

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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July 20, 2009

Paladin Labs Inc. Announces Research and Development Contribution from the National Research Council

<http://pr-canada.net>

Paladin Labs Inc. (TSX:PLB), a leading Canadian specialty pharmaceutical company, announced today that its biotechnology division, ViRexx, has received a contribution from the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP). This 14-month project will focus on the development of bio-nanoparticle-based siRNA therapeutic vaccines using Chimigen® Vaccine Platform for Hepatitis B (HBV) and Hepatitis C (HCV) infections.

"We are pleased to be working with NRC to further develop this promising technology, and the financial support, in addition to both technical and business oriented advisory services, from NRC-IRAP will accelerate the development of ViRexx's proprietary Chimigen® Platform for multiple uses in the field of infectious diseases," commented Dr. Rajan George, the Chief Technology Officer of ViRexx.

ViRexx is currently developing a Chimigen® HBV Therapeutic Vaccine to address the 370 million chronic carriers of Hepatitis B virus worldwide, who are poorly served by existing therapies. ViRexx is also developing Chimigen® HCV Therapeutic vaccines, as well as bio-nanoparticle-based siRNA therapeutic vaccines for both HBV and HCV infections.

"The acquisition of ViRexx gave us a very promising technology in Chimigen® Platform. We are excited to be working with NRC-IRAP on the development of this important technology platform", added Jonathan Ross Goodman, President and CEO of Paladin Labs Inc.

Screening for Hepatocellular Carcinoma in Patients With Hepatitis C Cirrhosis -- An Expert Interview With Robert G. Gish, MD

www.medscape.com

Hepatocellular carcinoma (HCC) generally develops within an established setting of chronic liver disease and cirrhosis. Data from a population-based study of cancer epidemiology show that the incidence of this liver malignancy continues to increase rapidly in the United States, with hepatitis C virus (HCV) infection responsible for the majority of cases. HCV is highly prevalent in the United States.

Although the number of new cases of HCV infection has fallen from a high of 240,000 per year in the 1980s to about 26,000 per year in 2004, the prevalence of individuals infected with the virus for more than 20 years is expected to continue to increase as the population ages. Therefore, this increasing incidence of HCC is expected to continue to rise as the burden of HCV-related disease increases. Infection with HCV increases the risk for HCC by promoting fibrosis and eventually cirrhosis, and the risk of developing HCC is greatest among individuals with HCV infection and cirrhosis. HCC is a potentially viable target for screening and surveillance for a number of reasons, first of which is that it occurs in a well-defined risk population. Routine screening and surveillance of cirrhotic patients has been advocated and is widely practiced.

Medscape spoke with Robert G. Gish, MD, Medical Director, Liver Transplant Program; Chief, Division of Hepatology and Complex GI, California Pacific Medical Center, San Francisco, California, to explore the latest data on the magnitude and determinants of HCV-related HCC, setting the stage for a discussion of the current recommendations for HCC screening and the

implications for clinical practice.

Medscape: What is the impact of the overall liver disease burden attributable to HCV infection, and why is the disease burden of advanced hepatitis C projected to sharply increase over the next few decades despite a decrease in new disease acquisition?

Dr. Gish: The disease burden attributable to hepatitis C infection continues to increase even though the rate of new hepatitis C cases continues to decline. This is due to the fact that hepatitis C infection can evolve into cirrhosis and cancer over a 20- to 50-year time period in at least 20% of patients. As hepatitis C disease "matures," there is an increased risk for liver failure and an increased risk for liver cancer that increases by a few percent each year. Typically, about 20% of all infected individuals develop cirrhosis, with an increased rate in patients with fatty liver, excess alcohol consumption, or HIV coinfection. Patients with cirrhosis, or advanced fibrosis, are at increased risk for liver cancer, and this risk is approximately 10% to 20%. Thus, 4% of all hepatitis C-infected individuals (approximately 5 million in the United States and 170 million worldwide) are at risk for hepatitis C-induced HCC.

Medscape: The most advanced histologic injury related to chronic liver disease, including hepatitis C, is cirrhosis, and it almost always precedes the onset of liver failure and the development of HCC. Can you describe the natural history of HCV-related cirrhosis with a view toward the association between chronic HCV infection and histologic cirrhosis?

Dr. Gish: From previous general information on hepatitis C, cirrhosis has been the focus of discussions in terms of risk for HCC. The rate of chronic HCV infection is influenced by an individual's age, sex, race, and viral immune response. It is estimated that up to 75% to 85% of persons infected with the virus will progress to chronic infection and then be at risk for the development of complications, including compensated and decompensated cirrhosis, and HCC. The rate at which cirrhosis progresses varies by individual and is affected by a number of factors, including the amount of alcohol consumed, age at time of initial HCV infection, degree of inflammation and fibrosis on liver biopsy, coinfection with HIV and hepatitis B, and the presence of other comorbid conditions such as metabolic syndrome. Approximately 10% to 15% of HCV-infected individuals will ultimately progress to cirrhosis within the first 20 years, with 20% or more progressing after 2 decades of disease. Results from the HALT-C [Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis] trial revealed that patients with chronic hepatitis C and advanced fibrosis who received 3.5 years of maintenance pegylated interferon can still be at risk for developing liver cancer; therefore, there is a consideration to initiate liver cancer surveillance in patients with advanced fibrosis.

Medscape: What is the risk for HCC in patients with advanced fibrosis?

