

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Feb 16, 2009

Lawmakers may pass health standards for body piercings this year

<http://seattletimes.nwsources.com>

By Chantal Anderson

Seattle Times staff reporter

Currently, the state doesn't regulate the body-piercing industry. But legislation establishing health and sterilization standards for body piercers and their shops has a good chance of passing this year, the sponsors say.

OLYMPIA — Whitney Nash, a bartender from Florida, is well-versed in the ways of the body-piercing industry after going through a piercing-apprenticeship program.

So Nash was surprised to learn that Washington, unlike Florida, has no body-piercing health regulations written into law. "Oh my God, are you serious?" Nash said. "That's insane."

The fact that infectious diseases — such as HIV/AIDS, hepatitis C, hepatitis B and MRSA — can spread through improperly sterilized equipment has prompted lawmakers, with encouragement from lobbyists, to take a stand.

For the fifth legislation session, bills that would regulate the industry have been introduced. But this year, sponsors are confident some form of regulations finally will pass.

Troy Amundson, a professional body piercer, has been lobbying for regulation since he contacted Rep. Sherry Appleton, D-Poulsbo, five years ago and urged her to write a bill.

After taking emergency-medical-technician training, he began to worry about the lack of health regulations in the field. Today, he represents more than 120 body-piercing and tattooing shops in Washington.

In 2001, the Legislature passed legislation setting health standards for tattoo parlors, but there is no agency in charge of enforcement. Body piercing remains unregulated.

"The regulations will do a lot to help and protect artists and to help us gain recognition as a professional industry," Amundson said.

Rion Wickersham, owner of Deep Roots, a tattoo and body-piercing shop in the University District in Seattle, said he supports regulations. His shop currently follows industry standards, and he says most shops follow the guidelines pretty closely to protect their reputations and their clients.

"I'm not worried about complying with the rules," he said. "We want there to be regulations."

Nash said any good shops support regulations and licensing. Last week, she got a piercing, a post embedded into her chest with a diamond stud, at Deep Roots.

The shop, which looks more like an art gallery with bright lighting and hundreds of pieces of jewelry on display, was recommended by a friend for its cleanliness.

"I knew they were safe," she said, adding that the piercer did everything by the book.

Kitty Candelaria, executive director of the National Hepatitis C Institute based in Manchester, Kitsap County, said regulations are needed to reduce the risk of disease being spread through the use and improper disposal of unsanitary equipment.

"Anything that has human blood on it — like gloves, or wraps, or gauze — that isn't disposed of in a proper way has the potential to introduce the infection," she said.

Appleton's bill, HB 1085, would establish health and safety standards for body-piercing shops. Violations would be a misdemeanor.

But Sen. Jim Kastama, D-Puyallup, said Appleton's "bill will do nothing except give a false sense of security" because no agency would be responsible to enforce rules.

Kastama is writing his own bill that would require health and safety standards, a licensing program for piercing and tattoo artists and their shops, and inspections every two years by the state Department of Licensing.

Appleton believes passing her bill is important to put the structure of health regulations in place. "I think it's about time that we did it."

The two lawmakers and Amundson met several weeks ago to agree on the terms of Kastama's bill.

Appleton, though, isn't sure how far the Legislature is ready to go. "I don't know if we will get the full package this year," she said.

Gov. Chris Gregoire hasn't taken a position on either bill, said spokesman Pearse Edwards.

Soap and Water Hand Washing Superior to Alcohol-Based Rubs in Reducing Presence of Influenza A

www.medscape.com

February 13, 2009 — Soap and water hand washing and alcohol-based rubs are effective reducing the presence of influenza A virus on human hands, according to the results of a study published in the February 1 issue of *Clinical Infectious Diseases*. Hand hygiene may play an important role in reducing the transmission of pandemic and avian influenza among healthcare workers, patients, and caregivers.

"Although person-to-person transmission of influenza virus is due primarily to aerosol spread, transmission on the hands of patients and their caregivers is also potentially important," write M. Lindsay Grayson, MBBS, MD, MSC, FRACP, FAFPHM, from the Infectious Diseases Department, Austin Health, the Department of Epidemiology and Preventive Medicine, Monash University, and the Department of Medicine, University of Melbourne, Australia, and colleagues. "Appropriate hand-hygiene practices should reduce transmission risk, but there are few in vivo data to confirm the antiviral efficacy of currently available HH protocols. Furthermore, the long-term viability of influenza virus on unwashed human hands remains unclear."

The researchers evaluated the use of 5 hand hygiene protocols on 20 healthcare workers who had previously undergone vaccination with the influenza virus. The hand hygiene protocols included 3 alcohol-based hand rubs (61.5% ethanol gel, 70% ethanol plus 0.5% chlorhexidine solution, and 70% isopropanol plus 0.5% chlorhexidine solution), soap and water hand washing, as well as a control protocol which contained no hand hygiene technique.

In an attempt to mimic a worse-case clinical scenario, a high contaminating concentration of live influenza A virus (H1N1 strain) was poured into the right palm of study participants and then allowed to air dry for 2 minutes. The concentration of H1N1 was evaluated by viral culture and real-time reverse-transcriptase polymerase chain reaction (PCR) both before and after the use of the hand hygiene protocols. In addition, a subset of the participants (n = 8) were assessed for the natural viability of the virus over time in their hands. Among these participants, hand hygiene techniques were not used and their hands remained contaminated for 60 minutes before being evaluated for the concentration of H1N1.

Interestingly, the results of the study revealed that the virus was undetectable in 30% of the participants following the 2-minute air drying period. Nevertheless, no further reductions in the viral concentration occurred following the additional 60-minute waiting period among the subset of participants used to assess the natural viability of H1N1. In the article, Dr. Grayson and colleagues explain that "human hands may be a naturally hostile environment for H1N1 and that the initial act of drying and possibly the presence of natural skin oils on the hands may also have an antiviral effect."

Among those participants with detectable H1N1 after the 2-minute drying period, the 3 alcohol-based hand rubs as well as soap and water hand washing were effective in reducing the viral concentration on participants' hands. However, soap and water hand washing was shown to be statistically superior ($P < .001$) to the alcohol-based hand rubs. The actual difference, though, in viral concentration on the healthcare worker's hands with soap and water hand washing vs the alcohol-based hand rubs was only 1-100 copies/ μ L.

"We believe that our findings have potentially important public health implications, because simple hand washing with unmedicated soap and water appears to be highly effective in removing influenza virus from hands and is, therefore, likely to be effective in preventing transmission of influenza, as long as [hand hygiene] is undertaken appropriately," the authors conclude. "For busy HCWs for whom the number of [hand hygiene] opportunities is likely to be very high, the use of [alcohol-based hand rubs] would seem to be a very suitable alternative."

Clin Infect Dis. 2009;48:285–291.

Scotland outbreak spurs call for change

<http://www.fayobserver.com>

By Jennifer Calhoun

Staff writer

Last year's Hepatitis C outbreak in Scotland County could mean the state will require more needle education for doctors' offices, a state health official said recently.

The state suspects that seven people were infected with the potentially life-threatening disease because of unsafe injection practices associated with nuclear stress test injections performed at the cardiology practice of Dr. Matthew Block, the mayor of Laurinburg.

Hepatitis C is transmitted through the blood — usually by infected needles — and can lead to liver cancer, liver failure or cirrhosis. Some patients can be treated successfully for the disease through long-term drug treatments, while others may require liver transplants or other forms of treatment, according to the Mayo Clinic's Web site.

More than 700 people were tested for the infection after the state Division of Public Health sent 1,200 letters in August to patients who took the test at Block's office between June 25, 2007, and Aug. 26, 2008, said Dr. Zack Moore, a state medical epidemiologist.

After testing, an additional 14 patients were diagnosed with the disease, but they were not necessarily infected from Block's office, Moore said.

Specifics of the improper injection practices have not been identified, but the North Carolina Medical Board ordered Block in August to quit performing the stress tests in his office. The order was lifted Jan. 28.

