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HCV Advocate

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NIH Launches New Study on African Americans and Hepatitis C

By Alan Franciscus
Editor-in-Chief

African Americans have a higher rate of HCV infection than any other population in the United States. This group is also more prone to chronic HCV infection, have lower treatment response rates to HCV medications, and have a marked difference in HCV disease progression.

Yet the reasons for these differences are unknown, because African Americans have largely been underrepresented in the majority of HCV clinical trials conducted to date.

Now, the National Institutes of Health (NIH) has started enrollment in a large, national, multi-center study that will, hopefully, shed some light on the reason for these differences.

HCV Infection among African Americans

African Americans are the group most likely to be infected with HCV in this country. Antibodies against HCV are almost twice as common in African Americans (3.2%) compared with whites (1.8%), and African Americans have a lower rate of natural HCV viral clearance than whites (91% and 68% respectively), making it more likely that they will develop chronic infection.

It is not known why African Americans have higher rates of HCV infection, but there is speculation that African Americans are at greater risk for contracting HCV through occupational exposure to infected blood (more African Americans are employed as health-care professionals), blood transfusions (required to treat sickle cell anemia, which mostly affects blacks), and other risk factors.

Another possible reason for the higher rate of

HCV is the lack of education or misinformation about hepatitis C within the African American community, which hinders prevention measures.

Genotype

Almost all African Americans with HCV are infected with genotype 1 (91%, compared with 67% among whites). This has important implications for anti-HCV treatment response, since genotype 1 responds less favorably to therapy.

Natural History

The natural history of HCV infection among African Americans is also unclear, because African Americans have not been included in many prospective trials (clinical trials in which participants are selected and their progression is followed over time).

However, one retrospective study (a study based on medical records, looking backward in time at events that happened in the past) conducted by the University of Illinois Medical Center may shed some light on disease progression in this population.

The researchers found that the rate of disease

See African Americans on page 6

HealthWise columnist Lucinda Porter, RN, is on vacation this month. She'll be back in November.

In This Issue:

Fatigue & HCV.....page 2
HCV & Dental Care.....page 3
Normal ALTs & HCV.....page 4

Fatigue: Most Widely Reported Symptom of Hep C

By Ian Campsall and C.D. Mazoff

Fatigue is the most widely reported and documented symptom of hepatitis C; so much so that it is most often the sudden onset of fatigue that prompts many people to seek medical advice allowing their condition to be diagnosed.

However, despite this fact, the debate over the exact nature of the relationship between fatigue and Hep C is ongoing

This is not surprising considering the difficulty inherent in attempting to establish a definition of something that is entirely relative in its affect on an individual patient, while still retaining sufficient scope in that definition so that it can be applied to the majority of Hep C patients. Fatigue is relative in that, as a symptom, it presents itself mainly as an inability to participate in activities that were previously a central part of the patient's life.

This means, therefore, that fatigue is closely linked to the individual patient's established lifestyle, and the degree to which it is affected. For example, the triathlete finds herself unable to compete, and the waiter finds that he can no longer cope with the stress of the job.

The difficulty for researchers lies in creating a scale to measure fatigue that can meaningfully compare its impact on a large sample of people with different medical histories, levels of physical fitness, and lifestyles. As the number of people infected with Hep C are identified worldwide, this difficulty becomes increasingly complex.

For the person living with Hep C this complexity has a much more immediate effect on his or her life. The person finds himself or herself in a situation in which access to treatment and benefits are dependant upon his or her ability to describe a symptom which may or may not be related to Hep C, and cannot be fully scientifically calculated.

Furthermore, the term "fatigue" itself is somewhat misleading, or, at least ambiguous enough to cause confusion. To the non-Hep C community "fatigue" suggests a general tiredness similar to what you could expect at the end of a busy workweek.

However, the levels of fatigue that some Hep C

patients are facing are so extreme that they are unable to function on a day-to-day basis. The term identifies the general sensation, but does nothing to express the magnitude. Instead, Hep C patients are forced to use a word that denotes the common experience of sleepiness to try to describe a debilitating set of symptoms.

Both Hep C patients and persons suffering from Chronic Fatigue Syndrome (CFS) have, to some degree, been stigmatized by the misleading name that their condition or symptom has been given. The word "fatigue" implies exhaustion, but fails to convey the debilitating effects that constant exhaustion has on a patient over time. A recent American study employing one hundred medical students found that if the name given to Chronic Fatigue Syndrome were changed, patients were likely to be considered more disabled and receive better care.

