

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Oct 18, 2008

Tattooed blood donors will soon be welcome

<http://www.santafenewmexican.com>

Starting Oct. 27, people will no longer have to wait a year after getting a tattoo before they can donate blood.

At past blood drives, those with recent tattoos were turned away because of concerns about the spread of hepatitis, HIV and other blood-borne diseases, according to United Blood Services.

But the rule is about to change.

After Oct. 27, donors that get tattoos at state-regulated tattoo shops with sterile needles and ink that isn't reused only have to wait one to two weeks until their tattoo heals before donating blood.

Those that got tattoos before Oct. 27 will still have to wait a year, but the new rule will apply to anyone that gets a tattoo after that date.

Visit www.unitedbloodservices.org for information.

Oct 20, 2008

Funding needed to stem Hep B cases

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

Health experts have called for a boost in funding to stem the flow of the hepatitis B virus and will release two reports in Brisbane.

Up to 6,000 new cases are reported across the country each year, while more than 160,000 Australians are affected by the blood-borne disease.

Hepatitis B is one of the leading causes of liver cancer, said Professor Stephen Locarnini of the Victorian Infectious Diseases Reference Laboratory.

"Unlike hepatitis C and HIV/AIDS, there is currently no government endorsed national strategy or support for people living with the virus," Prof Locarnini said.

"There's a perception that because we have an Australian vaccination program, we can afford to relax on hepatitis B.

"Vaccination is effective for prevention, but we also need to focus our efforts on helping people already living with chronic hepatitis B."

NSW Cancer Council CEO Andrew Penman is concerned about the potential for chronic hepatitis B cases to develop into liver cancer and is also calling for government action.

"If hepatitis B is left untreated, 25 per cent of chronically infected individuals will develop cirrhosis and five to 10 per cent will develop liver cancer," Dr Penman said.

"Hepatitis B is one of the leading causes of liver cancer and the longer we wait for the commonwealth government to take action, the more Australians we expose to the risk of liver cancer."

Globally, 400 million people are chronically infected with hepatitis B and it is the 10th leading cause of death worldwide.

Two reports into the virus will be released at Tuesday's sixth Australasian Viral Hepatitis Conference in Brisbane.

Monday Report, from the NIH Consensus Development Conference: Management of Hepatitis B

by Christine Kukka, HBV Project Manager

<http://www.hbvadvocate.org/news/reports/NIH%202008/NIHMondayreport.htm>

BETHESDA, MD—Hepatitis B experts from across the United States tackled some of the confusing and conflicting approaches to understanding and treating hepatitis B infection on Monday at the National Institutes of Health.

The NIH has convened a consensus conference, which will continue through Wednesday, so experts can develop common approaches to identifying the prevalence of hepatitis B in the United States, and defining which treatments are most effective.

The following issues were addressed during the Monday session:

Is the U.S. accurately estimating true prevalence of HBV infection?

While hepatitis B immunization has caused a large decline in new infections in the United States, currently the federal government's surveillance programs fail to screen many legal and undocumented immigrants who are infected with the hepatitis B virus (HBV).

W. Ray Kim, MD, MSc, MBA, associate professor of medicine in the Division of Gastroenterology and Hepatology at the Mayo Clinic, told the conference that many immigrants are missed in government surveys of HBV-infected populations.

In Olmsted County, MN, Kim described that 53 percent of all residents identified with hepatitis B are Asian immigrants, and 29 percent are African immigrants.

In Minnesota, 5.1 percent of Asian immigrants are chronically infected as are 8.4 percent from Africa, and 3.1 percent from Europe. In the United States, between 1994 and 2003, 26 percent of legal immigrants were from high HBV prevalence countries and 33 percent were from intermediate endemic areas.

In a survey of 1,000 refugees in New York City's Chinatown, immigrants in their 20s had a 25 percent positive rate for the hepatitis B surface antigen (HBsAg), which indicates a chronic infection.

“Despite decreases in new infections, the prevalence and burden of chronic HBV infection in the U.S. remain substantial and underestimated,” Kim said. He explained that hospitalizations of people with HBV has increased from about 15,000 to 65,000 nationwide in an average quarter, and the cost of HBV medications has doubled between 2006 and 2008. The number of patients with hepatitis B-related liver cancer on the liver transplant waiting list has increased 146 percent between 1985 and the present, which shows the rising burden of HBV infection in the country.

“We can't make a scientific projection of what will happen, but looking at Chinatown data, we could experience a second wave of HBV infection and liver disease-related deaths in the future,” he added.

Substandard care common for immigrants and others with HBV:

Because many immigrants with HBV are undocumented and uninsured, they are fearful of the U.S. medical system. They and their family members are not getting screened or vaccinated. Experts called for more culturally-sensitive programs to provide proper screening and care to this population. Early screening and prevention will in the long run provide better quality care and save health care dollars.

Would the U.S. government ever bar immigrants who are infected with HBV from entry into the U.S.?

Currently, no immigrant is required to be tested for HBV on entry into the United States. Currently the U.S. restricts immigration of people with HIV and tuberculosis. A representative from the U.S. Centers for Disease Control and Prevention, which recently recommended that doctors screen patients from countries with moderate prevalence for HBV (instead of just patients from high prevalence), said, “we do not want HBV to be an excludable condition. While we recommend testing among immigrants from other countries, we do not recommend anything that would interfere with immigration.”

High HBV DNA levels lead to higher rates of liver cancer and cirrhosis. High viral load, defined as more than 100,000 copies/mL, especially sustained over many years in older people--especially men--results in increased rates of cirrhosis and liver cancer.

Even when genotype is taken into consideration, sustained high viral load, rather than infection with a specific genotype, is associated with more severe liver damage and liver cancer. Experts made an argument for use of antivirals to decrease viral, which leads to fewer liver disease symptoms. More information will be posted tomorrow.

Combination therapy yields few benefits to date.

While hepatitis C has been successfully treated with a combination of antiviral and pegylated interferon, no such beneficial combinations have been found for hepatitis B treatment, according to reports. In general, a combination of interferon and antivirals has yielded no additional declines in viral load.

However, experts look forward to using newer antivirals, including tenofovir (Viread) which are stronger and cause less viral resistance, in new combinations in their search for an effective treatment.

The Unreal World: Sometimes it's just a mystery why some cancer patients survive

<http://www.latimes.com>

Marc Siegel

One man's grim prognosis leads him to try alternative treatment, despite his doctor's doubts. His remission raises more questions.

Just when I think I can predict a disease's deadly outcome, along comes someone to remind me how little we truly know about cancer. Sometimes, a patient survives against all probability, and I am left not knowing why.

"Sal Wittgen" (not his real name) was a poet. When I first saw him in my examination room, I noticed his shock of white hair and the wild look in his eye. Back in 1994, I discovered his liver tests were elevated then found he had hepatitis C, using the new blood test that had just become available.

His ultrasound showed that his liver had the beginnings of cirrhosis. A liver specialist prescribed the anti-viral treatment alpha interferon, but it made him fatigued and he quickly stopped it.

In 1997, when Sal was feeling fairly well, I sent him for a routine ultrasound of his abdomen that showed a mass in the liver. A liver biopsy revealed hepatocellular carcinoma, a vicious type of cancer that is very difficult to cure. Its five-year survival rate with conventional chemotherapy was only 4%. I suggested a liver transplant.

I won't survive it, Sal insisted.

Instead, he chose what was then a new kind of treatment: chemoembolization, in which chemotherapy is administered through the artery that feeds the tumor and then the artery is destroyed. Since 1997, this treatment has been used effectively for more than 1 million patients in more than 30 countries. But back in 1997, no one knew how well it would work.

His tumor shrank in response to the treatment, and though I kept waiting for the cancer to regrow and spread, his follow-up CT scans continued to be negative. But the hepatitis C virus continued to eat away at his liver.

Enough of poisons, Sal said. Instead, he turned to a heretical alternative medicine physician, Emanuel Revici, who was 100 years old and still practicing medicine.

Revici was born in Romania in 1896. He received a medical degree from the University of Bucharest in 1920. He moved to Paris, then Mexico City, where he began experimenting with drugs to treat cancer, then to New York in 1947, where he started the Institute of Applied Biology and conducted experimental cancer research. Professional cancer societies soon began to consider him anything but a scientist.

In the 1980s, he received more than a dozen patents for chemical formulations to use on cancer patients. But New York state soon challenged and restricted his medical license, and found him guilty of professional misconduct in 1988.

