

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Dec 28, 2008

Prisoners go untreated as hepatitis C sweeps jails

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

Julia Medew

THE vast majority of prisoners with hepatitis C in Victoria are not being treated for the virus, possibly breaching their human rights and putting the community at greater risk of infection.

New statistics from St Vincent's Hospital, which provides health care to prisoners in 13 of the state's 14 jails, show that only about 40 inmates, or 1.5 per cent of those believed to have hepatitis C, had been treated for the virus between 2004 and September this year despite a cure being available for many cases.

The chief executive of the Hepatitis C Council of Victoria, Helen McNeill, said the extremely low treatment rate was disturbing, given the risk of prisoners infecting each other and members of the community when they left prison.

- Less than 2 per cent of infected inmates receive treatment.
- Prisoner neglect may contravene charter of human rights.
- Untreated hepatitis C causing community rise in liver disease.

"If we have more than 4000 prisoners in Victoria, and research shows about 60 per cent of them have hepatitis C, this is an appallingly low number being treated," she said.

"We know prisons are a bit of a revolving door in terms of people coming and going, so the risk of people using drugs and infecting others with the virus is incredibly high. There's a range of other activities inside prisons which could lead to infection too, including illegal tattooing and biting."

Hepatitis C is a blood-borne virus that causes liver inflammation, and can lead to cirrhosis, liver cancer and death.

The slow-acting virus affects about 75,000 Victorians and an estimated 250,000 people nationwide, and although treatment is available under the Pharmaceutical Benefits Scheme, only 2 per cent of Australians with hepatitis C accessed the drugs last year.

With so few people receiving treatment, the number of people with advanced liver disease from untreated hepatitis C jumped by 33 per cent in the past five years, from 35,900 cases in 2003 to 47,600 in 2007.

Government-commissioned research has shown that prisons play a significant role in controlling the level of hepatitis C in the community because of the high proportion of injecting drug users carrying the virus inside jail. Research has shown that 75 per cent of injecting drug users continue to inject in jail, usually with crude and blunt injecting equipment.

Ms McNeill said it was difficult to explain the low treatment rate among prisoners, but said logistical factors could be a problem because some inmates had to be moved to another prison to receive the treatment for six to 12 months.

Father Peter Norden, convener of the Victorian Criminal Justice Coalition and former member of an advisory committee on hepatitis C to the Howard government, said the figures reflected the "deep-seated punitive dimension" of prison life.

Father Norden, a former prison chaplain, said the failure to provide basic health care to such a highly infectious group of was at odds with the charter of human rights. He questioned whether private ownership of prisons contributed to the problem.

The director of the Centre for Population Health Research at the Burnet Institute in Melbourne, Associate Professor Margaret Hellard, said a lack of resources and logistical issues in the prison system contributed to the poor availability of treatment.

"We need to improve our overall management of prisoners," she said. "This includes them being diagnosed as having been exposed to the virus, testing if the virus is still active in their bloodstream and informing them of their options, which may or may not include treatment during their time in prison.

"This problem should be viewed in the context of problems with treatment and management of hepatitis C in the broader community."

A State Government spokeswoman said she was unable to comment on the figures.

<http://hepcvic.org.au>

Dec 29, 2008

Drug-injection facility still sparks debate in San Francisco

<http://www.insidebayarea.com>

By Philip Hoover

Oakland Tribune correspondent

San Francisco is about to create the first legal drug-injection facility in the country — a place where users could bring in drugs obtained on the street, get clean needles and shoot up in a medically supervised room.

A year ago, the San Francisco Public Health Department, the Alliance for Saving Lives and a consortium of community members gathered to discuss the idea of opening a legal injection facility.

San Francisco's Tenderloin district — home to many drug users, as well as families and children — has been identified by officials as the most likely location of the Safer Injection Facility. But residents are concerned about the impact of a state-sanctioned center for drug use in their neighborhood.

The resistance doesn't surprise Capt. Gary Jimenez of the Police Department's Tenderloin station.

"I do know that on the issue of a safer injection facility, many people in the community are saying, 'Good, but not in my neighborhood,'" he said.

While Jimenez concedes that the Tenderloin would be an ideal site because of its high rates of injection-drug use and lethal overdose, he would rather see the center elsewhere.

"But I think the folks in Pac Heights and Bay View would say 'No thank you,'" he said.

Some Tenderloin residents have suggested incorporating the facility into existing social service programs.

"Instead of creating an entirely separate institution, there already are a number of services that this can be rather smoothly implemented into," said Lauren Enteen, a manager for the Harm Reduction Coalition, a member of the Alliance for Saving Lives.

The Tenderloin district is home to some 3,500 children, some who are frequently exposed to drug use near their schools and playgrounds. According to Jimenez, the injection facility would alleviate that problem by providing a sanctuary for those who inject on the city's streets and alleys, as well as a safe place to dispose of syringes.

"None of us want to shoot out here in front of kids," said Adam Archie, of San Francisco, a homeless drug user. "If we had a place to shoot, then we'd also have a place to put our dirty needles, which is a problem out here."

Supporters point to the success of injection facilities that have operated in Europe and Australia for more than 20 years, starting with Switzerland in 1986, and most recently in Vancouver, British Columbia, where the Insite facility was established in September 2003.

