

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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April 5th, 2007

Union: City lax on firefighters vaccinations

<http://www.nj.com/>

By Kevin Shea

TRENTON -- The state health department is investigating a fire department union official's complaint that city firefighters' hepatitis B vaccinations are not up to date, officials said.

William Paradiso, a battalion chief and president of the superior officers union, charged yesterday that the city has been lax with the vaccinations and their documentation for about two years and filed the complaint because firefighters are about to become medical first responders and more likely to come in contact with bloodborne pathogens.

The state's Public Employees Occupational Safety and Health (PEOSH) bloodborne pathogens regulations state employers must offer free hepatitis B vaccinations to all employees who have anticipated exposure to blood or other potentially infectious materials.

Employees may decline the vaccination, but must sign a "declination" statement, PEOSH regulations say.

What's worse, Paradiso said, is that since a PEOSH official went to fire headquarters Tuesday, the city administration and fire department leadership have been rushing firefighters into signing declination forms if they cannot remember being vaccinated.

"They're leaving people unprotected," Paradiso said.

Paradiso said if firefighters did not sign, they were threatened with possible discipline. He said it's just another symptom of the department's often changing leadership and the city not paying attention to firefighters until a state agency or the media get involved.

"We have to take (things like this) outside the city because the city never talks to us and they believe they are above state law," Paradiso said. "This is what happens when you do not have a bona fide leader."

A spokeswoman for the state Department of Health and Senior Services, which administers PEOSH, confirmed the agency has an open investigation into the hepatitis vaccinations in the city fire department and that an investigator was at the department Tuesday. The probe was initiated by a fire employee but she could not elaborate further.

Fire Battalion Chief Graham Smith, who returned a call left for interim Fire Director Henry Gliotone, also confirmed the probe and said the fire department presented the PEOSH representative with the department's documentation. The department expects to conclude the probe within two weeks, Smith said.

Smith, though, said he could not comment on whether all firefighters are up to date with hepatitis B vaccinations because it falls under confidential personnel information.

Smith, who is organizing the first-responder program, which is on the verge of launching, would not comment on Paradiso's claims that the department was rushing the documentation.

He did say, "At this time, we're taking proactive steps to make sure our people are protected and we meet the PEOSH regulations."

Paradiso said his concern is the health of firefighters, not the first-responder program, which has been in the works since September.

The program will dispatch fire vehicles to emergency medical calls to back up or assist Trenton Emergency Medical Service (TEMS), the city's front-line medical responders.

Since January 2007, the fire department has had four changes in leadership.

Congress cool to calls for hearings on health care

<http://www.lasvegassun.com>

By Lisa Mascaro

Amid hepatitis scares in 4 states, D.C. worries about doctor, clinic liability

Washington — Lawmakers from communities nationwide hit by hepatitis C scares similar to that in Las Vegas are calling for congressional investigations, but they may face stiff resistance from those concerned about exposing health care facilities to liability.

Nevada Democratic Rep. Shelley Berkley and colleagues from New York, Nebraska and Michigan are pushing for Congress to become involved. In all four states, thousands of residents may have been exposed to potentially life-threatening disease because of improper medical procedures at outpatient clinics.

Dr. Julie Gerberding, director of the Centers for Disease Control and Prevention, has said Nevada, where nurses improperly reused syringes and potentially exposed 40,000 patients to hepatitis and HIV, may be the "tip of the iceberg" nationwide.

Yet calls for a congressional investigation apparently are bumping up against concerns by lawmakers who fear health care practitioners could face costly lawsuits.

In Las Vegas, trial lawyers are running ads soliciting clients who received care at the Endoscopy Center of Southern Nevada, where 40,000 patients were potentially exposed.

At a meeting of Nevada lawmakers last week, Republican Sen. John Ensign said he faced resistance to his request for congressional involvement.

Ensign had consulted with a colleague, conservative Republican Sen. Tom Coburn of Oklahoma, a physician. Ensign suggested earlier that Coburn might be in a position to convene a hearing as the ranking member of a government oversight committee in the Senate.

Coburn, in an interview with the Sun, said he didn't believe the outbreaks in Nevada and elsewhere were broad enough to require federal intervention.

Coburn explained that his state experienced a similar outbreak and "it almost bankrupted our medical liability — doctors', physicians'."

The medical professionals involved "need to go to jail ... because they obviously violated all medical protocol," Coburn said. "But I don't think we need a hearing because not very many people are that stupid. I think it raises it to an issue where it scares people rather than fixing it."

Coburn added the issue should be left to the states because they license medical professionals and facilities.

Berkley and four other House lawmakers, Democrats and Republicans, have written to the health subcommittee of the House Energy and Commerce Committee seeking hearings on the subject. Those four are New York Democrats Anthony Weiner and Edolphus Towns and Nebraska Republicans Jeff Fortenberry and Lee Terry. Michigan Republican Rep. Vernon Ehlers has signed on to a letter Fortenberry is circulating among lawmakers to gather more support for a hearing.

"Unfortunately, these are not isolated incidents," Towns and Terry wrote to the committee. "In the last year alone, an estimated 70,000 Americans will or have received notification from state or county health officials urging them to be tested for HCV, HBV or HIV due to improper infection control practices at outpatient facilities," they wrote, using medical shorthand for strains of hepatitis and the virus that causes AIDS.

"Tragic events in Nebraska, Las Vegas, New York and Michigan underscore the importance of investigating the current practices and procedures."

New Jersey Democratic Rep. Frank Pallone Jr., chairman of the health subcommittee, said the agenda is filled through April, but "Shelley has pointed out very dramatically that this is an issue that needs to be addressed." He said it is under consideration.

On a parallel track, California Democratic Rep. Henry Waxman's committee on government oversight is expected to hold a hearing this month on a forthcoming General Accountability Office report on hospital-acquired illnesses that could serve as a venue for questions about the Nevada problems.

The committee is considering a separate hearing on the hepatitis C outbreaks, and the accountability office has received numerous requests which are under consideration, for an investigative report.

Ehlers, the Michigan Republican, said he had little concern about pushback from those trying to shield the clinics from liability and expects a hearing to be held. "Trial lawyers are everywhere. I'm sure they know about this already."