Sal was very impressed with Revici's philosophy of healing and his belief that cancer was due to an imbalance of fat in the body. Rather than crediting the lasting effects of that single chemoembolization, Sal began to credit the Revici purges and enemas and mystery combo chemicals for prolonging his life.

As time went on, I began to wonder if Sal really was in remission. Looking at his bloated belly on the examining table and smelling the ammonia-laced breath from his liver failure, it was difficult to believe he was doing better. But CT and MRI scans continued to show that he was clear of cancer.

I feel better than I look, Sal said.

Revici's "guided chemotherapy" was based on a urine analysis followed by a secret formula made of some combination of alcohols, caffeine, zinc, lithium, iron, selenium, magnesium, sulfur and fatty acids. A study published in the Journal of the American Medical Assn. in 1965 found that of 33 patients who were referred to Revici after they failed conventional treatment, 22 died, eight showed no improvement and the remaining three showed progression of disease.

But Sal had faith. He believed it was difficult to scientifically study Revici's methods because each patient was different. And certainly, it is true that response to a particular cancer treatment is often unpredictable, even with standard chemotherapy.

Genetics clearly play a role in this variability in response: Tumors may look the same from outside, but they can arise from variations in many different genes, making them more or less responsive to drug A, drug B or drug C. For example, a study from the Broad Institute of MIT and Harvard, published this month in the New England Journal of Medicine, reported a genetic pattern in liver tissue that correlates with survival and lack of recurrence of liver tumors.

As long as I keep writing my poems and see a great healer like Revici, I will stay alive, Sal said to me on several occasions.

There is little scientific evidence to support this idea, though plenty of popular books that espouse it. In 1986, alternative medicine guru Dr. Bernie Siegel (no relation) wrote in his book "Love, Medicine, and Miracles": "When a human being suffers an emotional loss that is not properly dealt with, the body often responds by developing a new growth." Siegel saw people's

cancers as challenges that a proper healer could help them vanquish with the help of positive emotions.

But a follow-up study of Siegel's patients published in the *Journal of Clinical Oncology* in 1993 found that women with breast cancer who went through his program died at the same rate as those who hadn't.

Sal's case would seem to run counter to conventional science. Was this just luck? In all studies of cancer, there are some patients who simply survive no matter how grim the prognosis.

Did that single chemoembolization save him or did he have a genetic predisposition to remission? Patients such as Sal fuel the myths of the Siegels and Revicis of the world without providing any real evidence to support their fringe treatments.

I am intrigued that Sal appeared to respond to the quackery dispensed by that aging huckster and his followers, but in the end, I stop far short of believing in it or recommending it to anyone else.

In late 2005, when Sal was finally admitted to the local Veterans Affairs hospital for a serious infection and out-of-control diabetes, obscured in the unpleasantness of his dying was the miracle of his cancer remission.

Dr. Marc Siegel is an internist and an associate professor of medicine at New York University's School of Medicine and the author of *False Alarm: The Truth About the Epidemic of Fear*. He can be reached at marc@doctorsiegel.com.

Hepatitis C treatment is cost-effective for the US prison population

<http://www.eurekalert.org>

Treating all U.S. prisoners who have hepatitis C with the standard therapy of pegylated-interferon and ribavirin would be cost-effective, says a new study in the November issue of *Hepatology*, a journal published by John Wiley & Sons on behalf of the American Association for the Study of Liver Diseases (AASLD). The article is also available online at Wiley Interscience (www.interscience.wiley.com).

U.S. prisons incarcerate more than 2 million inmates each year, and between 12 and 31 percent of them are infected with chronic hepatitis C (HCV), mostly related to high rates of intravenous drug use. The current standard treatment for HCV has been shown to be cost-effective in the general population and the Federal Bureau of Prisons recommends HCV treatment for those who meet the AASLD's criteria for treatment, as long as therapy is likely to be completed. However, each state adopts its own set of treatment guidelines, and many prisoners do not ultimately get treated.

Proponents for treatment argue that we have an ethical duty to provide prisoners with the best medical practices available, and treating HCV could reduce new infections as well as future medical expenses from advanced liver disease. Opponents point out that treatment is expensive and must be paid for by taxpayers, while many non-imprisoned HCV patients who don't have health insurance are denied access to this care.

Researchers, led by Sammy Saab of the David Geffen School of Medicine at UCLA, sought to determine if HCV treatment would be cost-effective in the male prison population (men make up over 87 percent of U.S. prisoners). They examined published literature for relevant studies and constructed a decision analysis model employing Markov simulation, using the generally accepted cost-effectiveness threshold of \$50,000 per quality-adjusted life years.

"Our model found that treatment was cost-saving for prisoners of all age ranges and genotypes when liver biopsy was not a prerequisite to starting antiviral therapy," they report. "In other words, treatment resulted in both decreased costs and improved quality of life." Treatment was also cost-saving in most situations that included a pre-treatment liver biopsy.

The authors had not expected treatment to be cost-effective, because of the high re-infection rates and non-liver mortality rates in the prison population. However, they write, "our results demonstrate that pegylated-interferon and ribavirin is cost-saving in the prison population, both in strategies with and without biopsy. Incorporating a pre-treatment liver biopsy may be the most cost-effective approach, however, as one could potentially exclude certain patients with no fibrosis from therapy."

"If the decision to treat is based on pharmacoeconomic measures," the authors conclude, "the results of our analysis suggest that treatment is cost-saving and should not be withheld in U.S. prisoners with hepatitis C."

Since the efficacy of treatment would be diminished by relapse to injection drug use and re-infection, treatment should be coupled with educational and substance abuse programs, they suggest. And because mental illness is widespread in the prison population, and can often be exacerbated by treatment, careful mental health screening and follow-up would be required.

Weighing Hepatitis C virus hold on membranes

<http://www.huliq.com>

by Harminka

Hepatitis C affects around 150 million people worldwide and is a major cause of chronic liver disease. Current treatment involves the anti-viral drugs interferon and ribavirin, both of which have serious side effects.

As part of ongoing research to combat the hepatitis C virus, researchers are studying how the virus' replication machinery attaches to cell membranes.

Membrane attachment is a necessary step in the replication of the hepatitis C virus. If doctors can prevent the virus from latching onto membranes inside the host cell, they may be able to control the disease. Curt Frank and Jeffrey Glenn of Stanford University and their colleagues have identified a helical portion of one viral protein, called NS5A, which seems to be one of the virus' membrane "adhesives."

To understand how this protein works, the scientists exposed the protein to a range of artificial membranes placed on a quartz crystal microbalance. This dime-sized device, which can measure

a mass increase of as little as 18 nanograms, recorded how much, if any, of the protein attached to the different membrane surfaces.

The team discovered that the protein targets a particular combination of lipid and proteins in cell membranes. With further research, they hope to better pinpoint where the virus latches on, so that drugs might be developed to interfere with the process. -American Institute of Physics

Oct 21, 2008

HIV Prevention, Treatment Hit by Local Funding Cuts

<http://www.citylimits.org>

By Alex Cotton

Numbers showing the city's AIDS epidemic rages on worse than thought arrived in tandem with state cuts for AIDS-fighting measures. In a climate with plenty of needs and ever fewer resources, this is the first in an ongoing series looking at reduced social services funding.

Hundreds of people marched across the Brooklyn Bridge to City Hall last month to demand a national AIDS strategy and protest the HIV/AIDS budget cuts in New York.

Louie Jones can get you a syringe, a cooker for heroin, and a tourniquet for free. He can also give you a card with a special code that gets you off the hook if the police happen to notice your drug injection paraphernalia. This is because Louie Jones, coordinator of Voices of Community Advocates and Leaders (VOCAL), runs a needle exchange program, an important component of the effort to contain the spread of HIV in the city, as well as a publicly-funded support group for Hepatitis C sufferers. And although Jones is more familiar with certain drug dens in Brooklyn than the towers along Wall Street, he's worried that fallout from the financial collapse may hurt his clients.

"Budget cuts kill," he said, summing up the effect that he fears decreased services could have on his clients.

Jones was referring to the \$600 million budget cuts imposed by Gov. David Paterson's administration in August, of which \$427 million have been enacted. As part of this effort to bring spending in line with decreased revenues, the governor asked for six percent across-the-board cuts in local assistance spending, which consists of aid to local governments and nonprofits and accounts for 70 percent of the state budget. This resulted in a \$1 million cut to HIV services, including education and prevention; \$390,000 less for the state's first and only Hepatitis C initiative – a 50 percent reduction; \$1.5 million less for New York's AIDS Drug Assistance Program; and \$500 million in cuts to Medicaid. These reductions come on the heels of \$5.5 million in cuts to HIV/AIDS services and prevention by the city for fiscal year 2009.