CFS sufferers are not the only group to have initially had their illness dismissed as something less than an actual diagnosable disease or condition by institutionalized medicine. Thirty years ago patients with Multiple Sclerosis were often labeled as having "hysterical paralysis" rather than a serious debilitating disease. It was only through a combination of advocacy and scientific research that MS came to be recognized as the debilitating disorder that we now know it to be.

Currently, CF and Hep C sufferers are still working to establish sufficient recognition and knowledge about their conditions so that they can have access to affordable treatment, and a level of benefits which allows them to live with dignity.

In some cases physicians accept a patient's description of fatigue without question; in other cases, they are less forthcoming. Some people have had their claims questioned; others have been called lazy, or have been told that they are mentally ill rather than physically ill.

If the person is newly diagnosed and still attempting to come to an understanding of what kind of impact hepatitis C will have on his or her life, statements such as these serve only to increase their fear and confusion. The patient turns to the physician as someone who can interpret and explain the

See Fatigue on page 8

Hepatitis C and the Importance of Dental Care

By Alan Franciscus
Editor-in-Chief

Poor dental health is a rising problem among people living with hepatitis C. Hepatitis C is associated with a wide range of dental problems ranging from dry mouth, tooth decay, gum infections, tooth sensitivity and mouth infections which can dramatically affect one's quality of life.

The majority of patients with hepatitis C experience periods of having a dry mouth. The degree of dry mouth can also be made worse with medications that many patients with hepatitis C are taking including, but not limited to, anti-depressants and interferon. Saliva plays a key role in lubricating the mouth and is important in speaking, tasting and chewing the food that we eat. Saliva can also prevent viruses, fungus and bacteria from causing infections in our mouths that can lead to tooth decay and gum disease.

A dry mouth in of itself can be frustrating and can be improved by frequently sipping water, chewing sugarless gum that will stimulate the salivary glands in your mouth to release saliva or by using a saliva substitute which can be purchased in your local pharmacy. As a result of dry mouth and lack of saliva for protection, patients with hepatitis C need to be concerned about tooth decay.

Tooth decay in the early stages is reversible so regular dental check-ups are important especially while on HCV medications. Other things that you can do to prevent tooth decay is to include good oral hygiene, using a soft toothbrush and fluoride toothpaste. Also reduce your carbohydrate (sugar) consumption, cut back on your intake of sweetened foods and beverages high in sugar. Again, chewing sugarless gum is good as it helps with saliva production and can also neutralize the acid that causes the tooth decay.

The first sign of a gum infection is most likely to be bleeding from the gum margin usually as a result of brushing your teeth, which can increase the risk for transmission. Other signs which would indicate more advanced gum infection include swelling and redness of the gums, receding gums, loose teeth, a bad taste or halitosis (bad breath). The main cause of gum infection is plaque which is a colorless sticky film of bacteria that forms on the teeth, produces toxins and

causes inflammation.

Patients with hepatitis C who are taking interferon therapy or those with cirrhosis have a much lower resistance to gum infection than others. In addition, hepatitis C patients who smoke worsen this gum condition. Gum infection can be reduced with appropriate thorough tooth brushing with a soft toothbrush angled at 45 degrees to the gum margin, as well as through dental floss use. Dental floss should be passed gently between the teeth and rubbed up and down to the gum margin.

People with hepatitis C will sometimes complain of having sensitive teeth. If enamel is lost from the surface of the tooth or if the root surface is exposed this can cause sharp pain when the tooth is exposed to hot or cold extremes. Causes of sensitive teeth include poor brushing, erosive foods (including lemons, grapefruit, vinegar and soda) frequent vomiting or gastric reflux and grinding of teeth most commonly during sleep. There are desensitizing toothpastes on the market as well as gum guards for people who are prone to grinding their teeth.

As discussed earlier, patients with hepatitis C often experience dry mouth due to lack of saliva production. This lack of saliva production can also cause mouth infections as bacteria, viruses and fungus can flourish, resulting in patients with hepatitis C being more prone to mouth ulcers and thrush. Thrush is an overgrowth of a yeast (fungus) called "candida." The medical name for thrush is candidiasis. In the mouth, thrush looks like creamy white patches or small red spots on the tongue, roof of the mouth (also called the hard palate), gums or throat. Crusting on the corners of the mouth is also a symptom of thrush.

