

The Search for an HCV Vaccine



By Liz Highleyman

Unlike hepatitis A and B, there is currently no vaccine to protect people from getting hepatitis C. An HCV vaccine remains a “holy grail” of hepatitis research. Many companies are working on candidates, but most experts do not expect an effective HCV vaccine for another 5-10 years.

IMMUNE RESPONSE TO HCV


In order to develop an HCV vaccine, researchers must learn more about how the immune system fights the virus—a process that is not yet completely understood. The immune system’s response to HCV involves both antibodies against the virus (humoral immunity) and helper and killer T-cell activity (cellular immunity). In most people, these immune responses do not eradicate the virus and they become chronically infected. But some people are naturally able to completely eradicate HCV, and understanding this process could help scientists devise a vaccine that mimics the workings of the immune system.

Most people produce antibodies against HCV about 7-30 weeks after infection (it is these antibodies that are detected on a hepatitis C screening test). But this antibody

response is rarely—if ever—enough to eradicate the virus. Unlike HAV and HBV, injection of anti-HCV antibodies (immunoglobulins) typically does not prevent infection. Scientists do not know whether antibodies alone can neutralize HCV, since studies to date have yielded conflicting results.

The cellular immune system also plays a vital role in fighting HCV. Helper T-cells (CD4 cells) direct the immune response, while killer T-cells (cytotoxic T-lymphocytes, a type of CD8 cell) attack HCV-infected cells in the liver. T-cells recognize pieces of the virus (proteins) displayed on an infected cell’s surface. Studies show that people who control HCV before it becomes chronic mount a vigorous T-cell response. But while most people’s T-cells can recognize and attack HCV-infected cells, this response is usually not enough to keep up with HCV replication and protect other liver cells from infection.

Vaccines may work either by stimulating the production of antibodies or by promoting T-cell activity. Since naturally produced HCV antibodies do not seem to completely eradicate the virus, researchers don’t hold out much hope that artificially induced anti-



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bodies alone will keep HCV under control. Studies suggest that killer T-cell activity is more strongly associated with protection than antibodies, and many vaccine candidates aim to stimulate both types of immune response.

Much vaccine research is directed at finding out which HCV epitopes, or proteins, are most likely to trigger a vigorous antibody or T-cell response. HCV consists of an envelope, or coat, and a core, which contains its genetic material (RNA), the nucleocapsid (which holds the genetic material), and several non-structural proteins (including protease and other viral enzymes). Researchers are not yet sure which viral proteins are best able to trigger an immune response, although there are several suspects. For example, some studies suggest that people who naturally mount an aggressive antibody response to the HCV E2 envelope protein are more likely to recover from acute hepatitis C.

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Depression:

Part 2:



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This is the second installment of the Hepatitis C Support Project's newest publication, Coping with Depression and Hepatitis C. See last month's newsletter for part one. The third and final part will appear in next month's newsletter

HCV TREATMENT AND DEPRESSION

The current standard treatment for chronic HCV infection is interferon given in combination with ribavirin. Interferon comes in two forms. One form involves three weekly injections. The pegylated form (Peg-Intron and Pegasys) has a molecule attached to it that stabilizes the interferon. Pegylated interferon injections are given once a week.

In his article, "Side Effects of Therapy of Hepatitis C and Their Management" (*Hepatology*, November 2002), Michael Fried, MD, states, "approximately 20% to 30% of patients treated with pegylated interferon and ribavirin report depression during therapy, making this a frequent cause of decreased quality of life and an indication for dose reduction and discontinuation." If you are considering treatment, tell your physician if you have a current or past history of depression or psychiatric illness. It is especially important to report severe depression, hospitalization for any psychiatric illness, or any suicide attempts.

Sometimes anti-depressant medications can be used in conjunction with HCV treatment. (The subject of professional help will be discussed in next month's newsletter.) Many patients state that anti-depressants can make a huge difference in their quality of life while they are undergoing HCV treatment. Some patients start on anti-depressant medications prior to treatment. Others start HCV treatment and then begin anti-depressant medication if they think they need it. Talk to your doctor about what would be best for your situation.

Breaking the cycle of depression usually involves a mind-body approach

WHAT CAN BE DONE ABOUT DEPRESSION?