With more than 100,000 New Yorkers living with HIV, the city has long been the center of the epidemic nationwide. But recent estimates by the city Department of Health and Mental Hygiene, using a new federal formula, amped up the urgency of these numbers: Local infection rates in 2006 were three times the national average. Infection rates were much greater in men than women, and particularly acute among blacks and men who have sex with men. And while

anti-retroviral therapy, which prevents HIV from progressing to AIDS, has become widely available, 2,076 New Yorkers died from AIDS in 2006.

Worldwide, 40 million people are estimated to have contracted HIV, the human immunodeficiency virus, or to be suffering from the variety of AIDS symptoms that can take a decade to appear.

While acknowledging that the state is facing a fiscal crisis, HIV/AIDS advocates have been questioning the wisdom of these across-the-board local assistance cuts, particularly at a time when new HIV infections have been rising in the city among certain identifiable groups, such as young gay men. The New York City AIDS Housing Network (NYCAHN), a Brooklyn-based nonprofit, staged a protest outside Gov. Paterson's Manhattan office early last month, demanding that he meet with them to discuss the impact of service cuts. NYCAHN also joined a rally and march across the Brooklyn Bridge a week later, on Sept. 18, calling on presidential candidates Sen. Barack Obama and Sen. John McCain to propose national AIDS-fighting strategies.

Derrek Chandler, 52, and Robin Bluford, 49, attend an HIV/AIDS rally at City Hall on Sept. 18 to protest budget cuts that threaten services they receive through Housing Works. Bluford believes that cutting support to new HIV patients will prevent people from getting tested.

“Six percent may sound like a small number, but groups that depend on that funding may need to close their doors,” said Charles Long, NYCAHN's development and communications director. Sean Cahill, the managing director of public policy at Gay Men's Health Crisis (GMHC), says these state cuts come just when GMHC is anticipating decreased support from private funders due to the economic downturn. While GMHC, which receives more than one-third of its funds from New York state, has felt the strain of decreased funding from federal sources since early 2007, Cahill is particularly worried that the recent state cuts will damage the city's many smaller service organizations.

“We've already seen clients coming to us from smaller groups that have had to cut services,” he said, noting a recent increase in the number of HIV-positive clients seeking legal services at GMHC.

Some state agencies, however, such as ADAP, the AIDS Drug Assistance Program, which provides free anti-retroviral therapy to poor people living with HIV, and OASAS, the Office of Alcohol and Substance Abuse Services, whose programs include methadone and needle exchange, say they've been able to absorb the state cuts without damaging services – despite a cut to ADAP of \$1.5 million, and to the OASAS Methadone Maintenance Program of \$776,000. “Since the governor's statement, we've been able to make reductions that will have no impact on patients, by making reductions in our general fund and looking for efficiencies,” said OASAS spokeswoman Dianne Henk. The city Health Department also was able to absorb the cuts without any harm to services, according to department spokesperson Jessica Scaperotti.

Yet small organizations, like Louie Jones', say they were forced to scale back services after the city's cuts this summer. VOCAL's Hepatitis C support group, for example, shrank from around a dozen members to three or four after Jones had to cancel their free transportation service.

“That is awful, to know that the need is great and we can’t provide the service,” he said, noting that untreated Hepatitis C can be fatal.

Terri Smith-Caronia, public policy director for Housing Works, an AIDS service organization, worries that it sets a bad precedent to cut programs that can provide a lifeline. “Once the state starts looking for spending cuts by diving into programs that provide actual medications, they’re going down a slippery slope,” Smith-Caronia said.

State officials acknowledge that Paterson’s cuts may be painful, but argue they are necessary to keep the state fiscally sound.

“There are many worthy programs that we simply can’t afford during these difficult fiscal times,” said state Division of the Budget spokesman Matt Anderson. The Citizen’s Budget Commission, a nonpartisan group dedicated to fiscal responsibility, has praised the governor for making tough decisions. However, the Commission questioned whether cuts to inefficient programs would have been wiser than across-the-board cuts.

“While the Governor’s proposed cuts in local aid may be admirably intended to spread the pain broadly,” the group said in a press release, “the CBC’s proposals to eliminate ineffective economic development programs and close unneeded prisons would save far more money with no harm to public services.”

Paterson called for a special session of the legislature Nov. 18 to ask for \$2 billion in additional reductions. Asked whether these will include further cuts to HIV and AIDS service organizations, Anderson wouldn’t rule anything out. “The governor will continue to do whatever is necessary to protect the fiscal health of the state,” he said.

For his part, Cahill of GMHC suggested that the governor dip into a rainy day fund or cut other areas rather than burden local groups with more reductions. “There’s a disconnect between the epidemiology and how the government is responding,” he said. “If you cut HIV prevention when HIV is being transmitted at higher rates than we thought, at minimum we should be spending more. That we’re cutting prevention funds is crazy.”

Prof. Robert Fullilove, a minority health expert at Columbia’s Mailman School of Public Health, also worries that decreasing HIV services could have negative consequences. “If these cuts mean people get sub-optimal care,” he said, “if it means increased risk of people spreading the virus and getting non-treatable variants of HIV, then we will have lost more than we’ve gained over the last 10 to 15 years.”

As a longtime advocate for HIV services in the city’s underserved neighborhoods, Fullilove wonders whether nonprofits should diversify their funding, rather than relying solely on the government. “I have long thought that it’s a fundamental weakness to put all our eggs in one funding basket, because the government holds us hostage to their fortunes,” he said. “If they’re in trouble, so are we.”

As an alternative model, he pointed to Housing Works, an AIDS service organization that derives 34 percent of its revenue from its businesses, which include a bookstore and café in Soho, seven thrift stores around the city and a catering company.

In the meantime, groups like NYCAHN plan to continue pressing the governor to meet with them to discuss the likely impact of cuts on their clients. “To make a further broad, sweeping cut without considering the effects would be irresponsible,” said NYCAHN’s Long, “particularly when the problem is getting worse.”

13,000 hepatitis patients get subsidies

<http://www.yomiuri.co.jp>

The Yomiuri Shimbun

The number of hepatitis patients who have received a newly introduced government subsidy for interferon treatment from April to June was 13,000, only slightly more than 10 percent of the central government's annual target, The Yomiuri Shimbun has learned.

The government aims to double the number of hepatitis patients who receive interferon treatment annually from 50,000 to 100,000 under the new subsidy system, which was introduced in April. It also aims to reduce to zero the number of hepatitis B and C patients in the country in seven years.

If the current pace holds, the number of patients who receive treatment in the current fiscal year will be similar to previous years.

According to Health, Labor and Welfare Ministry data compiled from prefectural government reports, about 17,000 hepatitis patients applied for the subsidy between April and June.

Only about 13,000 of those patients actually received the subsidy.

Interferon treatment is known to be particularly effective for hepatitis C treatment.

There were many patients who found it difficult to receive treatment because it costs about 70,000 yen to 80,000 yen a month.

The government therefore decided to introduce a financial aid system intended to reduce medical expenses in the long term by preventing hepatitis from developing into liver cancer and other serious diseases.

Hepatitis B and C patients are entitled to the subsidy system, and maximum medical costs shouldered by patients are broken down into three levels--10,000 yen, 30,000 yen and 50,000 yen--according to patient income. The central and local governments must pay the remainder of associated medical costs.

About 12.9 billion yen was allocated to the subsidy system in the fiscal 2008 budget.

Though the system is designed to alleviate financial burdens on patients who receive interferon treatment, some still find it difficult to receive treatment for financial reasons, according to organizations of hepatitis patients.

Household income, not individual income, is used to determine expenses borne by patients.

Under the current system, patients must pay some of the medical costs if their family members earn incomes--even if the patients do not. Some observers believe this caveat discourages many patients from receiving treatment.

Although the subsidy system sets a time limit of one year on the receipt of financial aid, some patients must undergo treatment for a longer period of time.

During routine interferon treatment, patients are given pegylated interferon and ribavirin combination therapy for 48 weeks.

Joji Takabatake, secretary general of a national federation of hepatitis patient organizations, stressed the need to lower the amount of medical costs shouldered by hepatitis patients.

