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# HCV Advocate

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## CDC Releases Recommendations for Viral Hepatitis in Prisons

By Liz Highleyman

The growing epidemic of hepatitis C and B among prisoners was in the spotlight this past January.

In the January 24 issue of *Morbidity and Mortality Weekly Report* the Centers for Disease Control and Prevention (CDC) published a report on "Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings," which includes recommendations for the prevention, testing, and treatment of viral hepatitis. The following week the CDC held a conference in San Antonio, TX, on management of hepatitis C in prisons, at which participants discussed how to implement the guidelines.

According to the CDC report, prisons are "on the front lines" in terms of preventing and treating viral hepatitis. Rates of hepatitis C and B—as well as HCV/HIV and HBV/HIV coinfection—are disproportionately high among the nation's incarcerated population. An estimated 16.41% of inmates show evidence of HCV infection (12.35% have chronic hepatitis C) and a similar 13.47% have evidence of HBV infection; rates vary widely by state. In addition, an estimated 39% of people with chronic HCV in the U.S. will pass through correctional institutions each year.

The guidelines recommend that all prisoners with a history of injection drug use or other risk factors should be tested for HCV and HBV. The agency stopped short of recommending universal testing for all prisoners, which remains controversial due to its high cost. The CDC further recommends that prisoners showing signs of liver disease should be assessed by hepatitis specialists to determine whether they need therapy; this should include liver biopsies if appropriate. Those who do need treatment should receive standard-of-care therapy—in most cases, ribavirin plus pegylated interferon for HCV.

In addition, hepatitis prevention should be incorporated into prison health education programs, including information about modes of transmission, risk reduction, hepatitis A and B vaccination, liver disease progression, and treatment options.

Also in January, the non-profit National Commission on Correctional Health Care (NCCCHC) took the opportunity to release its own report, "The Health Status of Soon-to-be-Released Inmates." This report deals with a variety of

communicable diseases—including viral hepatitis—and mental illness among prisoners. Like the CDC, the NCCCHC recommends that correctional facilities should follow accepted clinical guidelines for diagnosing and treating diseases in prisoners. The NCCCHC also called for a congressional investigation on prison health and the development of national standards for health care in prisons.

A major concern is the impact that the prison HCV and HBV epidemics will have on the nation's public health as a whole. The NCCCHC report estimates that over a million HCV-infected individuals were released to the community in 1996.

Therefore, according to the CDC report, comprehensive release planning for people with HCV or HBV should include education about how to prevent transmission, counseling about how to reduce further liver damage, referrals to substance use programs if appropriate, and referrals to medical specialists for follow-up care. The NCCCHC also recommends that prisons should link released inmates with community programs to help support continued care.

"Prisons and jails offer uniquely important opportunities for improving disease control in the community by providing health care and disease prevention programs to a large and concentrated population of individuals at high risk for disease," said report co-author Dr. Greifinger.

CDC: *Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings*

[www.cdc.gov/mmwr/preview/mmwrhtml/rr5201a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5201a1.htm)

NCCCHC: *The Health Status of Soon-To-Be-Released Inmates: A Report to Congress*

[www.ncchc.org/pubs\\_stbr.html](http://www.ncchc.org/pubs_stbr.html)

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# Generic Ribavirin on the Way

By Liz Highleyman

The high cost of prescription medications is one of the biggest—and fastest growing—challenges facing people with chronic hepatitis C and B in the U.S. today. Drug patents, which give pharmaceutical developers the exclusive right to sell their products, have been blamed for contributing to these exorbitant drug prices.

Generic drugs—cheaper versions of patented brand-name medications—could go a long way toward relieving this sticker shock. Generic drugs have the same active ingredients and clinical effects as brand-name drugs, and they are subject to the same standards for purity and quality as brand-name drugs. Like brand-name medications, generics are subject to rigorous review by the Food and Drug Administration (FDA). But generic drugs typically cost less than half as much as their brand-name equivalents. In fact, last July the Congressional Budget Office estimated that more extensive use of generics could reduce pharmaceutical costs by \$60 billion over the next 10 years.

Advocates for people with HCV have long desired a generic version of ribavirin, which, along with interferon, is part of the standard-of-care treatment for chronic hepatitis C.

On February 7, 2003, that hope came closer to reality when Three Rivers Pharmaceuticals announced that it had reached a settlement with Schering-Plough Corporation in its ribavirin patent lawsuit. Under the terms of the settlement, Schering will provide a non-exclusive license allowing Three Rivers to manufacture and sell generic ribavirin in the U.S. In return, Three Rivers will pay Schering a “reasonable” royalty based on generic sales.

“We are very pleased with the terms of the settlement,” said Three Rivers president Donald Kerrish. “It places Three Rivers one step closer to providing an affordable version of ribavirin to persons afflicted with hepatitis C.”

