce this risk (Cancer Epidemiol Biomarkers Prev 2009;18(6):1746–53).

Researchers examined whether coffee and green tea consumption was associated with a reduced risk of liver cancer by hepatitis virus infection status in the Japan Public Health Center-Based Prospective Study Cohort II.

A total of 18,815 subjects ages 40 to 69 years participating in a questionnaire and health checkup survey in 1993 to 1994 were followed for the incidence of liver cancer through 2006.

A total of 110 cases of liver cancer were newly documented. Hazard ratios for coffee and green tea consumption categories were calculated with a Cox proportional hazards model.

Compared with almost never drinkers, increased coffee consumption was associated with a reduced risk of liver cancer in all subjects. A similar risk tendency was observed in those with either or both HCV and HBV infection.

In contrast, no association was observed between green tea consumption and the risk of liver cancer in all subjects.

June 10, 2009

Cocaine users 'risk getting Hep C'

<http://www.politicnews.co.cc>

By Briar Burley
Newsbeat reporter

People who snort drugs like cocaine are putting themselves at risk of contracting Hepatitis C, health charities are warning.

Around 10,000 people get the virus every year in the UK, but many don't know they have it.

You can only contract Hepatitis C if your blood comes into contact with infected blood but, if left untreated, it can potentially be fatal.

People who share needles to take heroin or steroids are at the biggest risk.

But studies have shown it is also possible to get Hepatitis C if you share bank notes or straws when snorting drugs.

Tom, not his real name, found out he had Hepatitis C in a blood test and reckons he got it taking

drugs.

"I got into snorting drugs when I was a university student," he said.

"I've never injected drugs. My main exposure's been through snorting cocaine."

Drugs that are inhaled like cocaine are corrosive and can make the inside of your nose bleed.

If that happens, tiny spots of blood can fall onto the note you are using and if that's used by someone else, your blood can travel up their nose and into their bloodstream.

Liver infection

Charles Gore is from The Hepatitis C Trust. He says it's dangerous snorting drugs through a shared bank note or straw.

"If you are doing it and have a bleeding nose and it bleeds onto a note and you then pass it to somebody else, who's then going to snort through it to get the cocaine into their bloodstream, unfortunately they're likely to get your blood in there too, with the infection."

"By sharing the same gear to inject or snort cocaine, you could get Hepatitis C"

Department of Health advice on contracting Hepatitis C

Hepatitis C attacks the liver. Early symptoms are normally mild, like tiredness and feeling low, but long term it can cause cancer, organ failure and even death.

It's thought the chances of getting the virus are higher if you're injecting drugs, but cocaine use in Britain has doubled in the last 10 years.

That's got some health experts like Charles Gore worried: "People with liver disease only tend to get the really bad obvious symptoms when it's too late. If you've ever snorted drugs, go get a test."

Hepatitis C can be treated, but the medication is strong and involves injections.

Tom's just starting his: "My treatment will last for 28 weeks. It's made up of one injection once a week into my stomach and a morning and nightly dose of tablets".

Taking drugs in any form can cause harm. A spokesman for the Department of Health told Newsbeat: "By sharing the same gear to inject or snort cocaine, you could get Hepatitis C."

Liver Transplant in HBV/HIV Coinfected Patients Successful

<http://www.aidsmeds.com>

People coinfecting with both the hepatitis B virus (HBV) and HIV have excellent survival rates following a liver transplant, according to a study published in the June 1 issue of *AIDS*.

HBV can become a chronic disease in roughly 25 percent of people who are also infected with HIV. When this occurs, people are at increased risk of liver failure and liver cancer, usually many years after first becoming infected. HBV disease, however, progresses more rapidly in coinfecting people than in people not infected with HIV.

Moreover, when people develop end-stage liver disease, the only recourse is a liver transplant. For many years, people with HIV weren't even considered viable candidates for a transplant. After it became clear that antiretroviral (ARV) therapy was significantly extending the survival of people with HIV, however, advocates successfully lobbied for coinfecting people to be transplant candidates. Unfortunately, few studies have been published on the outcomes of liver transplant in coinfecting people.