Dr. Gish: Although chronic HCV infection may lead to cirrhosis, liver failure, and the development of HCC, not all patients will progress to these endpoints. The risk for HCC in patients with advanced fibrosis has recently been highlighted in a study by Lok and colleagues at 1%. It has also been referenced to be in the 2% to 5% range by other studies, including Bonis and colleagues' predictive model for the development of HCC, liver failure, or liver transplant for individual patients with chronic hepatitis C.

Medscape: Are there any marked regional differences/global differences in the incidence of

HCC?

Dr. Gish: At this time, there do not appear to be any marked regional differences in the incidence of HCC that are different or inconsistent with the regional prevalence of HCV infection. The global differences in HCC incidence tend to follow the overall global incidence of viral hepatitis B or viral hepatitis C and the evolution to cirrhosis in HCV-positive patients. There are other risk factors for HCC that could increase the risk for liver cancer in certain regions that may be genotype dependent or related to exposure to aflatoxins, but these risks have most notably been seen in the hepatitis B setting, not hepatitis C.

Medscape: What is the current standard for screening and surveillance for HCC in the setting of HCV-induced cirrhosis? Please provide the underlying clinical context driving these recommendations, with a view toward the clinical implications.

Dr. Gish: Surveillance refers to the regular testing of an individual for a disease or problem -- that is, the repeated application of screening tests. Screening is a term that should only be used to refer to the application of a diagnostic test in persons at risk. The standard screening and surveillance strategy for HCC in the setting of HCV-induced cirrhosis includes ultrasound examination, with the recommended surveillance interval of 6-12 months. Alpha-fetoprotein (AFP) measurement should be considered as a supplement to this screening and surveillance process; AFP alone should not be used for screening unless ultrasonography is not available. This HCC screening/surveillance process has been found to be cost effective.

The AASLD [American Association for the Study of Liver Diseases] guidelines on the management of HCC highlight the importance of screening and surveillance. The guidelines go into extensive detail about surveillance using AFP measurement and ultrasound examination every 6-12 months but focus on ultrasound as the predominant surveillance method. Specific hepatitis B carrier groups are identified and recommended for screening/surveillance, including Asian men 40 years of age or older, Asian woman 50 years of age or older, all cirrhotic hepatitis B carriers, those with a family history of HCC, individuals from sub-Saharan Africa who are over 20 years of age, and noncirrhotic hepatitis B carriers with high serum HBV DNA levels. The guidelines make a strong statement that patients with cirrhosis due to hepatitis C, cirrhosis due to alcohol, and cirrhosis due to other causes need to undergo screening and surveillance as well. As mentioned, this screening and surveillance process has been found to be cost effective. Ultrasound examination has been reported to have a sensitivity ranging between 65% and 80% and a specificity > 90% when used as a screening test. The 6- to 12-month interval for surveillance has been proposed based on the doubling time of HCC at a median of 6 months (range, 1-19 months).

Computed tomography (CT) scan and magnetic resonance (MR) imaging scan do not have a specific role as first-line initial screening or surveillance tools for liver cancer. These tools are complementary to ultrasound when 1 of 2 clinical scenarios presents: an increasing AFP level but a negative ultrasound, or an abdominal ultrasound that reports a suspected tumor. The other major setting for these other imaging modalities is when there is an abnormality found on ultrasound that needs to be confirmed by 1 or 2 imaging tests. On CT or MR, you expect to see a rapid vascular "blush" and then a rapid washout in the third and fourth phases of these vascular dynamic studies. These scans, according to UNOS guidelines, can serve either alone or be complementary for the diagnosis of HCC and obviate the need for a biopsy of the tumor to prove

it is cancer. CT scans are expensive, and each CT scan now has a radiation risk that is equivalent to approximately 130 chest x-rays with a theoretical long-term risk for increased chances of postradiation malignancy. MR scans appear to be safe, but nephrogenic sclerosing fibrosis may occur in patients who receive gadolinium. This has been predominantly seen in patients on dialysis, but informed consent for the use of gadolinium in patients with renal insufficiency needs to be completed.

AFP has been moved to a second-line test because of its poor sensitivity and specificity. The specificity is low at low AFP levels, and sensitivity is low when the AFP is > 100 ng/mL. Patients who are on the liver transplant waiting list almost universally have cirrhosis. Thus, these individuals will fall into the standard screening and surveillance process. Newer biomarkers, such as des-gamma-carboxy prothrombin and AFP-L3, an isoform of AFP, are emerging as novel tools either for enhancing surveillance for HCC or identifying those patients who have vascular invasion and who are at high risk for recurrent disease after different surgical or ablative procedures. All 3 of these biomarkers, AFP, AFP-L3, and des-gamma-carboxy prothrombin, are FDA approved, and there are emerging data that they may have utility in a number of clinical settings.

The degree of fibrosis/cirrhosis in hepatitis C is staged on a scale of 0-4, with stages 0-1 having little chance of progressing rapidly. To date, strategies for screening or surveillance in patients with stages 0-2 disease have not been recommended or defined. On the basis of emerging data from the HALT-C study, stage 3 or bridging fibrosis may emerge as the new trigger point for initial screening and subsequent surveillance for HCC. Finally, in terms of the considerable economic consequences, the annual cost of HCC in the United States was determined to be about \$454 million, with a per-patient cost of \$32,907. Stravitz and colleagues demonstrated the benefits of surveillance for HCC: the quality of the surveillance had a direct effect on HCC stage at time of detection, access to liver transplantation, and survival.

Medscape: Is there a role for liver biopsy in the screening/surveillance for HCC?

