

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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In This Issue:

- [Banned cancer drugs better than NHS ones](#)
- ['Lifer' honoured for work educating prison inmates about HIV infection risks](#)
- ['Dying' Chopper Read refuses transplant](#)
- [Eli Lilly Antidepressant \[Cymbalta\] Approved for New Use](#)
- [Bike races raise hepatitis C research funds](#)
- [Peregrine Pharmaceuticals Awarded Two New U.S. Patents Broadening Its Targeted Anti-Phospholipid Patent Portfolio](#)
- [Study finds depression can trigger diabetes](#)
- [FDA cautions consumers against cancer "cures"](#)
- [Simple trip to the GP can help slay the sleeping dragon](#)
- [Edmonton dentist tests positive for hepatitis B; 1400 patients to be informed](#)
- [Elevated Liver Enzymes Linked to Development of Diabetes](#)
- [More liver cancer patients getting transplants](#)
- [How Safe Are Tattoos?](#)
- [Vertex CEO preparing for '09 hepatitis drug launch](#)
- ['Liver stiffness' and insulin resistance connection in HIV/hepatitis C coinfecting patients](#)
- [Insulin resistance means coinfecting patients have a poorer response to hepatitis C treatment](#)
- [Novel Agents Will Drive The Hepatitis C Virus Drug Market to Increase Nearly Five-Fold to More than \\$10 Billion in 2017](#)
- [Longer Treatment Course Advisable With Hepatitis C Genotype 6](#)
- [Anti-HIV treatment may mean that progression of hepatitis C no worse in coinfecting patients than in those with only hepatitis C](#)

- [Citizens of the Week](#)
- [Ribavirin levels after four weeks of treatment predict which HIV/hepatitis C coinfecting and re-treated patients will respond](#)
- [HIV-positive gay men and sexual transmission of hepatitis C: it's no longer just northern Europe](#)
- [HIV and hepatitis coinfection in Africa: studies provide conflicting prevalence data](#)
- [Complaint about doctor languishes in state bureaucracy](#)

June 15, 2008

Banned cancer drugs better than NHS ones

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

Sarah-Kate Templeton, Health Editor

With privately bought drugs proving to be up to five times as effective as NHS treatments, The Sunday Times reports on the suffering the co-payments ban is inflicting on patients

The National Health Service is providing dying cancer patients with drugs that are five times less effective than those available privately and is refusing to treat them if they try to buy medicines themselves.

One drug for kidney cancer, routinely available through public health systems in most European countries but not to British patients, can reduce the size of tumours in 31% of patients, compared with just 6% of those prescribed the standard NHS drug.

The growing row over “co-payments” has prompted the government to reconsider the ban. Alan Johnson, the health secretary, has promised a “fundamental rethink” of the policy.

The shift comes as increasing numbers of cancer doctors defy the official Whitehall ban and allow patients to pay for drugs while still receiving NHS care.

Doctors at the Royal Marsden hospital in London and consultants at the NHS trust in Swansea are offering patients NHS care while they pay to receive drugs that will prolong their lives. Last week The Sunday Times revealed that about 16 consultants in Birmingham are ignoring the government guidance.

Research presented at the American Society of Clinical Oncology found that kidney patients taking the new drug Sutent lived six months longer than those prescribed alpha interferon, the NHS treatment.

The failure of the NHS to make more effective drugs available to cancer patients has been condemned as “unethical” by leading doctors.

John Wagstaff, professor of oncology at Swansea University, said: “This has created a very difficult situation for us. Having seen the latest data, I believe it is now pretty unethical to give many patients alpha interferon [rather than Sutent]. We are often forced to prescribe interferon because we do not have access to Sutent [on the NHS], but I am always upfront with the patients. I tell them what I think the most effective treatment is.”

Eight times as many patients in Germany and France receive Sutent as in Britain, according to figures held by Pfizer, the manufacturer. Sutent, which costs about £2,200 a month compared with about £800 for the NHS drug, is one of a number of life-prolonging new drugs at the centre of the co-payments row.

In advanced kidney cancer, when the patient cannot be treated with any other drug, Nexavar, another medicine, can double the period when the disease is held under control.

A trial of Nexavar, comparing the effect of the drug with a placebo, showed it to be so effective that the trial had to be halted early as it was considered unethical not to give it to all the patients in the test. Tumours were prevented from growing for an average of 5.5 months in patients taking Nexavar, against 2.8 months in those taking the placebo. Despite the findings, Nexavar is not routinely funded by the NHS.

Similarly, bowel cancer patients are up to four times as likely to see their tumour shrink if they pay for Erbitux than if they take irinotecan, the NHS-approved drug, alone. A study published in the New England Journal of Medicine in 2004 showed that 23% of patients experienced a reduction in the size of their tumour when they took Erbitux and irinotecan.

Other studies showed that just 5% of patients have the same benefit from taking irinotecan alone. Those taking irinotecan alone had their bowel cancer under control for 4.2 months, but this rose to 8.6 months when Erbitux was added.

Erbitux, costing about £3,000 a month, is funded for bowel cancer in most European countries. Patients in France are 13 times, in Spain 10 times and in Germany nine times more likely to get the drug than Britons.

The drug Avastin offers similar benefits. Research presented earlier this year showed that patients who receive Avastin and routine chemotherapy before surgery are twice as likely to be alive two years later as those who receive only the chemotherapy available on the NHS.

Fireman is denied treatment

A former fireman who developed liver cancer after 25 years' service has been told that if he pays for the only drug that can treat his disease his NHS care will be withdrawn.

Barry Humphrey, 59, from North Walsham, Norfolk, was told by NHS doctors that the drug Nexavar was the only available treatment for his advanced liver cancer.

However, consultants at Addenbrooke's hospital in Cambridge said the drug was not routinely funded by the NHS and told him that if he paid for it he would be billed for the rest of his NHS care.

Humphrey believes his cancer is linked to his time as a fireman. His cancer was caused by cirrhosis of the liver after he contracted hepatitis C. He believes he caught the virus from a casualty while on duty.

Research presented at the American Society of Clinical Oncology found patients with advanced liver cancer survive for an average of 11 months if they take Nexavar, while those denied the drug live for just eight months.

Humphrey's wife Hazel, 58, who also worked in the fire service, said: "Doctors said this would 'not be viable' because we would be deemed as opting out of the NHS and would need to pay for everything.

"I think it is absolutely disgraceful. When people are terminally ill, they want to spend as much time as they possibly can extending their life expectancy." She said the couple know the drug will not provide a cure but should have the right to spend their savings to prolong her husband's life.

They plan to sell a flat that they have been renting out to raise the cash for the drug, which costs about £3,000 a month. Humphrey, who has four children, six grandchildren and helps to care for his elderly mother, said: "I think this is morally wrong and indefensible."

Cambridge University Hospitals NHS Foundation Trust, which runs Addenbrooke's, said: "We are complying with the national guidance which says we cannot allow co-funding."

A family's battle

A woman with bowel cancer is fighting for the right to pay for a drug that could extend her life long enough for her to spend Christmas with her grandchildren.

Sheila Norrington, 59, a former NHS medical secretary from Maidstone, Kent, has been told by doctors that if she buys the drug Erbitux, which the health service will not pay for, she will lose her state-funded cancer care. Erbitux is the only drug capable of treating her advanced bowel cancer.

Norrington's husband, Goff, 61, a former sales manager, said: "We have been told that if we pay for it ourselves we will be thrown off the NHS completely and we will need to pay for everything privately. We are devastated. This is not going to cure my wife, but if it keeps her alive a little bit longer, then we would pay for it."

The couple say that although they could pay for a few cycles of the drug, which costs about £3,000 a month, they could not pay for all Norrington's care, including scans, blood tests and consultations.

Goff Norrington added: "We have two young granddaughters and this could make the difference between sitting round the table with them at Christmas or not. We think it is deplorable that patients can get this drug almost anywhere in Europe but we cannot get it in the UK."

A spokesman for Maidstone and Tunbridge Wells NHS Trust said: "We are governed by Department of Health policy on this issue."

The public's view

A poll for *The Sunday Times* shows strong support for allowing co-payment in the National Health Service, with 89% saying that people who buy additional cancer drugs should continue to get free NHS treatment.

Only 5% think allowing co-payment would create a two-tier NHS. Until now this has been the position taken by Alan Johnson, the health secretary.

Ministers had feared that allowing co-payment would upset less well-off patients, but the YouGov poll of nearly 1,800 people shows strong backing across the social spectrum and supporters of all three main parties.

'Lifer' honoured for work educating prison inmates about HIV infection risks

<http://canadianpress.google.com>

TORONTO — An Ontario man serving a life sentence for killing a policeman is to be honoured for years of efforts to educate prison inmates about how to lower their risk of becoming infected with HIV.