Thrush can make it difficult or painful to swallow and can cause chest pain. It can cause nausea and make your food taste different. This is further exacerbated when on interferon therapy. Daily intake of natural yogurt may help with thrush, but if that is not effective, thrush can be resolved by using a medicine called nystatin.

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HCV in People with Normal ALT

By Liz Highleyman
Contributing Editor

Traditionally, most doctors believed that HCV-infected people with normal levels of alanine aminotransferase (ALT) were at minimal risk of developing progressive liver disease, and therefore typically recommended that such patients should not receive treatment.

But recent research has shown that some people with persistently normal ALT levels—an estimated 20-30 percent—do indeed develop fibrosis and cirrhosis. With recent improvements in HCV treatment, these patients are now considered candidates for therapy.

What is ALT?

ALT (formerly known as SGPT) is one of the biochemical markers used as a liver function test. ALT is an enzyme produced by liver cells (hepatocytes). When liver cells are damaged or die, their cell membranes break down, releasing ALT into the bloodstream. ALT levels typically increase as a result of liver inflammation due to a variety of causes, including viral hepatitis, heavy alcohol use, or drug toxicity. An elevated ALT level—which may be detected during a routine medical check-up—is often the first sign that a person has a liver problem. ALT is considered the most specific biochemical marker for liver damage; other liver function tests such as AST, alkaline phosphatase, and GGT often signal other problems such as a heart attack or obstructed bile flow.

Although ranges vary considerably, the upper limit of normal ALT is usually said to be about 40-50 for

men and about 30-40 for women. The hormone estrogen may contribute to lower ALT levels in women. Some experts believe that these so-called “normal” ranges are, in fact, too high, because they are averages that include people with liver disease.

According to recent calculations by Dr. Daniele Prati and colleagues from Milan, Italy, a more appropriate upper limit of normal ALT may be about 30 for men and about 20 for women. Acute hepatitis or hepatotoxicity can cause ALT to increase to as much as fifty times the normal level. More mild elevations (2-4 times normal) may signal possible damage to the liver.

A single elevated ALT measurement is not very useful—in fact, single normal ALT readings are common in people with chronic HCV—and trends over time are more informative.

After initial infection with HCV, ALT levels typically rise within 4-12 weeks, but usually decline after several more weeks as the acute phase of hepatitis C ends. Studies show that some 30 percent of people with chronic hepatitis C have persistently normal ALT levels, and another 40 percent have ALT levels less than two times the upper limit of normal.

New Guidelines: Patients with Normal ALT

The 1997 National Institutes of Health (NIH) consensus statement on HCV treatment did not recommend therapy for patients with normal ALT levels. Most experts thought that liver disease progression rarely occurred in the absence of elevated liver

See ALTs on page 7

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Hepatitis C Support Project - A Tides Center Project

Patient Assistance Programs - Part One

Schering-Plough's Commitment to Care

By Liz Highleyman
Contributing Editor

Access to prescription drugs is one of the most pressing needs of people with chronic illness, and has become a major political issue as well.

Many people are finding it increasingly difficult to find health insurance that will cover expensive drugs for long-term and preexisting conditions.

Fortunately, many pharmaceutical companies have developed patient assistance programs to help people access necessary medications. Patient assistance programs help many people access various reimbursement programs or insurance benefits that they were not aware of or did not know they were eligible for.

Reimbursement specialists may help provide assistance with insurance verification, preauthorization, denied appeals, and referrals to state and local assistance programs.

Needless to say, drug companies are motivated to help patients explore every possible avenue for drug reimbursement. In cases in which no such alternatives are available, companies may provide medications themselves at low cost or for free.

Schering-Plough's Commitment to Care program is

designed to help low-income people access life-saving drugs at no cost. Through Commitment to Care (for people with hepatitis and cancer) and another patient assistance program for people with other illnesses, Schering-Plough helped some 40,000 patients access medications in 2001.

That year Commitment to Care—which covers Schering-Plough's Peg-Intron (pegylated interferon), Intron A (standard interferon), Rebetol (ribavirin), and Rebetrone (standard interferon plus ribavirin combination kit)—helped 10,000 patients locate reimbursement assistance and provided drugs for free to 16,000 more.