"I assume it won't be easy to increase the number of people who use the system unless the amount of medical costs patients are asked to pay is lowered to 20,000 yen or 30,000 yen," Takabatake said. "Because many patients find it difficult to use the current system, I don't think it will help stamp hepatitis out of this country."

But the health ministry attributes the unexpectedly low number of service recipients to a lack of publicity before the system was introduced.

"We believe a lack of PR activities is the main reason [for the low number] because it was introduced on short notice," a ministry official said. "In addition, many people aren't aware they have the disease after they are infected."

FDA keeps hold on Dynavax vaccine test

<http://www.bizjournals.com>

San Francisco Business Times

The Food and Drug Administration told Dynavax Technologies Corp. and its partner Merck & Co. that they can't restart a clinical trial of a hepatitis B vaccine.

The drug, **Heplisav**, has had its Phase III testing delayed since March, when the FDA put a clinical hold on it after a patient contracted Wegener's granulomatosis during the tests.

The FDA told Dynavax and Merck "the balance of risk versus benefit no longer favors continued clinical evaluation" of the vaccine in healthy adults and children.

Regulators held out some hope for eventual use of the treatment in kidney-failure patients, and asked for more data along those lines.

When to Treat, Antiviral Resistance, and Use of Antivirals During Pregnancy

Christine Kukka, HBV Project Manager

<http://www.hbvadvocate.org/news/reports/NIH%202008/NIHTuesdayreports.htm>

BETHESDA, MD--Hepatitis B experts examined who should be treated, when, and the benefits and risks of antiviral treatment during the second day of the National Institutes of Health's Consensus Development Conference on hepatitis B.

When to treat:

Anna S.F. Lok, professor of internal medicine and director of clinical hepatology at the University of Michigan Health System, recommended treatment when there was life-threatening liver disease, a high risk of "adverse outcome in the near future," and active inflammation and cirrhosis.

Despite the lack of credible, randomized clinical trials, Lok cited the life-saving benefits of using antiviral therapy in the face of sudden liver failure and decompensated cirrhosis.

Older age, male gender, and a long period of elevated viral load and ALT levels are also triggers for treatment, she explained. The hardest challenge is whether to treat younger patients, under age 40, who have normal ALT levels and moderately elevated viral loads. More studies are showing that even moderately elevated ALTs and viral load are producing liver damage, even in younger adult patients.

Monitoring for antiviral resistance

Experts also pressed for the need to create a standardized method for monitoring patients to identify when they develop resistance to antiviral medications. Marc Ghany, MD, investigator for the Liver Diseases Branch of the National Institute of Diabetes and Digestive and Kidney Diseases at NIH, recommended monitoring viral load, and other biochemical features every three months after treatment begins.

It may be beneficial to test a patient's HBV before treatment begins to see if they already have certain mutations that would enable viral resistance, he said, but the test is expensive (\$300) and is currently not performed in the U.S.

"But if viral load begins to rise," he said, "the tests should be repeated and then a test should be performed to test for genotype resistance (viral resistance)." If resistance is found, doctors can start a second antiviral, or switch to more potent antiviral, or they can stop treatment and observe what happens. However, if a patient has cirrhosis, antivirals should not be stopped because a life-threatening resurgence of ALT and viral load can occur.

Side effects from lengthy antiviral treatment identified

Researchers are finding that prolonged treatment, beyond two years with antivirals not only inhibits replication of the virus, but also interferes with cellular replication and causes myopathy, lipoatrophy, pancreatitis, nephrotoxicity and neuropathy. Researchers reviewed the risk from each antiviral, and called for additional study into the risks of renal insufficiency from the agents.

Use of antivirals during pregnancy to prevent mother-to-child transmission of HBV infection

Despite immediate treatment with HBIG (hepatitis B antibodies) and immunization, between 5 to 10% of infants born to infected mothers with high viral load develop chronic HBV infection. Lamivudine, which has been safely used in the third trimester of pregnancy to prevent perinatal transmission of HIV, is beginning to be used in HBV-infected women with high viral load during the third trimester of pregnancy to prevent transmission.

Researchers reviewed the potential side effects of the five available antiviral agents, and recommended that lamivudine may be the safest for use during pregnancy, given its safe record from HIV use. Tenofovir (Viread), which is a stronger antiviral than lamivudine, was not promoted because doctors are concerned about its potential impact on fetal bone development.

Reactivation of hepatitis B when chemotherapy or immune-stimulants are used:

Jay Hoofnagle, director of the NIH's Liver Disease Research Branch, detailed the alarming occurrence of HBV reactivation, which can lead to death, among patients with inactive or resolved hepatitis B when they are treated for non-hepatic cancers with chemotherapy or bone marrow replacement. Because antivirals can take up to a month to be effective, in some cases doctors have used antivirals to help these reactivating patients belatedly. Hoofnagle stressed the need for additional studies, and close collaboration with oncologists and other doctors who may be unaware of this risk.

Researchers at NIH Conference Find Few Valid Scientific Studies Confirm Benefits of Hepatitis B Treatment

Christine Kukka, HBV Project Manager

<http://www.hbvadvocate.org/news/reports/NIH%202008/NIHTuesdayreports.htm>

BETHESDA, MD--Hepatitis B experts at the National Institutes of Health's Consensus Development Conference found themselves defending the shortage of evidence-based research studies that justify the use of antivirals and interferon to treat patients infected with the hepatitis B virus (HBV).

The confrontation arose during the NIH consensus conference, when physicians and researchers specializing in hepatitis B presented evidence to a panel that will decide future priorities for funding research and clinical trials.

One expert, whose job was to critique available hepatitis B studies of what worked and what didn't, found little proof that antiviral treatment or interferon were effective at preventing either cirrhosis or liver cancer. At issue is the lack of randomized control studies, which use a control group that receives a placebo instead of treatment, in order to show the effectiveness of treatment.

The research and clinical trials were weak and failed to adequately follow patients for several years or use control groups, according to the report, and antiviral medications did not reduce death and pegylated interferon failed to prevent cirrhosis in HBeAg-positive patients.

Timothy J. Wilt, MD, MPH, professor of medicine at the Center for Chronic Disease Outcomes Research at the Minneapolis VA Medical Center, levied a harsh judgment on the clinical outcomes in the studies. He took researchers to task for not consistently tracking outcomes such as viral load (HBV DNA), ALT levels that indicate liver damage, and loss of the "e" antigen (HBeAG) or surface antigen (HBsAg), development of HBeAg or HBsAg antibodies, and specific improvements in liver health (histology) measured by liver biopsies.

His critique exposed the inconsistent studies, which have been performed by different researchers around the world over the past two decades, in a field of care that lacks many firm

benchmarks or goals. Some studies, for example, define reductions in viral load or ALT as a goal, others focus on “seroconversion” (loss of HBeAg and development of the “e” antibody), and others track improvements in liver health.

“Available drugs have not been demonstrated to improve clinical outcomes or resolve hepatitis B,” Wilt explained in his analysis.

“How do you not treat cirrhotic patients without putting them in jeopardy?” responded Jules L. Dienstag, MD, hepatitis B expert and dean of medical education at Harvard Medical School, to the charge that researchers did not use a control group.

Members of the panel picked up on Wilt’s findings of a lack of valid, randomized control studies and asked if treating with antivirals, which can lead to antiviral resistance, may be causing more harm than good.

Dienstag explained there was no cure for hepatitis B and physicians did not have the luxury to be able to follow patients for decades or use control groups, which would have essentially assigned patients who received placebos to death from liver disease.

“There are people who didn’t die because we used antivirals,” he told the panel. “You’re asking for scientific outcomes that are measured in decades, which is very difficult.”

Dienstag and others explained that treatment goals have changed over the years as more knowledge was gained about the infection and more antivirals developed. Physicians can point to tangible improvements in liver biopsy results as a result of treatment, he said, but they cannot prove that they were able to prevent development of cirrhosis.

“True, we don’t have many controlled trials,” Dienstag said, “but it wasn’t until antivirals came along 10 years ago that we even realized that cirrhosis was reversible.”

While pharmaceutical companies are required to perform randomized control trials for 12 months in order to win U.S. Food and Drug Administration approval for drugs, after that initial controlled trial, doctors and researchers often test the drugs in less rigorous clinical trials.

Oct 22, 2008

Resveratrol May Help Treat Fatty Liver

www.medscape.com

Kelley Colihan

October 16, 2008 — Scientists looking for ways to help treat fatty livers have discovered that an ingredient in red wine can help protect from -- and possibly even be used to treat -- fat buildup in the liver that goes hand-in-hand with chronic alcohol use.