Dr. Gish: There is no specific role for liver biopsy in screening or surveillance for HCC. However, liver biopsy has a role in those patients with indeterminate disease, with lesions typically between 1 and 2 cm, and is warranted in the setting of cirrhosis without classic imaging criteria, or the presence of a new liver mass in a patient without chronic liver disease or at low risk for HCC, especially if there is an atypical lesion or there is an absence of biomarkers. The use of liver biopsy to evaluate for HCC has now been relegated to a second- or third-line position. There are associated risks for tumor seeding and tumor tracking that range from 0% to about 12%.

Medscape: Successful antiviral therapy in patients with HCV-related cirrhosis may decrease the risk for HCC; thus, efforts to decrease morbidity and mortality associated with chronic HCV infection may be focused on viral eradication to prevent the onset of liver failure, slow progression to cirrhosis, and prevent development of HCC. However, because as many as 50% of patients fail to achieve a sustained virologic response to the current standard of care (combination pegylated interferon + ribavirin), there is increasing emphasis on emerging novel treatment options. What can you tell us about some of these therapeutic strategies on the near horizon and their potential to "disrupt" the natural history of HCV infection at an early stage in the disease course and thereby reduce the incidence of serious complications (eg, HCC)?

Dr. Gish: Successful antiviral therapy in patients with HCV-related cirrhosis decreases the risk for HCC, justifying the application of antiviral therapy, especially in those patients with advanced fibrosis or early cirrhosis. This reduction in risk is most profound in individuals who have sustained virologic response. New therapeutic strategies are evolving for the treatment of hepatitis C. Currently, combination pegylated interferon and ribavirin is the standard of care. This strategy is associated with a viral response rate in advanced fibrosis and early cirrhosis that ranges from about 30% to 40%. This is lower than the rate achieved in individuals with standard histology.

Recognizing the increasing burden of HCC due to HCV infection, the relatively low overall response rates to the current standard of care, and the fact that the associated side effects may affect adherence, outside of trying to optimize and enhance the current therapeutic approaches, the focus has shifted to the investigation of new approaches and therapies. New agents include the so-called specifically targeted antiviral therapies for HCV [STAT-C], which are aimed at specific HCV viral proteins -- they include protease and polymerase inhibitors. Although a number of agents are currently under investigation, the STAT-C therapies are perhaps, in terms of timeline, furthest along and likely the closest to having an impact on management. Recent data from the telaprevir* (selective HCV NS3-4A serine protease inhibitor) group published in *The New England Journal of Medicine* have shown enhanced sustained virologic response rates in the 60% to 70% range with treatment durations of 12-24 weeks for telaprevir-containing regimens.

Another NS3 protease inhibitor, boceprevir,* when used in combination with the current standard of care, also demonstrated significantly increased response rates (60% to 75% range) with 48 weeks of therapy. R1626,* an inhibitor of the NS5B-RNA-dependent HCV RNA polymerase, has also demonstrated good efficacy in achieving undetectable HCV RNA when used in combination with the current standard of care. Other strategies on the horizon include novel interferon preparations to help improve the side-effect profile, such as albumin-bound interferon* and long-lasting interferons*.

Medscape: Finally, what are some of the challenges to instituting effective screening/surveillance programs for HCC; and, looking to the future, what are the issues most important to address?

Dr. Gish: There are major challenges in instituting effective screening and surveillance programs for HCC. One of the most important issues is the perception in the community that there is no treatment for HCC. Another major hurdle is the lack of disease surveillance that can lead to an increased risk for this liver malignancy. It is estimated that less than 50% of individuals in the United States know that they are infected with HCV or hepatitis B virus.

There is also the issue of increased liver cancer risk in NASH [nonalcoholic steatohepatitis]-induced cirrhosis, but this has not clearly been communicated to the hepatology, gastroenterology, and primary care communities. It has also not been clearly communicated that HCC treatment includes potential cures, such as resection or ablation therapies or, more importantly, liver transplantation. Screening and surveillance has been deemed cost-effective and life saving, but this needs to be communicated to the general community as well. There are also technical issues with low-quality ultrasound studies due to lack of training and, in my opinion, a lack of defined protocols. Effective screening for disease states; subsequent institution of liver

cancer surveillance techniques that are of high competence; and, furthermore, recall programs that can be instituted through large healthcare systems or on an individual patient basis I believe will all eventually help improve HCC outcomes.

*The US Food and Drug Administration has not approved this medication/dosage for this use.

July 21, 2009

Idenix Pharmaceuticals Successfully Completes Proof-of-Concept Study of IDX184 for the Treatment of Hepatitis C Virus (HCV)

<http://www.lifesciencesworld.com>

(posted on 20/07/2009)

Idenix Pharmaceuticals, Inc. (Nasdaq: IDIX), a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral diseases, today announced that it has successfully completed a three-day proof-of-concept study of IDX184. Idenix is developing IDX184, a novel liver-targeted prodrug of 2'-methyl guanosine nucleotide, for the treatment of HCV.