In an attempt to prevent future outbreaks, state health officials have proposed a plan that would require at least one staff member from each medical facility in the state to complete an infection control course that includes safe injection practices, Moore said.

"We've used it as a way to make our policies stronger," he said. "As a result, we've looked back on our infection control laws in North Carolina and proposed some changes.

"We were a leader in the country in those laws back in 1992. Now we're just updating it and making them stronger. We've also used it as a chance to educate practitioners. Some good has come of it."

In September, a letter from the state was sent to all licensed health care facilities, ambulatory surgery centers, specialty care clinics and primary care clinics in the state advising them of unsafe injection practices.

Moore said he hopes the new policy will give the state a chance to become more involved with other partners at the local, state and national level.

"This has been — we've tried to use this unfortunate incident to make public health stronger," he said.

The state Division of Public Health will hold a hearing on the proposed changes March 26 in the Cardinal Room at 5605 Six Forks Road in Raleigh.

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Doctors Can Now Predict Which Hepatitis B Patients Have The Highest Chance To Achieve Treatment Success With Pegasys(R)

<http://www.medicalnewstoday.com>

New data presented showed that, for the first time, doctors can predict which hepatitis B patients treated with Pegasys® (peginterferon alfa-2a) have the highest chance to achieve a positive treatment outcome—and even a clinical cure.[i],[ii] The study results represent an important step forward, as some patients will now be able to feel confident during their Pegasys treatment about the likelihood of beating the disease.

Several studies at the major Asia-Pacific liver disease meeting (APASL) focused on measuring the decline in levels of a viral protein called surface or 's'-antigen, to provide insight into the likelihood of treatment success for patients treated with Pegasys. S-antigen clearance, considered a clinical cure, is associated with greatly reduced liver cancer, cirrhosis and an improved life expectancy.[iii],[iv],[v]

'In treating hepatitis B, we need to change mindsets and raise expectations so that patients and physicians are focused on achieving the best possible outcome—clearance of the s-antigen. These new data show that measuring s-antigen decline throughout treatment can help determine success in the long-term. Doctors can now therefore make a strong case to certain patients that Pegasys treatment may provide treatment success or even a clinical cure,' said Dr Patrick Marcellin, Professor of Hepatology at the University of Paris and Head of the Viral Hepatitis Research Unit in Hôpital Beaujon, Clichy, France.

'Unlike anti-viral tablets for hepatitis B, which just reduce the number of viral copies, Pegasys also boosts the body's immune system and mobilises it to fight the disease,' commented William M. Burns, CEO Roche Pharmaceuticals Division. 'Due to these immune-stimulating effects, the number of patients treated with Pegasys who achieve a clinical cure has been shown to continue increasing for years after the end of treatment. This supports its use as a first-line therapy for hepatitis B.'

Measuring success with Pegasys in the two types of hepatitis B

There are two types of patients with hepatitis B: those with early disease who still have the envelope or 'e'-antigen in their blood, and those who do not (called 'e-positive' and 'e-negative' disease, respectively). Although some of the treatment endpoints are different, s-antigen clearance is the ultimate goal of therapy in both types of hepatitis B.

All patients start off with e-positive disease. For e-positive patients, loss of the e-antigen after treatment, or 'e-seroconversion', signifies that therapy has worked well, and is a first important indicator of treatment success. In a new study looking at e-positive patients, the results showed that 50% of patients whose s-antigen levels dropped significantly 24 weeks after starting Pegasys treatment were able to achieve 'e-seroconversion', an important treatment endpoint for these

patients. Furthermore, approximately 20% of the patients with e-seroconversion went on to achieve s-antigen clearance, a so-called 'clinical cure', six months after treatment had ended.ⁱⁱ

In some patients, after many years of infection, the virus mutates and no longer produces the e-antigen; these patients are considered e-negative. In this form of the disease, the virus evades the body's immune system so that the infection and liver damage return.

According to another new study presented at APASL, the number of e-negative hepatitis B patients who achieved a clinical cure continued to increase, even after the end of treatment with Pegasys.ⁱ At year five, 12.2% of Pegasys-treated patients had cleared s-antigen, compared with just 3.5% of lamivudine-treated patients. Whilst modest, the number of patients who achieve s-antigen clearance on Pegasys therapy is a breakthrough because such high rates of s-clearance have never been shown with an oral anti-viral. ⁱ Furthermore, researchers observed that s-antigen decline during treatment was associated with the achievement of a clinical cure.ⁱ

The ability of a finite 48-week course of Pegasys to induce a long-term response with increasing s-antigen clearance rates in some patients makes it a cost-effective option compared with oral anti-virals, which may need to be taken for life.^[vi]

Measuring patients' response to therapy

New data were also presented at APASL on Roche's surface antigen test, Elecsys HBsAg II assay.^{[vii],[viii],[ix]} In line with Roche's commitment to tailor treatment according to each patient's needs, growing scientific evidence is showing that this test application for quantitative detection of the s-antigen - currently available on a research-only basis - represents a simple and reliable means of testing s-antigen levels, allowing doctors to accurately assess a patient's response to therapy and then to determine the most appropriate treatment approach.

About chronic hepatitis B

Chronic hepatitis B is a serious global healthcare problem that affects more than 350 million people worldwide. It is one of the principal causes of chronic liver disease, cirrhosis, and primary liver cancer. Approximately one million people die from chronic hepatitis B annually, making it the tenth leading cause of death worldwide. The ultimate objective of treatment in chronic hepatitis B is to induce s-antigen clearance, which is associated with complete and sustained remission of the liver disease, and improved life expectancy and is generally equated to clinical cure.

Pegasys in hepatitis B

Pegasys is approved for the treatment of chronic hepatitis B in over 60 countries. It is approved in the EU, the US and the People's Republic of China, among others.

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Article URL: <http://www.medicalnewstoday.com/articles/139189.php>

Tenofovir provides good hepatitis B virus suppression in HIV/HBV coinfecting patients

www.aidsmap.com

Liz Highleyman & Michael Carter

Most HIV/HBV coinfecting people who include tenofovir (Viread, also in the Truvada and Atripla coformulation pills) in their antiretroviral regimen achieve sustained suppression of hepatitis B virus (HBV), according to a presentation last week at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montréal.

Tenofovir - along with 3TC (lamivudine, Epivir) emtricitabine (Emtriva) and, to a lesser extent, entecavir (Baraclude) - has dual activity against both HIV and HBV. Using these drugs alone can select for drug-resistant virus. Although tenofovir has a relatively high barrier to resistance, current treatment guidelines recommend that HIV/HBV coinfecting individuals should include two dually-active agents in their antiretroviral regimen.

Karine Lacombe from INSERM in Paris and her colleagues looked at long-term control of hepatitis B, viral breakthrough and development of resistance in HIV/HBV coinfecting patients taking tenofovir.

The study included 165 coinfecting patients recruited from the national French HIV-HBV Cohort at seven centres between May 2002 and May 2003. All participants started antiretroviral therapy containing tenofovir and had been on the drug for at least six months at the time of the analysis, with a median duration of 31 months.

The researchers conducted tests to quantify HBV viral load, determine HBV genotype, measure concentrations of tenofovir in the blood, check for resistance mutations and monitor liver and kidney function.

Study participants had relatively well-controlled HIV disease, with a median CD4 cell count of 370 cells/mm³ and a median HIV viral load of approximately 70 copies/ml (55% below 50 copies/ml).

The median baseline HBV viral load was approximately 1800 IU/ml (21% below 60 IU/ml). Most patients (72%) had HBV genotype A, with genotypes D, E and G ranging from 8% to 12%. A majority of participants (63%) were hepatitis B "e" antigen-positive. About three-quarters also received 3TC, either before (72%) or during (76%) treatment with tenofovir.

Study participants were defined as non-responders if they had HBV viral load persistently above 2000 IU/ml despite treatment. Rebounders were defined as patients whose HBV viral load increased and stayed above below 2000 IU/ml after suppression. 'Blippers' were defined as individuals who achieved HBV viral suppression below 2000 IU/ml but whose viral load intermittently rose above this level.