This study zoned in on resveratrol.

You've likely heard about the antioxidant found in red wine, grapes, berries, and peanuts. Resveratrol has previously been linked to health benefits for cancer and heart disease.

It may seem counterintuitive to think that a main ingredient in something like red wine could actually help to protect the liver from damage, but that was one of the key findings.

The study, led by Joanne M. Ajmo at the University of South Florida Health Sciences Center in Tampa, looked at the effects of resveratrol in alcoholic fatty livers of mice.

Researchers found that alcohol-fed mice given resveratrol had less fat in their livers and the fat broke down more quickly than alcohol-fed mice not give resveratrol.

The researchers note that resveratrol has been shown to activate molecules that are also important in fat metabolism in the liver. Chronic alcohol abuse inhibits these molecules.

In this study, alcohol-fed mice treated with resveratrol also had enhanced activity of these molecules.

"Collectively, these results demonstrate that resveratrol treatment protected against the development of alcoholic [fatty liver] in mice," they write.

The authors write that alcohol along with "concentrated resveratrol could be a more potent and efficient way" of getting the health benefits of resveratrol alone.

The study appears in the October issue of *The American Journal of Physiology-Gastrointestinal and Liver Physiology*.

SOURCES:

Ajmo, J. *The American Journal of Physiology-Gastrointestinal and Liver Physiology*, October 2008; vol 295: pp 833-842.

News release, American Physiological Society.

Tattoos Could Result in More Than Beautiful Art

<http://www.examiner.com>

by Charlie Kuchinsky,
Norfolk Beauty Education Examiner

Thousands of people get new tattoos every year; adding their names to the millions who already sport them. Many of them consider tattooing an art form. While it is true, that many tattoos are cute or even quite beautiful, they might also hold something dangerous or even deadly. One might ask why this is the case? The reason is quite logical and simple. Even the smallest tattoos will result in thousands of needle pricks as the dye is inserted into the skin. Such an action obviously results in bleeding and, whenever blood is involved, there is a possibility of serious disease transmission. Possible illnesses could include Hepatitis B or C, HIV, MRSA, Syphilis, Tetanus, and Tuberculosis.

Another reason for bacteria transmission (other than blood) relates to the tattoo artists themselves. As much as no one cares to admit it, some artists take little precautions to ensure the safety of their clientele. Dirty equipment, poor sanitation conditions, and even worse personal

hygiene can cause situations that can lead to serious bacterial infection. Even those tattoo artists who take precautions can't be 100% sure of safe results. A few years back, actress Pamela Anderson obtained Hepatitis C as a result of having her husband's name tattooed on her finger. She went to a reputable artist, but that wasn't enough.

Studies conducted prior to and after that incident continue to show an alarming growth in the number of people who contract blood-related diseases from tattoos. Some research indicates that diseases like Hepatitis out distance those that are obtained as a result of shooting drugs with a dirty needle. Of that group, it is believed that close to 12,000 people die each year from Hepatitis or related problems resulting from the disease.

These problems aren't anything new, either. Both the medical community and tattoo businesses have been aware of the startling statistics for a number of years. That is why the practice of tattooing has been deemed illegal in states. It is also why the American Red Cross refuses blood donations from those who sport a tattoo that hasn't been in place for at least one year. While many call the statistics "false" or "heavily inflated," the fact remains that the CDC stands behind their claims about the danger of this artistic fad. They continue to implore states to establish some form of valid regulations over tattoo parlors. Some states have heeded the suggestion. Others have embraced a loose form of control. A few have even put serious control efforts in place but rarely do they enforce them.

That begs the question, "is enough being done to protect customers?" The answer is a resounding "No!" Most tattoo businesses remain unconcerned with hygiene issues because even the federal government fails to mandate any kind of regulation across the board. Even the Alliance for Professional Tattoo Artists (APT) recognizes the industry faces some very real problems. While there are hundreds of highly reputable tattoo parlors in the United States, there are many more that refuse to conform to any type of standards whatsoever. Worse still, they decline to make their customers aware of the dangers they may face from the procedure. Their *laze au faire* attitude comes more from an unwillingness to accept the statistics of the industry than a blatant attempt to put their customers in harms way.

With no regulations mandating how equipment is sterilized and dozens of people receiving new tattoos everyday, one has to wonder. How many tattoo guns move directly from one patient to another without any type of cleaning in between? Multiply that possibility with the thousands of tiny skin wounds that must be inflicted in order to complete the tattoo. The result should be one of abject horror. It is actually a wonder that more people don't contract any of the deadly diseases previously mentioned. However, those don't even scratch the surface of dangers involved. While many will escape serious disease that doesn't mean they won't have any kind of side effects. Many people who have received tattoos over the years report other skin ailments like serious allergic reactions to the ink used, permanent scarring, photosensitivity at the tattoo site, and even malignant tumors around the area.

Tattoos are also basically permanent. While they can be removed in some instances, most people can't afford the number of surgeries it would take to accomplish that. Therefore, many end up going back in to have the tattoo altered. This is usually to cover up the name of an old girlfriend or spouse. However, the end result is further exposure to many of the risks identified previously. It, therefore, makes sense that one should think seriously before agreeing to this permanent form

of body art. Chances are, after weighing all the pros and cons, it might not be worth the entire hassle. It is certainly not worth risking one's health or, worse yet, one's life.

Report: Violence, obesity, asthma on rise in Mass.

<http://news.bostonherald.com>

By Associated Press

BOSTON - A new report looking at health trends in Massachusetts is warning that girls and young children are increasingly involved in violent behavior, and deaths from domestic violence have tripled since 2005.

The Massachusetts Health Council report also finds that asthma rates, lack of access to dental care and obesity also are on the rise. And hepatitis C rates among younger people has increased.

Susan Servais, executive director of the council, said the state must take more steps to stem domestic violence, including more school violence prevention program and public education programs about domestic and dating violence.

On the positive side, the report found the number of smokers continues to fall and more people are being insured under the states' landmark health care law.

NIH panel says stricter clinical trials and consistent patient monitoring needed to improve treatment for hepatitis B patients

Christine Kukka, HBV Project Manager

<http://www.hbvadvocate.org/news/reports/NIH%202008/NIHFinalreport.htm>

Bethesda, MD – During a recent conference sponsored by the National Institutes of Health (NIH), an impartial panel recommended more long-term and scientific clinical trials focusing on the effectiveness of interferon and antivirals for hepatitis, and urged doctors to formalize how hepatitis B patients are monitored

NIH convened the conference to produce expert guidance to doctors about how hepatitis B should be monitored and treated. Hepatitis B experts testified before the panel during the three-day conference, pushing for clearer treatment guidelines to help physicians provide better quality care to their HBV-infected patients.

While there are five antiviral medications and two interferons approved for hepatitis B treatment, randomized control trials – where some patients are given a placebo instead of medication to accurately assess the drug's effectiveness – are sorely lacking, the panel pointed out. "Further controlled trials are needed to substantiate that these agents prevent disease progression to liver failure, cancer, or death," explained panel chair Michael F. Sorrell, MD, professor of medicine at the University of Nebraska Medical Center.

To address these gaps, the panel recommended that researchers conduct large studies, including placebo-controlled trials, to test the effectiveness of single drugs and drug combinations on liver

failure, cancer, and death. The panel also pushed for more studies that would better explain the natural history of this complex infection, which is prone to mutations that quickly develop resistance to medications, and can behave dramatically differently in people based on their immune health, age, gender, and viral strain or genotype.

Recommendations:

Clarify how to monitor disease progression and effectiveness of treatment: The panel identified elevated HBV DNA (viral load) and elevated levels of ALT (alanine aminotransferase, a liver enzyme that increases when liver cells are damaged or die) as the most important indicators for doctors to monitor when evaluating a patient's progression to cirrhosis and liver cancer. Older age, male gender, family history of liver cancer, and coinfection with the hepatitis C virus or HIV were also important indicators.

Whom to screen for HBV, no impact on immigration: The panel recommended routine hepatitis B screening of newly-arrived immigrants and their family members from countries where HBV infection prevalence exceeds 2 percent. These practices are intended to identify infection and help people receive treatment, the panel noted, and is not designed to exclude HBV-infected immigrants in any way.