This double-blind, placebo-controlled, monotherapy, dose-escalation study evaluated the safety and antiviral activity of IDX184. In this study, 41 treatment-naïve HCV genotype-1-infected patients were randomized to receive either IDX184 or placebo once-daily for three days. Four dosing cohorts (25 mg, 50 mg, 75 mg and 100 mg) of IDX184 were evaluated. IDX184 was well tolerated in this study with no serious adverse events reported and no discontinuations from the study. Patterns of adverse events were similar between IDX184- and placebo-treated patients. Viral load declines were observed in 30 of the 31 IDX184-treated patients, with no response in one patient in the 25 mg cohort. Significant viral load reductions were observed in the three higher dose cohorts (50, 75 and 100 mg/day). Post-treatment viral load data suggest no evidence of drug accumulation. The table below summarizes mean HCV RNA reductions observed in this study per cohort:

Cohort	Dose	End of Treatment Mean Change in HCV RNA (log10)	Patients with 1 log10 or Greater Reduction in HCV RNA at End of Treatment
A (n=6*)	25 mg/day	-0.47	1
B (n=8)	50 mg/day	-0.69	1
C (n=8)	75 mg/day	-0.70	2
D (n=9)	100 mg/day	-0.74	4
Control (n=8)	Placebo	+0.01	0

* Eight subjects were randomized to this cohort, two of whom were excluded from the viral load evaluation due to an error in dosing.

“We are pleased with the results of this study, which support the potential for IDX184 to be a best-in-class nucleoside/tide polymerase inhibitor with demonstrated antiviral activity and tolerability, coupled with a low once-daily dose,” said Douglas Mayers, M.D., chief medical officer of Idenix. “Now that we have successfully completed the proof-of-concept study in HCV-infected patients, we plan to advance IDX184 into a 14-day dose-ranging study in combination with the current standard-of-care, pegylated interferon and ribavirin, to determine the optimal IDX184 doses to advance into broader clinical trials.”

In the 75 and 100 mg/day cohorts, patients receiving IDX184 experienced improvements in two key markers of liver injury, with mean AST and ALT levels decreasing to below the upper limit of normal. These improvements were sustained for up to 6 days post-dosing, and most levels returned to baseline 14 days post-treatment.

“We have made great progress in our HCV discovery and development programs this year,” said Jean-Pierre Sommadossi, Ph.D., chairman and chief executive officer of Idenix. “With the successful completion of the proof-of-concept study for IDX184 and plans to file investigational new drug applications in the coming months from our non-nucleoside polymerase inhibitor and protease inhibitor programs, we are closer to achieving our ultimate goal of developing novel combinations of direct-acting antivirals for the treatment of hepatitis C.”

The company plans to report the full data set from this study at a scientific meeting later this year.

About IDX184

IDX184 is a novel, liver-targeted 2'-methyl guanosine nucleotide prodrug, which includes Idenix's proprietary liver-targeting technology. This technology enables the delivery of nucleoside monophosphate to the liver, leading to the formation of high levels of nucleoside triphosphate, potentially maximizing drug efficacy and limiting systemic side effects with low, once-daily dosing of drug.

Conference Call Information

Idenix will hold a conference call and webcast today at 4:30 p.m. ET. To access the call please dial 800-774-5358 U.S./Canada or 706-758-9475 International and enter passcode 20088902 or to listen to a live webcast and view accompanying slides, go to “Calendar of Events” in the Idenix Investor Center at www.idenix.com. A replay of the call will also be available from 6:30 p.m. ET on July 20, 2009 until August 3, 2009 12:00 a.m. ET. To access the replay, please dial 800-642-1687 U.S./Canada or 706-645-9291 International and enter passcode 20088902. An archived webcast will also be available for two weeks after the call on the Idenix website.

About Idenix

Idenix Pharmaceuticals, Inc., headquartered in Cambridge, Massachusetts, is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral diseases. Idenix's current focus is on the treatment of infections caused by hepatitis C virus. For further information about Idenix, please refer to www.idenix.com.

Hepatitis Trials Could Be Pushed Back

<http://www.fox5vegas.com>

Endoscopy Center Files For Bankruptcy

LAS VEGAS -- The Endoscopy Center of Southern Nevada has filed for bankruptcy, and trials for hundreds of alleged victims could be delayed.

Court proceedings were supposed to start this fall but could be pushed back months. The center filed for Chapter 7 protection which is a liquidation process that will require the center to sell off its assets.

Local attorneys said the filing is unfair.

"The Endoscopy Centers have been out of business nearly two years. Why wait three months before trial to file bankruptcy action to stop the proceedings?" said attorney Ed Bernstein.

Bernstein said his clients have waited long enough for their trial against the Endoscopy Center.

It's been more than a year since the hepatitis C scare. Allegations surfaced about unsafe injection practices after several people contracted the virus.

Bernstein said his legal team has been getting the run-around.

"Doctors have not testified. They've taken the Fifth Amendment. They've refused to give us documents, delaying techniques," Bernstein said.

He said these techniques only hurt the victims -- a move he believes the defense is going for.

"Victims get older. Evidence gets lost. Witnesses leave. The longer you delay, typically the more advantageous it is for the defense," Bernstein said.

Legally, the Endoscopy Center can file, and by law, all court proceedings must stop.

But Bernstein said these victims are in pain, and he said justice delayed is justice denied.

Now Bernstein and other attorneys must go to federal court to have a judge "lift the stay" and have the trials moved back and resume in state court. All of this will push back the trials for an unknown amount of time.

The center has not released any comment.

Health officials predicted up to 40,000 people could have been at risk for Hepatitis C.

Rock Island Chairman wants investigation into Hepatitis outbreak

<http://www.wqad.com>

Chris Williams

ROCK ISLAND COUNTY, Illinois - Tonight the Rock Island County Chairman says he'll ask for an investigation into the outbreak and handling of the Hepatitis A situation. Jim Bohnsack

told News 8's Chris Williams he'll ask the sheriff's department to look into the outbreak. With the public health and tax dollars at stake Bohnsack wants to know whether the outbreak could have been avoided and who's at fault.