"Studies in Vancouver show that people are more likely to engage in other services once they've used the injection facility," Enteen said. "We've seen less public injection, fewer fatal overdoses, less public disposal of syringes and more people trying to get clean. You just can't argue with Vancouver's findings."

The Canadian facility consists of three levels: the first floor is a safe injection center, the second a detoxification center, and the third a rehabilitation center. The idea is that clients will move up in the center, entering as drug users and eventually leaving clean.

According to figures presented at last year's symposium, hundreds of overdoses have occurred at the Insite facility yet resulted in no fatalities because medical staff were standing by. Additionally, users of the facilities aren't allowed to share needles, reducing the spread of hepatitis C and HIV.

The city of Oakland has funded the Casa Segura Needle Exchange program for 17 years, but hasn't discussed an injection facility.

"We'd probably wait to see what happens in San Francisco, and then there will be a precedent set," said Joy Rucker, executive director of Casa Segura. "Oakland just isn't as progressive as San Francisco in terms of looking at a public health model for injectors."

Dr. Paul Quick, a physician involved in the care of homeless people in San Francisco, said many of the city's homeless drug users suffer from underlying mental illnesses. For these individuals, the injection facility not only would address their addictions but also their mental health needs.

"When you have a facility that people can use safely, you stand on better moral ground as a

community to demand that people not use on the street." Quick said. "It's simply not acceptable for society to let addicts use on the street and die."

May hepatic granulomas be part of the histological spectrum of chronic hepatitis C?

<http://www.eurekalert.org>

While older large series of patients with hepatic granulomas have found sarcoidosis and tuberculosis to be the most common causes of hepatic granulomas, recent works have noted some patients with chronic hepatitis C and hepatic granulomas and no other obvious associations. Today, patients that undergo liver biopsy often have chronic hepatitis C that is being staged prior to possible anti viral therapy. The age of HIV and immunosuppression for organ transplants has also made opportunistic infections associated with hepatic granulomas more likely.

A research article to be published on November 7, 2008 in the *World Journal of Gastroenterology* addresses this question. The research team led by Ned Snyder from the University of Texas medical branch report a retrospective study of over 4 000 liver biopsies as well as a prospective study of 240 patients with chronic hepatitis C undergoing routine liver biopsies. They found that the most common association for hepatic granulomas was chronic hepatitis C. In the prospective study of patients with stable hepatitis C, almost 1% had hepatic granulomas.

In this paper, no reason for the association between granulomas and hepatitis C was found unless granuloma formation is part of the immune response to chronic hepatitis C. Hepatic granulomas have been associated with interferon therapy for hepatitis C and other disorders, but only one patient in the study had received interferon. Granulomas sometimes can develop in intravenous drug users from talc in the injection solution, but examination of the biopsies with polarized light revealed only one patient with crystalloid particles.

The authors concluded that granulomas are an uncommon part of the histologic spectrum of chronic hepatitis C. When granulomas are found in the liver of a patient with chronic hepatitis C, the clinician should be comfortable with the association after other pertinent diseases are excluded.

A reviewer felt this paper is a very good retrospective examination of characteristics associated with hepatogranulomas, with the added strength of the prospective surveillance.

Reference:

Snyder N, Martinez JG, Xiao SY. Chronic hepatitis C is a commonly associated with hepatic granulomas. *World J Gastroenterol* 2008; 14(41): 6366-6369
<http://www.wjgnet.com/1007-9327/14/6366.asp> Telephone: +1-409-7721501 Fax: +1-409-7724789

Fibrin glue deal talks stalled / Plaintiffs claiming substance caused hepatitis infections uncompensated

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

The Yomiuri Shimbun

Settlement talks have reached an impasse for plaintiffs involved in lawsuits against the government over claims they were infected with the hepatitis C virus after being administered fibrin glue during surgery.

The government has cited that a causal link is unclear between the glue, a compound of fibrinogen and other substances used as a surgical adhesive for stitches made in heart and other types of surgery, and the hepatitis infections.

Since the January enactment of a special measures law to provide compensation to patients, about 600 plaintiffs have reached a settlement with the government. The plaintiffs who received state compensation were infected with the virus after being administered with a fibrinogen blood product.

However, the vast majority of plaintiffs claiming they were infected by the virus after being administered fibrin glue have yet to be compensated.

So far, only four such plaintiffs have reached a settlement with the government, according to a national group of lawyers representing hepatitis C victims that were infected by the virus through tainted blood products.

This leaves about 160 plaintiffs who have been unable to claim what the government says are blanket relief measures.

A 27-year-old man from Kanagawa Prefecture was diagnosed with acute hepatitis after a heart operation when he was 5. His condition is now chronic.

For many years, he did not know what the source of his infection was, but in light of the many media reports on the issue of hepatitis caused by tainted blood products, he made an inquiry to the hospital that operated on him at the end of last year and learned that fibrin glue was used in his surgery.

He brought a case against the government in April, but no progress has been made toward reaching a settlement.

A doctor recommended that he undergo interferon treatment, which is known to be effective for hepatitis C sufferers. But treatments costs several tens of thousands of yen a month, and the man lacks the funds to pay for it.