To determine the success of liver transplants in this population, Mariagrazia Tateo, MD, PhD, from the University of Bari, in Italy, and her colleagues examined the outcomes of transplants in 75 people living with HIV performed at the Hôpital Paul Brousse, Centre Hepato-Biliaire, in Paris. Thirteen of the patients were coinfecting with HIV and HBV. Six were additionally infected with hepatitis C virus (HCV) as well as HIV and HBV. The average age of the patients was 46, and all had their HIV well controlled with ARV drugs.

People were followed, on average, for 32 months after their liver transplant. Survival over this time period was 100 percent. Ten of the HIV-positive patients had no rejection of their new livers. Three had mild to moderate rejection, which was ultimately overcome with changes to their immunosuppressive drugs used to prevent rejection.

Two HIV-positive patients had a recurrence of their HCV infection, but none had a recurrence of their HBV infection. Liver damage from the HCV recurrences, as well as damage to the energy-producing mitochondria of liver cells, was not evident in any of the HIV-positive patients studied.

“Our series thus demonstrate excellent results in terms of survival and the control of HBV replication following liver transplantation in HIV/HBV-coinfecting patients,” the authors concluded.

June 11, 2009

FTC: 12-14 yrs too long to protect biotech drugs

www.reuters.com

WASHINGTON (Reuters) - Generic versions of expensive biotechnology drugs would reduce the amount of money spent on health care in the United States, a Federal Trade Commission report said on Thursday.

Makers of brand-name biotechnology medicines, which can cost tens of thousands of dollars a year, are pushing for 12 to 14 years of protection from competition for their products as lawmakers craft plans to give the Food and Drug Administration authority to clear cheaper copycat versions.

But an FTC report found "the 12- to 14-year regulatory exclusivity period is too long to promote

innovation," particularly since brand-name companies "likely will retain substantial market share" after generic competitors are approved.

The FTC report found that competitors would likely enter the market only for drugs that had more than \$250 million in annual sales, and only two to three generic entrants would be expected.

"These FOB (follow-on biologic) entrants are unlikely to introduce their FOB products at price discounts any larger than between 10 and 30 percent of the pioneer products' price," the FTC said in its report.

Still, the FTC said, giving the FDA clear authority to approve generic biologics "would be an efficient way to bring these lower-priced drugs to market."

Biologic drugs -- which are usually injectable -- tend to be more expensive and complicated than traditional chemical medicines because they are made from living cells. They are used to treat everything from cancer to autoimmune diseases such as arthritis.

Brand-name biotech companies like Roche Holding's Genentech Inc and Amgen Inc have fought the creation of a generic industry for such drugs. The generic drug industry, on the other hand, is eager to move into the arena.

The FTC report was posted on the agency's website [here](#)

(Reporting by Lisa Richwine and Diane Bartz; Editing by Dave Zimmerman and John Wallace)

Change of venue sought in hepatitis trials

<http://www.upi.com>

LAS VEGAS, June 10 (UPI) -- A hearing is scheduled at the end of the month on a change of venue request for one of Nevada's largest-ever medical malpractice litigations, lawyers say.

The legal defense team for Dr. Dipak Desai and his endoscopy center argues that moving the 22 cases out of Southern Nevada is necessary because of an "avalanche of negative and sensational media coverage," the Las Vegas Sun reported Wednesday.

Desai and his Endoscopy Center of Southern Nevada are accused of allegedly using contaminated syringes and vials that resulted in patients being exposed to hepatitis C.

Plaintiff's attorneys say a change of venue will burden the center's former endoscopy patients, many of whom are elderly and dealing with the effects of the illness.

Desai's lawyers plan to ask District Judge Elizabeth Gonzalez to move the trials to Carson City when she holds a change of venue hearing June 30.

The first of 22 cases is scheduled for trial October 19.