Victims of 'bad blood' in dispute with lawyers

<http://nz.news.yahoo.com>

[New Zealand] – Victims infected with hepatitis C in the 1990s bad blood scandal are still awaiting compensation from the Government while they battle their lawyers over fees.

Lawyers are claiming thousands of dollars in legal costs from compensation awarded by the Government to people who contracted hepatitis C from contaminated blood products.

A dispute that has dragged on for 14 months is preventing some 25 victims with haemophilia from receiving lump sums from the Government and delayed some from starting treatment for hepatitis C, The Press newspaper reports.

In December 2006, the Government announced a \$31 million package for people infected with hepatitis from blood products before blood screening was introduced in 1992.

By then, about 180 people with haemophilia and almost 400 others had been infected.

To date, 486 victims have applied for one-off payments and the Government had paid out \$25.5m.

About 155 of the affected haemophiliacs have received payments ranging from \$43,200 to \$69,600, enabling many to start a chemotherapy-type drug course for hepatitis C, a liver-attacking virus that can lead to cirrhosis and cancer.

But 25 victims, including two from Christchurch, have held off accepting compensation while they are in dispute with their lawyers, who are seeking costs of \$12,700 to \$18,500 a person.

The victims were among 55 haemophiliacs and 215 clients who signed up for a class action to sue the Government for failing to introduce national screening earlier.

The action never went ahead after a political settlement was reached following 14 years of negotiation between the Haemophilia Foundation and successive governments.

But lawyers Johnston Lawrence, of Wellington, and Penney Patel Law, of Auckland, still want the fees that were agreed when the civil suit was being planned.

Despite 14 months of negotiation between the foundation and the lawyers, the dispute remains unresolved.

More lawyers for both sides and more costs will be involved in an attempt to settle the row through mediation in Wellington next month.

April 7th, 2007

Two more patients test positive for hepatitis C at Va. hospital

<http://www.kxan.com>

NEWPORT NEWS, Va. (AP) - Three people have now tested positive for hepatitis C at a Newport News, Virginia, hospital. But health officials say that's not out of the ordinary.

Riverside Regional Medical Center is providing precautionary testing to about 300 patients after a nurse anesthetist who worked there last year was accused of infecting patients in Texas with hepatitis C.

Retired Army Captain Jon Dale Jones has submitted to Riverside officials a lab report stating his hepatitis C is inactive now. That means it wouldn't spread to another person. He worked at the hospital from July 9 through December 22nd.

He was arrested last month in Miami on federal charges of assaulting three patients and possession of a controlled substance by fraud. At least 15 military service members or their relatives are believed to have been infected with hepatitis by Jones at William Beaumont Army Hospital in El Paso in 2004. He's also suspected of stealing their painkillers during surgery.

Jones has pleaded not guilty.

April 8th, 2007

'They're just dragging their feet'

<http://www.canada.com>

Sonja Puzic, Windsor Star

Darryle Trealout, 57, has been living with hepatitis C for most of his life since getting a blood transfusion when he was 19. He is frustrated with the delays plaguing the compensation process for victims.

Even though he wasn't diagnosed with hepatitis C until 1994, Darryle Trealout has been living with the incurable liver disease for two-thirds of his life.

The 57-year-old Amherstburg resident and his wife Mary-Ann believe he contracted hepatitis C when he received a tainted blood transfusion in 1969 at age 19.

The disease did not begin manifesting itself until many years later, but it has wreaked havoc on Trealout's health and life.

As his condition deteriorated over the years, he underwent numerous surgeries, including a liver transplant, and now has to travel to London on a regular basis to see a liver specialist.

\$1-BILLION DEAL

When the Canadian government completed in December 2006 a \$1-billion deal to compensate the "forgotten" victims of the tainted blood scandal, who contracted hepatitis C before 1986 or after 1990, the Trealouts were counting on their share. The deal is supposed to provide one-time payments to about 5,000 people who were infected with the virus prior to Jan. 1, 1986 or between July 2, 1990 and Sept. 29, 1998.

The government's first compensation package in 1998 was only for those who contracted hepatitis C between 1986 and 1990, when it was known that a test to screen donated blood was available, but not used.

But more than a year after the new deal was reached, the Trealouts say they are frustrated and disappointed by the delays plaguing the compensation process.

"They're just dragging their feet," Trealout said Monday.

The federal compensation for hepatitis C victims has been delayed because of a high volume of applications, said Liz Atkinson-Plato, a hepatitis C program co-ordinator and community health educator with the Teen Health Centre.

She said she spoke with the court-supervised administrators of the \$1-billion payout, Crawford Class Action Services, about two weeks ago and was told that more claims than expected have been pouring in.

"They're telling us that they're trying to be efficient and process them in chronological order, as they come in," Atkinson-Plato said.

"For some claimants, it's a quick process, but for others it seems to be taking a long time."

Some applicants have also been asked to send additional information to prove their eligibility for compensation.

Mary-Ann Trealout said she's received three letters from Crawford asking for further proof that her husband was infected with tainted blood and other documentation since she filed the application in late August last year.

But Trealout's doctor at the time of the blood transfusion in 1969 has since died. There are no records available from that long ago from the now-defunct Grace Hospital, where the transfusion took place, said Mary-Ann. The only tangible proof the Trealouts have is an affidavit from Trealout's brother, who drove him to the hospital to get the blood transfusion.

Even without an official record of the procedure, Trealout has received compensation from the Ontario government and the Red Cross, which supplied the contaminated blood. But applicants have been warned that previous compensation does not guarantee a share of the federal deal.

According to updates posted by Crawford on <http://www.pre86post90settlement.ca>, some claimants received their cheques in December 2007.

But Atkinson-Plato said she is not aware of any victims in Windsor-Essex who have received their share.

Andrea Monkman, who helped found the Hepatitis C Network of Windsor and Essex County, also said Monday she has yet to receive news of a local resident who got the promised money.

Monkman, who was infected with tainted blood in 1974, said she filed her application in December and is still waiting for a cheque.