"The glue may have saved my life, and I bear no grudge against the hospital," the man said. "But I can't think of anything else that could have caused the infection, and I want the government to compensate me soon."

Fibrin glue is believed to have been administered to about 79,000 people in the 1980s.

But the glue is applied to incisions and wounds and differs from fibrinogen, which is used as a hemostatic agent and administered by intravenous injection.

The government has said "the infection rate is unclear because [fibrin glue] is not injected directly into blood vessels."

Settlements have only been reached so far with individuals whose infection is clearly linked to the application of the glue.

"By March, we hope to collect scientific data and establish fixed criteria for settlements," a Health, Labor and Welfare Ministry spokesman said. "Should a clear causal link be found, we'll swiftly begin settlement procedures."

The lawyers group says it has confirmed cases of infection from the use of minute quantities of the glue, and on Friday submitted a written demand to five district courts at which lawsuits are in progress--those in Tokyo, Osaka, Nagoya, Fukuoka and Sendai.

"The glue's danger is clear," the demand states. "[The government] should reach settlements as quickly as possible."

Program helps ex-inmates reintegrate

<http://www.starbulletin.com>

By *Star-Bulletin* staff

The program, through the Hepatitis Support Network, offers health and economic services

The Hepatitis Support Network of Hawaii has established a program to help ex-offenders reintegrate into the community with social, health and economic services.

Andy Botts, director of the Prisoner Reintegration and Family Reunification program, will see relatives of ex-offenders and prisoners from 9 to 11 a.m. on Mondays and Thursdays at 1286 Queen Emma St.

The program started Dec. 18.

Botts became involved with the Hepatitis Support Network after learning he had hepatitis C when tested in prison.

He was treated and cured by Dr. Alan Tice, medical director of Infections Limited Hawaii.

A nonviolent drug offender, Botts had been in and out of institutions, including five years in a Thai prison, a release from the network said.

Botts will join with volunteers and faith-based and community organizations to help ex-offenders and their families.

"Costwise, a sensible approach to the management of nonviolent offenders would be better on

the outside of a prison instead of inside," Tice said.

He said treatment for infectious diseases such as hepatitis C "can change a person's perspective on life."

Free hepatitis screening can be obtained by calling 373-3488. Three sites in Honolulu offer treatment: Physician's Office Building III, Waikiki Health Center and the Kalihi-Palama Health Center, according to the network.

For more information or an appointment with Botts, call 942-4276.

Liver transplants from elderly donors are safe

www.reuters.com

YORK (Reuters Health) - Advanced donor age, per se, does not adversely affect the transplant recipient or the survival of the organ after liver transplantation, according to a report in the *Journal of the American College of Surgeons*.

Previous reports have indicated that the age of the donor -- older than 60 years - contributes to decreased organ and patient survival, as well as a poorer quality of life for the recipient, the authors explain. They hypothesized, however, "that proper selection of donors older than age 60 and even over age 70" can produce outcomes comparable to those obtained with younger donors.

Dr. William C. Chapman and colleagues from Washington University School of Medicine, St. Louis, Missouri, analyzed their experience with 741 adult-to-adult whole organ transplants -- 91 donors were 60 years or older and 650 were younger than 60 years.

There was no significant difference in the number of second transplants performed or signs that another transplant was going to be needed between patients who received organs from younger and older donors, the authors report.

Overall survival rates did not significantly differ between the two groups of patients, the researchers note. Five-year survival, for example, was 67.6 percent in the patients who received organs from older donors compared with 75.5 percent in those who received organs from younger donors.

Similarly, organ survival was not significantly different between recipients of organs from younger and older donors, even when the donors were separated into three age groups - younger than 60 years, 60 to 69 years and 70 years or older.

Time between organ removal and transplant was significantly shorter for organs from older donors than for organs from younger donors, the report indicates.

"Our analysis was not able to identify any significant disadvantage in graft or patient survival based on donor age," the authors noted.

Other donor risk factors, such as time from organ removal to transplant and variables associated

with the recipient are all "important to ensure optimal outcomes" of transplants from older donors, they add.

Overall, the investigators conclude that "older donors represent an important and safe expansion of the donor pool."

SOURCE: Journal of the American College of Surgeons, December 2008.

Dec 30, 2008

Miracle man' from Halifax survives three transplants

<http://www.patriotledger.com>

By Kyle Alspach

HALIFAX — Ken Ouellet had been in a hospital bed for 10 weeks, and he was nearly comatose. His doctor knew time was running out to find the Halifax man a new liver. "(The doctor) told me, 'You're going to die unless we can find you a transplant,'" Ouellet, 61, said.

Ouellet had been through this before – twice – and survived the third transplant last year after a liver was found.

In all, he has survived transplants of a kidney, pancreas and liver since 2003. And he's gained a nickname from his pastor and fellow parishioners at New Hope Chapel in Plymouth: "miracle man."

Ouellet, a former Marine sergeant who served in Vietnam, wears a thick mustache and has a full head of hair. Calmly stroking a pet cat on his lap, he shared his story of survival.