Whom to treat: The panel recommended treatment for patients with liver damage and complications from cirrhosis. However, immediate therapy was not recommended for patients with inactive forms of the disease, such as people in the immune-tolerant stage (with high viral load and normal ALTs, frequently found in children and young adults), and those with low viral load and normal ALTs. However, older adults with high viral load and normal ALTs have been found to have liver damage, so their ALTs should be monitored over time and if their ALT levels fluctuate, they should be treated.

What is the current prevalence of hepatitis B in the U.S.? While some researchers have estimated the true rate of HBV infected residents to be more than 2 million, the consensus statement stuck to current government predictions of infected residents at about 1 million residents. Many are of Asian or Sub-Saharan African descent. Critics claim current population surveys miss many undocumented residents from Africa and Asia, where infection rates are high.

Who has the highest risk of developing liver cancer? Long-term follow-up studies show that the HBV genotype C infection, found among people from Asia and the Pacific Islands, poses an increased risk of cirrhosis and liver. Other risk factors for liver cancer include being male, older, and having a family history of liver cancer. Co-infection with HCV increases the risk of cirrhosis and cancer.

What are the benefits and risks of current treatments for hepatitis B?

Currently, there are seven drugs for hepatitis B treatment, including conventional and pegylated interferon, and antivirals (lamivudine, adefovir, entecavir, tenofovir and telbivudine). While the goal of treatments is to prevent development of liver damage and cancer, "to date, no conclusive evidence from randomized control trials (RCTs) of antiviral treatment has demonstrated a beneficial impact on any of these primary clinical outcomes," the panel wrote in its report. "This is due to the fact that cirrhosis, liver cancer, and death often do not occur for many years after infection with HBV, and would therefore require long-term investigation of therapy to

demonstrate benefit.” As a result, only short-term or “intermediate” treatment outcomes are known, panelists added.

In studies of hepatitis B therapy, a variety of factors including loss of surface antigen (HBsAg), reduced viral load, loss of the “e” antigen (HBeAg) and development of the HBeAg antibody, normalization of ALT levels and improvement in liver health have been included either separately or together as treatment endpoints, which results in inexact science and no clear findings about which treatment regimen is best.

Due to the vagaries of the studies, and the reliance on “intermediate” results, such as temporary lowering of viral load during antiviral treatment, the panel recommended, “large RCTs, including placebo-controlled, of mono (using one treatment) and combined therapies with effects on clinical health outcomes (documented).”

Antiviral treatment recommended for patients receiving chemotherapy and immune-suppressing drugs: Panelists also stressed that people with resolved HBV infections and those who test positive for HBsAg and have any viral load, should be treated with antivirals prior to chemotherapy or bone marrow transplants. It takes about one month for an antiviral to begin to work, so antiviral treatment should begin about one month before the start of chemotherapy or immune-suppressing drugs.

Goal of treatment: In addition to preventing the development of liver damage and cancer, treatment endpoints should also include a reduction in HBV DNA levels, improvement in ALT level, and loss of HBeAg and HBsAg.

Future research needs: The long duration of illness and the complex course of HBV infection have created major challenges for effective clinical research. While RCTs may be difficult, randomized control trials are still needed, they stressed, even if it means providing a placebo instead of treatment to infected patients. The complex course of chronic HBV infection has resulted in the acceptance of intermediate or short-term end points for treatment, but that approach, “may lead to biased estimates of therapeutic effect,” panelists warned.

“To ensure that the results of different studies are comparable or may be combined for analysis, such studies should be conducted using standardized protocols, including definitions of populations, regimens, clinical definitions, diagnostic methods, intervals and techniques for follow-up, and, most importantly, standard definitions of improvement,” panelists wrote.

Clear monitoring guidelines also needed: While a variety of monitoring practices are recommended, no clear evidence exists for identifying the best monitoring protocol, they added. Researchers must use the same monitoring tests in order to scientifically evaluate how patients fare from treatment, they added.

The NIH consensus report is found at:

http://consensus.nih.gov/2008/hebB%20draft%20statement%20102208_FINAL.pdf

HIV-associated immunosuppression increases risk of liver cancer

David McLay

Immune suppression caused by HIV increases the risk of liver cancer, say researchers with the Swiss HIV cohort. Their report, published in the October 18th edition of AIDS, also suggests that the effect is most pronounced in the presence of hepatitis B virus infection. Liver cancer, they say, may become a significant issue in areas of the world where hepatitis B is endemic such as sub-Saharan Africa and Asia as lifesaving treatment allows people with HIV to live longer.

Deaths due to liver disease are becoming more common as people with HIV live longer thanks to antiretroviral therapy. Co-infection with hepatitis B or C virus is common among people with HIV, and there is evidence that co-infection with HIV and hepatitis B or hepatitis C increases the risk of cirrhosis and liver-related deaths.

However, there has been no clear evidence that HIV itself has an impact on the risk of liver cancer. A large 2001 study found that CD4 cell count at AIDS diagnosis did not predict cancer risk and suggested that the excess risk could be attributed to the high prevalence of hepatitis virus co-infection.

To further investigate the link between immune suppression and liver cancer, investigators undertook a case-control study using data from the Swiss HIV cohort. Investigators searched the cohort database for cases of liver cancer and identified 26 cases of hepatocellular carcinoma (HCC). For each patient, investigators then attempted to select ten matched control patients without cancer. They obtained a total of 251 controls.

When investigators compared markers of immune function between the two groups, they found that CD4 cell count taken within a year of diagnosis was associated with risk of liver cancer. Each 100 cells/mm³ decrease was associated with a 33% increase in risk (odds ratio [OR] 1.33, 95% CI: 1.06 - 1.68). Compared to a CD4 cell count above 500 cells/mm³, a CD4 cell count between 200 and 499 cells/mm³ was associated with an OR of 5.32 (1.15 - 24.5), and a CD4 cell count below 200 cells/mm³ was associated with an OR of 6.70 (1.24 - 36.1). Changes in CD4 cell percentage (OR for each 10% decrease 1.65, 1.01 - 2.71) and a history of AIDS (OR 2.40, 1.06 - 5.44) were also associated with an increased risk of cancer.

The investigators state: “Our present nested case-control study showed, for the first time, a specific association between HCC risk and low CD4+ cell count in the year preceding hepatocellular carcinoma diagnosis. These findings, therefore, complement previous reports that declining CD4+ cell counts increase overall liver-related deaths, predominantly due to liver failure, among [people with HIV]”.

Several factors did not appear to be linked to cancer, including CD4 cell count at enrolment into the cohort, HIV viral load and history of antiretroviral use. The investigators suggest that this last finding speaks against the hypothesis that HIV treatment, which is known to be toxic to the liver, may hasten liver damage and increase the risk of cancer.

The investigators made another striking finding: all cases of cancer were associated with infection with either hepatitis B or hepatitis C. Of the 26 cases, ten were in people with hepatitis B infection, eleven were in people with hepatitis C infection, and five were in people with both infections. Moreover, infection by each virus fell clearly into HIV transmission categories.

Among injecting drug users, 13 of 14 had hepatitis C virus infection, while among men who have sex with men (MSM) and heterosexuals, eleven of twelve had hepatitis B virus infection. There were no cases of cancer in the absence of hepatitis virus infection. This link between hepatitis virus infection and cancer remained unexplored because, as the investigators write, “matching for transmission category hampered us from evaluating the importance of hepatitis virus infections as independent risk factors for hepatocellular carcinoma”.

Investigators then looked at the impact of CD4 cell count on cancer risk in the two transmission populations. “The association between lower CD4 cell counts and HCC risk was also particularly strong for MSM/heterosexual/other and hence, due to the strong dichotomy mentioned above, for hepatitis B-related hepatocellular carcinoma.” In addition to corroborating evidence that hepatitis B virus worsens liver damage, especially at low CD4 cell counts, the investigators add that, “the hypothesis that immune suppression might actually reduce [hepatocellular carcinoma] risk due to less immune destruction of [hepatitis B virus]-infected hepatocytes appears...unlikely.”

Hepatitis C infection predominated in injecting drug users, and in this group there was no evidence of an increased risk of liver cancer with lower CD4 cell counts. This is at odds with other evidence that HIV increases liver disease and liver-related death in co-infected individuals, and the investigators offer that the injecting drug users control group was more immunodeficient than their gay men counterparts and this may have masked any effect of hepatitis C on cancer risk.

While preliminary, the study provides some interesting findings on the role of hepatitis C and hepatitis C in liver cancer among people with HIV. And the results might be far reaching, the investigators end: “The present findings are also relevant for the millions of [people with HIV] worldwide who live in [hepatitis B virus] endemic areas in sub-Saharan Africa and Asia as their survival also improves on [antiretroviral therapy]”.