Treatment with tenofovir yielded a significant improvement in liver function. The mean ALT level fell from 79 IU/ml at baseline to 40 IU/ml whilst the mean AST level fell from 62 UL/ml to 33 IU/ml. Kidney function did not change significantly (a potential concern because tenofovir can cause kidney toxicity).

HBV viral load fell below 2000 IU/ml after a median of eight months. At the end of follow-up, a large majority (90%) of participants were classified as controllers, with HBV viral load below this level. Dr Lacombe explained that most of these patients actually had undetectable HBV viral load below 12 IU/ml using a more sensitive test.

A total of 17 patients (10%) did not achieve sustained HBV suppression, including three individuals (2%) who never achieved suppression and were classified as non-responders.

Six participants -- the rebounders -- saw their HBV viral load rise and stay above 2000 IU/ml after previous suppression. The remaining eight patients (5%) -- the blippers -- experienced transient HBV viral load increases above this level.

After measuring blood concentrations of tenofovir, however, the researchers found that most of these individuals had inadequate levels. Amongst the participants judged to have adequate drug levels, only six -- two rebounders (1%) and four blippers (3%) -- failed to achieve sustained

HBV viral load suppression.

Looking at just the two true rebounders, HBV viral load rose a median 23 months after starting tenofovir, with a range of 20 to 25 months. Both patients had HBV genotype A. One was also taking 3TC and the other had done so in the past.

Amongst the four true blippers, blips occurred a median 22 months after starting tenofovir, with a range of 20 to 35 months. HBV genotypes were diverse: one with genotype A, one with A/G, one with G and one with both A/G and D. Two were also taking 3TC whilst two had no 3TC experience. Blips were small, reaching a maximum HBV viral load of about 4700 IU/ml.

Both of the true rebounders and three of the four true blippers had the L217R polymorphism mutation. In addition, two individuals were found to have HBV mutations not previously associated with resistance: S219A in one rebounder and R274W in one blipper.

HBV rebound and blips led to rising ALT levels in some patients, but no clinical symptoms were reported.

The investigators concluded that viral suppression in HIV/HBV coinfecting patients treated with tenofovir is rapid and sustained, with more than 98% (complete responders plus blippers) controlling hepatitis B if they receive adequate drug levels.

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Feb 17, 2009

Nosocomial Transmission of HCV Described in an Orthopedic Ward

www.medscape.com

NEW YORK (Reuters Health) Feb 16 - An outbreak of hepatitis C virus (HCV) infection on an orthopedic ward, with no obvious breach of infection control policies, led investigators to recommend against the use of multidose vials.

As described in the February issue of the *Journal of Medical Virology*, three patients who were treated on the ward were diagnosed with acute icteric hepatitis C over a 3-month period.

Dr. R. Stefan Ross of Essen University Hospital and the University of Duisburg-Essen, Germany, and colleagues investigated the outbreak by using HCV-PCR to perform HCV sequencing in 135 patients who had stayed in the unit and 104 staff members.

Ultimately, the investigators identified six patients (including the initial three) infected with very closely related HCV variants.

Dr. Ross and colleagues say that "patient-to-patient spread of the virus was inferred to have started from one patient with previous HCV infection to the other five patients during their

hospital stay."

However, the team did not uncover any breaches in infection control practices or any specific activity that might have led to nosocomial transmission.

Nonetheless, "As a result of the investigations, the hospital corrected the documentation of all medical and nursing activities undertaken in the ward, abandoned the use of all multidose saline and other medication vials, and included explicitly recommendations for the safe preparation and administration of injectable drugs into internal infection control guidelines," Dr. Ross and colleagues explain.

Thereafter, "no further nosocomial transmissions of HCV have been recorded in the orthopedic ward."

The investigators comment that this episode shows that nosocomial HCV transmission is not limited to hemodialysis, hematology or oncology settings.

J Med Virol 2009;81:249-257.

Hepatitis C in HIV positive gay men: Amsterdam, Paris, New York and UK compared

www.aidsmap.com

Gus Cairns

Several posters at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montréal examined the rise in sexually-transmitted hepatitis C in gay men with HIV, each highlighting different aspects of this new epidemic. Risk behaviour was compared between New York and the UK; researchers documented an apparently separate and long-lasting epidemic of HCV genotype 4 in France (in all other cities, genotype 1 predominated); and the New York investigators documented rapid progression of liver fibrosis in their patients, and also treatment success rates.

These studies have followed on from an alarming one presented at the World AIDS Conference in Mexico last year, which found that 18% of a group of HIV-positive gay men at a single clinic in Amsterdam had hepatitis C (HCV), a third of them with recent infection, and that its prevalence was growing rapidly. At the time Kevin Fenton of the US Centers for Disease Control questioned the limited public health response to the outbreaks of hepatitis C in Europe and called for a greater sense of urgency.

Amsterdam

The Amsterdam study presented at CROI (Van den Berk) looked specifically for acute HIV infection – defined symptomatically as marked rises in liver enzymes or testing positive for HCV. It found 46 cases of acute HCV infection between 2003 and August 2008 in a large cohort of about 1380 gay male HIV positive patients treated at a single hospital clinic. It found that although acute cases were not as common as in the other Amsterdam study, they were increasing exponentially. There were two in 2003, one in 2004, nine in 2005, 12 in 2006, six in 2007 and 14 in the first eight months of 2008 (equivalent to a 2008 incidence of 1.5% a year). Fifty-nine per

cent of patients, based on previous negative HCV tests, had had HCV infection for less than a year. Three-quarters of patients had genotype 1. None of the patients had classic risk factors such as injecting drug use or medical exposure to infected blood.

France

The French researchers (Ghosn) presented the results of a national cohort screen for cases of acute HCV infection. They looked through the records of HIV positive gay men in 115 clinical settings. They found 94 cases of acute HCV infection, defining it in this case as a positive HCV test within a year of a negative one. Of these 32 had complete medical and lab data and also had their HCV infection gene-sequenced.

The men investigated were aged 40 on average and had had HIV for ten years. Twenty two (62.5%) had undetectable HIV viral loads and over half had a CD4 count over 500.

Twenty out of the 32 patients had an STI diagnosed at the same time as HCV, of which 14 had syphilis; a concomitant STI was one of the largest risk factors for HCV. Other significant risks included unprotected anal sex and either surgery or endoscopy. Only five patients cited fisting, often suspected of spreading HCV, as a risk factor.

The researchers found that 14 out of the 32 had genotype 1a, the most common in most other developed-world epidemics, but that 16 or 50% were of the relatively uncommon genotype 4d. Of the genotype 1 viruses, ten were in three infection clusters of three or four members each, suggesting infection chains or a common source, and all 15 of the genotype 4d viruses were in a single cluster of near-identical viruses, suggesting a large connected network of gay men with HCV. Interestingly these viruses were similar to 4d viruses found in Paris in 2001-03, suggesting ongoing sexual transmission in the area.

New York...

Sexually transmitted HCV among HIV-positive gay men in America has lagged a few years behind the outbreaks in Europe, but has now established itself in New York. Two studies by the same team from Mount Sinai Hospital looked at aspects of the New York outbreak.

This team led by Daniel Fierer has previously documented alarmingly rapid liver fibrosis (scarring) in HIV-positive men who become infected with HCV, and a further study has confirmed this. In a cohort of 45 HIV positive gay men, of whom 24 agreed to a liver biopsy, one had stage 3 fibrosis, one step short of cirrhosis, 18 had stage 2 fibrosis, three had stage 1, and two had none.

The profile of the men was very similar to the French patients; they were 40 years old on average and their median CD4 count was 525. Three-quarters were on antiretrovirals of whom 94%, 64% of the total, had an undetectable viral load. The average time since HIV diagnosis was seven years.

Four patients (13%) spontaneously cleared infection. All the others were offered pegylated interferon and ribavirin treatment. Of these 41, half chose to delay or refused treatment. Of the other 21, six are still awaiting treatment, and of the 15 treated eight achieved a sustained viral response, equivalent to a cure, while two failed treatment. The others are still being treated or evaluated.