The problems started after a work accident in the early 1980s when Ouellet received a blood transfusion that was tainted with hepatitis C. His health was imperiled from then on: he became an insulin-dependent diabetic and needed regular dialysis.

Then his organs started failing.

"Even though I did everything I was supposed to, things got progressively worse," Ouellet said. "It was hell."

But he pushed ahead, with the support of his wife, Gillian. He underwent successful transplants of a kidney in 2003 and a pancreas in 2004.

The next year, his liver began to fail under renewed attack from hepatitis C. His health declined rapidly, forcing him to enter Beth Israel Deaconess Medical Center in Boston while he waited for a liver.

After 10 weeks there, Ouellet said it began to look like he could die any day. But an organ was found just in time, he said, and in July 2007 he survived his third transplant surgery.

Doctors told him he was the first triple-transplant survivor with hepatitis C at Beth Israel. His

mother-in-law, Grace Holmes of West Bridgewater, calls Ouellet a “walking miracle.”

The significance hasn’t been lost on others in his life, either.

“My pastor once stood me up in church and said, ‘Miracles do happen,’” Ouellet said.

Yet in the weeks after the liver transplant, Ouellet said, he had a nervous breakdown. He was on morphine, hallucinating and feeling overwhelmed by his emotions.

“I wanted to end it right there – I wanted to pull the plug, and say sayonara, I’m out of here,” he said.

But he didn’t, a fact he attributes to his family and his faith.

Ouellet had become a born-again Christian in 2002 in the midst of his declining health. After his breakdown, frequent prayer – and the prayers of his church and family – gave him the strength to pull through.

“Just being with the Lord through all this has been my salvation, I guess,” he said.

Gillian, his wife of nine years, has been at his side throughout.

“I feel like we’ve made it through to the other end,” she said.

Ouellet said that his immune system remains weak, but he feels the best he has in years.

He’s still unable to work – he used to be a cabinet-maker – but he doesn’t need his wife home full-time and can drive a car again.

Ouellet is now using some of his time to counsel others who are awaiting organ transplants at Beth Israel.

“I tell them, ‘If you do get your transplant, just keep your faith and do what the doctors tell you,’” he said. “I try to tell them there is light at the end of the tunnel, even though it’s really dark now.”

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Genotype Testing Is Crucial to Course of Therapy for Hepatitis C Patients

<http://www.aishealth.com>

By Angela Maas, Managing Editor, (amaas@aispub.com)

Reprinted from SPECIALTY PHARMACY NEWS, a monthly newsletter designed to help health plans, PBMs, providers and employers manage costs more aggressively and deliver biotech and injectables more effectively.

With hepatitis C patients, the length of treatment depends upon which of the six hepatitis C genotypes the person has. According to Beckie Fenrick, Pharm.D., director of clinical pharmacy at Blue Cross and Blue Shield of Florida, the treatment regimen for genotypes 2 and 3 is generally 24 weeks, while the regimen for 1, 4, 5 and 6 is 48 weeks. The most common genotypes in the U.S. are 1, 2 and 3.

Many health plans require physicians to provide the organization with the genotype information so they can be sure the patient is receiving the appropriate length of therapy. According to Enoch Strollo, vice president of sales and marketing for BioPlus Specialty Pharmacy, genotype testing costs typically between \$450 and \$600, and health plans typically cover this expense.

Some plans that spoke to SPN say they require genotype testing either before therapy begins or shortly thereafter.

According to Beverly Franklin-Thompson, Northeast regional pharmacy director for BlueCross BlueShield of Tennessee, BCBST allows patients to immediately begin treatment but then requires the physician to follow up with the patient's genotype. "This minimizes impediments to treatment initiation, allowing a patient to immediately fill the prescriptions for the hepatitis C medications," she says. After a physician notifies BCBST of the patient's genotype, "an approval for a specific duration of treatment is granted," she explains. "A nurse contacts the prescriber to assure that certain tests are being performed and to obtain the results of those tests so that the duration of treatment can be determined and authorization loaded. No prior authorization is required to begin therapy; however, to continue treatment beyond the first few months, clinical parameters such as genotyping must be obtained."

The Florida Blues plan requires physicians to determine patients' genotype so it can make sure patients undergo the appropriate length of therapy. The plan also has practitioners notify it of patients' viral loads at the 12-week mark. If there has been "an appropriate reduction, the approval for additional weeks occurs," Fenrick explains. CIGNA HealthCare also requires a follow-up lab test after the first 12 weeks of therapy, says Todd Cooperman, Pharm.D., director of specialty pharmacy clinical program development.

Mark Leeper, vice president of marketing and clinical program development for PrecisionRx Specialty Solutions, WellPoint, Inc.'s specialty pharmacy, says that when a plan does not require genotype testing, "we do highly encourage it." He explains that "a member's hepatitis C genotype will drive treatment and monitoring. Type 1 genotype is more difficult to treat and requires members to stay on the therapy longer. Also, changes in viral load are influenced by genotype. We conduct baseline information on viral load, and then repeat testing for all genotypes at four, 12 and 24 weeks. For Type 1, we continue testing at 36 weeks and 48 weeks. This schedule is important to allow physicians to adjust dosing to respond to the patient's viral load."