Reference

Clifford GM et al. Influence of HIV-related immunodeficiency on the risk of hepatocellular carcinoma. *AIDS* 22:2135 – 2141, 2008.

Should Hepatitis C Patients Who Smoke Marijuana Be Eligible For Liver Transplants?

<http://www.sciencedaily.com>

The pain is debilitating. The only option: smoking medical marijuana. That's the reality for many hepatitis C patients whose road to health includes a liver transplant. Although Canadian transplant centres are more willing than those in the United States, not everyone says yes to liver patients who smoke marijuana, and a University of Alberta researcher says that decision-making process is unacceptable.

Karen Kroeker, along with three other students at various universities, sent out surveys to a number of transplant clinics across the United States and Canada. Results found that the difference between the two countries were obvious in some patient groups: around 60 per cent of Canadian centres would either do the surgery or consider it for a liver transplant patient who smoked marijuana, while 70 per cent of U.S. transplant programs said absolutely not. Kroeker

also found that patients in both countries, who have no social support—meaning they have no family, friends or a social worker—aren't likely to receive the organ they need.

The problem Kroeker has with these results: the lack of literature to support the surgeons' decision. As a result of her findings, which will be published in the November issue of *Liver International*, Kroeker says physicians need to determine eligibility criteria for liver-transplant patients that pertains directly to the likelihood of a patient rejecting the organ and is based only on empirical medical evidence.

When a patient is being reviewed for eligibility, whether they smoke marijuana shouldn't be a factor, she says. "If we have evidence to say the patients don't do well, then I think that's a reason to exclude people," Kroeker said.

She cites alcohol use as an example. When transplants first began to be performed, those who drank alcohol weren't eligible for a new liver. Kroeker's study found, however, that surgeons conducted studies on the topic of abstinence and liver health and, as a result of that research, transplant rules changed. If the patient has been sober for six months, 94 per cent of the clinics in North America will now consider transplantation.

The same goes for HIV-positive patients. "When they first started transplanting, HIV was an absolute contraindication. No one even considered transplantation because the disease was a death sentence at that time." Kroeker adds that's no longer the case and that there is research being conducted on post-transplant HIV-patients that will help determine the viability of transplants in HIV-positive patients.

In reference to her findings, Kroeker said, "I think there should be a large-scale study," because too-little research is available on post-transplant patients whose eligibility may currently be in question.

"Unless you actually perform transplants for those people, how would you know how they do?"

Source: University of Alberta

Oct 23, 2008

Hepatitis B vaccine protection may wane in teens

www.reuters.com

By Will Boggs, MD

NEW YORK (Reuters Health) - Protection against hepatitis B appears to drop off in adolescents who got the hepatitis B vaccine beginning at birth, according to a new report.

Dr. Stephanie R. Bialek from the US Centers for Disease Control and Prevention, Atlanta, Georgia, and colleagues evaluated the occurrence of breakthrough infections and the persistence of protective levels of antibodies against hepatitis B in 105 teens who had been given the recommended series of hepatitis B vaccine starting at birth 15 years earlier.

Only eight of them showed evidence of new hepatitis B infection, the authors report, and no participant was chronically infected.

On the other hand, only seven of the other 97 participants had relatively high antibody levels against hepatitis B at the 15-year follow-up, the researchers report in *The Pediatric Infectious Disease*.

Less than half of the participants who elected to get a booster dose of hepatitis B vaccine had an expected antibody response at 14 days, which "might indicate waning immunity," Bialek's team found.

"At this point in time, we do not have any evidence from our surveillance systems of breakthrough hepatitis B virus infections occurring among vaccinated adolescents and therefore do not recommend additional doses of hepatitis B vaccine for adolescents or children who already received three doses of hepatitis B vaccine," Bialek told Reuters Health.

However, he added, "We need to continue surveillance for hepatitis B among vaccinated adolescents ... for making decisions about whether the additional doses of hepatitis B vaccine should be recommended in the future."

SOURCE: The Pediatric Infectious Disease Journal, October 2008.

The risk factors of idiopathic pulmonary fibrosis in HCV patients

<http://www.eurekalert.org/>

Hepatitis C virus (HCV) is one of the more common causes of chronic liver disease in world with a variety of extrahepatic complications such as essential mixed cryoglobulinemia, membranoproliferative glomerulonephritis, autoimmune thyroiditis, sialadenitis, and cardiomyopathy. IPF is present in patients with chronic HCV infection. However, there is little or no information on the yearly cumulative incidence and risk factors on the development rate of IPF in patients with HCV.

A research team led by Yasuji Arase from Toranomon Hospital of Japan addresses this question and this will be published on October 14, 2008 in the *World Journal of Gastroenterology*. In this study, they studied 6150 HCV infected patients who were between 40-70 years old (HCV-group). Another 2050 patients with hepatitis B virus (HBV) were selected as control (HBV-group). The mean observation period was 8.0 ± 5.9 years in HCV-group and 6.3 ± 5.5 years in HBV-group.

They found that fifteen patients in HCV-group developed IPF. On the other hand, none of the patients developed IPF in HBV-group. In HCV-group, the cumulative rates of IPF development were 0.3% at 10th year and 0.9% at 20th year. The IPF development rate in HCV-group was higher than that in HBV-group ($P = 0.021$). The IPF development rate in patients with HCV or HBV was high with statistical significance in the following cases: (1) patients ≥ 55 years ($P < 0.001$); (2) patients who had smoking index (package per day \times year) of ≥ 20 ($P = 0.002$); (3) patients with liver cirrhosis ($P = 0.042$). This result indicated that age, liver cirrhosis and smoking enhance the development of IPF in patients with chronic hepatitis C infection.

Reference:

Arase Y, Suzuki F, Suzuki Y, Akuta N, Kobayashi M, Kawamura Y, Yatsuji H, Sezaki H, Hosaka T, Hirakawa M, Saito S, Ikeda K, Kumada H. Hepatitis C virus enhances incidence of idiopathic pulmonary fibrosis. *World J Gastroenterol* 2008; 14(38): 5880-5886
<http://www.wjgnet.com/1007-9327/14/5880.asp>

Hatred for safe-injection sites is irrational

<http://www.theglobeandmail.com>

André Picard

The facilities will not cure drug abuse but they're integral to strategies for prevention and rehabilitation

In the waning days of the federal election campaign, there was an important development in the continuing saga surrounding Insite, Vancouver's safe-injection site.

Pivot Legal Society released documents, obtained under an access-to-information request, that show the RCMP paid for research that was clearly designed to attack and undermine Insite.

Numerous scientific publications have shown that providing addicts with clean needles, condoms and a safe place to inject can sharply cut the risk of transmission of diseases such as HIV-AIDS and hepatitis C, and prevent overdoses.

While safe-injection facilities may be emotionally unpalatable to many, they are a sound public health measure, particularly as an integral part of a broader strategy of prevention, treatment and rehabilitation.

A couple of government-sponsored reviews have come to the same conclusion, but because they did not fit the war-on-drugs ideology held by the federal Conservative government (or senior Mounties presumably), the RCMP went shopping for an opinion they liked: that Insite is a failure.

It has been pointed out by editorialists and columnists that although the RCMP can inform itself by consulting independent experts, it has no business shopping around for research that will provide predetermined conclusions.

The job of the national police is to enforce the law, not to attack and undermine laws and public policies they don't like.

This begs the question: Is the commissioning of politically motivated critiques of Insite the work of a rogue police force, or did this despicable behaviour have the tacit approval of the RCMP's political masters?

The answer to that key question is not going to come from a summary internal review.

And whatever the answer is, we are left with a disconcerting state of affairs. In the grand scheme of things, Insite is not, in itself, that important. It is a single safe-injection site that provides

temporary respite for a small group of drug users - a few hundred desperate souls on Vancouver's Downtown Eastside who are hooked on heroine, cocaine or speed.

But the attacks on Insite are really an attack on the philosophy of harm reduction, which is a pragmatic approach that recognizes that addiction and treatment are not flip sides of a black-and-white coin.

Addiction is an illness, one with powerful clutches. Treatment fails, often repeatedly, and treatment and rehabilitation from addiction (be it heroin, alcohol or tobacco) take time. In the interim, it is best to reduce harm as much as possible by preventing transmission of disease and other problems that are part and parcel of drug abuse.

There are hundreds, if not thousands, of harm-reduction programs around the country that are rooted in the same philosophy.