Hepatitis B virus triggers cell 'suicide' in patients with chronic infection

<http://www.eurekalert.org>

Scientists from UCL (University College London) have identified a key difference between people who can fight the Hepatitis B virus (HBV) off successfully and those who fail to do so – that a group of cells important in controlling the disease are triggered to ‘commit suicide’ in patients who are chronically infected. This discovery provides an important new focus for developing therapies or vaccines that boost the body’s ability to manage this infection.

The researchers analysed thousands of genes in T cells, critical players of the immune system required for control of HBV. They found that T cells from patients who were chronically infected were triggered to ‘commit suicide’. This could be an important factor in determining why these patients’ immune systems cannot fight the infection, and a process which could be a useful target for new treatments. Their findings are published today in the *Journal of Clinical Investigation*.

Hepatitis B virus (HBV) is one of the most common viruses in the world, and ranks as one of the top ten killer infectious diseases. More than 350 million people have long-term infection with HBV, which may lead to liver cirrhosis, liver failure or liver cancer. In the majority of adults infected, the immune system is able to control the virus very well and is, in fact, more effective than any currently available treatment. Understanding what goes wrong in people with chronic infection is crucial to the development of new therapies.

Lead author, Dr Mala Maini, UCL Division of Infection & Immunity, said: “We used microarray gene chips to screen more than 5,000 genes in T cells from both recovered and chronically infected Hepatitis B patients. This led to the discovery that, instead of successfully reacting to the virus, the T cells in the latter group were triggered to commit suicide by one of the cells’ own death-inducing proteins, called ‘Bim’. We are now looking into the fine mechanism driving this outcome.”

The paper’s first author, Ross Lopes, added: “If we can develop safe ways of blocking the suicidal tendency of the T cells, we may be able to prolong their survival, so they can do a better job of controlling Hepatitis B infection.”

The proportion of the world's population currently infected with HBV is estimated at between 3 and 6 per cent, but up to a third have been exposed. It is endemic in parts of Asia and Africa.

Chronic Hepatitis B may eventually cause liver cirrhosis and liver cancer, a fatal disease with very poor response to current treatments. The infection is preventable by vaccination at a young age.

Notes for Editors

Journalists seeking more information, or interviews with the researchers quoted, can contact Ruth Metcalfe in the UCL Media Relations Office on tel: +44 (0)20 7679 9739, mobile: +44 (0)7990 675 947, out of hours: +44 (0)7917 271 364, e-mail: r.metcalfe@ucl.ac.uk

'Bim-mediated deletion of antigen-specific CD8 T cells in patients unable to control hepatitis B virus' is published online ahead of print in the *Journal of Clinical Investigation* and is embargoed to Tuesday 8th April 2008 at 9pm GMT (5pm Eastern). Journalists can obtain copies of the paper by contacting the UCL Media Relations Office.

The paper's authors are from UCL Division of Infection and Immunity, UCL Centre for Sexual Health and HIV Research, Camden Primary Care Trust and the Singapore Institute for Clinical Sciences. Some of the authors receive funding from the Medical Research Council.

About UCL

Founded in 1826, UCL was the first English university established after Oxford and Cambridge, the first to admit students regardless of race, class, religion or gender, and the first to provide systematic teaching of law, architecture and medicine. In the government's most recent Research Assessment Exercise, 59 UCL departments achieved top ratings of 5* and 5, indicating research quality of international excellence.

UCL is in the top ten world universities in the 2007 THES-QS World University Rankings, and the fourth-ranked UK university in the 2007 league table of the top 500 world universities produced by the Shanghai Jiao Tong University. UCL alumni include Marie Stopes, Jonathan Dimbleby, Lord Woolf, Alexander Graham Bell, and members of the band Coldplay.
www.ucl.ac.uk

New Program Looks for Hepatitis B,C Patients for Research

<http://www.khnl.com>

HONOLULU (KHNL) -- Hepatitis Support Network of Hawaii and Infections Limited Hawaii created a new program for people with hepatitis B or C who would like to be informed of openings for hepatitis research studies in Hawaii.

HOPE Registry Program will help attract clinical trials to Hawaii through rapid enrollment, offer economic advantages to the community and provide new treatments years before they are available for general use.

HSNH is offering free testing for hepatitis B and C at a number of locations around the state.

For information about testing sites, free hepatitis B vaccinations or to sign up for the HOPE Registry program, call (808) 373-3488 or (808) 221-6204.

Nevada: Clinics Linked to Outbreak Give Up Licenses

<http://www.nytimes.com>

By THE ASSOCIATED PRESS

Two Las Vegas clinics at the center of a hepatitis C outbreak have surrendered their business licenses and paid a total of \$500,000 in fines. Mayor Oscar Goodman and lawyers for the clinics, the Endoscopy Center of Southern Nevada and the Gastroenterology Center of Nevada, say the clinics will not reopen. The moves avoided a public hearing at which clinic doctors and nurses had been called to testify about the City Council's preliminary revocation of the business licenses after six patients contracted the disease, which can be fatal, during procedures. A seventh patient has since been identified with the virus.

April 8th, 2007

Guidelines for Hepatitis C in Chronic Kidney Disease Issued

<http://www.medscape.com>

Laurie Barclay, MD

April 7, 2008 — The first global clinical practice guidelines for patients with chronic kidney disease (CKD) were presented on April 4 at the National Kidney Foundation 2008 Spring Clinical Meetings in Dallas, Texas, and published as a supplement to the April 2008 issue of *Kidney International*. These guidelines, developed by the Kidney Diseases Improving Global Outcomes (KDIGO) foundation, address the prevention, management, and treatment of hepatitis C virus (HCV) infection in patients with CKD and patients in hemodialysis units.

"The KDIGO guidelines are the first global guidelines in nephrology," guidelines authors Michel Jadoul, MD, head of nephrology, Cliniques Universitaires Saint Luc, Université Catholique de Louvain in Brussels, Belgium, tells Medscape Nephrology. "Hepatitis C was identified by the KDIGO board of Directors as a good topic for the first global guidelines in nephrology, relevant for both developed and developing countries. Hepatitis C is both a cause and consequence of CKD, and [there are] multiple opportunities for improving the care of CKD patients in this field, e.g. by reducing transmission to hemodialysis patients, especially in developing countries."