The Canadian HIV-AIDS Legal Network and Human Rights Watch is to announce Monday that they are giving their 2008 Canadian Award for Action on HIV/AIDS and Human Rights to Peter Collins, the groups have revealed.

Collins, 46, has spent the last 25 years in jail for killing an Ottawa policeman during a botched armed robbery. Just last week Collins, who is incarcerated at Bath Institution, a medium security prison about 20 kilometres west of Kingston, Ont., learned his second application for parole had been denied.

Peter Collins wasn't immediately available for interview. But his father, Michael Collins, said learning that Peter was being honoured for his advocacy for health services and HIV prevention tools for fellow inmates made him proud of his son.

"Definitely. We're all sort of just jumping at this point, really. It's amazing," said the elder Collins, who lives in Carleton Place in the Ottawa River Valley.

"All these years that we've been living with Peter being in prison and then to have this come out of the blue, that he's such a notable person that they're going to give him an award - it makes a nice change."

The HIV-AIDS Legal Network and Human Rights Watch cited Peter Collins' work as a peer education counsellor, saying he's been educating fellow inmates about HIV prevention since the late 1980s. He has advocated for better health care and HIV prevention services in prisons, including tattoo parlours that use sterile equipment and needle exchange programs.

Richard Elliott, executive director of the HIV-AIDS Legal Network, said the award not only recognizes Collins' efforts, "but also highlights how much still needs to be done to ensure prisoners' basic human right to protect themselves against HIV and hepatitis C."

He admitted the organizations use this award, given out annually since 2002, to focus attention both on the recipient and on HIV prevention issues that the groups are working on, in this case making sterile needles available to prisoners who use injection drugs to lower rates of transmission of HIV and hepatitis C in prisons.

Figures provided by Corrections Service Canada and published in the Canadian Medical Association Journal last year showed that in 2004 more than 3,300 male and female inmates in Canada's 54 prisons had hepatitis C in 2004 and almost 200 prisoners were infected with HIV.

A 2004 report on the health of inmates that was commissioned by the correctional service showed that inmates were 30 times more likely to inject drugs than non-prisoners. They were also 20 times more likely to have hepatitis C and 10 times more likely to be infected with HIV than the non-prison population.

Yet they do not have access to the needle exchange programs that injection drug users across the country have been able to avail themselves of for years, Elliott said in an interview.

"Drug use in prison is no more illegal than it is outside prison. It's still an offence," he said.

"But one of the central points in this whole debate about harm reduction and its role in drug policy is: It doesn't matter that drugs are illegal. That doesn't mean that we keep people from getting access to the health services they need."

Elliott noted that Switzerland, Spain, Germany and a few other countries have safely instituted needle exchange programs in prisons.

But with the current federal government's opposition to harm reduction measures - it cancelled the prison tattoo program and is opposed to Vancouver's safer injection site - Elliott doesn't see Canada following suit any time soon. "I think we're going backward, unfortunately, on some of these issues."

He said prisoners are entitled to the same kinds of health services people outside of prisons can receive. And he suggested it's in society's interest to prevent HIV and hepatitis C transmission in prisons.

"Because most prisoners do leave prison eventually. They serve their time. They go back into their communities. So what happens to their health while they're in prison obviously affects the broader public health," Elliott said.

"It makes fiscal sense, it makes human rights sense, it makes public health sense to have these kinds of health services available ... to prisoners. I think, unfortunately, the real barrier is an ideological one."

'Dying' Chopper Read refuses transplant

<http://www.news.com.au>

By Nuie Te Koha

*--Chopper says he has hepatitis C
--'Needs a liver transplant to save his life'
--But says he doesn't deserve one*

MARK "Chopper" Read has deadly hepatitis C and refuses to seek a liver transplant to save his life.

"I am dying and I accept that," the notorious criminal said yesterday.

"All I want now is to do the right thing and make sure my two young boys are looked after."

But Read, who is also a bestselling author and artist, has ruled out a life-saving liver transplant, saying he does not deserve it.

"A transplant would save me, but why would anybody give 53-year-old Chopper Read a liver over and above an 11-year-old girl with liver cancer?"

"They wouldn't – and I wouldn't ask. I need a transplant, but I don't want a transplant."

Doctors have given Read two to five years to live. Recently they told him he would die in 20 months if he did not stop drinking.

Read believes he contracted hepatitis C while using shared razor blades in prison.

"The diagnosis shocked me and I hit the bottle hard," he said. "I drank and drank and drank. If I kept drinking, I would've been dead quicker."

Read has two sons, Charlie, 8, and Roy, 4. He continues to paint and, on the advice of Archibald Prize winner Adam Cullen, is putting his art work in storage.

"I am told my paintings will be worth \$10,000 to \$20,000 after my death. I'm working hard, and putting half away for Roy, and the other half for Charlie."

The criminal cult figure says he does not fear death. "I am not frightened of dying," he said.

"But I want to get a few things done before I die. Most of all, I need to look after my sons."

Charlie lives in Tasmania and Roy in Melbourne with Read. "Fatherhood changed me," Read said.

"I reckon I became a human being at 45, when I saw my first boy born from a caesarean section. That's the moment I joined the human race.

"Then, when I was 50 and I saw my second boy born, I became a fully paid-up member of the human race. I have no regrets, but those moments told me what I should have been – a good human being."

Read strives to tell his boys to be good, productive people. "I don't want them to grow up doing the same things I did," he said.

He says he has no desire to learn more about hepatitis C. He sees a doctor twice a week and is taking medication.

"I do what I'm told and try to live a clean life. But this is killing my liver and killing me. I will die."

Read blames it all on jail-issue razor blades. "They didn't even have a name for hep-C back then. It was either non hep-A or non hep-B," he says.

"Prisoners who had never used needles in their life ended up getting hep-C. They made us use the same razor and watch us shave in front of the mirror."

But he has no regrets about his violent and colourful life.

"Regret is like saying if you had time over again, would you change anything?" he said. "Nah – I would run over the same a***holes if I had my time over."

June 16, 2008

Eli Lilly Antidepressant Approved for New Use

<http://www.therapeuticsdaily.com>

INDIANAPOLIS_Eli Lilly and Co. said Monday it received Food and Drug Administration approval to expand the use of its fastest-growing drug, the antidepressant **Cymbalta**.

Regulators approved Cymbalta to treat **fibromyalgia**, a chronic pain disorder. The drug already is approved for diabetic nerve pain, major depressive disorder and generalized anxiety disorder.

Lilly launched Cymbalta in 2004. It was the drugmaker's second-best seller last year, generating \$2.1 billion in mostly U.S. sales behind Zyprexa's \$4.7 billion. Cymbalta sales rose 37 percent in the first quarter to \$605 million.

Cymbalta's 2007 sales represented a 60 percent increase over 2006. That year, the drug notched \$1.3 billion in sales, a 94 percent increase over 2005.

Fibromyalgia affects about 5 million Americans. Researchers believe its cause may be related to genetics, stress and changes in brain and spinal cord chemistry and that it leads to increased pain sensitivity.

Federal regulators also are expected to decide the fate of the cardio drug prasugrel later this month or early next month. Lilly developed the drug with Japan's Daiichi Sankyo Co., and some analysts following the drug maker expect it to generate at least \$600 million in annual revenue.

Despite the Cymbalta news, Lilly shares dropped 89 cents, or 1.8 percent, to \$47.44 in morning trading Monday.

Bike races raise hepatitis C research funds

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

BY AMANDA HAMON

The Ann Arbor News

As Scott Mahler, of Ypsilanti, ascended the winners podium on South University Avenue on Sunday, his four children rushed to congratulate him.

Minutes earlier, Mahler had won an Ann Arbor Tour de Kids race - on his seven-year-old son's tricycle.

"I wanted them to come out and participate, and they thought it was only fair I participate, too. This is good family fun," said Mahler, laughing.

Mahler beat about nine other fathers - riding tricycles and unicycles - in the Dads' Dash, a Father's Day-themed race in the Tour de Kids.

The daylong Tour de Kids, staged on streets around the University of Michigan Diag, raised money for the Greenview Hepatitis C Fund for research at the University of Michigan Medical Center.

Organizers said about 330 kids ages 3 through 12 participated in races, with each participant receiving a medal. Races were categorized by age and gender.

The Tour de Kids returned this year with the help of sponsors after a four-year hiatus, said co-director Rob Pulcifer. This year's title sponsor is SpamStopsHere, an Ann Arbor-based company that sells e-mail filtering software.

"We're quite thrilled with how it turned out. Everyone seems to be very happy with it," he said.