"If our investigation shows the way I think I it's gonna be, McDonalds has got to be on the hook for that kind of money for all that expense that we've got", said Bohnsack.

The Milan McDonalds has been at the center of controversy after it closed last week and health officials revealed an employee at the fast food restaurant had tested positive for Hepatitis A.

Bohnsack says he'll wait until the vaccination push is over this week then contact the sheriff's department and ask them to look into the matter. If they find a business is at fault, and failed to report problems, Bohnsack said he won't hesitate to use all of the tools necessary to see that someone pays for this mess.

"We have a State's Attorney and we'll go after them if it's not the county's fault. If it is, we'll take measures to correct that", the Chairman added.

He admitted there is never a good time for an outbreak like this but this one is coming at very inopportune time financially. Budgets are already tight and county taxpayers just recently learned they'll foot the bill for the Rock Island Mayoral recount. Bohnsack says, last month state budget cuts forced the health department to lay off at least two workers but he feels that had no affect on how the department handled this crisis.

Smoking does not up mortality in liver transplant recipients

<http://www.rtmagazine.com>

NEW YORK (Reuters Health) - New research indicates that survival is similar for smokers and non-smokers who undergo liver transplantation.

At least one large insurance company is denying approval for liver transplantation unless the candidate has abstained from smoking for three months, according to Dr. Michael J. Englesbe and colleagues at the University of Michigan Health System, Ann Arbor. A review of their center's experience, however, suggests that such policies are unlikely to improve patient survival.

The findings, reported in the *Journal of the American College of Surgeons* for June, stem from a study of 2260 patients with chronic liver disease who were evaluated for liver transplantation from January 1, 1999 to June 1, 2007. The subjects included 760 active smokers and 1500 non-smokers.

Smokers were significantly younger than non-smokers and were more likely to be male, have hepatitis C, have less severe liver disease, and less likely to receive a transplant.

On multivariate analysis, substance use, more severe liver disease, hepatitis C, and older age were all linked to increased mortality ($p < 0.05$ for all).

Smoking did not increase (or reduce) mortality at any time point studied in evaluated patients or

transplant recipients, the researchers found.

"Decisions about the transplantation candidacy of smokers should be made on a patient-by-patient basis after a detailed clinical assessment of the patient," the authors state.

"Payer policies requiring abstinence from smoking potentially prohibit excellent liver transplantation candidates from receiving what is currently the only viable lifesaving therapy and puts undue weight on a less important issue," the researchers emphasize.

J Am Coll Surg 2009;208:1077-1084.

Hep C Scandal Has Colorado Rethinking License for Surgical Techs

<http://www.newsinferno.com>

The hepatitis C scandal that recently broke in Colorado has taken a new turn. Now, officials there are looking at a proposal to license and maintain oversight on surgical technicians, the Denver Post reports.

The proposal had been rejected but is receiving new light in the wake of the scandal that has expanded to two other states and has a victim toll that recently rose to 11. The Denver Post previously reported that 11 patients from the Rose Medical Center contracted the dangerous and sometimes deadly blood borne liver disease; New York and Texas are also investigating the outbreak. Officials say that the 11 cases may be linked to Parker, who has tested positive for hepatitis C.

Hepatitis C is spread by contact with infected body fluids, especially blood. The disease attacks the liver, and can lead to cirrhosis or cancer of the liver. There is no vaccine for hepatitis C and the disease can be fatal. The disease is incurable, but can be treated.

Kristen Diane Parker, 26, faces federal criminal charges for her alleged conduct. The former surgical tech worked at Rose from Oct. 21 to April 13 and at Colorado Springs' Audubon Surgery Center from May 4 until June 29. She was allegedly swapping sterile Fentanyl syringes with dirty saline-filled syringes to feed her addiction. Parker worked at Christus St. John Hospital outside Houston, Texas between May 2005 and Oct. 2006, the Associated Press (AP) previously reported and at Northern Westchester Hospital in New York's Mount Kisco between Oct. 8, 2007, and Feb. 28, 2008.

The AP also previously reported that Parker tested positive for hepatitis C before she began working at Rose, but never followed-up on the diagnoses. A federal magistrate has since ordered Parker jailed without bond, saying she switched the needles even though she knew she had hepatitis C, the AP said. It is unknown if Parker was positive for hepatitis C when she worked in New York.

News broke late last week that Parker was fired from the New York location in 2008, said the Denver Post; the reason remains undisclosed. That information is making the possibility for a central database of such problems more appealing and health officials are wondering if the rejected proposal could have helped spot Parker's moving from Audubon after being fired by

Rose, the Denver Post reported. “What regulation could have done in this instance was prevent the employment of the person at the second facility,” said Ned Calonge, chief medical officer for the Colorado Department of Public Health and Environment, quoted the Denver Post.

In 2004, a group of surgery assistants requested licensure and regulation; however, a review found no need for such oversight stating: “Not regulating surgical assistants had not ‘resulted in significant harm to Colorado consumers’; surgical responsibilities vary widely, and many different kinds of employees perform similar surgical functions; and licensing creates monopolies and fails to recognize overlapping skills and abilities,” said the Denver Post.

The proposal would enable the licenses and rights of medical professionals suspended by the state if and when serious allegations, with evidence, are presented and would allow viewing by potential employers.