Infection with HCV is more common in patients with CKD vs the general population. The new guidelines are intended to be globally applicable in a variety of clinical settings, particularly nephrology and transplant practices.

"HCV infection is a major worldwide public health problem with an estimated 170 million affected individuals globally, and 3.2 million Americans chronically infected with the virus," Bertrand L. Jaber, MD, MS, FASN, and an associate professor of medicine at Tufts University School of Medicine in Boston, Massachusetts, tells Medscape. He was not involved with writing these guidelines but was asked to provide independent commentary.

"HCV infection is associated with an increased prevalence of reduced kidney function, albuminuria, and an increased risk of developing end stage renal disease," says Dr. Jaber, who is also vice chair for clinical affairs, Department of Medicine at Caritas St. Elizabeth's Medical

Center, "HCV infection is also associated with increased mortality among patients undergoing maintenance hemodialysis and among kidney transplant recipients."

To detect HCV infection and to prevent transmission, the guidelines strongly urge testing for HCV in patients receiving maintenance hemodialysis and in those who are candidates for kidney transplantation. Testing of all kidney donors for HCV is also recommended, as are infection-control procedures including hygienic precautions that effectively prevent transfer of contaminated blood or fluids.

"The guidelines should help improve a lot the currently suboptimal prevention of hepatitis C transmission in many hemodialysis units worldwide, which is currently mainly nosocomial," Dr. Jadoul says. "The literature review highlighted substantial evidence that preventative strategies should concentrate on basic hygienic precautions, rather than strategies currently popular in many countries such as in Europe, Asia, etc. In addition, a detailed evidence-based review of the literature is now available as guidance for all nephrologists, virologists, hepatologists, hemodialysis nurses, and transplant physicians not necessarily familiar with the specifics of hepatitis C in CKD patients."

To read the rest of the article, go to: <http://www.medscape.com/viewarticle/572657>

A Drug's Ability To Achieve Sustained Viral Response in Genotype 1-Infected Patients Is the Most Important Driver of Prescribing Decisions for Hepatitis C Virus Treatment

<http://www.pharmalive.com/>

Surveyed Physicians Will Use Novel Drugs From Schering-Plough and Vertex/Johnson & Johnson in 75 Percent of Non-Responder Patients, According to a New Report from Decision Resources

WALTHAM, Mass., April 08, 2008, 2008 /PRNewswire/ -- Decision Resources, one of the world's leading research and advisory firms focusing on pharmaceutical and healthcare issues, finds that a therapy's effect on sustained virologic response in patients infected with genotype 1 hepatitis C virus-for both treatment-naive and treatment nonresponder patients-is the attribute that most influences gastroenterologists' prescribing decisions in treating the disease. Clinical data and expert opinion shows that Vertex/Johnson & Johnson's telaprevir and Schering-Plough's boceprevir, used in combination with a long-acting interferon-alpha plus ribavirin (Roche's Copegus, Schering-Plough's Rebetol, generics), have advantages in this attribute over Roche's Pegasys plus ribavirin, the sales leader and current gold standard treatment for the disease.

The new report entitled *Hepatitis C Virus: Blockbuster Sales Potential for Protease Inhibitor That Is Effective in Treatment Nonresponders* finds that surveyed gastroenterologists and hepatologists indicate that they would prescribe telaprevir or boceprevir, in combination with a long-acting interferon-alpha plus ribavirin, to 50% of their treatment-naive and 75% of their nonresponder patients with hepatitis C virus.

The report also finds that Human Genome Sciences/Novartis's Albuferon plus ribavirin plus telaprevir will become the clinical gold-standard treatment for hepatitis C virus from 2011 to 2016, following the approvals of Albuferon and telaprevir.

"Albuferon provides a dosing advantage over the current pegylated interferons, and the addition of a protease inhibitor to interferon/ribavirin therapy appears to improve efficacy," said John Lebbos, M.D. director at Decision Resources. "Surveyed gastroenterologists and hepatologists' high receptivity to the new protease inhibitors reflects their desire for more effective therapies in patients infected with genotype 1 hepatitis C virus."

About the Report

Hepatitis C Virus: Blockbuster Sales Potential for Protease Inhibitor That Is Effective in Treatment Nonresponders is a DecisionBase 2008 report from Decision Resources.

DecisionBase 2008 combines market forecasts with clinical and commercial end points to assess market share projections in 35 indications. These outputs are driven by quantitative and qualitative primary research. DecisionBase 2008 provides detailed market share, patient share, and price-per-day projections for emerging drugs in development. The market share projections are based on prescriber surveys that compare physicians' expectations of a potential target product profile with an emerging product profile of the leading drugs in development.

The report can be purchased by contacting Decision Resources. Members of the media may request an interview with an analyst.

About Decision Resources

Decision Resources, Inc. (<http://www.decisionresources.com>) is a world leader in market research publications, advisory services, and consulting designed to help clients shape strategy, allocate resources, and master their chosen markets. Decision Resources is a Decision Resources, Inc. company.

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April 9th, 2007

RF Ablation Plus Chemoembolization Comparable to Surgery for Early Liver Cancer

<http://www.medscape.com>

By Anthony J. Brown, MD

NEW YORK (Reuters Health) Apr 02 - Radiofrequency ablation combined with chemoembolization provides comparable overall and disease-free survival as hepatectomy for early-stage hepatocellular carcinoma, Japanese investigators report.

In their study, the overall survival rate at 5 years was 75% with the combined treatment and 81% with surgery. The corresponding recurrence-free survival rates were also similar, 27% and 26%.

The findings suggest that "radiofrequency ablation combined with chemoembolization provides patients with early-stage hepatocellular carcinoma similar results to surgical intervention," lead author Dr. Koichiro Yamakado told Reuters Health. He added that his team is now planning to conduct a randomized trial to confirm this.

Surgical resection is considered the gold standard for treating early-stage disease, but only 9% to 29% of patients are eligible for this procedure either because of underlying pathology that limits their hepatic reserve or because tumor nodules are spread throughout the liver, according to the report in the April issue of *Radiology*.