Debbie Green, director of the Greenview Hepatitis C Fund, said it may take a while before the revitalized Tour de Kids event raises as much as in previous years, when there were more participants and money went to other charities.

"Ann Arbor needs to get used to the event again. ... I don't think it'll take long," she said. "I think we'll probably double, maybe triple participation next year."

Mahler said he and his family were glad the event returned.

"It's actually my birthday today, and ... it's our Father's Day tradition to do this," he said. "We were so glad when we found out it was coming back."

Parents and children who participated said the event was a great way to exercise and spend time together.

When she heard the signal, three-year-old Caroline Dergis sped off with eight other girls on tiny bicycles. The girls' parents ran beside them as they neared the finish line, cheering the whole way.

Caroline's father, Mike Dergis, said he was glad to bring his family to an outdoor event where they could exercise.

Eve Wrest, of Grand Rapids, who was in town visiting family, came to the event with her husband and three children.

"We love it. They make such a big deal over the kids," she said. "It's a lot of fun."

Co-director Dawn Lovejoy said the event will be back next year.

"We already have people asking to be title sponsors for next year," she said.

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***Peregrine Pharmaceuticals Awarded Two New U.S. Patents
Broadening Its Targeted Anti-Phospholipid Patent Portfolio***
<http://biz.yahoo.com>

- *New Claims Cover Anti-Viral Applications of Novel Targeted Agents Under the Company's Anti-Phospholipid Technology Platform -*
- *Anti-Viral Potential of These New Agents Supported by Recent Studies Presented at American Association of Immunologists Annual Meeting -*

TUSTIN, Calif., June 16 /PRNewswire-FirstCall/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM - News), a clinical stage biopharmaceutical company developing monoclonal antibodies for the treatment of cancer and hepatitis C virus infection (HCV), today reported the issuance of two U.S. patents that significantly broaden the company's intellectual property leadership in the field of targeted anti-aminophospholipid agents. The new patents grant Peregrine broad anti-viral method claims using a range of phosphatidylethanolamine (PE) binding agents, including PE-binding peptides attached to anti-viral agents as well as those conjugated to antibodies or other substances.

"These are significant patents for Peregrine that substantially expand our intellectual property portfolio in the field of aminophospholipid-targeting agents," said Dr. Shelley Fussey, vice president of intellectual property at Peregrine. "These anti-PE agents appear to have anti-viral properties similar to the anti-phosphatidylserine (PS) monoclonal antibody bavituximab that we currently are testing in clinical trials in HCV patients and in preclinical studies for HIV and other

viral infections. We are especially pleased at the breadth of the issued claims, which provide Peregrine with U.S. patent coverage for methods of combating all relevant viruses using the claimed anti-PE peptide conjugates, either used alone or in combination with other anti-viral drugs. As peptide conjugates, anti-PE agents may be well-suited for use in some of these broad anti-viral applications."

The science underlying the two new patents was presented in April 2008 at the 95th Annual Meeting of the American Association of Immunologists by Dr. Melina Soares of the University of Texas Southwestern Medical Center.* She presented data showing that similar to PS, the target for Peregrine's bavituximab program, the aminophospholipid PE is normally located on the inside of cell membranes, but becomes exposed on the external surface of enveloped viruses and virus-infected cells. Using a biotin-conjugated form of the peptide drug duramycin, which is known to bind to PE, Dr. Soares and her colleagues demonstrated that exposed PE could serve as a broad-spectrum target for anti-viral therapy. Specifically, they showed that duramycin linked to biotin neutralized multiple enveloped viruses and that it showed therapeutic efficacy in a lethal mouse model of cytomegalovirus.

U.S. Patent #7,378,386 issued on May 27, 2008 and U.S. Patent #7,384,909 issued on June 10, 2008.

*M. Melina Soares, Susan Mims, Gustavo Barbero, Shuzhen Li and Philip E. Thorpe, "Anti-Viral Effects of Phosphatidylethanolamine-Targeting Agents", American Association of Immunologists Annual Meeting, San Diego, California, April 7, 2008.

June 17, 2008

Study finds depression can trigger diabetes

<http://www.reuters.com>

By Will Dunham

WASHINGTON (Reuters) - People with depression have a higher risk of developing the most common form of diabetes than others, according to a study published on Tuesday that sheds light on the interplay between the two conditions.

The study indicated that the relationship between type 2 diabetes, the form of the disease closely linked to obesity and sedentary lifestyle, may be a bit like a two-way highway. Not only can diabetes lead to depression, as has been well established, but depression can also lead to diabetes.

U.S. researchers led by Dr. Sherita Hill Golden of Johns Hopkins University School of Medicine in Baltimore tracked an ethnically diverse group of about 5,000 men and women between ages 45 to 84 for about three years.

They found that people with symptoms of depression were 42 percent more likely to develop diabetes by the end of the study than those without such symptoms. They also found that the more serious the symptoms, the higher the risk of diabetes.

The researchers statistically accounted for factors including obesity, lack of physical activity and smoking, and found that the risk for diabetes was still 34 percent higher in patients with depression.

"When we looked at the people in our study who had elevated symptoms of depression, they were more likely to eat more calories, they exercised less, and they were more likely to be current smokers. And as a consequence, they were also more obese," Golden, whose study was published in the Journal of the American Medical Association, said in a telephone interview.

"And those are all known risk factors for type 2 diabetes. So it seems that some of the adverse health behaviors associated with depressive symptoms were an important component of that relationship (between depression and diabetes)."

Golden added that depression also pushes up the levels of stress hormones such as cortisol.

TRIGGER EFFECT?

Diabetes is a disease marked by high levels of sugar in the blood. In type 2 diabetes, the body becomes resistant to the effects of the hormone insulin or the body produces some, but not enough, insulin to keep a normal blood sugar level.

Elevated cortisol levels can impair insulin sensitivity in the body and encourage belly fat, a risk factor for diabetes.

The study also measured the risk for developing depression among people who already had diabetes. To do this, the researchers excluded people who had elevated symptoms of depression at the outset of the study.

People who had been treated for diabetes were 54 percent more likely to develop depression symptoms than the others.

An anomalous finding was that people who were deemed pre-diabetic -- the precursor to diabetes -- as well as people who actually had diabetes but did not know it were about 20 percent less likely to develop depression than non-diabetics.

The researchers suspect this may be at least in part because those people did not have the psychological burden of knowing they had a serious disease like diabetes.

Evidence is building that depression can trigger diabetes.

A study last year in the journal Archives of Internal Medicine headed by Mercedes Carnethon of Northwestern University in Chicago found that people age 65 and older with symptoms of depression were more likely to develop diabetes than those without depressive symptoms.

Carnethon participated in the new study as well.

(Editing by Julie Steenhuisen and Eric Walsh)

FDA cautions consumers against cancer "cures"

<http://www.reuters.com>

WASHINGTON (Reuters) - Consumers should beware of products sold on the Internet that claim to cure cancer, U.S. health officials said on Tuesday, threatening penalties against more than two dozen companies selling creams, tea and pills as treatments for the disease.

The U.S. Food and Drug Administration said a variety of Web sites sell such products, which can harm patients with potentially risky ingredients or by keeping them from seeking proven therapies.

"FDA is very concerned consumers will purchase these products on the Internet and use them instead of products that have been proven safe and effective," said Michael Levy, head of the FDA's Division of New Drugs and Labeling Compliance.

Levy and other agency officials said their warning letters targeted roughly 125 products that claim to treat, cure or prevent cancer. The FDA has not received any reports from consumers who have fallen ill taking them, officials said, but called on the companies to stop making promises.

They could not say how many such products have been sold. Some included various ingredients such as bloodroot, shark cartilage, coral calcium and various mushrooms, according to the agency.

Representatives for the American Herbal Products Association said such ingredients are not harmful but that manufacturers of products that include them are not allowed by law to make medical claims.

"These companies are making drug claims and it is simply illegal to market an unapproved new drug," said Michael McGuffin, president of the association which represents a variety of herbal product makers.

Cancer is a condition that comes in many forms and causes cells to grow out of control. Approved treatments include such methods as surgery, radiation, chemotherapy and other medications.

"FDA expects prompt and complete corrective action," said David Elder, director of the FDA's Office of Enforcement. "Firms that don't heed the warnings that we've delivered and other firms marketing similar unapproved products may face further regulatory action."

The agency can levy fines, impose injunctions and seize products, among other penalties.

FDA officials conceded that the Internet makes it easy for companies to shut down one site and start up another. They also said it can be difficult to track down who actually operates a website, which can be registered in one country but run in another.