He says if those patients with genotype 1 "don't respond by week 12, they are unlikely to respond, and continuing with therapy is not productive."

Sara Deno, Pharm.D., a manager of clinical services for BioScrip, Inc., who also oversees the adherence and therapy optimization program BioScripCare for hepatitis C, says that plans can structure prior authorizations so that patient response is checked at various intervals.

A Local Hero's Story Inspires Another Hero!

<http://www.wtkr.com>

"He's a hero," Teresa Janik said. "It's all him."

When Teresa Janik heard the story of Smithfield Police Lt. Kurt Beach, who contracted Hepatitis C while trying to save a baby's life on the job 20 years ago, her heart immediately went out to him.

"Thank you for trying to save a baby and risking your life," Theresa told Newschannel 3.

Teresa wanted to help, so when she heard the Lt. needed a new liver the Newport News mother of two called to see if she was a match. Unfortunately, she wasn't, but doctors thought she could be for a 12-year-old little girl.

"When they told me they wanted me to test I just prayed and prayed every single day, let me match her," Theresa said.

Teresa's prayers were answered. On Monday, she'll give the little girl she's never met part of her liver.

"You're giving a part of your body to a stranger?" Newschannel 3 asked.

"Yeah," Teresa said. "She could be my family member."

Teresa has lost one sister to breast cancer and another is fighting the disease right now. She says for years she's watched strangers give platelets, blood, anything they could to possibly save their lives. So, she couldn't help but to try to save the little girl.

"This will cure her. If the liver takes and it grows with her she will no longer have a liver problem," Teresa said.

A Good Samaritan who set out to save Lt. Beach's life says she can't wait for her hero to hear his story inspired a miracle.

"I'm very excited for him to find out that his story has made this happen, because that's the only thing that has made this happen," Teresa said. "I would have never sought out liver donation, didn't know anything about it and if I could donate two parts of it, I would donate the other part to him."

Newschannel 3 called Lt. Beach and told him Teresa's story. He broke down on the phone. He said he was so thankful his story motivated someone to give the gift of life.

At this point, the Lt. doesn't have a donor himself, but his doctors are very hopeful. So many Newschannel 3 viewers volunteered to be tested doctors say they don't need any more possible matches for the Lt. right now.

They do need people like Teresa who are willing to help anyone. If you're interested in being a



Good Samaritan living liver donor visit

https://www.vcuhealth.org/transplant/transplant_liver_living/transplant_liver_living.htm.

Caring Ambassadors Program Releases "Hepatitis C Choices, 4th Edition"

<http://biz.yahoo.com>

VANCOUVER, WA--(MARKET WIRE)--Dec 30, 2008 -- The Caring Ambassadors Hepatitis C Program is pleased to announce the publication of the 4th edition of "Hepatitis C Choices," a comprehensive book that addresses all aspects of hepatitis C and its treatment. In accordance with its mission to provide state-of-the-art information, Caring Ambassadors has sought out the most recent advancements on the various aspects of the disease and included these updates in the newest edition.

"We are extremely excited about the new chapters in the 4th edition that were authored by nationally renowned experts," said Lorren Sandt, Hepatitis C Program Director. "We have added important new information on mental health, hepatitis C in women and children, immunological research, and a number of other important topics that affect the hepatitis C community."

In 2009, there will be as many fatalities due to complications associated with hepatitis C as there will be due to HIV/AIDS. "Hepatitis C Choices" is a resource for hepatitis C patients to use in order to optimize wellness and to avoid the damaging outcomes of hepatitis C that occur when infection is ignored. "Hepatitis C Choices, 4th Edition" is available at www.HepCChallenge.org. The book can be viewed or downloaded online free of charge, and hard copies of the book can also be ordered online.

About Hepatitis C

Hepatitis C is the most common chronic blood-borne viral illness in the United States. Chronic HCV ultimately leads to cirrhosis in 20% to 30% of those infected, with 10% of those progressing to liver failure or liver cancer for which liver transplantation is the only possible proven lifesaving measure available. Over the past decade, the incidence of liver cancer has increased greatly. There has been a 41% increase in new cases and a 35% increase in deaths. Hepatitis C can be cured in approximately 50% of the people who are eligible for treatment.

About the Caring Ambassadors Program

The CAP mission is to facilitate wellness for people living with long-term disease through state-of-the-art information and awareness building. CAP is a 501(c)(3) nonprofit public charity, founded in 2001, and headquartered in Vancouver, Washington. The Caring Ambassadors Hepatitis C Program is devoted exclusively to meeting the needs of the hepatitis C community and committed to improving the lives of people living with hepatitis C.

Source: Caring Ambassadors Program

Sorafenib Has Ushered in an Era of Hope for Liver Cancer Patients

www.medscape.com

Zosia Chustecka

December 22, 2008 —Although there has been some hype associated with it, sorafenib (Nexavar, Onyx/Bayer) has "ushered in an era of hope for patients with hepatocellular carcinoma," declares an editorial in the December 20 issue of the *Journal of Clinical Oncology*.

This is a lethal and invasive cancer, and until sorafenib, no systemic treatment had been shown to confer a survival advantage in a randomized clinical trial, write the editorialists, Robin Kelley, MD, and Alan Venook, MD, from the University of California, San Francisco. "The flurry of activity surrounding sorafenib is an exciting development," they comment.