Twenty-one men were matched with similar HCV-negative men to look at risk factors. The only factors that reached significance were unprotected receptive anal sex, with or without ejaculation, unprotected oral sex with ejaculation, use of sex toys, and 'sex while high'. Again, fisting was not a significant risk factor but there was an interesting difference between receptive fisting, which was not a risk factor at all, and insertive fisting (the 'top'), which was of borderline significance ($p=0.07$).

... and the UK

The second study (Fishman) compared the New York and UK outbreaks and looked at differences in the risk behaviours between 21 HCV/HIV positive gay men (not the same cases as in the first study) and 60 UK cases previously reported by the HIV and Acute HCV Group (Danta 2007). Soberingly, from a UK perspective, the frequency of previously reported risk factors was a great deal higher in UK patients than their New York counterparts.

UK patients were somewhat younger (average 36 versus 40) and had had HIV for less time (3.7 versus eight years), though their CD4 counts were the same, and a higher proportion of UK patients had undetectable HIV viral loads (59% versus 48%).

New York patients were more likely to have ever injected drugs (24% versus 3%), and were more likely to have shared injection equipment (15% versus 1.7%) or shared crack pipes.

Apart from those factors, the UK patients had the lion's share of risky behaviours. Just to take a few: 73% of UK patients had been fisting 'tops' and 57% 'bottoms' compared with 33% and 24% of New York men; 67% of UK men had practised fisting in a group compared with 12% of New Yorkers; and 94% had had unprotected receptive anal sex in a group situation compared with 77% of New York men. They had also used far more non-injectable recreational drugs: 80% versus 24% had used ketamine, 77% versus 38% cocaine, and 80% versus 38% had used ecstasy. A third had used LSD compared with none of the Americans. The greater use of drugs in the UK was called a "notable finding" by the researchers, though perhaps surprisingly, they did not look at methamphetamine use.

The UK men also had higher rates of STIs with 85% having had a lifetime history of STIs compared with 38% of the Americans. All these differences were highly statistically significant.

Lastly, another US study found that only a minority of HIV-positive gay men are being screened for viral hepatitis of any kind in US HIV clinics. The study of eight clinics by Karen Hoover found that only 43% of men were tested for hepatitis A, 33% for hepatitis B, and 48% for hepatitis C. Practice varied but was "suboptimal" at all clinics, the researchers comment.

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Researchers show how immune system reacts to a hepatitis B infection

<http://www.news-medical.net>

Researchers at the Helmholtz Centre in Braunschweig demonstrate how the immune system reacts to a hepatitis B infection.

Hepatitis B is the most prevalent infectious disease in the world. It results in either an acute infection or, in rare cases, it can develop into a chronic disease. Researchers at the Helmholtz Centre for Infection Research (HZI) in Braunschweig have now examined the way in which the immune system reacts differently to both chronic and acute hepatitis B. To achieve this, Carlos A. Guzmán, Head of the "Vaccinology and Applied Microbiology" working group and Robert Geffers, Head of the "Gene Expression Analysis" platform, examined the incidence and species of special defence cells, T helper cells, along with their role in the development of the disease in conjunction with their Indian colleagues. With the aid of genetic analysis, they showed how the genes in these immune cells are regulated differently according to the development of the disease. These new results can help doctors to discover whether an infection is curable or whether by settling in the liver, it will develop into a chronic case. These results are now published in the scientific journal, *Hepatology*.

Approximately 300 to 420 million people (5 to 7% of the world's population) have a chronic hepatitis B infection. India is one of the countries, in which hepatitis B is very common. A differentiation is made with the development of the disease between acute and chronic hepatitis B. The most common symptom of an acute infection is jaundice. In 5% of the infections, the disease becomes chronic, that is to say, the viruses remain in the liver. If left untreated, chronic hepatitis B can lead to a change in consciousness, cirrhosis and cancer of the liver. Until today scientists have not fully understood the role that the immune system plays in characterising an acute or chronic hepatitis B infection.

A decisive factor in achieving an appropriate immune reaction is the quick mobilisation of immune cells. These specifically attack the infected liver cells without destroying any

unnecessary liver tissue in the process. Subspecies of the T helper cells play a decisive role in achieving this necessary balance between immunological defence and tolerance: effector T cells and regulatory T cells (Treg). Whilst the effector T cells fight a virus infection and kill off the infected host cells, the Treg cells shut down an immune reaction and cut off the effector T cells. They counteract any destruction of the tissue.

The international team of research scientists examined how these T helper cells influence the development of the hepatitis B disease. To this end, they took blood samples from Indian patients with hepatitis B and compared the extent to which the altered incidence of the T cell subsets in the blood influences the development of the illness and which genes are responsible for this.

Guzman's and Geffers's teams were able to show that, with acute hepatitis B, the effector T cells are extremely active and destroy infected host cells. Treg cells prevent effector T cells damaging healthy liver tissue during this stage of the infection. On the other hand, T effector cells are largely inactive with chronic hepatitis B infections: the Treg cells prevent an immune reaction and, in doing so, increase the number of hepatitis B viruses that are able to live in the organ. The immune system's constant struggle against the virus leads to a slow destruction of the liver tissue. The researchers checked their observations with gene activity: They demonstrated that more than one hundred genes in effector T cells are regulated differently in an immune reaction to acute hepatitis B than to a chronic case.

"The molecular mechanisms and the specific gene activities of a hepatitis B infection were unknown up until now. We now have a much better understanding of how acute and chronic hepatitis B infections develop and which processes are involved", says Carlos A. Guzmán. "With gene analysis we are able to further investigate the molecular links, which, in many ways, are a reason for the clinical observations". The doctor thus has an opportunity to improve his diagnosis with so-called "marker genes" and to improve his treatment of the patients with targeted, immunotherapeutic measures", says Robert Geffers, who conducted the gene analysis of the blood tests.

<http://www.helmholtz-hzi.de/en/>

A potential marker of increased histological activity in hepatitis C virus infection

<http://www.eurekalert.org>

Early, vigorous and sustained lymphocyte proliferative responses specific to hepatitis C virus (HCV) have been regarded as pivotal for viral clearance. On the other hand, antibody responses' contribution is still controversial. Research data have been accumulated regarding the significance of specific antibody classes during chronic infection. Particularly, the relation of IgA and alcohol-induced hepatic damage has been recognized, but its possible implication in HCV chronic infection has not been explored so far.

A research article to be published on November 28, 2008 in the *World Journal of Gastroenterology* addresses this question. This article investigated the HCV-specific immune responses in chronic treated and untreated patients, in paired samples taken 6 months apart. IgG,

IgM and IgA levels, as well as IgG1-4 subclasses and peripheral blood lymphocyte proliferative responses against core, envelope and NS3 antigens were assayed by ELISA and CFSE staining, respectively.

Over 70% of the patients showed specific IgG and IgM against HCV capsid, E1 and NS3, while the hypervariable region-1 of E2 was recognized by half of patients. Anti-capsid IgM and IgG levels increased over time, while IgA levels did not; instead, an increase in IgA positive samples was observed. Particularly, IgA against HCV structural antigens positively correlated with necro-inflammatory activity. IgG subclasses evaluation against capsid and NS3 revealed that more than 80% of the individuals were positive for IgG1. On the contrary, less than 30% of the patients showed a positive proliferative response of CD4+ and CD8+ T cells, the viral capsid being poorly recognized.

Correlation analysis between demographic variables and humoral response revealed that alcohol consumption was negatively correlated with the responses of the main classes IgM, IgA and IgG, as well as IgG4. On the other hand, presence of specific IgG4 positively correlated with the fact of being treated with the standard therapy and the grade of necro-inflammatory activity. Additionally, the necro-inflammatory activity, also correlated with IgA, while fibrosis did not.

These results confirm that while the cellular immune response is weak and narrow, a broad and vigorous humoral response is present in chronic HCV infection. Particularly, the association of specific IgA response to necro-inflammatory activity paves the way to further studies to confirm its usefulness as a non-invasive, easy-to-measure marker of histological activity in chronic HCV infection.