The agency listed the companies targeted by the letters on its website

<http://www.fda.gov/bbs/topics/factsheets/fakecancercures.html>

Simple trip to the GP can help slay the sleeping dragon

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

By Ed Gane

It's a disease often called the sleeping dragon because those infected may remain relatively free of clear-cut symptoms for years.

Many New Zealanders are thought to have the disease but most will be unaware of it.

It even slips under the radar of many doctors. But it can be devastating. Every at-risk New Zealander should be checked for the hepatitis C virus.

About 45,000 to 50,000 people have the hepatitis C virus (HCV), which is spread by contact with contaminated blood.

Those at highest risk include people who have injected drugs using unclean or shared equipment, and some migrant groups from countries with a high prevalence of HCV.

Also included are people who received unscreened blood, blood products or organ transplants before universal screening for HCV in blood and organ donors.

Screening was introduced in July 1992 but people who received either blood products, transfusions or organ transplants overseas after this date may still be at risk.

Almost 20 per cent of people with HCV infection will not have any of these risk factors for previous exposure to HCV.

In many of these, inadvertent transmission might have occurred through sharing a toothbrush with someone with HCV infection, especially if one or both have the common disease of gingivitis or bleeding gums. Or they could have shared a razor with someone with HCV infection, or had a tattoo or body piercing performed without sterile, disposable equipment.

HCV infection causes the liver to become inflamed and eventually stop working properly and, devastating though this is, many infected people will show no signs at all for many years.

Those who do will report tiredness, sensitivity to alcohol or just feeling unwell - not symptoms that scream a life-threatening condition.

Despite the vague signs of illness, hepatitis C can be extremely serious. The disease can wreak havoc on the liver and can eventually lead to cirrhosis or liver cancer.

In 2005, liver cancer was the world's third most common cause of cancer deaths and most of those cases were the result of infection with the hepatitis B or C virus.

Since 2000, the number of liver cancers caused by HCV has increased more than five-fold at the Auckland Hospital Liver Unit.

In the Western world, more liver transplants are carried out for complications of HCV infection than for any other cause.

However, most people with HCV will never develop liver failure or liver cancer but many will still suffer from fatigue, sore joints and muscles and the general malaise brought on by this disease.

The direct costs associated with the management of people with HCV infection are projected to exceed \$400 million by 2030. The indirect costs (from reduced quality of life and reduced earning capacity) will add considerably to the impact of the HCV epidemic on our society.

But there is treatment and there is hope. A blood test will tell whether you have been exposed to the virus and, if you have been exposed, a second test will confirm if you have become infected by the virus. (Once the initial illness subsides, 60 to 80 per cent of people will continue to have chronic HCV).

Cirrhosis of the liver can be prevented by earlier detection and management of HCV infection. Antiviral therapies will cure most people with HCV infection.

These have been available and funded by Pharmac since 2004. Despite this, fewer than 10 per cent of New Zealanders with HCV infection have ever received antiviral treatment.

Studies in Australia and the United States suggest that more than 50 per cent of New Zealanders infected with HCV need to be treated to avoid the expected doubling of cases of liver cancer and liver failure by 2020.

For those who are not successful in getting rid of the virus, there are possible new treatments just over the horizon.

But, in the meantime, they need to keep themselves as healthy as possible by stopping smoking, not drinking alcohol, eating a low fat and healthy diet and getting plenty of exercise.

A healthy lifestyle will reduce the effects of the liver disease HCV eventually triggers.

The message is simple. If you think you may have been at risk for HCV, get tested. It's a simple visit to the GP and a simple blood test.

And if you have HCV, being diagnosed will, at the very least, allow you to improve your quality of life and treatment is available which may cure you.

If you think you may be at risk of having HCV virus, book a visit to the doctor or contact the Hepatitis C Support Group toll free on (0800) 224-372.

Edmonton dentist tests positive for hepatitis B; 1400 patients to be informed

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

By Jordan Jackle, *The Canadian Press*

EDMONTON - The patients of an Edmonton dentist who quit his practice in February after testing positive for hepatitis B will now be contacted and told about the situation.

Health authorities started calling patients of Dr. Byron Wong on Tuesday. Wong has practised in Alberta since 2001. Dr. Gerry Predy, vice-president of Capital Health, said the chance the disease was transmitted to any of Wong's 1,400 patients is very low - somewhere between one in 10,000 and one in 100,000.

"We don't anticipate that this is something people should be overly concerned about," said Predy.

Although the chances are small, officials decided to inform the public upfront rather than having it be found out later where it could "generate concern beyond what it should generate."

Predy said it took until now for an expert panel to determine how to handle the situation, complete a risk analysis and compile a list of his patients.

"He wasn't putting anyone else at risk by virtue of this time frame that's elapsed," Predy said.

He said Wong, 37, has been co-operative and gave permission for his name to be released so that his current and past patients can be tested as a precaution.

But that's as much information Predy was willing to give. He responded to some questions from reporters, including whether Wong would be able to practise again, by saying some details must be withheld to protect the dentist's medical privacy.

"There's a number of complexities following this situation," Predy said, adding that the situation is very unique. "Not just the individual has hepatitis B, but some of the other circumstances around it."

He wouldn't clarify what he meant.

Dr. Jonathan Skuba, president of the Alberta Dental Association and College, said this particular scenario has never happened before in the province. There are no current rules forcing dentists to get tested for infectious diseases, but if they find out they have one it must be reported.

"No health profession in Alberta has required blood testing of their health practitioners," Skuba said. "Knowing the nature of viruses and infections it would almost become impossible because someone could register, test negative, and a week later test positive."

Predy suggested Wong's patients wait until Capital Health nurses get in touch with them, although they can contact the department if they have questions.

He said the number of hepatitis B cases has been decreasing. In the 1990s, there were around 30 cases per year compared to between five and 10 right now. During followups in response to these cases, he said no one has revealed they'd recently had dental work.

Predy said children above 10 and adults up to the age around 28 are likely immune to hepatitis B as a result of elementary school vaccinations. Also, dental students are now required to get the shots.

"Vaccine given at that age is highly effective, probably over 99 per cent."

Hepatitis B is a disease of the liver caused by a virus. Most people who get hepatitis B recover in about three months. Other people get over their illness but do not get rid of the virus and become carriers who will have the hepatitis B virus for the rest of their life, though they won't have any symptoms.

They often do not know they are carriers and may spread the hepatitis B virus to others.

In a small number of people, the disease is severe enough to cause death.

June 18, 2008

Elevated Liver Enzymes Linked to Development of Diabetes

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

NEW YORK (Reuters Health) Jun 09 - Results of a study published in the June issue of *Diabetes Care* suggest that elevated liver enzymes, even in the normal range, are associated with an increase in incident diabetes.

"Emerging evidence suggests that a strong link exists between certain liver enzymes such as gamma-glutamyl transferase (GGT) and alanine transaminase (ALT) and diabetes," Dr. Matthias B. Schulze, of the German Institute of Human Nutrition Potsdam-Rehbruecke, Nuthetal, Germany, and colleagues write. "These liver enzymes may be involved in several critical processes that affect the risk of developing conditions such as diabetes and cardiovascular disease."

To investigate further, the researchers conducted a case-cohort analysis of data from participants in the European Prospective Investigation into Cancer and Nutrition (EPIC)-Potsdam study. The sample analyzed included 787 individuals with incident diabetes over a mean follow-up of 7.0 years and 2224 participants without diabetes.

Compared with individuals in the lowest quintile of GGT, the adjusted hazard ratios (HRs) for incident diabetes were 1.13 for quintile 2, 1.67 for quintile 3, 2.77 for quintile 4, and 2.67 for quintile 5 (p for linear trend < 0.001). For ALT, the corresponding HRs were 0.93, 1.28, 1.35, and 1.93, respectively (p for linear trend < 0.001).

The magnitude of the associations between GGT and incident diabetes were higher among men than women (p = 0.004). No significant difference was observed between men and women for ALT.

"Although the mechanisms for these associations along with possible avenues of interventions require further investigation, the considerable knowledge base at present seriously merits

considering elevations of GGT and possibly those of ALT as pointing to an increased potential for developing diabetes," Dr. Schulze and colleagues conclude.

Diabetes Care 2008;31:1138-1143.

More liver cancer patients getting transplants

www.reuters.com

NEW YORK (Reuters Health) - In early 2002, a new donor organ allocation system gave priority for liver transplants to people with early liver cancer. It led to a six-fold increase in the proportion of liver transplant recipients with liver cancer, research shows.

The allocation system is dubbed MELD, for Model for End-Stage Liver Disease (MELD). According to data from the United Network for Organ Sharing, during the 5 years immediately before adoption of the MELD prioritizing system, 4.6 percent of liver transplant recipients had liver cancer, compared with 26 percent in the 5 years immediately after adoption of MELD.