Hepatitis C increases risk of cardiovascular disease

www.aidsmap.com

Michael Carter

Hepatitis C virus increases the risk of coronary artery disease, a large American study published in the 15th July edition of *Clinical Infectious Diseases* (now online) has found. The study involved over 160,000 individuals, approximately half of whom were infected with hepatitis C. Despite having fewer risk factors for cardiovascular disease, the hepatitis C-infected individuals were more likely to have been diagnosed with coronary artery disease.

“This is the largest study to determine the role of hepatitis C virus infection in the risk of coronary artery disease”, write the investigators.

A number of infectious diseases, including HIV have been associated with an increased risk of cardiovascular disease. Many patients with HIV are co-infected with hepatitis C, and these individuals have a higher risk of early death from a number of causes than patients who are only infected with HIV.

Studies looking at the association between cardiovascular disease and hepatitis C have yielded conflicting results.

However, it is biologically plausible that hepatitis C may increase the risk of disease such as heart attack and stroke as hepatitis steatosis (fatty liver), a common complication of hepatitis C infection, has been associated with increased levels of inflammation and metabolic syndrome.

Investigators from the US ERCHIVES study, compared the risk factors and prevalence of coronary artery disease between 82,000 hepatitis C-infected veterans and 90,000 hepatitis C virus-negative veterans.

The individuals infected with hepatitis C had fewer traditional risk factors for heart disease and stroke than the uninfected patients. They were less likely to have high blood pressure (42% vs. 50%, $p < 0.001$), diabetes (21% vs. 22%, $p < 0.001$), and hyperlipidaemia (39% vs. 72%).

Total mean cholesterol was lower in the hepatitis C-infected patients (175mg/dl vs. 198mg/dl, $p < 0.001$), as was mean LDL-cholesterol (102mg/dl vs. 119mg/dl, $p < 0.001$) and mean triglycerides (114mg/dl vs. 179mg/dl, $p < 0.001$).

However, the hepatitis C-positive patients were significantly more likely to have liver problems (78% vs. 29%, $p < 0.001$), kidney disease (3% vs. 1%, $p < 0.001$), anaemia (11% vs. 10%, $p < 0.001$) and abuse or be dependent on alcohol (39% vs. 19%, $p < 0.001$), or drugs (31% vs. 12%, $p < 0.001$).

Even though the individuals infected with hepatitis C had a lower prevalence of traditional risk factors for coronary artery disease, the investigators’ statistical analysis (which controlled for possible confounding factors) showed that the hepatitis C independently increased the risk of such diseases by 27% (adjusted hazard ratio, 1.27, 95% confidence interval: 1.22-1.31). Traditional risk factors for cardiovascular disease were also significant in both groups of patients.

A combination of factors including cytokine levels, increased levels of markers of inflammation, thrombosis, endothelial dysfunction, behavioural and social risk factors, malnutrition and liver problems are the likely to be the reason why patients with hepatitis C have an increased risk of cardiovascular disease, the investigators believe.

“In a comparison of hepatitis C-infected subjects with hepatitis C-uninfected control subjects, hepatitis C infection is associated with a higher risk of cardiovascular disease, even after adjustment for traditional risk factors”, conclude the investigators. “The reason(s) and mechanism(s) of this association need further study.”

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Higher Donor Risk Index Linked to Liver Graft Failure

<http://www.modernmedicine.com>

Steatotic livers seem safe in transplant recipients with hepatitis C

THURSDAY, June 11 (HealthDay News) -- The donor risk index appears to have a particularly adverse effect on outcomes in liver transplant recipients with hepatitis C virus (HCV), but liver grafts with steatosis don't seem to worsen three-year survival in patients with this infection, according to the results of two studies published in the June issue of *Liver Transplantation*.

In the first study, Daniel G. Maluf, M.D., of the Virginia Commonwealth University in Richmond, and colleagues analyzed data from 16,678 liver transplant recipients in the Organ Procurement and Transplantation Network database, which included calculating the donor risk index from donor characteristics. Though increasing donor risk index was associated with an increase in the relative risk of graft failure and patient death in HCV-positive and negative patients, these risks grew higher in HCV-positive patients.