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<http://www.wjgnet.com/1007-9327/14/6844.asp>

Feb 18, 2009

Mortality After Elective Surgery High for Cirrhotic Patients

www.medscape.com

NEW YORK (Reuters Health) Feb 06 - Patients with cirrhosis, even if it is not complicated by portal hypertension, have a high risk of death with common elective surgeries, researchers report in the January issue of the *Journal of the American College of Surgeons*.

Dr. Shimul A. Shah and colleagues at the University of Massachusetts Medical Center in Worcester used the Nationwide Inpatient Sample to identify all patients undergoing one of four elective surgeries: cholecystectomy, colectomy, abdominal aortic aneurysm repair, and coronary artery bypass grafting (CABG), between 1998 and 2005. In-hospital mortality was the primary endpoint.

About 2.8 million patients underwent one of the surgeries; 22,569 patients had cirrhosis, and 4,214 of them had portal hypertension.

Mortality rates increased with increasing severity of liver disease for each operation. Hazard ratios for mortality in patients with cirrhosis versus those without were 3.4 for cholecystectomy, 3.7 for colectomy, 5.0 for abdominal aneurysm repair, and 8.0 for CABG.

Corresponding hazard ratios for mortality in patients with cirrhosis and portal hypertension were 12.3, 14.3, 7.8 and 22.7.

Dr. Shah and colleagues say, "These values can be used as a frame of reference for the individual surgeon when considering different treatment options for patients with liver disease who may benefit from elective surgery, and for providing informed consent to these patients."

J Am Coll Surg 2009;208:96-103.

Blood Loss, Low Platelet Count Increase Risk of Ascites After Liver Resection

www.medscape.com

By Will Boggs, MD

NEW YORK (Reuters Health) Feb 06 - Extensive blood loss and low platelet counts increase the risk of massive ascites after liver resection for hepatocellular carcinoma (HCC), according to a report from Japan in the January issue of the *Archives of Surgery*.

"Routine administration of diuretic agents and, when necessary, unhesitating use of fresh frozen plasma (FFP) are useful in avoiding postoperative liver failure in cirrhotic patients with large amount of ascites," Dr. Takeaki Ishizawa told Reuters Health.

Dr. Ishizawa and colleagues from the Graduate School of Medicine, University of Tokyo, sought to identify risk factors for massive ascites after liver resection for HCC and to evaluate its postoperative management.

Patients who developed massive ascites had greater blood loss, were more likely to receive red blood cell transfusions, and required larger volumes of intraoperative FFP than did patients without massive ascites, the authors report.

In multivariate analysis, blood loss greater than 1000 mL and preoperative platelet count below 100,000 per microliter were independent risk factors for massive ascites.

Perioperative diuretic and FFP use were higher in the massive ascites group, and the total volume of postoperative FFP transfusion was larger in the massive ascites group than in the group without massive ascites.

Apart from a higher incidence of pleural effusion in the massive ascites group, the researchers note, postoperative morbidity was similar in the two groups.

Times to removal of abdominal drains, duration of postoperative hospital stay, total hospital costs, and transfusion costs were all higher in the massive ascites group than in the group without massive ascites, the investigators say.

"Recently, we have managed postoperative ascites using routine administration of diuretic agents and autologous FFP transfusion," Dr. Ishizawa said.

"We are now conducting further work to evaluate efficacy of autologous FFP transfusion in avoiding allogeneic blood products in the management after liver resection for HCC," Dr. Ishizawa added.

Arch Surg 2009;144:46-51.

Romark Announces Presentation Of New Data For Controlled Release Nitazoxanide In Chronic Hepatitis C

<http://www.medicalnewstoday.com>

Romark Laboratories, a privately held biopharmaceutical company, announced results from international Phase I and II clinical trials evaluating a controlled release version of **nitazoxanide** in the treatment of chronic hepatitis C virus (HCV) infection. In the phase II study in treatment-naive patients infected with HCV genotype 4, 82% (n=17) and 100% (n=16) of patients receiving low and high doses of controlled release nitazoxanide, respectively, experienced undetectable serum HCV RNA (<12 IU/mL) after 12 weeks of combination therapy with peginterferon and ribavirin.

The data, part of Romark's OPTIMA HCN (OPTImizing MAnagement of Hepatitis C with Nitazoxanide) development program, were presented this weekend in an oral presentation at the 19th Conference of the Asian Pacific Association for the Study of the Liver (APASL) in Hong Kong. The presentation titled "Controlled Release Tablet Improves Pharmacokinetics, Viral Kinetics and Tolerability of Nitazoxanide for Treatment of Chronic Hepatitis C," abstract FP052, was given by Emmet B. Keeffe, M.D. of the Romark Institute for Medical Research, Tampa, FL.

"We continue to be encouraged by the results of the ongoing nitazoxanide clinical development program," said Jean-Francois Rossignol, M.D., Director of the Romark Institute for Medical Research and discoverer of nitazoxanide. "These data show that controlled release nitazoxanide exhibits favorable pharmacokinetics and tolerability, and - in combination with the standard of care therapy - robust antiviral activity in a small number of patients with HCV genotype 4. We look forward to reporting interim data from our U.S. studies evaluating the standard nitazoxanide tablet in patients with chronic hepatitis C genotype 1 later this year."

In the Phase I study, OPTIMA HCN-1, a total of 12 healthy adult volunteers were enrolled to evaluate pharmacokinetics following oral administration of nitazoxanide at 675 mg or 1,350 mg twice daily with food for seven days. This was a randomized, double blind crossover study. The 675 mg and 1,350 mg twice daily doses of controlled release nitazoxanide produced trough plasma concentrations of tizoxanide, the active metabolite of nitazoxanide, that were approximately 3x and 12x the trough concentrations observed in historical studies using a standard nitazoxanide 500 mg tablet. Controlled release nitazoxanide showed favorable safety

and tolerability throughout the course of the study, with mild to moderate adverse events (primarily GI-related) reported.

In a subsequent Phase II study, OPTIMA HCN-2, a total of 41 treatment-naive patients with chronic hepatitis C genotype 4 were randomized to receive nitazoxanide at 675 mg (n=17), nitazoxanide at 1,350 mg (n=16) or placebo (n=8) twice daily for four weeks followed by the same regimen plus standard of care with peginterferon alfa-2a (Pegasys(R); 180 micrograms once per week) and ribavirin (Copegus(R); 1,000 or 1,200 mg daily according to body weight) for 36 weeks (48 weeks for the placebo arm).

Interim virologic response rates are as follows: for the low and high-dose nitazoxanide arms, rapid virologic response (RVR, HCV RNA<12 IU/mL after 4 weeks of combination therapy) 59% and 63% respectively, compared with 50% for the placebo group; complete early virologic response (cEVR, HCV RNA<12 IU/mL after 12 weeks of combination therapy) 82% and 100%, respectively, compared with 63% for the placebo group; early virologic response (EVR, greater than or equal to 2 log₁₀ decline in HCV RNA after 12 weeks of combination therapy) 88% and 100%, respectively, compared with 63 percent for placebo. In this study, a dose-related decline in serum HCV RNA was observed beginning on day 4 of combination therapy and was maintained through week 16.

Controlled release nitazoxanide was also shown to be well-tolerated without serious adverse events or drug discontinuations secondary to adverse events in these patients with chronic hepatitis C.

"These studies further demonstrate our commitment to optimizing treatment of chronic hepatitis C using nitazoxanide as an integral part of anti-hepatitis C therapy," added Dr. Rossignol. "We are excited about the development of controlled release nitazoxanide and plan to study once daily dosing in future trials."

About Nitazoxanide and Hepatitis C

Nitazoxanide, the first of a new class of broad spectrum antiviral drugs known as the thiazolides, is undergoing worldwide development as a treatment of chronic hepatitis C. Nitazoxanide is a potent inhibitor of hepatitis C virus (HCV) replication in HCV genotype 1-derived replicon cell lines, and in vitro studies have shown that it does not induce mutations in the virus that confer resistance. In phase II clinical trials, the addition of nitazoxanide to peginterferon alfa-2a with or without ribavirin significantly increased sustained virologic response rates in patients with chronic hepatitis C infected with HCV genotype 4. Phase II clinical trials of the standard nitazoxanide (Alinia(R)) tablet are ongoing in the United States in patients with HCV genotype 1.