In the medical journal *Gastroenterology*, Dr. George N. Ioannou from the Veterans Affairs Puget Sound Health Care System, Seattle and colleagues also note that the introduction of the MELD priority system was "successful" in achieving high survival rates after transplantation for people with liver cancer.

This success is likely related to both the selection of patients with early-stage liver cancer "and the ability to promptly transplant these patients because of the arbitrarily high priority score assigned to them," the investigators say.

"We hope that these results are useful in continuing to optimize the policies that guide liver transplantation for (liver cancer) in the United States," they conclude.

Drs. Michael Volk and Jorge A. Marrero of the University of Michigan, Ann Arbor write in a related editorial: "The question still remains, however, if these patients receive enough benefit to justify the harm caused to other patients by the use of scarce organs."

SOURCE: Gastroenterology, June 2008.

How Safe Are Tattoos?

<http://empowher.com>

By Shannon Koehle

EmpowHer Health Report

Developing one's body into a canvas for expression, a memorial, or a work of art, tattoos have become increasingly fashionable.

However, it is also a trend linked to numerous health risks.

Slowly disassociating itself from negative perceptions, the Center for Disease Control has assisted this process. As the CDC says, “No cases of HIV transmission through tattooing in the United States” has ever been reported since data collection began in 1985.

Similarly, in a 2006 CDC position stance on tattoos, between 1986 and 2006, less than 1 percent of those who acquired hepatitis C reported having any tattoos.

While there is a risk associated with any percutaneous exposure for incurring numerous blood-borne pathogens like HIV, hepatitis, tetanus, and tuberculosis, the CDC says, “No data exists in the United States indicating that persons with exposures to tattooing alone are at increased risk for HCV (Hepatitis C Virus) infection.”

Receiving a tattoo is said not to increase one’s risk for hepatitis C, but a 2006 CDC study discovered actions that are linked to hepatitis C include receiving three or more tattoos, receiving tattoos in an unprofessional setting, and receiving tattoos from reused, needles that were not sterilized.

The Mayo Clinic says, “Given the popularity of tattoos, complications are relatively uncommon.” However, additional health risks associated with tattoos include:

- Skin disorders like granulomas and keloids
- Bacterial skin infections
- Allergic reactions (These can occur years after tattoo applications)

Another rare side affect are magnetic resonance imaging (MRI) complications. These include complaints of swelling or burning radiating from a tattoo’s site and image quality interference for those with permanent eyeliner.

While health risks for those receiving tattoos are low, for those who experience negative reactions, the problem may reside in the ink.

The safety of tattoo ink is unclear, says the U.S. Food and Drug Administration.

Right now, neither long- nor short-term health affects are known because of “other public health priorities and a previous lack of evidence of safety concerns, [the] FDA has not traditionally regulated tattoo inks or the pigment used in them.”

Similarly, since the tattoo inks are not FDA approved, the FDA says some grades of ink used are industrial, generally used for printers or automobile paint.

However, once one has deliberately and thoughtfully considered receiving a tattoo it is recommended one go to a state or locally licensed shop where non-disposable items are autoclaved (soaked in a heat sterilization machine), new, packaged instruments are used, and artists wear gloves over washed hands.

Similarly, the Alliance of Professional Tattooists, a nonprofit educational organization promoting tattoo safety says, “Ask questions about the shop’s safety procedures. . . The personnel should be

willing and able to answer your questions.” Additionally, if they are unable or unwilling to answer any questions the customers have, leave and find a more professional venue.

June 19, 2008

Vertex CEO preparing for '09 hepatitis drug launch

www.reuters.com

SAN DIEGO, June 19 (Reuters) - Vertex Pharmaceuticals Inc (VRTX.O: Quote, Profile, Research, Stock Buzz) will be prepared to launch its experimental hepatitis C drug next year even though U.S. regulators have not said whether they would review it based on a mid-stage trial, the company's chief executive said.

"That's Plan B," CEO Joshua Boger said late on Wednesday at an event at the BIO International Convention in San Diego.

He said Plan A continues to be completion of a pivotal trial of the drug, telaprevir, in hepatitis C patients not previously treated, with data expected in the first half of 2010. If positive, Vertex would then file for regulatory approval in the second half of 2010.

But the company "has to be ready," despite the expense, to launch in the third quarter of next year should the U.S. Food and Drug Administration agree to a faster timeline, Boger said.

Vertex last week reported positive interim results from a Phase 2b study of the drug in hard-to-treat patients who failed to respond to prior treatment, leading many observers to expect accelerated approval of the drug.

The interim results found 52 percent of the patients who received telaprevir as well as the standard interferon/ribavirin combination had undetectable levels of the hepatitis C virus after 36 weeks, compared with 30 percent of patients treated only with the standard therapy.

Boger said Vertex expects to take the final data from the trial to the FDA late this year or early next year.

Should the agency agree to review it, he said the application would be only for patients who have stopped responding to other therapies.

Boger said preparing Vertex to scale up for a launch next year is expensive, but needs to be done because having telaprevir on the market as soon as possible will save lives.

Hepatitis C is a viral infection of the liver. An estimated 170 million people worldwide are chronically infected with the hepatitis C virus, according to the World Health Organization.

Vertex is developing telaprevir in partnership with Johnson & Johnson (JNJ.N: Quote, Profile, Research, Stock Buzz). (Reporting by Deena Beasley; Editing by Braden Reddall)

'Liver stiffness' and insulin resistance connection in HIV/hepatitis C coinfecting patients

www.aidsmap.com

Michael Carter

Spanish investigators have found that HIV/hepatitis C coinfecting patients with insulin resistance have significantly higher liver stiffness scores. The study is further evidence of the association between insulin resistance and poorer outcome in coinfecting patients, and was presented to the Fourth International Workshop on HIV and Hepatitis C Coinfection in Madrid on June 19th.

Tests to measure liver stiffness, such as FibroScan are painless, quick and acceptable to patients, and they are now widely used to monitor fibrosis in patients coinfecting with HIV and viral hepatitis. There is increasing evidence that insulin resistance is associated with poorer outcomes in patients coinfecting with HIV/hepatitis C and a multi-centre team of Spanish investigators wanted to see if there was any association between insulin resistance and fibrosis, as measured by liver stiffness.

For the purpose of the study, insulin resistance was defined as a homeostasis model assessment (HOMA) score of 2 or above, and significant fibrosis was assessed as being present if a patient had a liver stiffness score of 7.2 kPa (kilPascals) or higher.

A total of 111 patients from hospitals across Spain were included in the study. Most of these patients (79%) were male, 55% were infected with the hard to treat hepatitis C genotype 1, 4% were also infected with hepatitis B virus, and 90% were taking anti-HIV treatment.

A total of 49% of these patients had a liver stiffness score of 7.2 kPa with 33% having a score of 9 kPa or above.

Results showed that there was a statistically significant relationship between insulin resistance and liver stiffness, with 32% of patients with a HOMA score below 2 having a liver stiffness score of 7.2 kPa or above compared to 58% of patients with a HOMA score above this level ($p = 0.02$).

Multivariate analysis confirmed that association between insulin resistance and liver stiffness ($p = 0.04$). This analysis also showed that a CD4 cell count below 200 cells/mm³ ($p = 0.02$) and infection with hepatitis B virus ($p = 0.04$) were also associated with liver stiffness.

Reference

Merchante N. et al. Insulin resistance is associated with liver stiffness in HIV/HCV coinfecting patients. Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 1, 2008.

Insulin resistance means coinfecting patients have a poorer response to hepatitis C treatment

www.aidsmap.com

Michael Carter

Insulin resistance means a poorer response to anti-hepatitis C treatment in HIV/hepatitis C coinfecting patients, according to a French study presented to the Fourth International Workshop on HIV and Hepatitis C Coinfection in Madrid on June 19th. Measures to improve insulin resistance, such as exercise or weight loss could, the investigators suggest, improve the chances of hepatitis C therapy achieving good results.

HIV/hepatitis C coinfecting patients have a poorer response to hepatitis C therapy than patients who are only infected with hepatitis C. A number of factors have been associated with response to treatment for hepatitis C including patient characteristics. Some patient characteristics, such as age, gender and race, cannot be changed. But others, such as body mass index (BMI) and, importantly for the purposes of this study, insulin resistance, are potentially modifiable.

Investigators from the prospective French HOMA-VIC-ANRS HC-02 study wished to gain a better understanding of the impact of insulin resistance on the outcome of hepatitis C therapy in coinfecting patients.