There are wet shelters that provide alcohol to homeless alcoholics, who are turned away from traditional shelters. There is distribution of glass pipes to crack addicts. There are needle-exchange programs and methadone-maintenance programs for intravenous drug users. There are condom-distribution programs for street-level sex workers.

Technically, many of these programs operate on the margins of the law. The irony here is that Insite, with an exemption from the law and the backing of the courts, is getting the most grief.

The bottom line is that, more often than not, these programs work.

Alcoholics turned away from shelters end up on the streets drinking Lysol and are frequent visitors to emergency rooms. Crack addicts tend to smoke rock from busted-up pop cans that leave their lips bloodied and raise the risk of blood-borne infections. Junkies desperate for a hit share needles if clean ones aren't available, fuelling outbreaks of HIV and hepatitis C.

Heroin addicts treated with methadone can be weaned from their addiction or, at the very least, they temporarily break their pattern of injecting.

These programs are intended to reduce harm to individuals with substance-abuse problems. They also recognize that outbreaks of infectious disease often have their genesis in these high-risk groups. In other words, if you minimize HIV and hepatitis C infections among IV drug users, you largely keep those infections away from the broader population.

These programs are not a panacea. They will not eliminate the scourge of alcohol and drug abuse. But they do not pretend to do so.

These methods were developed over time by street-level workers who recognized that no amount of repression and political rhetoric would eliminate drug abuse in society, but that at least some harm could be attenuated.

This insight was hard-earned.

Yet, our federal government and our national police force, rather than embracing harm reduction as complementary to law enforcement, have developed a hatred for Insite that is irrational and unseemly, one that threatens and undermines public health policy to its core.

Oct 24, 2008

Hepatitis C Victim Spreading Awareness

<http://www.newschannel34.com/news>

Curtis Hadlick of Binghamton is going through an ordeal, but wants to share his story to raise awareness of the challenge for four million people in the U-S living with Hepatitis C.

He was diagnosed with it back in 2006.

However, he has never done drugs, gotten tattoos, or had a blood transfusion.

Usually those are the ways people contract it.

The Hep C also caused cirrhosis, which takes about 30 years to develop from the disease.

In 2006 he was told he had five years to live.

Currently, he feels exhausted and has to fight confusion.

Curtis wants people to know that the only way to get Hepatitis C from someone else is by blood-to-blood contact.

Curtis says, "I think if you've done drugs or transfusions or any thing to do with blood, needle sticks if you've worked in the healthcare system. You should get tested before it develops into cirrhosis. I want people to be aware that coughing, sneezing on someone, you're not going to get it."

105 Cases May Be Linked To Endoscopy Centers

<http://www.ktnv.com>

The Southern Nevada Health District says 105 clients may have gotten Hepatitis C from visiting a network of Endoscopy clinics in the Valley.

Right now, the Health District says they are certain of only nine cases that are directly linked to the dirty syringes used at the Endoscopy centers.

There are 101 others that are possibly linked to the Endoscopy Center of Southern Nevada.

Four more cases may possibly be linked to another Endoscopy center.

35 people who came down with Hepatitis C after visiting one of the Endoscopy centers also engaged in other high risk behavior that may have put them in the path of the deadly disease.

In the middle of the investigation are the Endoscopy centers on Shadow Lane and Burnham Avenue.

These are two locations where health inspectors say staff was regularly reusing syringes and double dipping into medication vials that were intended to be used only once.

As a result, the Health District says patients who already had Hepatitis C were able to pass the disease to other patients who went for treatment on the same day.

The confirmed danger days are July 25, 2007 and September 21, 2007, but there may be others.

The Southern Nevada Health District has created a database of all the Endoscopy patients who have been tested.

They have taken a look at 7,331 so far.

Hep B falling under our radar

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

Health editor Adam Cresswell reports

JOHN Smith ought to have died 16 years ago, when the transplanted liver he had received the previous year was attacked by the hepatitis B virus circulating in his system.

His original liver had become riddled with cirrhosis as a result of the virus, which he now thinks he had unknowingly been carrying for decades.

Now the same thing was happening to the replacement organ. Under normal practice at that time, he would have been refused further transplants on the grounds that donor organs were too precious to be thrown away on someone whose condition meant they would almost certainly be quickly destroyed.

Luckily for Smith, now 73, experimental new antiviral drugs were then becoming available. In a world-first procedure, he was given his second liver transplant, and over the following months was dosed with drugs designed to keep replication of the virus in check and to give his transplanted liver time to stabilise.

It worked. Smith pulled through. His besieged immune system, relieved of some of the pressure by the antiviral drugs, later recovered sufficiently to start making its own antibodies against the virus. Although hepatitis B cannot be eradicated from the body, he now has the infection well under control and depends on drugs for continued good health much less than previously the case.

Smith had only found out in 1987 that he was infected, something he thinks must have happened during an army vaccination campaign in the 1950s in which needles were not changed between different soldiers.

The discovery came about by chance after he went to see his GP to have his ears syringed. An unusual heart rhythm led to a referral to a specialist, who in turn noticed a yellowing of the whites of his eyes -- a telltale sign of jaundice, the result of a liver that was already on its last legs.

"It's a horrible thing to go through," says Smith, from Sydney's western suburbs. "I think it should be taken very seriously ... You wouldn't want anyone else to go through it."

Unfortunately, infectious disease experts are warning that too few in Australia are taking the threat of hepatitis B as seriously as John Smith thinks we should.

This week two reports painted a grim picture of a largely unsung hepatitis B epidemic in Australia, which already encompasses a population of 160,000 infected Australians, and 6000 new cases across the country each year.

Despite its negligible public profile, hepatitis B is a significant health problem. Unlike the better-known hepatitis C, hepatitis B cannot be eradicated from the body, but merely kept in check. For the last 10 years there has been a clutch of antiviral drugs that help to do this.

But left untreated, 25 per cent of people infected with hep B will develop cirrhosis, and 5 to 10 per cent will develop liver cancer.

Higher risks attach to those who contract hepatitis B as babies, 95 per cent of whom will develop chronic hepatitis -- compared to just 5 per cent of people exposed in later life, as was Smith.

Stephen Locarnini, director of the WHO Collaborating Centre for Virus Reference and Research at the Victorian Infectious Diseases Reference Laboratory in Melbourne, says recent estimates suggest the pool of hep B-infected Australians could be over 200,000 and growing. Whatever the exact number, he says it exposes the fact that Australia's main strategy for holding back the disease is failed and broken.

"Over the years we have felt we could control hepatitis B through vaccination, and that most of the cases of hep B that we would see in our lifetimes could be pretty well managed. But over the last 10 years numbers have been increasing dramatically."

A safe and effective vaccine became available in 1982, and routine vaccination of children was introduced in Australia in 2000.

"Although Australia is a low-prevalence country, because of migration (from countries where hepatitis B is common) our numbers have gone up."

This, in Locarnini's view, holds the key to hepatitis B's low profile, and the low priority it gets on the national agenda. Tackling the disease inevitably involves acknowledging people from particular countries, predominantly in the Asia-Pacific region -- and bureaucrats and community leaders see that as a potential Pandora's Box of stigma that they would rather leave firmly closed.

"We have spent the last decade thinking the situation was under control, when in fact it wasn't," says Locarnini, who is also professor of virology at Monash University.

"That's what we have had a panic attack about -- that we have missed the mark. We started (examining the issue) a year ago, and now we have this national needs assessment, and we are doing an economic impact report. We're calling for a funded national strategy (to tackle the problem)."

Education and awareness programs should be part of the strategy, Locarnini says. Part of the issue is that the current poor understanding of hepatitis B is not exactly helping to reduce its spread: it is often portrayed even by doctors as a virus spread through sex and sharing needles -- which, while true, does not explain the fact that most people with chronic hepatitis B in Australia were infected at birth or in childhood. Nor does it encourage parents to think their child may be vulnerable to hepatitis B if they have the virus themselves.

The needs assessment document, released at this week's Australasian Viral Hepatitis Conference in Brisbane, also cites evidence that many people with hepatitis B were offered little support or information to help them understand the virus or the implications of having it. Access to treatment is also limited in some circumstances, particularly for Indigenous people.

The Cancer Council NSW has backed the call for more to be done about hepatitis B, saying the "longer we wait for the government to take action, the more Australians we expose to the risk of liver cancer".

"Many people's health is at stake here and the government must step up to take urgent action," Cancer Council NSW CEO Andrew Penman said.