Help for depression can come in a variety of ways. Sometimes mild depression can be improved with self-help measures alone. Prolonged or severe depression usually requires professional treatment. Sometimes professional intervention and self-help measures can reinforce each other.

The mind and the body are not separate and independent from each other. Your body affects your mind and your mind affects your body. Stress can weaken the immune system and make it harder to resist diseases. Feeling unwell can lead to increased fatigue and more depression. Breaking the cycle of depression usually involves a mind-body approach.

SELF-HELP

Information

Separating fact from fiction can be enormously reassuring. Patients sometimes hear or read something that is incorrect and which inadvertently leads them to believe their health or prognosis is worse than it really is. The Internet is a valuable tool, but not always reliable. Know your sources and do not settle for anything less than the most current and accurate information. Write down questions that you have and bring them to visits with your doctor so that you cover all of your concerns.

Support

The benefits of support cannot be understated. Support can come from friends, family and community. Support groups, especially those designed for people with HCV, can be invaluable. Sometimes the process of talking about inner concerns can be healing.

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DEPRESSION

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Exercise

Exercise is probably the single most effective self-help antidote for fatigue and depression. This is hard to fathom, especially if getting out of bed is an ordeal. Like most things, exercise is something that is best practiced in moderation. If you are unaccustomed to exercise, have a complicated medical condition, or are over 50 years old, it is advisable to speak to your health care provider before embarking on this. If you are ready to take this on, start slowly. Five to fifteen minute intervals, two to three times daily, can really help fend off relentless fatigue. This is especially true if you can practice this in a relaxing environment, such as at a park. Remember that 5 minutes of exercise is better than no exercise! Resist the all or nothing temptation. Also, resist the temptation to over-exercise. Balance is the key. When it comes to exercise, there are many activities from which to choose. Walking is perfect because it requires no special equipment except comfortable shoes. Biking, swimming, dancing, and gardening can be fun as well as therapeutic. Yoga, Tai Chi, Qigong, and Pilates are highly regarded as beneficial activities. As you venture into the realm of exercise, include stretching as part of your regimen. Start slowly and increase your activity according to how your body responds. The goal is to find a balance of activity that revitalizes you during the day and promotes sleep at night.

Balance Rest and Activity

Schedule a daily rest period. Rest is like fuel for the body. Just as you plan to put fuel in your car, do the same for your body. Consider resting as a preventative measure and try to rest before you get too fatigued. Those times you feel more energetic, resist the temptation to skip a rest break. This will only lead to increased inefficiency or fatigue later. Balance is the key. Pace yourself, take breaks, plan ahead, and delegate. Ask for help. Create short cuts. Organize your work areas so you can work more efficiently. Break large tasks into smaller ones, and do what you can as you are able.

Sleep

Inadequate or poor quality of sleep can lead to feelings of daytime tiredness. Make sure you are getting sufficient sleep. The National Sleep Foundation states that the average adult needs seven to nine hours

of sleep per night. If you believe that insufficient sleep is contributing to your fatigue, gather more information and seek help. Sleep issues are well understood and much can be done to improve the quality of sleep.

Positive Thinking

Positive thinking is a learned skill. Performed on a regular basis, positive thinking can replace negative thinking. A recent study evaluated people with chronic fatigue. After interviewing them, it was noted that people often said to themselves and others, "I am tired." Two groups were then formed and half of the people were not instructed to do anything differently. The other half of the study group was instructed to substitute the phrase, "I am getting my energy back" every time they felt they were tired. The outcome of this study was that the people in the second group reported a significantly reduced fatigue level. This example of the power of positive thinking can be a useful tool in overcoming inertia.

Hint: Practice positive thinking even if you do not believe it. Over time, positive thinking can become a habit, and can help improve many aspects of your health.

Stress Reduction

Too much stress takes its toll on a person's health. Avoiding unnecessary stress is easier said than done. There are a number of techniques that can help with stress-reduction. Some examples are yoga, meditation, visualization, and stress-management.

Substance Use

Alcohol, tobacco, excess caffeine and illicit drugs can cause or worsen depression and anxiety. Alcohol is a depressant and is incompatible with HCV. The psychological and physical impact of illicit drug use has been well documented. Tobacco and caffeine are stimulants and can cause increased anxiety. Although quitting the use of these substances can be difficult, it can be done. There is help available for all sorts of substance cessation. Ask your doctor for available resources in your community.