Their study involved 238 patients, 74% of whom were male. The patients had a liver biopsy on entry to the study to assess their degree of fibrosis, and were then provided with 48 weeks of hepatitis C therapy consisting of pegylated interferon Alpha-2b plus ribavirin. Tests were also undertaken to see how many patients had insulin resistance, which was defined as a homeostasis model assessment (HOMA) score above 2.5. After the completion of therapy, the investigators performed statistical analysis to see which factors, including insulin resistance, were associated with a poorer treatment outcome.

Insulin resistance was present in just under a third of patients, and significant fibrosis (defined as a fibrosis score of two [F2] or above), was present in three-quarters of individuals.

A sustained virological response was achieved by 40% of patients. Statistical analysis showed that insulin resistance was associated with a significantly poorer response to hepatitis C therapy (32% vs. 40%, $p = 0.05$), severity of fibrosis ($p = 0.04$), infection with hepatitis C genotypes 1 and 4 ($p < 0.0001$), and age over 40 years ($p = 0.0006$).

The association between a poorer insulin resistance and a poorer response to therapy was confirmed when the investigators restricted their analysis to patients infected with hepatitis genotype 1 – the hardest to treat of all hepatitis C genotypes – with only 18% of patients with insulin resistance clearing infection with hepatitis C compared to 54% of patients without insulin resistance.

Coinfecting patients with insulin resistance could, the investigators conclude, increase the chances of achieving a good response to hepatitis C therapy by taking simple measures shown to be effective against insulin resistance such as exercise and weight loss. Therapy with drugs such as metformin could also be a useful intervention, they suggest. They note that such action could be taken before or during hepatitis C therapy.

Reference

P Cacoub et al. Insulin resistance impairs sustained response rate to peginterferon plus ribavirin in HIV-HCV co-infected patients: HOMA-VIC-ANRS HC-02 study. Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 2, 2008.

Novel Agents Will Drive The Hepatitis C Virus Drug Market to Increase Nearly Five-Fold to More than \$10 Billion in 2017

www.earthtimes.org

Hepatitis C Virus Market is One of the Most Active Areas of Infectious Disease Drug Development in Recent Years, According to a New Report from Decision Resources WALTHAM, Mass., June 19

WALTHAM, Mass., June 19 /PRNewswire/ -- Decision Resources, one of the world's leading research and advisory firms for pharmaceutical and healthcare issues, finds that market to treat hepatitis C virus will grow by nearly five-fold during the next decade, increasing from approximately \$2 billion in 2007 to more than \$10 billion in 2017 in the United States, France, Germany, Italy, Spain, United Kingdom and Japan. The new Pharmacor report entitled Hepatitis C Virus finds that, as drug makers have recognized the high unmet need and significant commercial potential that exists, the hepatitis C virus market has been one of the most active areas of infectious disease drug development in recent years.

According to the report, market growth over the next decade will be driven by the introduction of novel agents in the protease inhibitors and polymerase inhibitors drug classes that specifically target the hepatitis C virus. Among the range of products in clinical development, the most promising agents in these classes include Vertex/Johnson & Johnson/Mitsubishi Tanabe's telaprevir, Schering-Plough's boceprevir, Roche's R-1626, Roche/Pharmasset's R-7128, Roche/InterMune's ITMN-191, Tibotec's (Johnson & Johnson) TMC-435350, and Pfizer's PF-868554. Currently available clinical data suggests that all of these orally administered agents have the potential to significantly improve the efficacy of treatment, achieving higher sustained virologic response than current treatment, particularly in difficult-to-treat genotype 1 patients.

The hepatitis C virus market has been dominated by Roche and Schering-Plough, and both companies market pegylated interferon-alpha and ribavirin agents. These two companies have competed intensely in this market and have attempted to differentiate their pegylated interferon products, with Roche gaining an edge in market share. Through internal development and collaboration, Roche and Schering-Plough have developed next generation products that will allow them to remain key players in the hepatitis C virus market through 2017.

"Hepatitis C virus, which represents a large and relatively under-tapped market, has a complex epidemiology and is characterized by a large and aging chronically infected patient population which, over the next decade, is projected to increasingly present with late-stage complications of the infection, such as cirrhosis," said John Lebbos, M.D., director at Decision Resources. "Since current treatment with pegylated interferon-alpha agents and ribavirin achieves cure in less than half of patients and is associated with significant side effects, substantial opportunity exists for drug developers that can deliver safer and more effective therapies."

About Decision Resources

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Longer Treatment Course Advisable With Hepatitis C Genotype 6

www.reuters.com

NEW YORK (Reuters Health) Jun 19 - There is a higher rate of sustained virologic response in patients with chronic hepatitis C virus (HCV) genotype 6 infection who are treated for 48 weeks with peginterferon or interferon and ribavirin, compared to those who receive only 24 weeks of treatment, according to California-based investigators.

Dr. Mindie H. Nguyen of Stanford University Medical Center, Palo Alto and colleagues note that this genotype is common in HCV patients from parts of China and Southeast Asia. However, there have been no studies of treatment and response in this group of patients, they point out in the May issue of the *American Journal of Gastroenterology*.

The researchers retrospectively examined data on 190 Asian-Americans who received an HCV genotype 6 diagnosis. Of this group, 66 were treatment-naïve. The drop-out rate was high due to contraindications, inability to pay for medication, and other reasons.

The treatment-naïve patients were treated for either 24 or 48 weeks with peginterferon plus ribavirin or interferon plus ribavirin.

In the 54 patients for whom follow-up data were available, significantly more patients treated for 48 weeks with the peginterferon combination (75%) showed a sustained virologic response compared to those who received the shorter treatment course (39%).

There was a trend, but no significant difference in response in patients who were treated with peginterferon rather than the interferon combination for 24 weeks (39% versus 51.6%).

Dr. Nguyen told Reuters Health that further studies are required to confirm the optimal duration of therapy, "but given these findings, patients who are treatment eligible should receive a full course of 48 weeks of peginterferon and ribavirin as tolerated."

In fact, she added that results from a multicenter randomized controlled study of the sustained virologic response of patients HCV genotype 6 "treated for 24 versus 48 weeks are expected to be available early next year."

Am J Gastroenterol 2008;103:1131-1135.

Anti-HIV treatment may mean that progression of hepatitis C no worse in coinfecting patients than in those with only hepatitis C

www.aidsmap.com

Michael Carter

Anti-HIV treatment may mean that the rate of liver fibrosis is significantly slowed in patients with HIV and hepatitis C coinfection, according to a German study presented to the Fourth International Conference on HIV and Hepatitis C Coinfection in Madrid. The investigators found that there was no difference in degree of liver damage between HIV/hepatitis C coinfecting patients who received antiretroviral therapy and that seen in individuals who were only infected with hepatitis C.

This finding adds weight to the recommendation in the recently revised British HIV treatment guidelines that early initiation of HIV therapy is especially important in HIV/hepatitis C-coinfecting patients.

It is now well established that HIV/hepatitis C coinfecting patients experience faster hepatitis C disease progression than patients who are only infected with hepatitis C. It is thought that this is because of the damage to the immune system that HIV causes. There is some evidence that the use of anti-HIV treatment can help slow the rate of liver disease in coinfecting patients, but this is still a controversial area.

To gain a better understanding of the capacity for HIV therapy to prevent hepatitis C-related liver damage, investigators at the University of Bonn designed a study involving 141 patients. A total of 84 of these patients were only infected with hepatitis C virus, the remaining 57 were coinfecting. The investigators used FibroScan investigations to assess the degree of liver stiffness in these two groups of patients. Demographic, and hepatitis/HIV-related disease data were analysed by the investigators to see if they could identify any factors associated with an increased risk of liver stiffness.

The two groups of patients were broadly similar, although the coinfecting individuals were more likely to be infected with the hard to treat hepatitis C genotype 1 (82% vs. 70%), and were significantly more likely to have acquired hepatitis C after receiving infected blood products (44% vs. 0%).

Of the coinfecting patients, 82% were taking HIV therapy, and the median CD4 cell count was 430 cells/mm³.

FibroScan investigations showed that both groups of patients had comparable, but nevertheless severe, liver stiffness (14.4 kPa in the mono-infected patients vs. 12.4 kPa in the coinfecting individuals). This degree of liver stiffness is indicative of cirrhosis.

Although the investigators were unable to present data on the duration of hepatitis C infection in their patients, they believe that the large number of coinfecting patients who were infected with hepatitis C after receiving infected blood products suggests that a significant number of patients had been infected over 25 years ago.

Most of the coinfecting patients were taking HIV therapy or had high CD4 cell counts, but the CD4 cell count was below 200 cells/mm³ in 14% of coinfecting patients. Average liver stiffness scores were 18.4 kPa amongst these patients with a low CD4 cell count compared to 11.5 kPa for patients with better immune function. This difference did not reach statistical significance, but this was because of small numbers and suggested to the investigators that a higher CD4 cell count was protective against hepatitis C-related liver damage.