While patients need not be indigent to qualify for assistance through the Commitment to Care program, various financial and insurance criteria apply. Eligibility is determined on a case-by-case basis. The program is telephone based, and requires less paperwork than some other patient assistance programs.

To register for the Commitment to Care program, patients can call toll free 800-521-7157.

Part 2 will feature information on InterMune's patient assistance program for Infergen.

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African Americans

Continued from page 1

progression to liver cirrhosis in African Americans was lower than the rate for whites.

After the second decade of HCV infection, 0% of African Americans in the study progressed to cirrhosis compared with 26% of whites; in the third decade the respective rates were 18% versus 31%, and the fourth decade rates were 33% versus 47%.

Even though similar data were reported by researchers from the University of Southern California, it is difficult to draw accurate conclusions since both studies were retrospective, which could bias the results. However, even allowing for potential bias, these findings do suggest that African Americans may progress to cirrhosis more slowly than whites.

HCV Treatment Response

It is remarkable how much lower response rates to interferon-based therapies have been among African Americans compared with whites. In several studies the sustained response rate among African Americans was one-third to one-half lower than the response rate observed among whites. In the recent multinational studies of pegylated interferon plus ribavirin, African Americans represented less than 5% of the patients enrolled, and their response rates were again less than average—even after controlling for genotype.

Due to the low numbers of African Americans in these studies, however, an accurate estimate of response rate cannot be made.

Virahep-C Trial

In 2000 the Division of Digestive Diseases and Nutrition of the National Institute of Diabetes and Digestive and Kidney Diseases published a request for application (RFA) to conduct a multicenter clinical trial of pegylated interferon plus ribavirin therapy in a cohort of patients that would include an adequate number of African Americans to establish an accurate estimation of the response rate in this group.

The request also initiates basic research studies looking at the reasons for non-response and antiviral resistance among African Americans with hepatitis C. The RFA “Study of Viral Resistance to

Antiviral Therapy of Chronic Hepatitis C (Virahep-C)” was published in September 2000; applications were received in December and reviewed by a special study section in March 2001.

In July 2001 eight clinical centers and a data coordinating center received awards. In addition, four ancillary studies were funded to focus on analyses of the basis for antiviral resistance.

The participants are shown below:

Clinical Centers:

Beth Israel Deaconess Medical Center (Dr. Nezam Afdhal)

New York-Presbyterian Medical Center (Drs. Robert Brown and Lorna Dove)

University of Michigan (Drs. Hari Conjeevaram and Robert Fontana)

University of North Carolina (Drs. Michael Fried and Scott Smith)

University of Maryland (Dr. Charles Howell)

University of Miami (Drs. Lennox Jeffers and Shawn Baker)

University of California at San Francisco (Dr. Norah Terrault)

University of Illinois at Chicago (Drs. Thelma Wiley and Thomas Layden)

Ancillary Studies:

Cedar-Sinai Medical Center, Los Angeles: Host genetics (Dr. Huiying)

Indiana University: Interferon signaling (Dr. Milton Taylor)

St. Louis University: Virology (Dr. John Travis)

Portland Veterans Administration Medical Center: Immunology (Dr. Hugo Rosen)

Data Coordinating Center:

University of Pittsburg, School of Public Health (Dr. Steven Belle)

NIH Staff: Dr. Patricia Robuck, Project Officer
Dr. David Kleiner, Pathologist

The protocol and manual of operations for Virahep-C have now been completed.

The main study will enroll 400 adult patients with chronic HCV of genotype 1 who have never been treated with interferon. Of the total, 200 patients will be African American and 200 will be white. All will

See African Americans on page 7

ALTs

Continued from page 4

enzymes, and thus assumed that people with persistently normal ALT levels were unlikely to benefit from treatment. Indeed, studies showed that people with normal ALT levels—like those with elevated levels—had low response rates using interferon monotherapy, which was then standard treatment.

And some patients who had normal ALT before therapy developed elevated levels when they started interferon. According to the 1997 statement, “Current studies suggest that treatment of patients with persistently normal ALT is not beneficial and may actually induce liver enzyme abnormalities. Therefore, these patients should not receive therapy outside placebo-controlled trials.”