Laughter and Recreation

Finding pleasurable activities that you can participate in may improve your mood and prevent thoughts and feelings that can contribute to depression. Try to pick at least one pleasurable activity and find the time to do it often. Finally, it is worth promoting some-

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Extrahepatic Manifestations of Hepatitis C:

Part 3: Autoimmune Disorders



Kara Wright, PA-C

Many patients with chronic hepatitis C experience extrahepatic manifestations of the disease. In previous articles, we have discussed blood disorders and dermatologic disorders. There are also a number of autoimmune disorders which can arise in patients with hepatitis C.

Autoimmune disorders typically occur for unknown reasons when the body's immune system, which is meant to defend the body against bacteria, viruses, and any other foreign product, malfunctions and produces antibodies against healthy tissue, cells and organs. In addition to the disease itself, the treatment for hepatitis C (interferon and ribavirin) will often unmask any autoimmune disease as well.

The most common autoimmune disorder that manifests in patients with chronic hepatitis C is **thyroid disease**. The thyroid gland is responsible for regulating normal metabolism.

Antibodies against the thyroid are present in 5-12% of patients with HCV. Factors which seem to increase the risk of getting thyroid disease are female gender and older age.

Thyroid disease is discovered by a simple blood test and can usually be treated easily with medication. Symptoms typically include weight changes, hair loss, fatigue and dry skin.

Another disorder is **sialoadenitis**. This is similar to **Sjogren's syndrome**. These two disorders are inflammatory conditions in

which the immune system damages the body's moisture producing glands, such as the salivary ducts and the tear ducts. This causes dry eyes, dry mouth and dry skin. Sialoadenitis is usually treated with topical agents such as moisturizing eye drops for symptomatic relief.

The autoimmune illness **immune thrombocytopenic purpura** (ITP) has been linked to chronic hepatitis C. ITP is a syndrome of unknown etiology characterized by the presence of autoantibodies against platelet membrane proteins. This means the platelet counts are very low which makes it more difficult for the blood to clot. The *American Journal of Gastroenterology* shows that random chance is not the reason for the occurrence of ITP in individuals diagnosed with chronic hepatitis C. Statistically speaking, the number of HCV patients diagnosed with ITP was greater than would have been otherwise expected within the study population (Immune thrombocytopenic purpura in patients with chronic hepatitis C virus infection. *Am J Gastroenterol*, 2002; 97(8): 2040-2045).

ITP is characterized by red or purple spots on the skin, easy bruising as well as nosebleeds, bleeding gums or very heavy periods. The condition is usually diagnosed with blood tests and can be treated by a physician.

Rheumatoid arthritis is often noted in hepatitis C patients. Rheumatoid arthritis (RA) is a symmetric arthritis affecting several pe-

ripheral joints (such as the fingers and toes). This disease is of unknown etiology and ultimately leads to deformity and destruction of joints due to erosion of cartilage and bone. The most common symptoms are symmetrical peripheral polyarthritis, morning stiffness, positive autoimmune blood tests, and radiographic erosions. Rheumatoid arthritis can be a very devastating and debilitating disease. It is unknown how hepatitis C is associated with the disease. There are also cases where the hepatitis C virus itself causes some joint pains, and also causes a false positive blood test for RA. Patients with RA and a risk factor for hepatitis C should be tested for the HCV antibody.

Patients with RA should see a specialist for treatment. There are a number of medications used to treat symptoms and the disease.

Systemic lupus erythematosus (SLE) or lupus for short is another autoimmune disorder which has been associated with hepatitis C. Systemic lupus erythematosus (SLE) is a chronic inflammatory disease of unknown cause which can affect the skin, joints, kidneys, lungs, nervous system, serous membranes and/or other organs of the body. Patients with SLE are subject to numerous symptoms, complaints, and inflammatory involvement that can affect virtually every organ. The most common pattern is a mixture of constitutional complaints such as fever, fatigue

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HCV Viral Load Tests



Alan Franciscus, Editor-in-Chief
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Viral load tests are blood tests that measure HCV ribonucleic acid (RNA, or genetic material) in the blood. The presence of viral RNA indicates that the virus is actively replicating (reproducing and infecting new cells). A viral load test is usually first done after a person has tested positive for exposure to HCV based on an antibody test. A blood sample is taken and the amount of HCV RNA in a milliliter of blood is measured. Viral load tests confirm whether an individual is actively infected with HCV. Viral load test results were previously measured in number of copies, but are now typically reported in terms of International Units per milliliter (IU/mL).