The investigators concluded that their study confirms earlier research showing that coinfecting patients taking antiretroviral therapy have their rate of liver disease slowed. They added, "our findings... may be a hint that fibrosis progression in well-treated HIV-positive patients will no longer be different from that in hepatitis C virus-monoinfected patients."

Reference

Grunhage F. et al. No difference in liver fibrosis in a cohort of HIV/HCV-coinfecting patients on HAART compared to HIV-negative HCV-patients assessed by transient elastography. Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 8, 2008.

Citizens of the Week

<http://www.zwire.com>

By: Denise Miller

When Virginia Sharpy learned five years ago that her husband, Dave, had liver cirrhosis, she thought he had received a death sentence.

Virginia's mother had died within a few years of the same diagnosis, and she feared her husband would share the same fate.

The Sharpys' story however, is not one of death, but of survival against tremendous adversity.

In 2001, Dave learned he had hepatitis c, which he thinks he contracted as an emergency medical technician in the 1970s.

"By the time they found it, my liver was pretty shot," he said.

He started medication injections, which he called "chemo light," and was perpetually exhausted for months.

"I had side effects galore; it was a nasty process," Dave said.

"The treatment makes you sicker than the disease," Virginia said. "These medications would come with long warning labels of the bad things that could happen to you. And most of them did."

Meanwhile, Dave was having some dental issues and lost three teeth. After visits to specialist after specialist, an ear, nose and throat doctor finally found a squamous cell tumor in the sinus area below his eye that had to be removed.

"They scooped it out like a grapefruit, and it took a year to rebuild the area with prosthetics," he said. He also underwent almost two months of radiation, and had a feeding tube installed in his stomach.

Dave is now cancer- and hepatitis-free, and his liver is in good enough shape that he likely won't require a transplant. Though there's a bit of a cavern below his left eye, you wouldn't know by looking at him of the ordeal Dave survived with the help of his wife of 26 years.

"I've always been good about taking care of myself, but it was Virginia's time to shine taking care of what I was, which was a mess," Dave said.

Virginia admitting to having a hard time with the gross stuff that comes along with illness.

"I'm not a medical kind of person. Anything on the inside, I don't want to see on the outside," she said.

But she was the pillar of strength when it came to handling the day-to-day operations of their home, and managing complicated correspondence with insurance companies; she filled several binders keeping track of payments.

"It was about \$350,000 in medical bills, and I was bringing home pills in big shopping bags," Dave said. "She took care of it all. There's no way I could have paid any attention to that."

When there was a dispute with an insurance company about who should pay for the prosthesis, Virginia took matters into her own hands.

"I wrote a letter to the insurance company: This is not cosmetic; this is not dental. This is medical. You paid to scoop his head out, and you will pay to put it back together, because if I have to parade him in front of the insurance board without his prosthetic to show that he cannot eat and speak without this, I will," she said.

The result? "We got it paid for," she said with a proud smile. In fact, the prosthodontist who helped Dave asked for a copy of Virginia's letter, because none of his other patients had ever had such success with insurance payment.

As hard as it was to face her husband's illness and possible death, Virginia said their experiences made them stronger.

Dave once asked Virginia if she'd considered leaving when things got bad.

"I said, 'Heck no, just the opposite.' When you face adversity in your life, you can let it enhance you or diminish you. We chose to let it enhance us," Virginia said.

Now that he's relatively healthy, Dave serves on the committee of the Relay for Life of Snoqualmie Valley, which raises money to fight cancer. He also volunteers to counsel cancer patients who face surgery similar to his.

"When you go through it, you have no one, and your neighbors and friends don't know how to deal with it," he said. "It's a way to try to share, let them know there's a light at the end of the tunnel. I want to give something back, because I've been so fortunate."

* Do you know Valley residents who deserve recognition for their good work? Nominate them for Citizen of the Week, an award co-sponsored by the Valley Record and Replicator Graphics. Send your ideas to editor@valleyrecord.com.

Ribavirin levels after four weeks of treatment predict which HIV/hepatitis C coinfecting and re-treated patients will respond

www.aidsmap.com

Michael Carter, Friday

Blood levels of ribavirin after four weeks of treatment may predict which HIV/hepatitis C coinfecting patients receiving hepatitis C "rescue therapy" are likely to have a good response to such treatment, according to Spanish research presented to the Fourth International Workshop on HIV and Hepatitis Coinfection in Madrid on June 20th. But in a separate study presented to the Workshop, the same team of researchers found that increasing the daily dose of ribavirin to 2000mg did not increase the chances of patients achieving a sustained response to hepatitis C therapy.

A significant number of coinfecting patients have received hepatitis C therapy with what would now be considered "sub-optimal" treatment consisting of standard interferon (rather than the pegylated form of the drug) and/or a low dose of ribavirin (600mg daily rather than the now-recommended 1000mg or 1200mg daily depending on weight).

Investigators wished to see if it was possible to retreat these individuals with the now-recommended standard treatment and presented data from a pilot study involving 61 individuals, 50 of whom had completed treatment.

The patients had a mean age of 50 years, 82% were men, and 78% were infected with the harder to treat hepatitis C genotypes 1 and 4. HIV therapy was being taken by 90% of the patients with good results, mean CD4 cell count being 680 cells/mm³ and 90% of patients had an undetectable HIV viral load.

Hepatitis C therapy produced a sustained virological response in 32% of patients – a response rate comparable to that seen in chronically coinfecting patients receiving current standard of care anti-hepatitis C treatment for the first time.

Many of the factors associated with a better chance of treatment success have been well established in earlier studies and include infection with hepatitis C genotype 2 or 3 ($p = 0.002$) and a baseline hepatitis C viral load below 500,000 copies iu/ml ($p = 0.02$).

But the investigators found that patients who had a successful response to hepatitis C therapy had significantly higher blood plasma concentrations of ribavirin after four weeks of treatment (2.57 ug/ml vs. 1.92 ug/ml, $p = 0.02$), and in multivariate analysis, higher concentrations of ribavirin at this time were an independent factor for successful anti-hepatitis C treatment ($p = 0.01$).

The investigators chose to monitor ribavirin levels at four weeks to ensure that levels of the drug had reached a “steady state.” But some delegates to the conference expressed concern that monitoring drug levels at this time may be too late as it is already possible to tell which patients have had a rapid response to hepatitis C therapy and will successfully respond to hepatitis C therapy. It was suggested that ribavirin levels can be adequately monitored as little as 24 hours after initiation of treatment with the drug. Measuring of drug levels at this point would give increased ribavirin doses the opportunity to affect outcomes.

The findings of the Spanish study involving previously-treated patients were echoed by that of a French study presented as a poster to the Workshop. This study involved 68 coinfecting individuals starting anti-hepatitis C therapy for the first time. Levels of ribavirin at week four were significantly associated with a subsequent sustained virological response to therapy.

But is there really any value in increasing ribavirin doses? Evidence from the same team of investigators suggests not. They designed a study involving 147 HIV/hepatitis C coinfecting patients. These patients were randomised into two arms. The first received standard hepatitis C therapy of pegylated interferon plus a weight-based dose of ribavirin (1000mg per day for those below 75kg, 1200mg daily for those weighing above 75kg). The other arm of the study also received pegylated interferon, but for four weeks were given an increased dose of ribavirin – 2000mg daily. Anaemia can be a side-effect of ribavirin so these patients were provided with weekly erythropoietin (EPO) therapy to boost their red blood cell count.

After four weeks of treatment the investigators found that blood levels of ribavirin were identical in the two arms of the study. Furthermore, the rate of rapid virological response – a reliable indicator of subsequent sustained virological response – was also identical between the two study arms at 23%.

The factors associated with outcome have been well established in earlier studies: hepatitis C genotype, hepatitis C viral load, and stage of fibrosis.

But higher doses of ribavirin supported by EPO appeared to be safe – rates of anaemia or severe anaemia were comparable in the two study arms, and similar numbers of patients in both arms adjusted their ribavirin dose because of side-effects.

Reference

Labarga P. et al. Ribavirin plasma levels are predictive of HCV clearance after rescue therapy with peg-interferon-a2a plus weight-adjusted ribavirin in HIV/HCV co-infected patients. Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 13, 2008.

Dominguez S. et al. Early therapeutic drug monitoring of ribavirin is predictive of tolerability and sustained virological response in HIV-HCV coinfecting patients. Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 41, 2008.

Labarga P. et al. Early virological efficacy and haematological safety of pegIFN alpha-2a plus high doses of ribavirin in HIV/HCV-coinfecting patients (PERICO Study). Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 15, 2008.