Schering’s Rebetol brand of ribavirin costs about \$10 per capsule. The Three Rivers version—to be sold under the name Ribasphere—is expected to cost under \$5. “Rebetol is \$10 a capsule for a drug that we believe costs 10 cents to make,” said Brian Klein of the Hepatitis C Action and Advocacy Coalition. Brand-name manufacturers claim such high prices are necessary in order to provide a sufficient profit to encourage innovation and to pay for the costs of drug development. Critics, however, point out that most large pharmaceutical companies spend more on marketing and advertising than they do on drug research and development.

Don’t look for generic ribavirin in stores just yet. Three

Rivers is still awaiting FDA approval for Ribasphere—a process that has dragged on for two years. Advocates say the delay is especially troublesome since a larger company, Roche, quickly got FDA approval for its new brand-name ribavirin, Copegus. (Much to the relief of patients and their advocates, Roche priced Copegus 43% lower than Rebetol when it went on the market in January.)

The Three Rivers lawsuit stems from disagreements over patents. Schering’s original patent on ribavirin expired in June 2002. Under the 1984 Hatch-Waxman law—which was intended to expand the availability of generic drugs—generic manufacturers can apply for approval before the brand-name patent ends. When this happens, the patent-holder gets an automatic 30-month patent extension to negotiate with the generic maker.

But critics contend that pharmaceutical companies have been able to “game the system” by filing additional patent applications for minor changes in things such as manufacturing processes, inactive ingredients, packaging, and labeling information. For each new patent application, the company gets another automatic 30-month extension—allowing some companies to prolong patent protection for years. Some brand-name manufacturers have even paid off generic makers to stop them from introducing competing products. The Federal Trade Commission discovered a pattern of repeated delays in bringing generic drugs to market. Although courts have often ended up rejecting frivolous secondary patent applications, the delays due to the automatic extensions cost consumers millions of dollars.

One way a company can get a patent extension is to update a drug’s labeling information, for example by adding new data from recent clinical trials. The Three Rivers lawsuit concerned the wording of Schering’s detailed package information about how ribavirin should be used, its side effects, and clinical trial data—specifically recently added information related to pegylated interferon. In all, Schering has some eight patents on Rebetol, many added in the past few years.

A similar move in 2001 by Bristol-Myers Squibb—which argued that the FDA could not legally approve a generic version of its diabetes medication, Glucophage, because of a recent label change related to use of the drug in children—so annoyed lawmakers that they began working on legislation to close the loophole. Said Senator Charles Schumer (D-NY), “Drug companies are not spending all their time

# Side Effect Management of Hepatitis C Treatment

Kara Wright, PA-C and Scott Becker, MD

Estimates are that over four million Americans, or roughly 1% of the U.S. population, harbor the hepatitis C virus. The current recommended treatment for hepatitis C includes pegylated interferon injections once weekly and weight based oral ribavirin taken twice daily. These two medications have significant side effect profiles and require treatment courses for up to 48 weeks. It is important to manage these adverse reactions so that patients will continue the full course of treatment, allowing the best chance to eliminate the virus. The most frequent side effects and strategies for their management will be discussed here.

Hematologic parameters are frequently affected, including anemia, neutropenia and thrombocytopenia. Anemia is a common side effect of ribavirin due to its accumulation in the red blood cells and subsequent hemolysis (destruction of red blood cells). This is compounded by interferon's suppression of all three cell lines in the bone marrow. Anemia is most prominent during the first 4-6 weeks of therapy and generally reaches a steady state. The symptoms of anemia include fatigue, rapid heart rate, palpitations and shortness of breath. Patients' blood counts are monitored during the first 4 weeks of therapy and monthly thereafter to maintain the hemoglobin level above 10 g/dL. Strategies for addressing more significant decreases in hemoglobin include dose reduction of ribavirin and the use of erythropoietin, a growth factor that stimulates red cell production. Patients with cardiac disease should be watched closely for signs and symptoms of anemia. Iron supplements to elevate blood counts are contraindicated as there is some evidence that increasing iron stores in the liver may exacerbate liver damage.

Neutropenia (a decrease in white blood cells) occurs in up to 70% of patients. A CBC (complete blood count) with differential should be monitored during the first 4 weeks of therapy and monthly thereafter to check the white cell counts. The absolute neutrophil count (ANC) is calculated by multiplying the WBC count by the percentage of neutrophils in a complete blood count with differential. Although there has been no documented evidence that low white counts cause an increased risk of infection during interferon treatment, most experts consider dose reduction of interferon by 50% if the ANC is less than  $750 \times 10^3$  / mL. Filgrastim (Neupogen), a growth factor that stimulates neutrophil production in the bone marrow, can be a useful adjunct in maintaining normal neutrophil counts.

Thrombocytopenia, or low platelet count, occurs in 2-5% of treated patients and frequently occurs in patients with liver disease and hypersplenism (enlarged spleen). Platelet counts are monitored with each blood draw. Platelets help the blood to clot, and decreased levels may present as easy

bruising, frequent nosebleeds or petechiae (a small pinpoint rash). Dose reduction of interferon may be necessary if platelets drop below  $55,000/\text{mm}^3$ . Most experts agree that patients should have a platelet count of at least  $70,000/\text{mm}^3$  at the outset of treatment.