In treating small hepatic tumors, radiofrequency ablation has been shown to achieve overall survival rates comparable to that of surgical resection, but it is associated with lower recurrence-free survival. Combining radiofrequency ablation with chemoembolization might solve this problem.

To investigate, Dr. Yamakado, from Mie University School of Medicine, and colleagues compared the survival outcomes of 104 patients treated with chemoembolization followed by radiofrequency ablation and 62 treated with hepatectomy. Eligibility criteria included no prior treatment for hepatocellular carcinoma, three or fewer tumors with a maximum diameter no greater than 3 cm or a single tumor no greater than 5 cm, Child-Pugh class A, no vascular invasion, and no extrahepatic metastases.

The 1- and 3-year overall survival rates with each treatment strategy were nearly identical, at 98% and 94%, respectively, in the combination therapy group, compared with 97% and 93% in the hepatectomy group. The corresponding recurrence-free survival rates were also similar with combination therapy (89% and 69%) and hepatectomy (92% and 64%).

The findings suggest that radiofrequency ablation plus chemoembolization is a suitable alternative to hepatectomy for early-stage disease, the authors conclude, but "a randomized controlled trial is warranted to clarify whether this combination therapy could provide the same results as hepatectomy over long-term periods."

Radiology 2008;247:260-266.

Elevated AST, ALT Linked to Higher Future Mortality Rate

<http://www.medscape.com>

NEW YORK (Reuters Health) Apr 01 - Elevated liver enzymes discovered during routine medical care are associated with increased mortality risk over the subsequent decade, results of a study published in the March issue of *Hepatology* indicate.

Although aspartate aminotransferase (AST) and alanine aminotransferase (ALT) determinations have been used routinely in clinical practice for decades to detect liver disease, Dr. W. Ray Kim and colleagues note, "their role as a predictor of mortality has not been examined until recently."

The researchers from the Mayo Clinic College of Medicine, Rochester, Minnesota, identified all adult residents of Olmsted County, Minnesota, who had at least one health care encounter at the Mayo Clinic in 1995, and extracted their AST or ALT results from a laboratory database. The subjects were followed forward from January 1995 to April 2006 and their survival was determined. The authors calculated standardized mortality ratios (SMRs), based on Minnesota white death rates.

During 1995, AST was measured at least once in 18,401 residents. Of these, 2350 (13%) had results greater than the upper limit of normal (ULN). A total of 6823 subjects had their ALT measured during this time, and 911 (13%) had results higher than normal.

Overall, 4639 deaths were observed in the study population between 1997 and 2006.

An abnormal AST up to 2 times ULN was associated with a 32% increased risk of death, and more than 2 times ULN was linked to a 78% increase in risk compared with the reference population.

An abnormal ALT up to 2 times ULN was associated with a 21% increase in mortality risk, and more than 2 times ULN was associated with a 59% increase in risk.

In contrast, patients with normal AST or ALT had a lower than expected risk of death (SMR 0.95 for AST and 0.61 for ALT).

"Of decedents with available data, AST was significantly higher among those who died of hepatobiliary causes," Dr. Kim's team writes. "Of those with available data, decedents from hepatobiliary causes had higher ALT than those with other causes of death."

They note that liver disease is generally silent until it becomes advanced. "Measurement of aminotransferases may allow early detection and treatment of conditions that could lead to significant morbidity and mortality in the future."

Hepatology 2008;47:880-887.

April 10th, 2007

Combo Treatment Ups Liver Cancer Survival

<http://www.cancerpage.com>

By Anthony J. Brown, MD

NEW YORK APR 08, 2008 (Reuters Health) - As a treatment for hepatocellular carcinoma larger than 3 cm, transarterial chemoembolization (TACE) plus radiofrequency ablation (RFA) leads to better survival than either modality alone, according to a report in the *Journal of the American Medical Association* for April 9.

This is the first randomized controlled trial to compare TACE-RFA with TACE or RFA alone in patients with larger hepatocellular carcinomas, lead author Dr. Bao-Quan Cheng, from Shandong University in Jinan, China, told Reuters Health.

The study involved 291 consecutive patients seen at a single center in China who were randomized to receive one of the three treatments. The main end point was survival.

During a median follow-up period of 28.5 months, the median survival period in the TACE-RFA group was 37 months compared with 24 and 22 months in the TACE and RFA groups, respectively. Patients treated with TACE-RFA were about 88% more likely than those treated with TACE or RFA to survive ($p < 0.001$ for both).

On subgroup analysis, TACE-RFA was better than RFA in improving the survival of patients with unimodular carcinoma ($p = 0.001$) and superior to TACE in increasing the survival of those with multinodular disease ($p < 0.001$).

Overall, 54% of TACE-RFA-treated patients had an objective response rate that lasted at least 6 months. By contrast, the rates in the other groups did not exceed 36%.

Dr. Cheng said that further research is needed to determine if these findings apply to patients in countries other than China. The gastroenterologist explained that in China, hepatocellular carcinoma is typically due to hepatitis B virus, whereas in Western countries, hepatitis C virus, alcohol abuse, and other diseases are the main causes.

SOURCE: JAMA 2008;299:1669-1677.

April 11th, 2007

Studies suggest statins fight it

<http://www.tulsaworld.com>

By KIM ARCHER *World* Staff Writer

An Oklahoma researcher says a common drug can reduce the deadly virus in patients.

OKLAHOMA CITY -- A University of Oklahoma researcher has found that a common cholesterol-fighting drug reduces the hepatitis C virus in patients with the deadly disease.

"It is the first time in 10 years that a new class of drug has been discovered to have an inhibiting effect against the virus," said Dr. Ted Bader, principal investigator and director of liver diseases at the OU Health Sciences Center.

Hepatitis C, a blood infection, is the leading cause of liver-related deaths in Oklahoma. The disease is the reason for most of the 70 liver transplants performed in Oklahoma each year. The virus is spread mainly by contact with contaminated blood or blood products.

More than 80,000 Oklahomans have chronic hepatitis C, but fewer than 5 percent of them have been treated. It often is asymptomatic and can lead to progressive liver disease.

Bader said he first learned of the possibilities of using cholesterol-fighting statins to reduce the virus in patients from a Japanese study.