About Romark Laboratories

Romark Laboratories (<http://www.romark.com>), a privately held biopharmaceutical company, has discovered and developed a new class of small molecule antivirals known as thiazolides. The Company is developing nitazoxanide, the first of the thiazolide class, for the treatment of chronic hepatitis C, and is developing other new thiazolides for treating viral diseases including chronic hepatitis B, herpes and influenza. Alinia(R) (nitazoxanide) is approved by the U.S. Food and Drug Administration and marketed by Romark for the treatment of infections caused by Cryptosporidium or Giardia.

Aethlon Medical Announces Completion of 30-Day Hepatitis-C Treatment Study

<http://www.earthtimes.org>

SAN DIEGO - (Business Wire) Aethlon Medical, Inc. (OTCBB:AEMD) announced today that it has completed a 30-day treatment case study to further evaluate the safety and efficacy of the Aethlon Hemopurifier® as a candidate treatment for Hepatitis-C Virus (HCV) infection. The Hemopurifier® is a first-in-class medical device that assists the immune response in combating infectious disease through real-time therapeutic filtration of infectious viruses and immunosuppressive proteins. As in previous studies, which demonstrated robust viral load reductions resulting from three Hemopurifier® treatments administered in a one-week trial, the study enrolled an HCV patient suffering from end-stage renal disease (ESRD) requiring regular kidney dialysis treatment. The study goal was to further demonstrate the Aethlon Hemopurifier® inhibits the progression of HCV in infected ESRD patients. The study protocol provided for 12 Hemopurifier(R) treatments to be administered during the patient's normally scheduled dialysis treatment. As a result, a 4-hour Hemopurifier® treatment was administered thrice weekly over a period of 30 days. There were no observed adverse events were reported in any of the treatments. The study was conducted at the Fortis Hospital in Delhi, India. Aethlon will disclose viral load and associated data upon receipt from testing laboratories. The insight obtained from the study will help define future clinical protocols and early commercialization strategies. The study data may also be utilized to expand the scope of an IDE submission to the FDA to include the potential use of the Hemopurifier® in the United States as a device designed for the single-use removal of HCV from blood. At present, the focus of Aethlon's IDE submission has been directed towards high risk bioterror and emerging pandemic threats.

It is estimated that up to 20% of the 1.6 million global ESRD population is infected with HCV. Beyond the treatment of infected ESRD patients, the overall opportunity for the Hemopurifier® is HCV care is significant, as approximately 180 million people worldwide (3% of the world's population) are HCV infected. According to the World Health Organization (WHO), only 30-50% of infected patients will beneficially respond to the 48-week pegylated interferon-ribavirin treatment standard.

“While we still have much work ahead, I am proud that our research and clinical programs allow us the opportunity to expand the therapeutic filtration industry beyond kidney dialysis and into the much larger infectious disease and cancer markets,” stated Aethlon Chairman and CEO, Jim Joyce. “The continued demonstration of Hemopurifier® safety and effectiveness increases the likelihood that our technology will be available to extend and improve the lives of those suffering from these horrific conditions,” concluded Joyce.

In a previous studies conducted the Fortis Hospital, six ESRD patients received a series of three, 4-hour Hemopurifier® treatments every other day during the course of one week. The treatment regimen also mirrored the patient's normal kidney dialysis schedule, allowing for the inclusion of the Hemopurifier® without disrupting dialysis treatment. Robust viral load reductions were observed in three HCV patients who completed the three-treatment protocol. Patient #1 had a

95% reduction three days post treatment and 89% reduction seven days post treatment. Patient #2 had a 85% reduction three days post treatment and 50% reduction seven days post treatment, and patient #3 had a 60% reduction three days post treatment and 83% reduction seven days post treatment.

Aethlon additionally disclosed that it soon expects the receipt of viral load and blood chemistry data resulting from a recently completed 30-day HIV treatment case study. The Hemopurifier® is the first medical device to target the treatment of both HIV and HCV, as well as a broad-spectrum of other infectious viral pathogens.

About Aethlon Medical

Aethlon Medical creates diagnostic and therapeutic filtration devices to improve the health of individuals afflicted with infectious disease and cancer. The Company's lead product, the Aethlon Hemopurifier®, is a first-in-class artificial adjunct to the immune system proven to capture infectious viruses and immunosuppressive particles from circulation. The device targets to inhibit disease progression of Hepatitis-C Virus (HCV) and Human Immunodeficiency Virus (HIV), and serves as a broad-spectrum treatment countermeasure against bioterror and emerging pandemic threats. The Hemopurifier® also holds promise in cancer care, as research studies verify the Hemopurifier® effectively captures immunosuppressive exosomes that are secreted by tumors to kill-off immune cells. At present, over sixty-five (65) Hemopurifier® treatments (representing approximately 260 hours of treatment time) have been conducted in multi-site studies at the Apollo Hospital, Fortis Hospital, and Sigma New-Life Hospital in India. The studies enrolled end-stage renal disease (ESRD) patients infected with either HCV or HIV. In addition to establishing treatment safety, robust viral load reductions have been reported in HCV-infected patients who completed a three-treatment protocol during the course of one week.

Research studies have also demonstrated the Hemopurifier® is effective in capturing a broad-spectrum of viruses untreatable with drug therapy, including several of world's deadliest bioterror and pandemic threats. These include: Dengue hemorrhagic fever (DHF), Ebola hemorrhagic fever (EHF), Lassa hemorrhagic fever (LHF), H5N1 avian influenza (Bird Flu), the reconstructed 1918 influenza virus (r1918), West Nile virus (WNV), and Vaccinia and Monkeypox (MPV), which both serve as models for human smallpox infection. The studies were conducted with the assistance of researchers representing: The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID); The Centers for Disease Control and Prevention (CDC); The National Institute of Virology (NIV); The Battelle Biomedical Research Center (BBRC); and The Southwest Foundation for Biomedical Research (SFBR).

In additional to therapeutic market opportunities, Aethlon is leveraging principles underlying the Hemopurifier® technology platform to establish a pipeline of clinical and research diagnostic products and services. Additional information regarding Aethlon Medical can be accessed online at www.aethlonmedical.com.

Abbott and Enanta Initiate Phase 1 Clinical Trial on ABT-450 HCV Protease Inhibitor

www.earthtimes.org

ABBOTT PARK, Ill., and WATERTOWN, Mass., Feb. 18 /PRNewswire-FirstCall/ -- Abbott

(NYSE: ABT) and Enanta Pharmaceuticals announced today the advancement of their Hepatitis C (HCV) collaboration with a first-in-human study evaluating **ABT-450**, an oral protease inhibitor for the treatment of chronic HCV. The objectives of the trial include assessment of safety, tolerability and pharmacokinetics. ABT-450 was discovered as part of a worldwide alliance between Abbott and Enanta to discover, develop and commercialize protease inhibitors for the treatment of HCV.

"Hepatitis C is a serious global health concern, with 170 million people currently infected by six different HCV genotypes," said John M. Leonard, M.D., senior vice president, Global Pharmaceutical Research and Development, Abbott. "As a global leader in the development of antiviral therapies and diagnostics, Abbott is bringing its decades of antiviral experience, particularly with protease inhibitors, to this collaboration and to the fight against HCV."

"ABT-450 demonstrated favorable potency in vitro across various HCV genotypes and highly resistant strains," said Jay R. Luly, Ph.D., president and CEO of Enanta Pharmaceuticals. "We look forward to working with Abbott to advance ABT-450, and to our building a pipeline of HCV protease inhibitors that addresses this widespread disease."

Phase 1 Study Design

The Phase 1, double-blind, placebo-controlled study for ABT-450 announced today is a single, ascending oral dose trial in healthy volunteers.