The study showing that sorafenib prolonged survival compared with placebo in advanced liver cancer was first reported at the American Society of Clinical Oncology (ASCO) meeting in June 2007. On the basis of these results, the drug was approved in both Europe and the United States a few months later. And at the end of 2007, this trial was listed as one of the major clinical advances in cancer in 2007 in the ASCO annual review.

Pivotal Trial Now Published

The full report of this trial, Sorafenib Hepatocellular Carcinoma Assessment Randomized Protocol (SHARP), was recently published (Llovet JM et al. *N Engl J Med* 2008;359:378-390). Conducted in 602 patients, it showed that sorafenib prolonged overall survival to 10.7 months, vs 7.9 months on placebo (hazard ratio, 0.69; $P < .001$).

"This study offers the first hope for life prolongation for the more 600,000 patients who die each year from hepatocellular carcinoma worldwide," Drs. Kelley and Venook comment. But they add: "With the first hope of an active therapy in a grim disease, there is a natural tendency toward expansiveness — the hype." They say that clinicians need to question whether the patients who took part in the trial are similar to the patients they see in their office and how far the results can be generalized.

Differences in Viral Hepatitides

There are several key differences between the patients in the SHARP trial and the majority of patients with hepatocellular carcinoma, the editorialists point out. Foremost among them is the proportion of patients with viral hepatitides. About half of the trial participants had a viral cause of the disease, hepatitis C in approximately 30% and hepatitis B in another 20%. In contrast, more than 70% of patients with hepatocellular carcinoma in the United States and Western Europe test positive for hepatitis C virus (HCV), and worldwide, hepatitis B (HBV) infection accounts for 60% to 80% of liver-cancer cases and ranks second only to tobacco as a human carcinogen.

Recently, sophisticated genetic analyses of liver-cancer tissue have detected underlying differences between HCV- and HBV-associated liver cancers, the editorialists point out, and they speculate that these and liver cancers of other etiologies may turn out to have different natural histories and different responses to targeted therapies.

Corroborating but Different Results from Asian Trial

Corroborating but different results have since been reported from an Asian trial, in which more than 70% of the 226 patients were positive for hepatitis B, the editorialists comment. Results from that trial were reported at this year's ASCO meeting and were welcomed as providing confirmation that sorafenib is effective also in that patient population. The full report of that trial, led by Ann-Lii Cheng, MD, from the National Taiwan University Hospital, in Taipei, has just been published (Cheng AL et al. *Lancet Oncol*. Published online December 16, 2008).

This Asian trial also showed a significantly longer survival in patients on sorafenib, 6.2 months, vs 4.1 months on placebo (hazard ratio, 0.67; $P = .0155$). However, although this benefit is of the same relative magnitude as was seen in the SHARP trial, the patients in both cohorts of the Asian trial did appreciably worse than the patients in the SHARP trial, the editorialists point out. The Asian patients had poorer performance status, more prior therapies, and more severe liver disease, but "it is unclear what factors account for the differential outcomes," they write.

Differences in Underlying Liver Dysfunction

Another important point for the clinician to note is that, in contrast with most patients with hepatocellular carcinoma, the majority of participants in the SHARP trial had a limited extent of underlying liver dysfunction. The editorialists point out that 97% of the study population was classified as Child-Pugh class A (CPA) cirrhosis.

Thus, the SHARP trial, by definition, did not explore safety or efficacy of the drug in patients with greater degrees of liver compromise, but 2 smaller studies have suggested that sorafenib may have less clinical benefit and significant toxicity in such patients, they point out.

The Food and Drug Administration (FDA) approval for sorafenib applies to any patient with hepatocellular carcinoma, but the National Comprehensive Cancer Network (NCCN) practice guidelines point out that the data so far are inadequate to define dosing or safety in patients with CPB or worse liver function, and they also advise extreme caution in patients with elevated bilirubin. "As a cancer drug with an FDA label more permissive than the algorithm of the NCCN, sorafenib is an exception to the rule," the editorialists comment.

Sorafenib "Offers Real Hope"

"In summary, the SHARP results can at this point be applied to a minority of patients with advanced hepatocellular carcinoma," the editorialists conclude. "Nonetheless, sorafenib offers real hope of efficacious treatment for patients with advanced hepatocellular carcinoma and preserved liver function."

Further trials are planned, they add, and data from the soon-to-be-launched registry Global Investigation of Therapeutic Decisions in Hepatocellular Carcinoma and of its Treatment with Sorafenib may provide a clearer profile on risk and benefit in patients treated outside the clinical-trial setting.

In addition, combinations and new products are being investigated. The combination of sorafenib plus doxorubicin is being studied in an ongoing trial, while another plans to test the combination of sorafenib with erlotinib (Tarceva, Roche), with the comparator in both cases being sorafenib monotherapy. In addition, sunitinib (Sutent, Pfizer) has also demonstrated modest activity in liver cancer, prompting Pfizer to support a head-to-head comparator trial of sunitinib against

sorafenib. "A new era of research in liver cancer has dawned," Drs. Kelley and Venook proclaim.