July 22, 2009

Members of Congress Speak Out on Hepatitis B and C

<http://www.asianweek.com>

An Open-to-the-Public Hepatitis B & C Screening hosted by House Representatives on Capitol Hill Draws Crowds and Builds Awareness of the Diseases’ Devastating Effects

WASHINGTON, DC - Demonstrating their long-held commitment to the elimination of hepatitis B and C on July 21, Congressman Mike Honda (D-San Jose), Congressman Anh “Joseph” Cao (LA-02), Congressman David Wu (OR-01), Rep. Bill Cassidy (R-LA-06), and Congressman Charlie Dent (PA-15) gathered with more than 70 other people on Capitol Hill to learn about and get tested for the two serious diseases. The public event, which provided free hepatitis testing, educational materials, and counseling services, was initiated by the Chinese American Medical Society, in partnership with the Association of Asian Pacific Community Health Organizations (AAPCHO) and several other health advocacy groups.*

“Yesterday’s screening event was an important milestone,” said Jeff Caballero, executive director of AAPCHO. “It marks the beginning of a unified effort between the hepatitis B & C community and our congressional champions, working together to tackle our national legislative challenges. After we’ve accomplished our legislative goals towards eliminating these diseases, we will all be able to say that it started here, with this event on Capitol Hill and others like it around the country.”

A Silent Disease with a Deadly Impact

Chronic viral hepatitis is a highly contagious virus that infects the liver, causing liver disease, liver cancer, and premature death. Although hepatitis B and C are treatable diseases when detected early and properly managed, an estimated 4.6 million people living in the United States are currently infected with either hepatitis B or hepatitis C. Both are considered “silent diseases” because frequently, those infected have no obvious symptoms. Without proper screening and treatment, viral hepatitis patients frequently die from liver cancer or liver disease and can pass the infection on to others.

Reducing Disparities and Empowering Vulnerable Communities



There are serious disparities in infection rates among many minority communities. In the U.S., as many as 1 in 10 Asian Pacific Islander Americans are chronically infected with the hepatitis B virus and hepatitis C infection is 2 to 3 times more prevalent among African Americans as it is among Caucasians.

Congressman David Wu (OR-01), a co-host of the event, views yesterday's screening as a step towards reducing disparities through education and action: "When it comes to maintaining your health, knowledge is power...It is vital that people take advantage of opportunities to get tested for hepatitis B. Testing is essential to early detection and appropriate treatment."

Congressman Charlie Dent (PA-15) praised Tuesday's event as also a valuable chance "for lawmakers and their staff to learn more about hepatitis, be educated about hepatitis testing, and demonstrate Congress's commitment to the elimination of chronic viral hepatitis."

Framing hepatitis B & C awareness within the broader discussion on health care, Congressman Anh "Joseph" Cao (LA-02) pointed out "[as] Congress works to achieve national health care reform, it is vital that preventive health care is part of the debate. Hepatitis B and C are treatable illnesses when detected early, and today's event is a tremendous opportunity to educate the American people on the ability they have to either reduce or prevent the progression of this disease."

"The valuable role that AAPCHO and its partnering organizations undertake in educating the public on preventing, diagnosing and treating chronic hepatitis B and C is an important component in addressing the overall health of our communities, and work of increasing interest as Congress continues to deliberate on comprehensive health care reform legislation," acknowledged Congresswoman Madeline Bordallo, Chair of the Health Task Force of the Congressional Asian Pacific American Caucus.

*Other Participating organizations include: Hepatitis B Foundation; Caring Ambassadors Program; Hepatitis Education Project; Hepatitis B Initiative-DC; National Alliance of State and Territorial AIDS Directors (NASTAD); and the National Viral Hepatitis Roundtable (NVHR).

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 Pacific Islanders in the United States.

<http://www.aapcho.org>

Top Hepatitis C Treatments Equally Effective

<http://health.usnews.com>

Landmark assessment also finds treating early helps prevent liver failure

WEDNESDAY, July 22 (HealthDay News) -- A landmark hepatitis C virus study shows that the top two treatment options are equally effective and safe.

The long-awaited study, thought to be the largest of its kind, is important for the 180 million people worldwide -- 4 million in the United States -- who are infected with hepatitis C virus and

at risk for liver scarring, organ failure and death.

Hepatitis C is America's leading cause of liver failure, liver cancer and liver transplantation. The disease is transmitted by contact with blood through sexual activities, drug use or personal care items.

The study of 3,070 adults at Johns Hopkins and 118 other U.S. medical centers showed that treating patients with either of the two standard antiviral therapies is safe and helps prevent liver damage.

The report appears online July 22 in the *New England Journal of Medicine*.

The drug therapies -- peginterferon alfa-2b plus ribavirin, or peginterferon alfa-2a plus ribavirin - worked in 39.8 percent and 40.9 percent of patients, respectively. Commonly observed side effects included anemia, fatigue, headache, nausea, insomnia and depression.

The equality of the only two U.S. Food and Drug Administration-approved drug-treatment regimens for suppressing the virus surprised the researchers, according to a news release from Johns Hopkins.

"When considering treatments for hepatitis C infection, patients and their doctors now have solid evidence that they can weigh both antiviral therapies equally for effectiveness, safety and tolerability," Dr. Mark Sulkowski, medical director of the Johns Hopkins Center for Viral Hepatitis and the study's co-principal investigator, said in the news release.

While 10 percent to 13 percent of the study's participants quit the treatment because of side effects, Sulkowski said that was "within expectations for this type of therapy."