About Enanta

Enanta Pharmaceuticals is a research and development company that uses its novel chemistry approach and drug discovery capabilities to create best-in-class small molecule drugs in the anti-infective field. Enanta is developing novel protease, polymerase and cyclophilin-based inhibitors targeted against the Hepatitis C virus (HCV). Additionally, the company has created a new class of macrolide antibiotics, called Bicyclolides, which overcomes bacterial resistance. Antibacterial focus areas include superbugs, respiratory tract infections and intravenous and oral treatments for hospital and community MRSA. Enanta is a privately held company headquartered in Watertown, Mass. Enanta's news releases and other information are available on the company's web site at <http://www.enanta.com>.

About Abbott

Abbott is working to advance the treatment of Hepatitis C (HCV) through a multifaceted discovery and development program that leverages the company's deep experience in antiviral medicines. Compounds in various states of development include protease inhibitors (ABT-450) and polymerase inhibitors (ABT-333 and ABT-072). In addition to developing HCV therapies, Abbott also offers laboratory tests for patient diagnosis, blood screening tests for hospitals and blood banks, and molecular diagnostic tests to measure HCV viral load and resistance.

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 69,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's web site at <http://www.abott.com>.

Liver Cancer Incidence Has Tripled Since 1970s, But Survival Rates Improving

<http://www.sciencedaily.com>

ScienceDaily (Feb. 18, 2009) — A new study examining data on incidence trends, mortality rates and survival rates from the National Cancer Institute’s Surveillance Epidemiology and End Results (SEER) cancer registries indicates that the incidence of liver cancer in the United States tripled between 1975 and 2005.

Researchers also found for the first time that one- through five-year survival rates improved significantly for patients diagnosed with liver cancer between 1992 and 2005, in part because more patients were diagnosed at earlier stages, when treatment is more effective. Earlier diagnosis may be due to increasing awareness and screening to detect localized disease in patients at risk for liver cancer.

“Although the study could not determine why liver incidence rates are increasing, these trends may be partially attributable to an increase in chronic hepatitis C, which together with hepatitis B is a major risk factor for liver cancer,” said Dr. Sean Altekruze, an Epidemiologist with the NCI’s SEER Program and the study’s lead author. “Additional research into the factors related to this increase in incidence will be vital to preventing these rates from rising further.” Dr. Altekruze noted that heavy alcohol consumption, fatty liver disease, obesity, diabetes mellitus and iron storage diseases may also contribute to the increasing incidence of liver cancer.

The study found that between 1975 and 2005, liver cancer rates tripled, from 1.6 cases per 100,000 people to 4.9 per 100,000. From 1992 to 2005, liver cancer incidence trends increased significantly:

African-Americans and Hispanics both experienced an approximately 67 percent increase in liver cancer incidence between 1992 and 2005 (4.2 to 7.0/100,000 and 4.8 to 8.0/100,000, respectively), and whites experienced an approximately 50 percent increase in incidence (2.6 to 3.9/100,000) during this time period.

Between 2000 and 2005, incidence rates increased most markedly among African-American men (42 percent, 28.7 to 40.8/100,000), Hispanic men (43 percent, 23 to 32.8/100,000), and white men (43 percent, 11.5 to 16.5/100,000) 50 to 59 years of age. These increases may be partially due to an epidemic of hepatitis C infection that began in the 1960s, when men in this age range were young adults.

From 1992 to 2005, liver cancer incidence rates among Asians and Pacific Islanders were the highest of all racial groups overall; however, rates increased by a relatively modest 17 percent (10.0 to 11.7/100,000) in this time period. Researchers attribute a substantial portion of liver cancer cases in Asians and Pacific Islanders to higher rates of hepatitis B among some Asian subgroups.

One-year survival rates nearly doubled between 1992 and 2005, rising from 25 percent of

patients to 47 percent. Dr. Altekrose points out that while the increasing survival rates are encouraging, further improvement is still needed, noting that one-year survival rates are still below 50 percent.

ASCO Perspective

Jennifer Obel, ASCO official and Attending Physician, NorthShore University HealthSystem said, "Early screening for patients with hepatitis C, a leading risk factor for liver cancer, has directly contributed to increasing survival rates for patients living with liver cancer. When detected early, there are significantly more treatment options for liver cancer – in most cases, the earlier it is caught, the better the prognosis. This study points to the need to identify even more at-risk individuals through early screening programs to improve prognosis with potentially curative therapy."

Adapted from materials provided by American Society of Clinical Oncology.

Senate panel passes bill to help Smithfield officer

<http://hamptonroads.com>

By Julian Walker

The Virginian-Pilot

Early in his career with the Smithfield Police Department in 1988, Kurt Beach took a call involving a nonresponsive infant.

Beach, now 52, attempted to revive the 9-month-old, performing CPR. From that contact, Beach contracted Hepatitis C, a potentially fatal blood-borne disease that can lead to liver failure.

He didn't learn of his condition for another seven years; he made the grim discovery in 1995 after donating blood. He is now on a liver-transplant waiting list.

Legislation working its way through the General Assembly, HB2243, would cover as much as \$250,000 in costs associated with his treatment, including anti-rejection drugs needed after he undergoes a liver transplant.

With Beach in the audience, the bill unanimously passed the Senate Finance Committee on Tuesday morning. Senators on the committee and the crowd in the meeting room gave Beach a round of applause as his wife, Kathie, watched.

"Everything is coming together for my family," Beach said afterward, seeming in high spirits. "I'm looking forward to the bright side of life, getting back to serving my community and loving my family."

Legislation is needed, said bill sponsor Del. William Barlow, D-Isle of Wight County, because Beach was denied workers' compensation because his illness was discovered after Virginia's five-year statute of limitations to apply for benefits had lapsed.

"Kurt Beach is a symbol for public safety workers around the state," Barlow said.

Now that the bill has passed the committee, the full Senate could vote on it in days.

Beach was too weak to travel to the state Capitol last month when the bill tailored for his situation was before a House of Delegates subcommittee, which also passed the measure.

On medical leave from his position as a Smithfield police lieutenant, Beach said he hopes to rejoin the force once he recovers.

Feb 19, 2009

New U.S. health insurance program envisioned

www.reuters.com

By Will Dunham

WASHINGTON (Reuters) - A prominent private U.S. health policy group on Thursday proposed creating a major new public health program and government-operated insurance exchange as part of a plan to expand coverage and rein in health care costs.

The Commonwealth Fund, a leading private health policy research group, unveiled a comprehensive plan for changing a U.S. health care system that is the world's most expensive yet lags many other nations in important measures of quality.

They hope the Obama administration and lawmakers consider the ideas as they move forward this year with plans for major changes in the health care system. This plan is one of many being advanced as U.S. policymakers move toward action.

The proposal favors a mix of public and private insurance options over the idea of a fully government-run health system.

Every American would be required to have some form of public or private health insurance, and one choice would be a new nationwide government program for anyone under 65, the age when eligibility for the existing Medicare program begins.

More than 40 million people would be expected initially to sign up for the new program, the group's Cathy Schoen said.

The government would also operate an insurance exchange similar to the one run by the state of Massachusetts, giving people the option of comparing coverage and choosing among a menu of private insurers or the new public program.

The plan envisions wide adoption of health information technology, greater disease prevention efforts and insurance payment changes that reward efficiency and penalize waste.

Commonwealth Fund leaders said their proposal is designed to achieve nearly universal insurance coverage while enhancing the quality of the health care system and controlling costs.

"The aim here is not to move away from the private insurance industry," said Dr. James Mongan, president and CEO of Partners HealthCare System Inc in Massachusetts, who headed the

Commonwealth Fund commission that drafted the proposal.

U.S. Census Bureau figures show 15 percent of Americans had no health insurance in 2007, a total of 45.7 million people. Within two years, only about 4 million Americans would remain uninsured under the new proposal.

Americans spent \$2.2 trillion on health care in 2007, according to a government report released in January, representing 16.2 percent of U.S. gross domestic product.

Health spending would continue to increase, but the rate of increase would be slower than current projections over the next decade. The plan would reduce annual growth from a projected 6.7 percent to 5.5 percent and save a cumulative total of about \$3 trillion by 2020, the Commonwealth Fund said.