TYPES OF HCV VIRAL LOAD TESTS

There are two categories of HCV viral load tests:

Qualitative viral load tests — These tests determine the presence of HCV RNA in the blood. This type of test is usually used to confirm chronic infection with HCV. If viral RNA is detected, a positive result is reported; if viral RNA is not detected, the test result is negative.

Quantitative viral load tests — These tests measure the amount of virus in one milliliter of blood. They are often used to assess whether or not treatment with interferon or interferon plus ribavirin is likely to be successful and, later, if treatment is working.

There are currently three tests commonly used for HCV viral load testing:

Polymerase chain reaction (PCR) — PCR tests detect HCV RNA in the blood, which indicates current active infection. This type of quantitative PCR test is very sensitive, and can measure as few as 50 IU/mL.

Branched-chain DNA (bDNA) — The bDNA method quantitative viral load testing is easier (and cheaper) to use for a large number of samples, but only measures viral loads greater than 500 IU/mL. This means that if a person has a viral load below 500 IU/mL, HCV could be present in the blood but not detected by the test.

Transcription-mediated amplification (TMA) — TMA technology allows for the amplification and detection of nucleic acids (components of genetic material) in the blood. This test can measure as few as 5-10 IU/mL. This newer test appears easier and cheaper to use, streamlining test processing and producing consistent, reliable, and more rapid results.

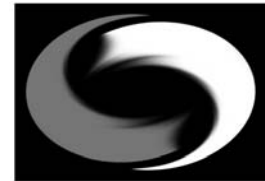
INTERPRETING VIRAL LOAD TEST RESULTS

HCV viral load is often reported as low or high.

Expressed as copies/mL:

- Low: less than 2 million copies
- High: more than 2 million copies

Expressed as International Units (IU/mL):



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HCV VACCINE

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CHALLENGES AND OBSTACLES

"Despite knowledge of HCV for more than a decade, there has been little progress in the development of a vaccine," explains Jay Hoofnagle, MD. "The obstacles to development of a vaccine against this virus are many. [D]evelopment of an HCV vaccine will require fundamental breakthroughs in immunology."

One of the major barriers to vaccine development is the fact that HCV is a highly variable virus. In addition to its six major genotypes (1 through 6), it also has further divisions known as subtypes (for example, 1a and 1b), and even smaller variations called quasispecies. HCV mutates, or changes, rapidly and continuously as it replicates, and a single individual usually harbors many versions of the virus. By mutating so rapidly, the virus can escape detection by the body's immune system. By the time antibodies against one HCV strain are produced, the virus has mutated to a different form. Vaccines that are effective against a single form of the virus are unlikely to work against other versions. Therefore, an ideal vaccine would use HCV epitopes that are common to multiple strains of the virus. For example, while the E2 envelope protein is highly variable and mutates at a fast rate, the nucleocapsid and non-structural core proteins are more "conserved" and mutate less rapidly.

Along with HCV's variability and rapid mutation, several other obstacles stand in the way of developing an effective vaccine. HCV is difficult to isolate from patients, is hard to grow in laboratory cell cul-

tures, and is not easy to test in animals. Chimpanzees are the only animals that can be infected with HCV, but the disease develops differently in chimps than in humans. HCV can also be studied in mice or other small animals with transplanted human liver cells, but again this is not an ideal model. Also, there are no good tests to determine how well antibodies neutralize HCV.

"The obstacles to development of a vaccine against this virus are many.

[D]evelopment of an HCV vaccine will require fundamental breakthroughs in immunology."

Jay, Hoofnagle, MD.

VACCINE CANDIDATES

Numerous approaches have been tried to stimulate the immune system to mount a response to HCV. Vaccines often utilize the E2 envelope protein, which is thought to be the major target of anti-HCV neutralizing antibodies, as well as the more highly conserved nucleocapsid and non-structural core proteins, so that the vaccine will be effective against multiple HCV strains.