The researchers also found that the sooner patients get into treatment, the better.

"Treatment success is highly dependent on starting before liver cirrhosis has already set in, which can take from a year to decades," Sulkowski noted in the news release.

Evidence from the study also will help doctors learn more quickly whether the patient is responding to the drug therapy. This will allow patients to avoid side effects and the expense of taking unnecessary drugs.

The study was funded by the Schering-Plough Corp., the maker and provider of the study drugs ribavirin and peginterferon alfa-b.

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Mass. General-based research center will investigate why immune system fails to control hepatitis C

<http://www.eurekalert.org>

Collaborative project wins five-year, \$15 million NIH grant

A research consortium based at Massachusetts General Hospital (MGH) has been awarded \$15 million from the National Institute of Allergy and Infectious Diseases to investigate how the hepatitis C virus (HCV) resists suppression and clearance by the immune system. The five-year grant will support a Cooperative Center for Translational Research in Human Immunology, which also will focus on how some individuals successfully recover from HCV while the infection becomes chronic in most of those infected, with a special emphasis on immunological events in the liver as the site of HCV replication.

"Hepatitis C is a major global health problem for which existing therapies are inadequate," says Raymond Chung, MD, director of Hepatology in the MGH Gastrointestinal Unit and co-director of the research center. "Improving our understanding of how and why the virus consistently evades immune system control should lead us to better ways of treating hepatitis C and possibly other chronic viral infections." Chung will lead a project to better define the role of the liver cells called hepatocytes in the innate and adaptive immune response to HCV infection.

Center co-director Paul Klenerman, PhD, of Oxford University will examine properties of the T cells that migrate to the liver in response to HCV infection. Additional principal investigators and project goals are:

- Georg Lauer, MD, PhD, MGH Gastrointestinal Unit, and John Wherry, PhD, Wistar Institute – investigate the functional capacity of CD4 and CD8 T cells within the liver in chronic HCV infection;
- Todd Allen, PhD, Ragon Institute of MGH, MIT and Harvard, and Matthew Henn, PhD, Broad Institute of MIT and Harvard – examine how selection pressure applied by T cells affects HCV evolution;
- Gordon Freeman, PhD, Dana-Farber Cancer Institute – develop a panel of reagents designed to modulate signaling in key immune cells;
- Joseph Misdraji, MD, MGH Pathology – create a library of liver cells and tissue from HCV-infected and uninfected patients to use in study experiments;
- Nicholas Haining, MB, ChB, Dana-Farber – develop high-throughput technology platforms to examine and modulate signals inhibiting the immune response.

Almost 170 million people worldwide are infected with HCV, 50 to 80 percent of whom will develop chronic hepatitis, which can lead to cirrhosis, liver cancer or liver failure. Identifying the factors that allow HCV to survive in spite of the immune response against the virus may also improve understanding of immune system failure in other chronic infections, including HIV, Epstein-Barr virus, and tuberculosis.

Massachusetts General Hospital, established in 1811, is the original and largest teaching hospital of Harvard Medical School. The MGH conducts the largest hospital-based research program in the United States, with an annual research budget of more than \$500 million and major research centers in AIDS, cardiovascular research, cancer, computational and integrative biology, cutaneous biology, human genetics, medical imaging, neurodegenerative disorders, regenerative medicine, systems biology, transplantation biology and photomedicine.

Advanced hepatitis drug approved

<http://www.google.com>

An advanced hepatitis drug is to be made freely available to thousands of patients in England for the first time after new guidance on its use was issued.

Tenofovir is currently the only medicine for chronic hepatitis B infection that does not induce resistance after two years.

It has already been approved in Scotland and Wales.

On Wednesday the National Institute for health and Clinical Excellence (Nice) which assesses the cost effectiveness of new treatments backed the drug's use on the NHS in England.

The decision means primary care trusts in England will now start funding the treatment, branded under the name VIREAD.

Professor Graham Foster, consultant hepatologist at Barts and The London NHS Trust in east London, said: "The Nice final guidance recommending VIREAD is a significant advancement for the management of hepatitis B."

More than 325,000 people are believed to be living with chronic hepatitis B in the UK.

The virus is up to 100 times more easily transmitted than HIV. Victims are at risk of developing cirrhosis of the liver and cancer.

Syringe reuse in Alberta didn't spread HIV, hepatitis: Liepert

<http://www.calgaryherald.com>

By Darcy Henton, *Edmonton Journal*

Health Minister Ron Liepert says there's no evidence that the reuse of syringes in some procedures at a High Prairie hospital caused the spread of HIV and hepatitis.

Liepert, commenting Tuesday on a report into the incident by the Alberta Health Quality Council, said the medical advice his department has received suggests the levels of those diseases in that community are not out of line with the norm.

"The real good news is pretty much all of the testing has been completed in High Prairie and although there are instances of individuals that have tested positive for HIV and hepatitis, there has been no ability to link any of those diseases with the issue around the reuse of syringes," he said.

"I think we can rest assured that that issue is behind us."

Liepert added: "It's one of those things that you can't ever be 100-percent certain, but I am confident that due diligence was done."

The health minister refused to blame doctors or nurses for not following protocols, but said the lesson learned is there should be better monitoring to ensure that when new standards and policies are prescribed by his department, they are followed.

"Obviously the review the Health Quality Council has found that was not the case and going forward we're going to do a better job of ensuring that the monitoring takes place and that new standards are followed," he said.