In the other study, Patrizia Burra, M.D., of the University of Padova in Italy, and colleagues analyzed data from 116 patients with or without HCV who underwent liver transplants with follow-up biopsies over the next three years. No steatosis was found in 50.9 percent of the grafts before transplantation, and steatosis was mild in 39.6 percent of samples. No correlation was seen between graft steatosis and later fibrosis, nor were differences seen in 36-month survival based on patients' HCV status or presence of steatosis in the graft.

"It is now possible to create an allocation algorithm that can systematically and objectively account for the variable impact of donor characteristics on liver transplant outcomes within the context of recipient diagnosis and disease severity. I believe that this would be the most equitable and transparent way to distribute the differential risk posed by the donor pool to individual transplant candidates," writes Sandy Feng, M.D., of the University of California in San Francisco, in an accompanying editorial.

June 12, 2009

Consensus Interferon May Help Hepatitis C Patients Failing Initial Therapy

<http://www.medscape.com>

Anthony J. Brown, MD

June 12, 2009 — Consensus interferon (CIFN) combined with ribavirin is a safe and effective treatment for some patients with chronic hepatitis C who did not respond to initial therapy with pegylated interferon and ribavirin, new research shows.

CIFN, also referred to interferon alfacon-1 and by the brand name Infergen, is a wholly synthetic interferon.

Up to 50% of patients fail to respond to pegylated interferon and ribavirin as initial therapy for chronic hepatitis C, according to the report in the June issue of *Hepatology*. Failure to eliminate the virus places patients at risk for progression of their liver disease.

The best approach for patients who fail to respond to initial therapy is unclear, the report indicates. Some physicians have adopted a "watchful waiting" approach and "are anticipating new antiviral therapies with either protease inhibitors or polymerase inhibitors." The safety and efficacy of these new agents when combined with peginterferon and ribavirin in treating nonresponders, however, remain to be determined.

This study is the first to examine the use of CIFN in patients who have failed to respond to initial therapy, lead researcher Dr. Bruce R. Bacon, from Saint Louis University School of Medicine, told Reuters Health.

"The population of patients enrolled in the study was a very difficult-to-treat group, with a high proportion of patients who were prior null responders and about 60% of patients with advanced fibrosis/cirrhosis," he explained. "That any of these patients responded is good news."

The study involved 487 patients who failed initial therapy with peg-interferon and ribavirin and were treated with CIFN and ribavirin. Roughly half of the patients received CIFN at a dose of 9 mcg/day and half received CIFN at a dose of 15 mcg/day.

In the overall analysis, the sustained virologic response rates were 6.9% and 10.7% in the 9- and 15-microgram/day CIFN groups, respectively. When the analysis looked at patients with a >2-log₁₀ drop in hepatitis C virus RNA during initial therapy with peg-interferon, the corresponding rates jumped to 11% and 23%.

In patients with lower baseline fibrosis scores (F0 to F3), the sustained virologic response rates were 7.8% and 13.1% in the 9- and 15-mcg/day CIFN groups, respectively. Once again, the corresponding rates were higher when only patients with a >2-log₁₀ drop in hepatitis C virus RNA during initial therapy were considered: 10.7% and 31.6%.

Adverse events were common, although rarely a cause for treatment discontinuation. Neutropenia, fatigue, leucopenia, depression, and nausea were among the most common side effects.

"The current study shows the benefit CIFN holds for difficult-to-treat patients with chronic hepatitis C who have failed to respond to previous treatment with pegylated interferon and ribavirin," the researchers state. "The greatest sustained virologic response rate during retreatment in the present study was observed in F0-F3 patients who had a partial virologic response during their prior course of treatment."

Dr. Bacon added, "The take-home message is to select your patients carefully, and that this is an opportunity to try a new form of treatment in prior non-responders."

Hepatology. 2009;49:1838-1846.

What Is The Relationship Between Hepatocellular Carcinoma And Type 2 Diabetes Mellitus?