DNA-based (nucleic-acid) vaccines consist of purified DNA that encodes HCV proteins that researchers hope will trigger an immune response. Recombinant (chimeric) virus vaccines consist of other viruses (such as adenovirus,

canarypox, or vaccinia) that are genetically engineered to carry HCV proteins. Synthetic peptide (subunit) vaccines use strings of HCV proteins. Other vaccine candidates utilize genetically engineered virus-like particles. All these various approaches have shown some degree of success, inducing humoral and/or cellular immune responses in some studies, although results have been mixed. Concerns remain about the safety of DNA-based vaccines (which could possibly trigger cancer) and recombinant virus vaccines.

Several promising vaccine candidates are under development. This past July, researchers from Inogenetics reported updated results from a Phase II trial of its E1 protein vaccine, showing that seven out of nine patients (78%) who received two courses of the vaccine had either stable or improved liver histology scores based on before and after liver biopsies, suggesting that the vaccine can halt or reverse liver damage. Chiron is working on a vaccine approach that has protected some chimps from infection altogether, while others were acutely infected but did not progress to chronic hepatitis C. A combination DNA/peptide vaccine is scheduled to begin Phase I safety trials this year. Epimmune is testing vaccine candidates based on proteins it selects using a computer program that identifies HCV peptides that both trigger an immune response and are highly conserved. And in November 2002, Intercell began a Phase II study of its therapeutic vaccine, which is based on five peptides identified by studying people with natural immunity to HCV.

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HCV VACCINE

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CONCLUSION

Given the challenges of stimulating a strong immune response against HCV, many experts expect that a successful vaccine will utilize a combined approach to induce both antibody production and T-cell activity. "Studies in humans and in chimpanzees indicate thus far that an ideal vaccine should induce broad humoral, T helper, and cytotoxic T-cell responses," says Martin Lechmann, PhD, of the National Institute of Diabetes and Digestive and Kidney Diseases. "Therefore, the final product might be a combination of different approaches, such as a combination of DNA and recombinant subunit protein vaccines."

Even if a vaccine cannot prevent acute hepatitis C (so-called sterilizing immunity), it may be able to decrease the chances of chronic infection. And in those who develop chronic infection, a therapeutic vaccine may help reduce long-term liver damage. While an effective HCV vaccine is still several years in the future, research is progressing to make this long-time dream a reality.

Did you know?

- *One in 1,000 compounds make it to human testing.*
- *One in five of these receive marketing approval.*



Medical Writers' Circle is a publication of the Hepatitis C Support Project. It consists of a series of articles written by medical professionals about the management and treatment of hepatitis C. The articles are available for printing at the Hepatitis C Support Project website.

www.hcvadvocate.org

HCV VIRAL LOAD

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- Low: less than 800,000 IU/mL
- High: more than 800,000 IU/mL

If no HCV RNA is found by a test, a person’s viral load is said to be undetectable. Note that whether viral load is undetectable depends on which test is used. PCR and TMA tests can measure viral loads much lower than those a bDNA test can detect. Importantly, the blood of an individual with a very low viral load may still contain HCV even though the current tests cannot measure it; that is, the virus may not have been truly eradicated from the body.

Viral load test results can vary depending on how a blood sample is handled and stored. Furthermore, results may vary from lab to lab. For this reason, most experts recommend that people should get their viral load testing done by the same laboratory each time, so that results are more comparable.

Changes in viral load are sometimes expressed in terms of logs. A log change is a 10-fold increase or decrease. For example, a change from 1,000,000 IU/mL to 10,000 IU/mL is a 2-log decrease.

CONVERTING COPIES PER MILLILITER TO INTERNATIONAL UNITS

There is no standard conversion formula for converting the amount of HCV RNA reported in copies per milliliter to the amount reported in

International Units. The conversion factor ranges from about one to about five HCV RNA copies per IU. Usually the lab report will list the conversion from IU/mL to copies/mL. See Table 1 for a conversion of common viral load tests from IUs to copies.

USES OF VIRAL LOAD TEST RESULTS

Viral load test results have many uses, such as confirming active HCV infection, and predicting and measuring HCV treatment response before, during, and after therapy.