"I said, 'Eureka!' and I took off out of the chute," he said. "It's a compound already on the pharmacists' shelf."

When he sought grants from different sources to fund the study, other scientists laughed at him, he said.

"It's a long-standing myth that statins hurt the liver," Bader said. "They still haven't taken those warnings off the commercials for Zocor and Crestor."

Bader persisted and got a license from the U.S. Food and Drug Administration to test Fluvastatin against hepatitis C. He initiated a small trial study among 31 veterans with chronic hepatitis C at the Department of Veterans Affairs Medical Center in Oklahoma City.

"All had abnormal liver tests, and they were improved after taking Fluvastatin. These were people on whom the standard treatment had failed," he said.

Standard treatment is a once-a-week regimen of interferon and an antiviral called ribavirin for 48 weeks.

Bader and his fellow researchers are set to launch a phase II, a randomized controlled trial of as many as 170 patients with hepatitis C who have never been treated for the disease. He will administer a combination of interferon, ribavirin and Fluvastatin.

"Fluvastatin alone is not going to cure hepatitis C," he said. But in combination with interferon, the treatment is promising.

Because Fluvastatin is not approved for use against hepatitis C, people should not try taking it to combat the disease on their own, Bader said. People might take it and become resistant to the drug.

"My goal in life is to increase the cure rate," Bader said. "When patients are cured, they feel dramatically better, their health-care costs plummet, their risk of liver cancer drops dramatically, and if they do not have cirrhosis, they will not need a liver transplant."

"Moreover, they are no longer infectious."

Husband fails in appeal on 'very sad' Hep C case

<http://www.independent.ie>

By Tim Healy and Jason O'Brien

The Supreme Court has left the husband and full-time carer of a hepatitis C sufferer with just €5,000 compensation for loss of earnings.

It ruled yesterday that carers have only one bite of the cherry when it comes to specific claims against the Hepatitis C Compensation Board.

The decision prevents the man bringing a second claim for loss of earnings, despite having given up his job to care full-time for his wife after her health significantly deteriorated.

The man was given the award by the hepatitis C compensation tribunal following a claim he made in 1997.

The tribunal described that award as final and it was not appealed.

He was awarded €100,000 by the tribunal in a separate claim in 2004 for the loss of the company of his wife due to the health problems created by hepatitis C.

However, the man later claimed that, due to his wife's health deteriorating, he had to leave his job in 1999 and care for her full time from 2000.

Rejecting his appeal yesterday, the judge said that this was "a very sad case", but the court had to address issues of law "and not social policy".

The Hepatitis C Compensation Tribunal Act 1997 did not provide for the type of award claimed and perhaps it was a matter the Oireachtas "may address", she added.

A support group claims that the ruling may serve to remind the public of the plight of women who contracted hepatitis C, and the problems their families face.

Eleanor O'Mahony, chair of Positive Action, said that the struggle had slipped from the public consciousness in recent years.

Deterioration

"We have quite a few people who, because they are in the third decade or fourth decade of the illness, they are getting progressively worse, not just with the deterioration in their liver but the side effects," Ms O'Mahony said.

"We've had a number of transplants and we've had a number of deaths, unfortunately.

"As the age profile grows, people are getting sicker."

The group, which provides information and support to women who have contacted hepatitis C from infected products administered, said that the ruling of the Supreme Court that a €5,000 award to a husband for loss of earnings for bringing his wife to medical consultations was tough, but fair.

"It is a sad day for that family to think that this is the value of the woman at the end of the day," Ms O'Mahony said.

"Unfortunately, he accepted the full and final award in 1997."

- Tim Healy and Jason O'Brien

A 'New Normal': Life After Hepatitis

<http://www.lvrj.com>

By John Przybys

Review-Journal

Despite fear of unknown when diagnosed, patients prove that surviving the disease possible

Debra Fox knew something was wrong.

She felt tired. The wound from her recent surgery wasn't healing well. And, worst of all, her urine had taken on a brownish color.

Fox, who had worked in the mental health care field and also as a medical transcriptionist, did some research. And, soon, tests by her doctor would prove her suspicions correct.

Hepatitis C. Contracted, Fox suspects, through hospital error during a surgery she had a few months earlier.

About 12 weeks ago, Fox completed a 42-week course of treatment for hepatitis, a regimen that pretty much trashed her 2007. It was exhausting, physically and emotionally grueling, and, in every way, life-changing.

But, so far, it seems to have worked. And while the 48-year-old knows her life will never be as it was before -- she calls her post-treatment life "the new normal" -- she hopes that talking about her experience can help to calm the fears of at least some of those Southern Nevadans who are waiting to learn whether hepatitis treatment lies in their futures, too.

It has been more than a month since a cluster of hepatitis C cases was traced back to valley endoscopy clinics where syringes and single-use vials of anesthetics were used improperly. Now, more than 40,000 people are awaiting word on the results of HIV and hepatitis tests and, along the way, probably learning more about hepatitis than they ever cared to know.

Hepatitis is a viral disease that attacks the liver, causing inflammation and, in some cases, liver damage, cirrhosis and cancer. There are five varieties of hepatitis -- A, B, C, D and E -- and the

viruses that cause it can be transmitted by contact with infected blood or stool. Infection could result from eating contaminated food or drinking contaminated water; getting tattoos, piercings or medical procedures done with nonsterile equipment; through sexual activity; or intravenous drug use.

It's those last two that have fueled public misunderstanding about hepatitis. Even in many news reports, says Robert Barone, an infectious disease therapist who facilitates hepatitis C support groups at the Community Counseling Center, "it makes it sound like most people who have it are IV drug users. As a result, a stigma has arisen very similar to what we went through back in the '80s with HIV."

"I've seen an awful lot of people in the support group here in the last four or five years, and I think if 10 people out of maybe 200 or 300 were IV drug users, I'd be surprised," he adds.

Barone is, himself, a hepatitis survivor. In 1970, after being involved in an auto accident in Europe, Barone was transfused with several units of hepatitis B-infected blood, "and I didn't realize it for almost a year."