<http://www.medicalnewstoday.com>

Hepatocellular carcinoma (HCC) is the fifth most common malignancy worldwide and the third leading cause of cancer-related deaths. Type 2 diabetes mellitus has been associated with HCC. However, the relationship between type 2 diabetes mellitus and the underlying liver cirrhosis, and the effects of antidiabetic therapy on HCC risk have not yet been fully evaluated.

A research team led by Dr. Valter Donadon from Pordenone Hospital addressed this question. Their study was published in the *World Journal of Gastroenterology*.

Enrolled in this study were 465 HCC patients, 618 cirrhosis patients and 490 control subjects. They evaluated the odds ratio (OR) for HCC by univariate and multivariate analysis. Moreover, OR for HCC in diabetic subjects treated with insulin or sulphonylureas and with metformin were calculated.

The prevalence of diabetes mellitus was 31.2% in HCC, 23.3% in cirrhotic patients and 12.7% in the Control group. By univariate and multivariate analysis, the OR for HCC in diabetic patients were respectively 3.12 (95%CI: 2.2-4.4, $P < 0.001$) and 2.2 (95%CI: 1.2-4.4, $P = 0.01$). In 84.9% of cases, type 2 diabetes mellitus was present before the diagnosis of HCC. Moreover, we report an OR for HCC of 2.99 (95%CI: 1.34-6.65, $P = 0.007$) in diabetic patients treated with insulin or sulphonylureas, and an OR of 0.33 (CI 0.1-0.7, $P = 0.006$) in diabetic patients treated with metformin.

This study demonstrates that type 2 diabetes mellitus is an independent risk factor for HCC and pre-exists in the majority of HCC patients. In male HCC, patients with type 2 diabetes mellitus, their data shows a direct association of HCC risk with insulin and sulphonylureas treatment and an inverse relationship with metformin therapy.

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Low-Fat Diet Helps Genetically Predisposed Animals Avoid Liver Cancer

<http://www.medicalnewstoday.com>

In a study comparing two strains of mice, one susceptible to developing cancer and the other not, researchers found that a high-fat diet predisposed the cancer-susceptible strain to liver cancer, and that by switching to a low-fat diet early in the experiment, the same high-risk mice avoided the malignancy. The switched mice were lean rather than obese and had healthy livers at the end of the study.

The findings, from a joint University of Pennsylvania School of Medicine and Case Western Reserve University study, appear online this month in *Human Molecular Genetics*.

The investigators studied hepatocellular carcinoma (HCC), a type of liver cancer that is one of the leading causes of cancer death worldwide. Thirty percent of cases of this type of liver cancer are associated with obesity, type 2 diabetes, and related metabolic diseases, although a direct link between these and liver cell cancer has not been completely established. "The connection between obesity and cancer is not well understood at this point," says senior co-author John Lambris, PhD, the Dr. Ralph and Sallie Weaver Professor of Research Medicine at Penn. The researchers hope the results will lead to the development of blood tests that can detect precancerous conditions related to diet.

The remaining seventy percent of HCC cases result from hepatitis B and C viral infections, exposure to the fungal toxin aflatoxin, chronic alcohol use, or genetic liver diseases.

The usual outcome of hepatocellular carcinoma is poor, because only 10 to 20 percent of these tumors can be surgically removed. If the cancer cannot be completely removed, the disease is usually deadly within 3 to 6 months. Hepatocellular carcinoma causes close to 700,000 deaths worldwide per year, mostly outside the US.

The researchers tested the long-term effects of high-fat and low-fat diets on males of two inbred strains of mice and discovered that one strain, named C57BL/6J, was susceptible to non-alcoholic steatohepatitis (NASH) and hepatocellular carcinoma on a high-fat, but not a low-fat diet. The other strain, called A/J, was not susceptible to disease on a high-fat diet. The mice were fed their respective diets for close to 500 days, weighed periodically, and then analyzed for the presence of disease.

RNA profiles of hepatocellular carcinoma versus tumor-free liver tissue at the end of the experiment showed that two signaling networks one centered on Myc and the other on NF-kappa B were involved. This result is similar to findings obtained from studies on the two major classes of hepatocellular carcinoma in humans.