HIV-positive gay men and sexual transmission of hepatitis C: it's no longer just northern Europe

www.aidsmap.com

Michael Carter, Friday, June 20, 2008

The epidemic of sexually transmitted hepatitis C virus amongst HIV-positive gay men appears to be gaining a foothold in southern Europe, according to a study presented to the Fourth International Workshop on HIV and Hepatitis Coinfection in Madrid.

Outbreaks of sexually transmitted hepatitis C virus amongst HIV-positive gay men have been reported in the UK, Netherlands and Germany. Although there are high rates of HIV/hepatitis C coinfection in southern Europe, this is due to injection drug use and it appeared that there was little evidence of sexual transmission of hepatitis C.

But now investigators in Milan have found convincing evidence of sexual transmission of hepatitis C amongst HIV-positive gay men in the city, particularly after 2006.

Their retrospective study involved 272 gay or bisexual men who received HIV care in the city between 1996 and the end of 2007. All these individuals had at least two hepatitis C antibody tests allowing the investigators to gain an understanding of the incidence of new hepatitis C infections.

A total of 21 men were found to have been infected with hepatitis C during the time period under analysis. There were no infections in the period before 2000, matching the epidemiology of the infection in HIV-positive gay men in northern Europe. But three men (4%) became infected with hepatitis C between 2001 and 2005. The outbreak gathered pace after 2006 with 18 new infections (12%) by the end of 2007.

Median age of the men diagnosed with new hepatitis C infection was 40 years. None of the patients cleared the infection spontaneously. Only five patients accepted hepatitis C therapy, resulting in the clearance of the infection in two patients.

Syphilis was also present in a third of patients at the time of hepatitis C diagnosis. None of the cases seen before 2005 involved concurrent syphilis infection. The cluster of hepatitis C and syphilis concomitant infections in 2006 – 07 could indicate the transmission of these infections within sexual networks. Such a hypothesis is supported by evidence from northern Europe where high rates of sexually transmitted infections, notably syphilis, were seen in HIV-positive gay men with recent hepatitis C infections.

The investigators recommend that HIV-positive gay men with risky sexual behaviours should be considered for regular hepatitis C screening. Such screening is already recommended in the UK and has helped detect incident hepatitis C infections in this population.

Reference

Gallotta G. et al. Acute hepatitis C virus in HIV co-infected men who have sex with men: Milan, 1996 – 2007. Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 47, 2008.

HIV and hepatitis coinfection in Africa: studies provide conflicting prevalence data

www.aidsmap.com

Michael Carter, Friday

HIV-positive patients in Kenya have a low rate of coinfection with hepatitis B virus or hepatitis C virus, according to an international study presented to the Fourth International Workshop on HIV and Hepatitis Coinfection in Madrid on June 20th.

But a separate Spanish study presented as a poster to the Workshop has found rates of hepatitis B and hepatitis C coinfection amongst HIV-positive African migrants comparable to those seen in Europeans. Injecting drug use was not a risk factor for hepatitis C infections in these patients, instead the investigators believe these infections originated in medical practice.

There is limited information regarding the prevalence of hepatitis coinfection amongst HIV-positive individuals in Africa. Therefore investigators from Kenya and London's Chelsea and Westminster Hospital performed blood tests on HIV-positive patients attending the HIV clinic at the Aga Khan University in Nairobi, Kenya, to gain a better understanding of the prevalence of HIV and hepatitis B or hepatitis C coinfection amongst patients of the clinic.

Tests were performed on a total of 378 HIV-positive individuals. A total of 23 (6%) were found to be coinfecting with hepatitis B, four patients (1%) were coinfecting with hepatitis C, and one patient was infected with HIV and both hepatitis B and hepatitis C.

Statistical analysis revealed that older age was significantly associated with coinfection ($p < 0.05$). Unsurprisingly, a lack of hepatitis B vaccination was revealed as a risk factor for infection with this virus ($p = 0.0001$). Neither drug use nor sexual behaviour appeared to be risk factors for either hepatitis infections.

The investigators concluded that hepatitis coinfection amongst patients in Kenya appeared to be significantly less frequent than that seen in cohorts of HIV-positive patients in Europe and the Americas. But they acknowledged the small size of their study sample and called for further research into this matter to be undertaken in a larger cohort.

Spanish study finds hepatitis B and C coinfection rates comparable in HIV-positive African migrants and HIV-positive Spaniards

But research suggesting that rates of HIV and hepatitis coinfection in sub-Saharan Africa may be comparable to those in southern Europe was also presented to the Workshop.

Investigators in Madrid analysed rates of hepatitis B and hepatitis C coinfection amongst 268 individuals recently diagnosed with HIV at a specialist HIV clinic in the city.

A total of 89 (34%) of these individuals were migrants from sub-Saharan Africa, 52 (20%) were from Latin America, and 122 (46%) were Europeans, mostly Spanish.

Similar proportions of African (5.5%), Latin American (3.8%) and European (4.1%) patients had chronic hepatitis B infection (HBsAG+).

But Africans (65%) were significantly more likely ($p < 0.001$) than either Latin Americans (42%) or Europeans (41%) to have evidence of past exposure to hepatitis B infection indicated by higher hepatitis B surface antigen and hepatitis B core antigen.

Rates of hepatitis C infection were comparable between Africans (9%) and Europeans (10%), but there were no cases of HIV/hepatitis C coinfection amongst Latin Americans.

The investigators conclude that the rates of chronic hepatitis B are comparable between Europeans and African and Latin American migrants. But African patients were more likely to have isolated core hepatitis B antigen, suggesting “a distant immune response and deeper immune suppression.”

None of the hepatitis C cases observed in Africans were attributed to injecting drug use. Instead, the investigators suggested that “exposure to contaminated blood transfusions, medical equipment or needle-stick injuries in healthcare settings, including traditional healers could be responsible.”

Reference

Nelson M. et al. HIV, hepatitis B and hepatitis C coinfection in Kenya. Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 71, 2008.

Rivas Gonzalez P. et al. Viral hepatitis in newly diagnosed HIV immigrants in Spain – unexpected HIV rates of HCV antibody and “isolated anti-HBV core” among sub-Saharan Africans. Fourth International Workshop on HIV and Hepatitis Coinfection, Madrid, abstract 61, 2008.

Complaint about doctor languishes in state bureaucracy

<http://www.newsday.com>

BY Michael Amon

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Raymond Bookstaver expected a prompt response in July 2005 when he filed a complaint against Dr. Harvey Finkelstein, the Plainview physician who authorities say reused syringes and put patients at risk of disease. He says he contracted hepatitis C in Finkelstein's office and is suing the doctor.

Nearly three years later, Bookstaver said Thursday the state Office of Professional Medical Conduct had not told him the results of its probe. Investigators, he said, had not even interviewed him yet.

As it turns out, his complaint was closed last September, but OPMC neglected to inform him, said Claudia Hutton, a state Department of Health spokeswoman.

"We apologize for the error," Hutton said.

Hutton said Bookstaver, 50, of Hicksville, soon will receive a letter stating that the case had been resolved without disciplinary action. The letter will say nothing about whether Bookstaver was infected in Finkelstein's office.

"Oh, that's very nice of them," Bookstaver said, adding: "It just boggles the mind how they don't care."

New York is among a handful of states that do not name physicians unless they are found guilty of misconduct and that do not hold disciplinary hearings in public. Bookstaver was never told that, in Finkelstein's case, a hearing was never held, and that the doctor was placed under state monitoring for three years. The state never determined how Bookstaver was infected.

"New York's system is designed to protect the doctor," said Matthew Lifflander, a Manhattan lawyer who served on a State Legislature medical conduct task force in the early 1970s and is an advocate for tougher discipline laws. "It is overly bureaucratic and overly secretive, and everything takes too long."

State officials said Bookstaver's complaint took longer to resolve than most. An average complaint is dismissed or forwarded for a hearing in 234 days, Hutton said. Bookstaver's complaint, filed on July 27, 2005, was handled by OPMC's New Rochelle office, which then had the highest caseloads in the state, a state comptroller's audit found.

Bookstaver received epidural spinal injections for back pain from Finkelstein in July 2004. His hepatitis C diagnosis came in October 2004 and he made his complaint after getting a May 2005 Health Department letter saying Finkelstein patients were at risk.

As the months wore on, Bookstaver said, his wife, Loretta, made regular phone calls to OPMC but learned little.

Frustrated, she wrote letters in August 2006 to Sens. Hillary Rodham Clinton and Charles Schumer, who forwarded her complaints to the Health Department.

Dennis Whalen, then the department's No. 2 official, wrote back to Clinton with details of a probe into hepatitis C transmissions. But, he told the senator, the separate "OPMC matters are strictly confidential."