(Editing by Julie Steenhuysen and Todd Eastham)

Free needles for drug users 'good use of NHS money

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

John Carvel, social affairs editor guardian.co.uk

'Medicine watchdog advocates combining needle exchange schemes with treatment

Providing free needles and syringes to people who inject heroin and cocaine is a cost-effective use of NHS money, the government's medicines watchdog said today.

The National Institute for Health and Clinical Excellence (Nice) issued its first guidance on how harm reduction services for addicts should be run throughout England, suggesting combining non-judgmental needle exchange schemes with treatment to help users come off drugs.

Prof Mike Kelly, director of the institute's public health division, said there are about 200,000 injecting drug users in Britain. He estimated about 25% of users share needles, putting themselves at a greatly increased risk of being infected with Hepatitis C or HIV.

Kelly said: "The cost to the NHS of caring for someone who injects drugs is around £35,000 over their lifetime. From a societal perspective, the average [lifetime] cost rises to an estimated £480,000 when you take into account the high cost of crime including criminal justice costs."

About 40% of drug users who inject are already infected with Hepatitis C and their risk of death is 10 times higher than among the population at large.

If needle exchange schemes are run well, they can provide an effective conduit for doctors, nurses and pharmacists to gain direct contact with hard-to-reach groups – the first step towards encouraging them to seek treatment.

Providing injecting drug users with extra years of healthy life was cost-effective for taxpayers, said Nice.

Kelly added: "Keeping in check the epidemic of Hepatitis and maintaining HIV at its relatively low levels is an important aim that this guidance will serve."

Needle and syringe exchange schemes have been provided throughout England for more than 20 years. They provide injecting drug users with sterile equipment, needle disposal bins and advice on safer injecting practices. Primary care trusts (PCTs) have had discretion on how to run services to meet local needs.

The Nice guidelines include advice on how PCTs should tailor the service to encourage injectors to seek treatment by offering more accessible opening times and locations.

Dr Mathew Hickman, chair of the Hepatitis C prevention working group at the Advisory Council for the Misuse of Drugs, said: "Needle and syringe programmes are a critical component of public health action to prevent Hepatitis C infections among injecting drug users.

"Evidence suggests that a combination of interventions is most effective. This means that staff need to use the opportunity they have with injectors actively to promote and refer people into treatment, such as opiate substitution programmes."

Dr David Sloan, vice-chair of the Public Health Interventions Advisory Committee, said: "Although HIV rates remain relatively low among injecting drug users in the UK, bad practice, such as the sharing of needles among multiple users, makes these individuals extremely vulnerable to any future outbreak."

Beaumont Army Medical Center to provide update on shots inquiry

<http://www.elpasotimes.com>

By Chris Roberts / *El Paso Times*

EL PASO -- Officials are to meet Thursday at Beaumont Army Medical Center to discuss the progress of an investigation into the possible exposure of more than 2,000 diabetes patients to infectious diseases such as HIV and hepatitis, according to a center official.

As of midday Wednesday, 76 percent of the 2,114 patients who might have been exposed through the improper use of an insulin pen had been contacted, officials said.

Of that number, 71 percent have come in for testing to see whether they have contracted any of the diseases, officials said.

Results of the testing won't be available for another week or two, officials said.

A small number of the people contacted have declined testing at the center, a Beaumont spokesman said.

Potential exposure to the diseases occurred when insulin pens containing multiple doses meant for use by a single person were instead used to give injections to multiple people, Beaumont officials said.

Clean needles were used for each injection, they said.

The improper procedure was in use between August 2007 and the end of January.

Also on Wednesday, the El Paso Times obtained a copy of answers provided by Beaumont commander Col. James Baunchalk to questions posed by U.S. Rep. Harry Teague, D-N.M., about the incident.

In response to a question asking how the incorrect procedure was created and practiced without being corrected by a supervisor, Baunchalk wrote that the answers would be provided in the results of two investigations, one internal and one external.

Baunchalk also said that 170 of the diabetes patients were New Mexico residents and that if they have to travel more than 50 miles one way for testing, they will be offered reimbursement for travel costs.

Asked what Beaumont Medical Center will do if it no longer has up-to-date contact information for patients who might have been exposed, Baunchalk wrote, "... all available databases and medical records will be queried to obtain accurate and current contact information."

Beaumont "will make every effort to contact all patients who may have been involved," he wrote.

Anyone who thinks he or she might be at risk should call 866-770-0194.

Feb 20, 2009

Do All HCV-Infected Patients Need a Liver Biopsy Before Treatment?

www.medscape.com

Rowen K. Zetterman, MD, FACP
Dean, Professor of Medicine,
Creighton University School of Medicine,
Omaha, Nebraska

Question

Is liver biopsy indicated for all HCV-infected patients before initiating therapy, regardless of genotype?

Answer

Hepatitis C virus (HCV) has multiple genotypes of which genotype 1 is the most common in the United States. Cirrhosis does not develop in all patients infected with HCV. Elevated serum aminotransferase levels do not reliably predict the presence or absence of either fibrosis or progressive disease. This prompted a recommendation for pretreatment percutaneous liver biopsy in patients with genotype 1 HCV infection to establish prognostic information (presence of necroinflammatory disease and fibrosis that indicate progressive disease), and to delay treatment in those lacking such evidence because these patients were assumed to be at lower risk for cirrhosis. The American Association for the Study of Liver Diseases (AASLD) practice guideline, published in 2004, indicates that liver biopsy should be considered "when the results will influence whether treatment is recommended.[1]"

Genotype 1 HCV infection has a sustained treatment response to pegylated interferon and ribavirin of approximately 40%. Treatment response can be further reduced by concomitant fatty liver; cirrhosis; older patient age at treatment; or lifestyle activities, such as excessive alcohol consumption. In patients with genotype 2 or 3, the sustained viral response to pegylated interferon and ribavirin is 80% or greater. New combination therapies under development will improve the response to treatment of patients with HCV infection, including genotype 1.

As these new therapies improve the treatment response of all genotypes, the need for a liver biopsy to select those who should be treated will diminish.

Currently, I suggest that a liver biopsy be considered for patients with genotype 1 HCV infection if clinical parameters suggest that the liver disease might be a consequence of disease other than HCV, if there is an additional reversible component to identify that could improve response to therapy (e.g. alcoholism or fatty liver due to obesity), or if patients need further proof that they have liver disease that is likely to progress to cirrhosis. In patients with genotypes 2 and 3, treatment without biopsy is suggested.

The Silent Threat of Hepatitis B

<http://health.nytimes.com>

By PETER JARET

Dr. Nancy Reau is an assistant professor of medicine at the University of Chicago's Center for Liver Disease, where she specializes in treating hepatitis. Here are five things she says everyone should know about hepatitis B.

Hepatitis B is a silent threat. People with chronic infections may feel fine for a long time, even as the virus is causing damage to the liver. Recent evidence shows that during the immune tolerant phase, when most researchers had assumed the virus was quiet, the liver may be sustaining injury. By the time symptoms appear, liver damage may be advanced. That's why it is so important to be tested if you have any reason to think you might have been exposed.

People infected with hepatitis B should be tested for hepatitis C and H.I.V. Both of these viruses can be transmitted via routes that are similar to hepatitis B. Co-infection raises the risk of complications. In addition, many doctors encourage people with hepatitis B infection to be vaccinated against hepatitis A to protect their livers from additional damage. Hepatitis A is typically transmitted in contaminated water or food.

Family members and close contacts of people infected with hepatitis B should be tested for the virus. If they have not been exposed to it, they should be vaccinated.

Not every person infected with hepatitis B needs to start treatment right away. Many people live with the virus and never develop serious symptoms. Most doctors counsel patients to wait until liver function tests and a biopsy show signs that the virus is beginning to cause damage. By waiting, doctors can limit the amount of time patients need to be treated and lower the risk that drug-resistant viruses will emerge.

Current drugs are very effective at controlling the virus and preventing damage. And because the

liver can regenerate itself, some patients with advanced disease may see their condition improve significantly after beginning treatment.