At the end of the experiment, mice susceptible to cancer showed characteristics of NASH such as inflammation and fibrosis, and, in some cases, cirrhosis as well as hepatocellular carcinoma, in their livers. A switch from a high-fat to a low-fat diet reversed these outcomes in groups of

C57BL/6J mice that were fed a high-fat diet early in the experiment. The switched C57BL/6J mice were lean rather than obese and had healthy livers at the end of the study. All mice kept on a high-fat diet for the duration of the experiment had liver tumors at the end of 500 days.

A similar change in diet may have important implications for preventing liver cancers in humans, suggest the researchers. "The reason these findings are so provocative is that it relates to diet and we now have a unique model we know will develop cancer," says Lambris.

"By waiting for evidence of disease before terminating the study, instead of using an arbitrary endpoint as is done in most experimental studies, we were able to discover an important new experimental model for a common cancer in humans," says senior co-author Joseph Nadeau, Professor and Chair of the Department of Genetics at Case Western Reserve University School of Medicine.

The work was funded by the National Center for Research Resources and the Charles B. Wang Foundation.

Co-authors, in addition to Lambris and Nadeau are Maciej M. Markiewski from Penn, Annie E. Hill-Baskin, David A. Buchner, Haifeng Shao, David DeSantis, Nathan A. Berger, and Colleen Croniger from Case Western, and Gene Hsiao, and Shankar Subramaniam from University of California, San Diego.

Source: University of Pennsylvania School of Medicine

Are Angiotensins Involved in the Hemodynamic Changes of Cirrhosis Patients?

<http://www.medicalnewstoday.com>

Liver cirrhosis has been recently studied in the light of the new view of the renin angiotensin system (RAS). While the angiotensin converting enzyme (ACE)-Ang 2-AT1 receptor arm contributes to liver tissue injury and fibrosis and the maintenance of basal vascular tonus in non-compensated cirrhosis, the activation of the ACE2-Ang-(1-7)-Mas receptor arm exerts anti-fibrotic actions and probably has also a role in arterial vasodilation in liver cirrhosis. In a previous study published last year in WJG by the same research group, it was shown that chronic treatment with propranolol in cirrhotic patients was characterized by marked changes in the precursors of the RAS cascade (renin and Ang 1 with repercussions on the 2 main RAS components, Ang 2 and Ang-(1-7), in the splanchnic and peripheral circulation. Therefore, the circulating profile of RAS components at different stages of liver cirrhosis and their role in hemodynamic changes of cirrhosis remained unclear.

A research article published in the *World Journal of Gastroenterology* addressed this issue. The research team led by Prof. Santos from the Federal University of Minas Gerais measured the circulating levels of angiotensins in patients at different stages of liver cirrhosis by radioimmunoassay, and further evaluated the influence of RAS components on hemodynamic changes during liver transplantation.

The study showed that the progression of liver dysfunction is characterized by marked changes

in circulating Ang-(1-7) and Ang 2 levels. In the initial stages, there were a predominance of Ang-(1-7) rather than Ang 2. On the other hand, advanced stages of cirrhosis showed an activation of the peripheral and splanchnic RAS, and a deviation toward the formation of Ang-(1-7) in the splanchnic circulation. Furthermore, there was a positive correlation between the Ang-(1-7)/Ang 2 ratio and cardiac output and a negative correlation between this ratio and systemic vascular resistance, indicating that the final functional effects of the RAS may reflect a balance between these 2 opposing peptides.

The relationship between Ang-(1-7) and Ang 2 may play a role in hemodynamic changes of human cirrhosis. The peptide Ang-(1-7) probably predominates in the peripheral circulation in the initial stages of human cirrhosis and in the splanchnic circulation in the advanced stages, both contributing to a reduction in vascular resistance and consequently to hyperdynamic circulation. In the peripheral circulation of patients with advanced cirrhosis, when compared to the splanchnic circulation, Ang 2 probably leads to extra-splanchnic vasoconstriction. Although further studies with a larger number of patients should address the precise role of RAS in human cirrhosis, this research opens the possibility that future therapies interfering with the RAS in both the systemic and splanchnic circulation should lead to more success in the management of the hemodynamic changes in human cirrhosis.