"The SHARP trial is pivotal in the systemic treatment of hepatocellular carcinoma because it puts an end to the time of no belief in therapy for patients with advanced disease," says another editorial. "It has defined a standard that other new therapies have to match with or have to be added onto," editorialist Peter Galle, MD, from the University of Mainz, in Germany, writes in the November issue of the *Journal of Hepatology*.

We have won the battle but not the war

However, Dr. Galle also adds some words of caution and points out that this is just the beginning of systemic treatment of advanced hepatocellular carcinoma. "Survival improvement of 3 months is great — but the problem is far from being solved." Further options include teaming sorafenib with other drugs and maybe using it after resection or ablation. "We have won the battle but not the war," he writes.

Dr. Kelley reports no conflicts of interest. Dr. Venook reports receiving research funding from Amgen, Genentech, Novartis, Pfizer, GlaxoSmithKline, and Bristol-Myers Squibb. Dr. Galle reports having received lecture and consultancy fees from Bayer.

J Clin Oncol. 2008;36:5845-5848.

J Hepatol. 2008;49:871-878. Abstract

FDA approves new HIV, hepatitis screen

<http://www.upi.com>

PLEASANTON, Calif., Dec. 30 (UPI) -- The U.S. government Tuesday approved a nucleic acid test that screens for less common forms of HIV that recently have appeared in the United States.

The U.S. Food & Drug Administration approved the test from the Swiss firm Roche Diagnostics to screen donated blood for HIV-1 Group M RNA, hepatitis C RNA and hepatitis B DNA.

The test, called the **cobas TaqScreen MPX Test** for use on the cobas s 201 system, is a qualitative test for human plasma. The test, which is not intended for use as an aid in diagnosis, is designed to further increase the safety of blood supplies by identifying infections earlier than traditional serology tests -- identification of antibodies in the blood, statement from the drug company said.

"Roche is committed to meeting the needs of blood centers with tests and systems that ensure the highest blood safety," Daniel O'Day, head of Roche Molecular Diagnostics, the business area of Roche Diagnostics that developed the test, said in a statement.

"Our multiplex test has been widely adopted and has demonstrated excellent performance in blood centers worldwide."

Poorly trained health workers risk exposure to hepatitis

<http://english.vietnamnet.vn>

VietNamNet Bridge – Health workers in the country are at serious risk of contracting the hepatitis B virus due to exposure to blood and body fluids and lack of knowledge on safety measures.

Among the 35mil healthcare workers worldwide, about 3mil experience percutaneous exposures to bloodborne pathogens each year.

A seminar focusing on hepatitis B and liver cancer prevention in HCM City this week highlighted the problem for health workers.

About 17.6 per cent of them may be exposed to the hepatitis B virus, the disease that can cause a host of effects including possible complications of liver cirrhosis and liver cancer, warns Doctor Huynh Tan Tien, director of Labour Health and Environmental Protection Centre.

Seminar participants learned about factors that could cause skin injuries allowing the transmission of the virus which include hypodermic injection, a piece of glass, a stitch, an injection needle and taking blood samples.

The health ministry has recognised hepatitis B disease as a possible occupational infection along with tuberculosis and HIV/ AIDS.

Health-workers are exposed to blood and other body fluids in their work, so they are at increased risk of infection with bloodborne viruses including hepatitis B virus (HBV) and hepatitis C virus (HCV).

The hepatitis virus could live a long time in a dried blood stain, so the infectious ability of this virus is 50-100 times higher than HIV, warned the health expert.

Tran Van Thao, Deputy director of HCM City's Children Hospital 2, said the medical institute has co-ordinated with the Labour Health and Environmental Protection Centre to administer hepatitis B vaccinations to the hospital's health workers.

According to the World Health Organisation (WHO), among the 35 million healthcare workers worldwide, about 3 million experience percutaneous exposures to bloodborne pathogens each year, two million of those to Hepatitis B, 0.9 million to Hepatitis C, and 170,000 to HIV.

WHO suggests most blood exposures in health settings are preventable. Protective measures include immunisation against hepatitis B, provision of personal protection and the management of exposures.

Elimination of unnecessary blood draws and injections also minimises the potential for exposure.

In Viet Nam, according to Doctor Nguyen Chan Hung, director of HCM City's Tumour Association, liver cancer (a complication of hepatitis B) among males ranks as the third most contracted cancer, after lung cancer and stomach cancer.

The number of people infected by hepatitis B accounts for from 10 to 15 percent of the country's population, according to the Ministry of Health.

(Source: Viet Nam News)

A rigorous method for liver biopsy

<http://www.eurekalert.org>

Liver biopsy is still considered the gold standard for grading, staging and "stad-ging" the chronic liver disease. In addition, it remains a primary source for acquiring new knowledge on the liver pathology. Demand for precise evaluations of the fibrosis and inflammatory tissue detectable in liver biopsy samples has been fuelled by the need to understand the closest-to-real effects of new antiviral molecules on the lesions characterising the histological patterns of chronic viral, toxic, metabolic and autoimmune diseases. The current scoring systems do not quantify these lesions, but only describe subjective classes of severity labelled with ordinal numbers, and the available automated methods based on observer-computer interactions do not abolish observer subjectivity or use an inadequate measurement unit, and also take too long to analyse entire histological sections.