Back in the States, Barone underwent a liver biopsy. "They told me I had six or eight months to get my affairs in order," he recalls. "My family kind of freaked. It took me almost two years to believe that I wasn't going to die."

That's not an unusual reaction, says Evelyn McKnight, founder of HONORreform, a patient advocacy group. McKnight contracted hepatitis C in 2001 while being treated for cancer.

"I think whenever you get some health news that is unfavorable, you run through all the possibilities, including the worst-case scenario," McKnight says.

Fox was diagnosed with acute hepatitis C (meaning a short-term, as opposed to a chronic, or long-term, infection) in January 2007. The previous November, she underwent surgery to remove an ovarian cyst, and she believes she was infected with hepatitis by unclean equipment used during the procedure. (Her lawsuit against the hospital is pending.)

Fox says she was healthy and physically active -- she'd even run her first marathon -- before the hepatitis diagnosis. When the news came, she was both shocked and crushed.

"I said, 'You've got to be kidding me,' " says Fox, who describes herself as "the original goody two-shoes. In other words, no risk factors."

"I'm not a weeper," Fox adds. "I wept."

"That first weekend, I thought: I'm dead. I won't be able to have sex. I'm a pariah."

It also crossed Fox's mind that some people would think the worst of her, because so many consider hepatitis as "that druggie prostitute disease."

Fox and her husband have been married for 15 years. Unlike some who undergo the long,

grueling course of hepatitis treatment, their marriage survived. But the ripple effects of having, and battling, the disease affected every facet of her life.

"It's not just your marriage," Fox says. "It's your children. It's your insurance coverage now and in the future. It's your employment. It's what is your extended family going to think and what are your friends going to think."

Fox began treatment in March 2007 with daily ribavirin pills and weekly interferon injections. According to the U.S. Centers for Disease Control and Prevention, that combination of drugs is the treatment of choice for hepatitis C and can rid patients of the virus in five to eight out of 10 people.

However, the treatment also can bring severe side effects. Fox understood going in that the side effects can range from mild to moderate to significant. "I had the worst side effects," she says.

"The side effects were as bad as anything I've ever experienced in my entire life, including back surgery," says Fox, who describes them as akin to having severe flu compounded by "the worst hangover you've ever had."

"That first night I remember I was shaking. I had chills. And you think, 'I'm going to die.' "

But, Fox adds, "the caveat here is: It's different for every single person who undergoes it. There are not a lot of generalities."

Nor did Fox ever reconsider her decision to undergo treatment, figuring then and now that it offered "my best good chance" to beat hepatitis.

A few months into treatment, Fox lost her job in the information technology industry. The regimen left her unable to do the traveling the job required and, Fox says, the constant fatigue and "brain fog" the drugs caused made it difficult to concentrate and to remember things.

"All of a sudden, I became physically fragile after being robust," Fox says. "Nausea. No appetite. You can't even carry on the activities of your life."

Barone was out of work for 10 years after receiving his hepatitis B diagnosis. "The first two years I was pretty much bedridden," he says. "At the time, there was no treatment, really." (Today, several drugs can be used to treat chronic hepatitis B.)

At the time, Barone was a contract worker for the federal government. But, during treatment, he lost his health insurance, "so you can just imagine my medical bills over a 10-year period."

Hepatitis treatment also can be mentally and emotionally difficult. In fact, Fox says, doctors often prescribe antidepressants to patients before they begin it.

"The depression the first two years was monstrous," Barone says. "It was just awful."

But that began to change when, oddly enough, Barone started to become angry.

"The person who cut my hair wouldn't cut my hair anymore," he says. "My dentist wouldn't see me anymore. A couple of family members wouldn't come to the house anymore. A couple of friends -- ex-friends, I call them -- wouldn't come near me because they thought I was contagious."

And, Barone says, "I saw what it was doing to my family members and people who cared for me."

Ultimately, Barone says, "anger helped in that I got my ass out of bed and I started doing things that I didn't think I could do because, the first two years, I was in bed most of the time. I was weak, so I didn't have much choice."

"Anger certainly helps, because it motivates you," Barone says.

And, Barone adds, "the most important thing was: I survived." Just as importantly, Barone says it was his bout with hepatitis B that led him into his career in counseling.

Fox completed her course of treatment almost 12 weeks ago. Tests so far reveal good news, although she's still feeling the effects of the rigorous drug therapy.

"Things take a long time to recover," Fox says. "I still have the brain fog and I still have memory recovery problems."

She also suffered kidney problems and now may have developed rheumatoid arthritis because of the treatment.

Mentally, Fox says, "my biggest problem with handling the post-treatment stuff is, it's very slow. I was always a Type A (driven personality) and I can't be a Type A anymore."

But, as of now, "I'm still undetectable for the (hepatitis) virus," she says. "Hopefully, I'm still going to be undetectable."

Does that mean she's cured? Some doctors consider favorable tests six months later as a cure, "but some don't," Fox says.

Barone has been free of hepatitis since 1981. But, he notes, "I still can't donate blood."

"We put 'cured' in quotation marks," Barone says. "So it's a matter of semantics, and how you interpret that word."

Barone urges those who have, or fear they may have, hepatitis to, first, "take the time to educate themselves and ask the right questions."

Then, Barone says, they should understand that "you can lead a fairly normal life, whatever 'normal' means. But some people will give in to it and think of themselves as sick all the time."

Like Barone, Fox now works with hepatitis support groups, sharing her experience with them. "If

a single person feels better as a result of talking to me, then it's worth it," she says.

It's easy "to feel sorry for myself and be scared about the circumstances," she says. "You hear people say, 'I'm going to have a biopsy. I'm terrified.' Well, don't be terrified until you need to be, and most of the time it turns out you don't need to be."

Barone, even now, has two papers handy that he shares with clients. One is the written report confirming his hepatitis B test results. The other is the report 10 years later in which "they pronounced me cured."

"I have both of those with me," Barone says. "The reason I carry them is, I show them to people who are very depressed and upset. When they see what I went through and how I survived it, it gives them a lot of hope."

SUPPORT GROUPS

The Community Counseling Center's hepatitis C support group meets Tuesdays at 3 p.m. at 1120 Almond Tree Lane. For more information, call 369-8700, ext. 224.