Reference:

Vilas-Boas WW, Ribeiro-Oliveira Jr A, Pereira RM, Ribeiro RC, Almeida J, Nadu AP, Simões e Silva AC, Santos RAS. Relationship between angiotensin-(1-7) and angiotensin 2 correlates with hemodynamic changes in human liver cirrhosis.

Source: Lai-Fu Li, World Journal of Gastroenterology

Thomas Weisel analyst rates Idenix 'Overweight'

<http://www.forbes.com>

NEW YORK -- Idenix Pharmaceuticals Inc. received a positive rating from a Thomas Weisel Partners analyst Friday, based on the company's hepatitis C treatment program.

Thomas Weisel analyst Stephen Willey gave the stock an "Overweight" rating and expects shares to reach \$8 over the next 12 months as it pushes ahead with development of **IDX184** for hepatitis C. He said a recent deal for the HIV treatment candidate IDX899 with GlaxoSmithKline (GSK - news - people), that is worth about \$450 million, will give the company some financial flexibility in the coming years.

Both the hepatitis C and HIV drug candidates are part of the same class of new drugs called nucleoside inhibitors, or NI's, which have the potential to become potent antivirals with fewer toxic side effects, Willey said.

"Idenix is the only small cap (company) with access to clinical and preclinical pipeline candidates from all three primary antiviral classes in hepatitis C," he said, in a note to investors. "This makes the company a potential target for one of the many larger players looking to establish a control premium within the hepatitis C space through the consolidation of antiviral assets."

Hepatitis C is caused by a blood-borne virus that can lead to liver scarring or liver cancer. Current treatments on the market include combinations of the drugs peginterferon and ribavirin, but less than half on it are cured. There is currently a large push by several companies to develop treatments that directly target the virus, making the outlook for the hepatitis C market very competitive.

Norm swaps barstool for saddle at Chicago motorcycle charity ride

<http://www.clutchandchrome.com:80/>

Green Ribbon Ride features George Wendt as it raises money at Saturday's event

A famous face is joining a group of motorcycle enthusiasts for a scenic ride through Chicago's western suburbs to raise money for a local charity.

Television and film star George Wendt will make an appearance at the Gear up for Green Ribbon Ride taking place Saturday morning and starts at the Kendall County Fair Grounds in Yorkville Illinois.

Organized by the Walter Payton Center Guild, proceeds from the rally support research and treatment of hepatitis, colon cancer, organ transplantation, diabetes and obesity at the University of Illinois Medical Center's Walter Payton Liver Center.

Additionally, 30 percent of this year's proceeds will benefit the treatment of gastrointestinal and liver diseases at Jesse Brown VA Medical Center.

The ride finds its roots in the Gastrointestinal and Liver Disease (GILD) Council who are dedicated to improving the quality of life of family members, friends, neighbors and business associates afflicted by hepatitis C, colon cancer and digestive, liver or nutritional diseases. Over the last 10 years, state budget cuts have dramatically decreased state funding for the UIC's Digestive Disease and Liver Center. With the help of individuals, corporations and organizations, the GUILD Council established the Chicago Green Ribbon Motorcycle Rally as a fundraising effort for UIC.

Best known for his role on the popular television show 'Cheers' playing Norm, George Wendt started his stage career by appearing in the comedy group 'The Second City' and went on to have regular appearances on Saturday Night Live.

The ride is celebrating its seventh year and expecting hundreds of riders to enjoy the scenic rides through Chicago's western suburbs. It's the first-ever warm-weather Chicago motorcycle rally. Motorcycle enthusiasts gather from the Chicagoland area to display their prized machines and enjoy live music, food, family entertainment and raffles.

In 2008, more than 800 Riders attended the Chicago Green Ribbon Motorcycle Rally, which raised over \$50,000 for the UIC Medical Center.