A research article to be published on December 28, 2008 in the *World Journal of Gastroenterology* addresses this question. The research team led by Nicola Dioguardi from Italy described a quantitative analysis method of liver biopsy sections with a machine called "Metriser" which, at a speed of 0.1 mm²/s, automatically measures the residual hepatocyte mass (including hepatocytes vacuolisation), inflammation, fibrosis and the loss of liver tissue tectonics.

In the absence of any other means of obtaining correct reproducible information concerning the status of liver tissue, the authors explored the possibility of constructing the first totally computer-aided and strictly objective method of rigorously, rapidly and easily obtaining metrical measurements of liver lesions directly from bioptic specimens. The method provides: (1) the metrical extension in two-dimensions of the residual hepatocellular set including the area of vacuoles pertinent to abnormal lipid accumulation; (2) the geometric measure of the inflammation basin, distinguishing intra-basin space and extra-basin dispersed parenchymal leukocytes; (3) the magnitude of collagen islets, which were considered truncated fractals and classified into three classes of magnitude; and (4) the Tectonic Index that quantifies alterations (disorders) in the organization of liver tissue.

This study not only introduced a new kind of liver biopsy measurement but also described a histological picture in verbal and repeatable terms.

Reference:

Dioguardi N, Grizzi F, Fiamengo B, Russo C. Metrically measuring liver biopsy: A chronic hepatitis B and C computeraided morphologic description. *World J Gastroenterol* 2008; 14(48): 7335-7344 <http://www.wjgnet.com/1007-9327/14/7335.asp>

American Social Health Association Announces New Hepatitis Education Website Available

<http://carolinanewswire.com>

RESEARCH TRIANGLE PARK, N.C. -- The American Social Health Association (ASHA) is very pleased to announce the launch of an online Hepatitis A, Hepatitis B, and Hepatitis C Education Website for Men Who Have Sex with Men (MSM). The Website was funded by and developed in collaboration with the Centers for Disease Control and Prevention (CDC).

Hepatitis is a preventable disease caused by a virus that damages the liver. It is transmitted from one person to another in different ways depending on the type of hepatitis. In some cases it causes acute or short-term infections while in other instances it causes chronic or long-term infections. While people from any background may be at risk for hepatitis, the disease disproportionately impacts MSM.

This new Website, which was developed with extensive feedback from MSM, offers visitors comprehensive information regarding transmission, prevention, and treatment of hepatitis A, B, and C. In addition to boosting awareness among the MSM online community about the risk factors for hepatitis, this resource seeks to increase intentions among this population to engage in safer sex practices and to receive hepatitis A and hepatitis B vaccinations.

Visit the Website at www.ashastd.org .

The American Social Health Association is a trusted, non-profit organization that has advocated on behalf of patients to help improve public health outcomes since 1914. We are America's authority for sexually transmitted disease information

Endemic Hepatitis E Not Confined to Tropics

www.reuters.com

By Will Boggs, MD

NEW YORK (Reuters Health) Dec 31 - Hepatitis E virus (HEV) infection is endemic in Germany, where it probably exists as a food-borne zoonosis, according to a report in the December 15th issue of *The Journal of Infectious Diseases*.

In fact, "HEV seems to be endemic in most industrialized countries and is not restricted to tropical or subtropical regions only," Dr. Ole Wichmann from Robert Koch Institute, Berlin, told Reuters Health. "Physicians in the industrialized countries need to consider hepatitis E as a differential diagnosis in patients with acute liver disease even in the absence of a recent travel history."

Dr. Wichmann and colleagues evaluated epidemiological and molecular characteristics of both travel-associated and autochthonous HEV infections in Germany.

Among the 66 cases analyzed, 45 (68%) had autochthonous HEV infection and 21 (32%) had travel-associated HEV infection, the authors report. The majority of patients in both groups were male.

Symptoms did not differ between cases with travel-related or autochthonous infections, the researchers note.

Consumption of raw or undercooked beef, wild-boar meat, and offal was significantly associated with autochthonous HEV infection, the report indicates, while risk factors for travel-related infection included eating fresh salad, consuming drinks with ice cubes, and drinking tap water.

HEV infection was inversely associated with pet ownership, the investigators say.

"There are two research questions of interest for us," Dr. Wichmann said. "First, it would be important to investigate these meat products (e.g., sold in grocery stores) in order to assess how often they are contaminated with HEV. Second, further studies are needed to identify other routes of HEV transmissions than those identified in our study to explain infections that have not been caused by the consumption of offal or wild boar meat."

Although this study provides further evidence for transmission of HEV as a zoonosis, "neither this study nor previous studies have presented good evidence to explain autochthonous hepatitis E among individuals in industrialized countries who have not reported consumption of undercooked or raw meats or exposure to HEV-reservoir animals," write Dr. Mark H. Kuniholm and Dr. Kenrad E. Nelson from Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, in a related editorial.

"Continued monitoring and evaluation of HEV infections globally is an important public health priority," the editorial concludes.

J Infect Dis 2008;198:1732-1741,1727-1728.