Assay	Conversion Factor
Amplicor HCV Monitor v2.0 (manual procedure)	1 IU/mL = 0.9 copies/ml
Cobas Amplicor HCV Monitor v2.0 (semi-automated procedure)	1 IU/mL = 2.7 copies/ml
Versant HCV RNA 3.0 Quantitative Assay	1 IU/mL = 5.2 copies/ml
LCx HCV RNA Quantitative Assay	1 IU/mL = 3.8 copies/ml
SuperQuant	1 IU/mL = 3.4 copies/ml

Higher HCV viral loads may be associated with a greater risk of HCV transmission, particularly transmission from mothers to infants during pregnancy or birth. Viral load has not been correlated with the risk of sexual transmission. Furthermore, a correlation between HCV viral load and disease progression has not been shown.

Confirming active HCV infection — After a person has tested positive for HCV antibodies, an HCV viral load test is usually performed to confirm active HCV infection. This test is necessary because in up to 25% of people exposed to HCV, the virus can be

cleared on its own.

Before treatment — Viral load measurement can help predict how well HCV treatment will work.

The lower the pre-treatment viral load, the more likely it is that a person will respond to current HCV therapies.

During treatment — A decrease in viral load while on therapy indicates that treatment is working. A treatment is said to produce a complete virological response if it reduces viral load to an undetectable level. After 12 weeks of antiviral treatment, a 2-log drop in viral load or elimination of detectable HCV is an indication that the medications are working. If a person does not achieve a 2-log drop in viral load or elimination of detectable HCV after 12 weeks, it is unlikely that he or she will be able to eradicate HCV from his or her body. Viral load tests during treatment can also detect viral breakthrough, or increases in viral load that occur after a previous undetectable test result.

Note: A log drop in viral load is measured by decreasing the number by one zero. For instance, a one log drop in a viral load of 1,000,000 International Units is 100,000 International Units; a two log drop in a viral load of 1,000,000 International Units is 10,000 International Units.

After treatment — Viral load measurements can be used after cessation of therapy to monitor for relapse—that is, to see if the virus becomes detectable again after being undetectable when treatment was completed.



AUTOIMMUNE

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and weight loss with skin and musculoskeletal involvement.

Lupus usually begins with one or more of the following symptoms: Unexplained nonspecific symptoms such as fever, fatigue, weight loss, or anemia, sun sensitive rash, muscle aches or arthritis, neurologic symptoms such as seizures or psychosis, hair loss, inflammation of the veins, recurrent abortion, or kidney disease.

SLE is diagnosed based on clinical findings and blood work results. One simple blood test is the anti-nuclear antibody (ANA). The ANA is positive in virtually all patients with SLE. There are two autoantibodies that are highly specific for SLE: anti-double-stranded DNA (dsDNA) antibodies, and anti-Sm antibodies. These can help confirm a diagnosis.

Diabetes mellitus (DM) is noted in hepatitis C patients as well. In one study, it was observed that HCV genotype 2a was over represented in the DM patients, but it is unknown why this is the case. One theory suggests that patients with DM have more needle stick exposure so are at increased risk of obtaining hepatitis C through this route. In addition, we know that cirrhosis may lead to impaired glucose tolerance and therefore cause diabetes.

Although autoimmune disorders are *somewhat rare*, they are continuing to be seen in conjunction with hepatitis C. Patients should be aware of these disorders and watch for the signs and symptoms, so they can be treated promptly.



DEPRESSION

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thing that can be infectious: laughter. Having HCV can be painful and burdensome – if we let it. Laughter is not a cure, but it can lighten the load. It is the one contagious condition that feels good and for which you do not need a doctor's order. Prescribe it for yourself today!

Good Nutrition

Try to eat a low-fat, high fiber diet. Eat a variety of foods that include fruit, vegetables, and whole grains. Eating well does not take a lot of effort, but may involve a little planning. There are plenty of available healthy food choices without having to cook from scratch. For instance, vegetables are available pre-cut and can be tossed into soup, a salad, or an omelet. Fast food restaurants now offer healthy alternatives to the usual fried fare. A sandwich made from whole grain bread and piled high with vegetables is simple, healthy, and delicious.

Next month: Part 3 – Professional Help and Medication

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• *hcs*FACT*sheets*•

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