The NIH held a consensus conference in June 2002 to revisit the 1997 recommendations. Dr. Bruce Bacon of St Louis University reviewed the state of medical knowledge about HCV patients with normal ALT. Most studies show that people with persistently normal ALT levels have mild liver disease and experience a rate of disease progression about one-half that seen in people with elevated ALT.

But ALT levels are not well correlated with long-term liver disease progression; elevated ALT is a reflection of liver inflammation, not fibrosis. Some people experience serious liver damage with normal ALT levels, while others have elevated ALT but minimal or no liver disease progression. Women and people of African descent seem especially likely to have normal ALT levels despite extensive liver damage.

An estimated 25 percent of patients with normal ALT have advanced liver tissue damage, and the only sure way to detect such damage is with a liver biopsy. Studies indicate that only about 25-40 percent of people with normal ALT have completely normal liver histology as determined by biopsy. In addition, most research indicates that people with normal ALT levels have the same distribution of HCV genotypes and similar HCV RNA viral loads as people with elevated ALT.

The growing recognition that as many as one-third of patients with chronic HCV may develop progressive liver damage despite persistently normal ALT levels is reflected in the new 2002 NIH consensus guidelines released this past August. The revised

guidelines state that, “All patients with chronic hepatitis C are potential candidates for antiviral therapy,” and should be evaluated on a case-by-case basis. Treatment is recommended for patients with an increased risk of developing cirrhosis—and this group includes some people with persistently normal ALT levels.

Is ALT Useless?

As research accumulates showing that ALT has little value as an indicator of cumulative liver damage, it is clearer than ever that liver biopsy is the “gold standard” for determining the extent of liver tissue damage, hepatocyte death, and fibrosis. But this does not mean that ALT is useless. ALT remains an inexpensive and noninvasive tool for detecting liver problems. Elevated ALT levels are still useful as an initial signal of possible liver damage, including drug toxicity. ALT levels can also help show whether HCV treatment is work-

See ALTs on page 9

African Americans

Continued from page 6

receive a course of pegylated interferon alpha 2a (Pegasys) plus ribavirin and will be followed rigorously for symptoms, side effects, compliance, serum biochemical markers of liver disease, and HCV RNA levels. Special blood samples will be taken at specified intervals for studies of immune function, interferon signaling, and genetic analyses.

The study is being conducted under a clinical research and development agreement with Hoffmann La-Roche to provide the study medications and support for virologic and other measurements. The initial patients are scheduled to start enrollment in August 2002, and full enrollment is expected within twelve months.

The explanation of the nature and determinants of response to antiviral therapy and a more clear understanding of the efficacy of combination therapy in all groups of patients with HCV are areas of high priority for the NIH in the long-term initiative on prevention and control of hepatitis C.

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Fatigue

Continued from page 2

symptoms that he or she is experiencing and offer clarification and help. It is these kinds of misinterpretations that fuel the sense of rage and abandonment that many Hep C patients feel.

While progress has been made in developing improved cooperation between patients, doctors, and healthcare policy makers, there is certainly more work to be done.

Hep C patients have described levels of fatigue that are comparable to “being so thirsty that no amount of water would quench the sensation,” or being unable even to speak or sit up. One of the most tiring aspects of the fatigue is having to deal with symptoms that contradict one another. One person described his need to sleep as really being a need to retreat from low-level muscle and bone pain, as well as other painful bodily sensations, such as skin and limbs feeling as though they were simultaneously scalded and frozen.

These changes in sensation, known as paresthesia, may cause a person to feel utterly disconnected from any sort of surrounding pace or rhythm. He or she simply wants to “curl up” and withdraw from the world to protect himself or herself from the overwhelmingly conflicting sensations. It is not necessarily a feeling of sleepiness comparable to what a person might feel at the end of a long day, but an inability to cope with such a massive wave of feelings and sensations all of which are at odds with one another.

The combination of fatigue, paresthesia, and sense of being disconnected from the social world can lead to isolation from family and friends as well as to depression. The loss of energy can mean that patients do not feel like cooking or exercising and, consequently, do not eat properly which in turn means an even greater loss in energy, poorer health, and disrupted sleep patterns.

Without help this process can develop into a vicious cycle and significantly lower the patient’s quality of life. Extended studies of the relationship between Hep C and fatigue are rare.