"What I want to ensure is that going forward, if new health standards are put in place . . . they are followed."

Sustained response to interferon improves fibrosis in HIV/HCV co-infected patients

www.aidsmap.com

Liz Highleyman

HIV-positive people who achieve a sustained virological response (SVR) to hepatitis C treatment using pegylated interferon plus ribavirin may experience regression of fibrosis and even cirrhosis, according to study findings presented on Wednesday at the Fifth International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention in Cape Town, South Africa.

Considerable research has shown that liver fibrosis (build-up of scar tissue) tends to develop more rapidly in HIV-positive people co-infected with hepatitis C virus (HCV) than in those with hepatitis C alone. Over time, fibrosis can lead to cirrhosis, liver cancer, and end-stage liver failure.

Spanish researchers conducted a study with a dual aim: to assess fibrosis progression in patients who underwent combination hepatitis C treatment and to evaluate the accuracy of transient elastometry (FibroScan) for staging liver disease in a HIV/HCV co-infected cohort.

Liver biopsy is considered the "gold standard" for assessing liver damage, but it is uncomfortable, expensive and carries a small risk of complications. Researchers have therefore explored a variety of non-invasive methods including blood biomarkers and imaging. FibroScan uses sound waves to measure liver "stiffness."

This prospective cohort study included 294 HCV/HIV co-infected patients treated for hepatitis C between 2000 and 2008. A subset of 171 participants underwent a liver biopsy before treatment and 157 also were tested using FibroScan during follow-up. Liver fibrosis was staged on a scale ranging from 1 (absent or mild fibrosis) to 4 (cirrhosis). Fibrosis regression was defined as a decrease of at least 1 point.

Most participants (80%) were men and the mean age was 41 years. They had been infected with HCV for about 18 years on average. Half had hard-to-treat HCV genotype 1 and just over one-third had genotype 3. At baseline, about half had mild or moderate fibrosis, but 23% had evidence of cirrhosis.

The group had well-controlled HIV disease. They were receiving antiretroviral therapy if indicated and 78% had HIV viral load below 50 copies/ml. At study entry, the average CD4 cell count was about 500 cells/mm³, but the lowest-ever count was 172 cells/mm³ and about one-quarter had received an AIDS diagnosis.

Participants were treated with pegylated interferon plus weight-adjusted ribavirin. Treatment was planned for 48 weeks, and about half completed the full year. Overall, 43% achieved SVR, or continued undetectable HCV viral load six months after finishing treatment.

FibroScan testing was done a median of 44 months after treatment (with a range from one to 88 months). Outcomes were fairly evenly distributed, with 28% experiencing fibrosis regression or improvement, 35% having no change, and 37% experiencing progression or worsening.

Patients who achieved SVR were significantly more likely than non-responders to experience fibrosis regression: 38% of sustained responders had at least a one-point drop reduction in fibrosis score and 24% had at least a two-point drop.

Even some patients with cirrhosis experienced improvement, characterized as "cirrhosis reversal." Again, this was more likely amongst patients who achieved SVR.

A subset of 96 patients received a second FibroScan test a median of 52 months after treatment (or about eight months after the first one). Results were similar or better, indicating continued improvement over time.

After adjusting for other factors, SVR was the only factor significantly associated with fibrosis regression. In contrast with past studies, HCV genotype, baseline HCV viral load, CD4 cell count, type of hepatitis C treatment, and antiretroviral therapy did not predict treatment outcomes.

The researchers concluded that fibrosis improvement occurs in a substantial proportion of sustained responders to interferon-based treatment. Though less common, some non-responders also experienced fibrosis regression.

These findings, they said, support wider use of hepatitis C treatment in HIV/HCV co-infected patients. The goals of future therapies, they added, should be fibrosis regression as well as viral eradication.

Reference

Marti-Belda P et al. Fibrosis regression in HIV/HCV coinfecting patients with sustained virological response to pegylated interferon plus ribavirin. Fifth IAS Conference on HIV Treatment, Pathogenesis and Prevention, abstract MoAb203, 2009.

July 24, 2009

Feds indict Rose surgery technician on 42 counts

<http://www.denverpost.com>

By Felisa Cardona

The Denver Post

Kristen Diane Parker, the former surgery scrub technician suspected of exposing patients to hepatitis C, was indicted by a federal grand jury today on an additional 42 criminal counts.

The new charges against 26-year-old Parker include product tampering and obtaining controlled

substances by deceit.

"I would like to reassure the victims of Kristen Parker that prosecuting this case is a priority and that their interests will be well-represented," said acting U.S. Attorney for Colorado David Gaouette.

Earlier this month, Parker was denied release pending the outcome of her case and remains in federal custody.

She originally was charged by prosecutors with three criminal counts related to tampering with medications meant for patients at Rose Medical Center in Denver and the Audubon Ambulatory Surgery Center in Colorado Springs.

Parker, who has hepatitis C, is accused of stealing a narcotic drug, fentanyl, from surgery rooms and then injecting herself with a syringe containing the drug. Prosecutors say she then filled the same dirty syringe with saline and put it back on the surgical tray before a procedure.

So far, 19 patients from Rose have tested positive for hepatitis C that might be linked to Parker, according to federal prosecutors, an increase from the 11 cases previously announced by health officials.

All of the new charges only cover Parker's alleged conduct at Rose and not her last employer, Audubon.

Testing on patients continues, and more charges could come in later indictments.

Parker could spend the rest of her life in prison if she is convicted.