Another support group for hepatitis and other liver diseases meets the first Monday of each month at 6 p.m. in the Physicians Conference Room at Sunrise Hospital and Medical Center, 3186 S. Maryland Parkway. For details, call Sandra Hart at 796-9111.

FORMS OF HEPATITIS

There are five forms of hepatitis, designated as A, B, C, D and E. It's hepatitis C that is the focus of the current public health investigation about practices at valley endoscopy clinics.

While the types of hepatitis differ in terms of how they're contracted and how they're treated, all are viral diseases that attack the liver. Hepatitis can occur in both acute and chronic forms, and hepatitis C can lead to cirrhosis, or liver scarring, liver cancer or other liver damage.

"What (the liver) does is destroy the cells that metabolize all the things we eat, the junk we take in, the drugs we take," says Dr. Echezona Ezeanolue, an assistant professor of pediatrics who teaches infectious diseases and clinical epidemiology at the University of Nevada School of Medicine.

The liver is a "very resilient" organ, Ezeanolue adds, and can continue to function even if a portion of it is destroyed. That means "you might get an infection and (part of) the liver is destroyed but it's still functioning very well," he says.

In fact, in some cases, the hepatitis C already has caused damage to the liver by the time it's discovered, and that can happen long after the infection actually occurred.

"A person may be infected for 20 years before they start to show symptoms," notes Evelyn McKnight, founder of HONORreform, a patient advocacy group. "By the time they seek medical care and are diagnosed, they may have very significant liver damage."

Hepatitis can be transmitted in several ways. Hepatitis A, for example, is found in the stool of

people with hepatitis A, and is spread when someone ingests something -- food, for example -- that has been contaminated with the stool of an infected person. Hepatitis B and C, in contrast, are transmitted when blood from an infected person enters the body of an uninfected person through, for example, a tainted blood infusion, sharing needles used for injecting drugs or an accidental needle stick among health care workers.

Ezeanolue estimates that between 50 percent to 85 percent of people who are infected with the hepatitis C virus go on to develop a chronic infection. But, he says, not all chronic infections will develop into acute hepatitis C.

"So everybody thinks once you've been exposed and once you get it, you're going to develop disease. That's not true."

For more detailed information about hepatitis and hepatitis C, follow the links on the U.S. Centers for Disease Control and Prevention's hepatitis Web site.

By JOHN PRZYBYS

Contact reporter John Przybys at jprzybys@reviewjournal.com or (702) 383-0280.

Slightly abnormal blood test may point to a 'silent' form of hepatitis B

<http://www.physorg.com>

Silence isn't always golden. In the case of hepatitis B, people with a past — and seemingly resolved — infection often don't know that they still have a silent form of the disorder. Now, new research suggests that slightly abnormal results from a blood test, once thought to be a fleeting curiosity, can tip off doctors to the presence of this potentially infectious and lethal viral renegade.

In the first study to screen for multiple markers of hepatitis A, B and C in more than 100 patients entering an opiate-addiction treatment program, researchers at Rockefeller University were able to look at the coinfection of these liver diseases and reveal a startling fact: that a high percentage of recovering injection-drug users who had hepatitis B in the past are still infected with hepatitis B DNA in the absence of actively replicating virus.

This report, led by Mary Jeanne Kreek, head of the Laboratory of the Biology of Addictive Diseases, raises a public health concern in the midst of an ongoing debate about whether to treat patients with this asymptomatic yet potentially infectious disease. The scientists published their findings in the March 17 issue of *Addiction*, making a broader cross section of clinicians and researchers aware of the ethical and medical concerns surrounding silent hepatitis B.

Kreek and her colleagues, including Gavin Bart, a coauthor of the study, identified and first reported on the silent form of the virus in 2002, when blood tests from patients with past hepatitis B infection came back with a slightly unusual test pattern. Those with a past infection usually develop two main hepatitis B antibodies, molecules made by the immune system to fight off the virus when it is actively replicating. Kreek and Bart, however, found that 40 percent of

the patients tested for these markers had one antibody, not two.

“This test pattern is slightly unusual but normally, when you see this pattern you would say this person has had past infection and you would look no further,” says Bart, who is now the director of the division of addiction medicine at the Hennepin County Medical Center in Minnesota and an adjunct faculty member at Rockefeller University.

But Kreek and Bart went further.

In addition to screening for hepatitis B antibodies (among other protein markers of the disease), the researchers, in collaboration with David Ho, scientific director of the Aaron Diamond AIDS Research Center, created a highly sensitive test to look for low levels of hepatitis B DNA that wouldn't typically be detected by commercially available DNA kits. When a patient recovers from a hepatitis B infection, the antibodies usually neutralize the viral DNA, according to Bart. Yet, of the patients with the unusual test pattern, Kreek and Bart found that 20 of them, or 60 percent, had hepatitis B DNA.

“That's a huge percentage,” says Kreek, who is also Patrick E. and Beatrice M. Haggerty Professor and senior attending physician at Rockefeller. “When you think about the number of persons with heroin addiction, this adds up to a lot of people.”

The presence of hepatitis B DNA in the absence of actively replicating virus means that these patients are not ill with the disease but could be infectious. However, in the event that a patient requires immunosuppressive therapy for cancer or has an immune disorder such as AIDS, the virus could conceivably replicate and further compromise the patient's health. Kreek and Bart also report that 13 of the 20 patients who had silent hepatitis B also had chronic hepatitis C, an entirely different liver disease that affects more than 80 percent of injection-drug users. Labs around the world, including Kreek's, have shown that patients coinfecting with silent hepatitis B and hepatitis C may respond less well to treatment than those without the silent virus.

While some physicians recommend treating silent hepatitis B as soon as it is diagnosed, others recommend treating it only if patients develop other immune-compromising illnesses in order to avoid unforeseen complications and limit costs. However, it is still unclear whether treatment of silent hepatitis B will improve the response to treatment for hepatitis C. Fortunately, a vaccine against hepatitis B is available and can help protect people from becoming infected with the virus. “That's why we are recommending that everyone get vaccinated,” Kreek says, referring to her team. “Everyone.”

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Source: Rockefeller University