One study conducted in 1999 at the Department of Hepatology, Mater Misericordiae Hospital and University College in Dublin Ireland used the Fatigue Impact Scale (FIS), a standardized questionnaire designed to assess a patient’s perceptions of the impact of fatigue on his or her ability to function, to try to define a correlation

between the amount of liver damage and the level of fatigue. The study employed a cohort of Irish women who were PCR-positive for HCV genotype 1b, and had all been infected in 1977 after being inoculated with contaminated anti-D products. The researchers assessed the damage to the patients’ livers using the Knodell histological activity index (HAI) score on their previous liver biopsies. Both clinical and laboratory evidence of cryoglobulinaemia, Sjogren’s syndrome, connective tissue diseases, autoimmune thyroid disease and glomerulonephritis were also recorded.

While those who were infected with Hep C did have significantly higher FIS scores than the healthy control group—in other words they were more fatigued—the study did not find any statistical difference between those patients with more or less severe liver damage, nor between persons with autoimmune diseases and those without, or between patients previously treated with interferon and those who had not been treated.

The study concluded that fatigue has a much more significant impact on persons infected with Hep C than upon those who are not. However, there was no correlation between the degree of damage to the liver and the level of fatigue, nor could the fatigue be explained only by the presence of other autoimmune disorders.

While there is still a great deal of work to be done, both to advance our scientific understanding of the relationship between Hep C and fatigue and to improve the care available to patients who are having to cope with it, progress is being made. Studies on patients who have had a sustained response to treatment have shown a decrease in fatigue. Light exercise has also been helpful in improving energy levels. Of course, a physician should be consulted before beginning any new form of treatment.

But, as one person noted, the best way to break out of the cycle of loneliness, isolation, and fatigue is to talk with other persons living Hep C and participate in building a strong community that can offer support and improve quality of life for all.

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ALTs

Continued from page 7

ing. Although reduction in HCV viral load is the primary indicator of treatment response, a normalization of elevated ALT levels can also show that therapy is having the desired effect. Therefore, ALT levels should be measured regularly in people undergoing HCV treatment.

Some people who have normal ALT levels when they start therapy may experience an increase, especially if they are using pegylated interferon. This may be because interferon stimulates immune system activity against HCV-infected liver cells—leading to a greater degree of inflammation—or somehow flushes the enzyme out of the cells. After therapy is complete, ALT measurements can signal a possible relapse. In conjunction with biopsy, ALT levels can help suggest when treatment might be beneficial.

According to the new NIH consensus statement, “Adult or pediatric patients with persistently normal or slightly elevated ALT levels and minimal or no fibrosis on liver biopsy may be reassured of a favorable prognosis and decide to defer antiviral therapy in the light of treatment side effects.”

Treating People with Normal ALT

Studies show that people with normal and elevated ALT levels typically respond similarly to HCV treatment. This was true of the relatively low response rates achieved with interferon monotherapy, and—although research is still preliminary—also seems to be the case with the higher response rates seen with combination treatment using standard or pegylated interferon plus ribavirin.

New and improved combination therapies have shifted the risk/benefit ratio for treating people with normal ALT levels. Since we now know that as many as one-third of people with persistently normal ALT can develop serious liver damage including cirrhosis, and since therapy appears to work well in such patients, experts now recommend that these people should be considered for therapy.

Certainly many HCV-infected people with persistently normal ALT levels do not need treatment. Progression to cirrhosis tends to be slow in this group, and a variety of factors should be considered when making a decision about whether or not to treat. Clearly, more research is needed on the natural

history of liver fibrosis in patients with normal ALT levels. Today, the recommendation is that most people with detectable HCV viral load—regardless of their ALT level—should receive a biopsy to determine their degree of liver damage and whether treatment is likely to be beneficial.

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FDA Approves New Hepatitis B Treatment

By Alan Franciscus
Editor-in-Chief

On September 20, the Food and Drug Administration (FDA) approved Hepsera (adefovir dipivoxil) tablets for the treatment of chronic hepatitis B (HBV) in adults. Hepsera is a nucleotide analogue drug produced by Gilead Sciences of Foster City, California. FDA approval was based on several studies which showed that Hepsera not only reduced HBV DNA viral load and ALT levels, but also significantly reduced scarring of the liver. Hepsera is also active against both wild-type HBV and HBV virus that is resistant to lamivudine. Interferon and lamivudine are the only other drugs that are FDA approved to treat HBV. According to a Gilead spokesperson, the drug should be ready to ship in early October 2002.

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