Flu-like symptoms are among the most common side effects of interferon treatment. Interferon is a natural substance made by the body when infected with the flu; therefore injecting interferon causes similar reactions. Symptoms include myalgias, fever, chills, headaches and fatigue.

Myalgias (muscle aches) occur in 55% of patients. Hydration is an important treatment in decreasing this side effect. Analgesics such as acetaminophen or NSAIDs given before injections help diminish symptoms. Patients frequently find it helpful to get a massage, relax in a whirlpool or hot tub, and participate in an exercise program. Some patients will continue to have myalgias despite these treatments and may require prescription medications. In this case, prescription NSAIDs may provide symptomatic relief. Tramadol (Ultram or Ultracet) and gabapentin (Neurontin) have also been used successfully.

Fever frequently occurs after interferon injections. Adequate fluid intake and treatment with acetaminophen prior to and after injections helps decrease fevers. Fevers are typically transient, passing within a day or two after injection.

Headaches occur in 60% of patients and can be a debilitating side effect for many. Limiting caffeine and alcohol intake and maintaining adequate hydration help decrease symptoms. Acetaminophen and NSAIDs are frequently useful. Migraine medications such as Midrin, Zebutal, Fioricet or Imitrex may be necessary. Zolof is useful for retro-orbital headaches. Other pain relievers, such as tramadol (Ultram or Ultracet) and, in rare cases, acetaminophen with codeine, may be needed.

Fatigue is the most consistent of all side effects and may have a profound effect on the quality of life and the ability to work and function normally. Fatigue also increases symptoms of depression, irritability, and difficulty in concentrating. Patients are advised to eat a healthy diet, exercise at least 30 minutes 3 times a week, and get plenty of sleep. Hydration is, again, a useful adjunct. A variety of medications including Provigil, Ritalin and testosterone have been used with variable success.

Psychiatric adverse events are common during interferon treatments, afflicting up to 57% of patients. McHutchinson and Schiff found in a 1998 study that depression was the single most common reason for discontinuation of treatment for HCV infection. Psychiatric symptoms include depres-

# Preparing for HCV Treatment: Tips for the Journey

## Part 3 of a Three-Part Series on Health Self-Advocacy

By Lucinda K. Porter, RN, CCRC

In the five years since I began writing this column, I have witnessed significant progress in the arena of treatment for chronic hepatitis C virus (HCV) infection. The introduction of pegylation has ushered in a generation of alfa-interferons with higher rates of viral clearance and reports of improved side effect profiles. Medical providers are becoming increasingly skilled in their management of patients during treatment. Patients have increased access to resources for information and support. All of these factors may offer some benefit to patients, hopefully helping to improve their experiences while undergoing HCV therapy.

The following are some tips for assisting patients during their treatment phase. These suggestions were collected from patients. There is some sensible philosophy in these tips. Remember, perspective and attitude can be powerful allies. Use all the tools that are available to you.

- ◆ Support, support, support: Self-disclosure is a complicated issue (see the HCSP FACT sheet on hepatitis C disclosure). However, even without full self-disclosure, patients can ask for help. Since HCV treatment can have some psychosocial side effects, telling family members and close friends is a good idea.

- ◆ Think positively: Positive thinking is a term we often bandy about without really following through. Seeing the “bright side” is both an art and a discipline. One patient told me that every night when she couldn’t sleep, she would just tell herself over and over, “I can beat this.” She did.

### HealthWise

- ◆ Do not let lab results or other people tell you how you feel: Recently a patient told me that he went to bed because his doctor’s office told him his lab results “looked terrible.”

When his doctor got back to him, he was told his results looked “great.” He went from feeling well, to feeling awful, back to feeling well all based on external factors.

- ◆ Establish and review your goals: Before starting treatment, write down your goals. Make them broad and flexible. Include objectives such as “improvement of quality of life” or “want to give treatment my best effort,” rather than only focusing on permanent eradication of virus. Reflect on these goals on days when treatment presents challenges.

- ◆ Try to lead a normal life: There is more to life than interferon and ribavirin. Involvement in life can be a great distraction when not feeling well.

- ◆ Lower your standards: Aspiring to climb Mt Everest is all very well and good, but not during treatment. An acceptable goal might be to walk 5 days every week. If you are one who has never missed a day of work, now might be a good time to use some of that accumulated sick leave.

- ◆ Do not make decisions during the night: The night hours can be lonely and frightening. Few of us feel courageous and strong while tossing and turning. Save assessments and decisions for the daytime hours.

- ◆ Do not make any unnecessary life-changing decisions during treatment: Seek advice from those you trust before implementing major changes.

- ◆ Challenge your thinking and self-talk: Try not to over generalize or turn difficult moments into catastrophes.

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**Hepatitis C Support Project - A Tides Center Project**

# National Harm Reduction Conference: Part Two – Focus on Hepatitis C

Alan Franciscus  
Editor-in-Chief, HCV Advocate

Part two of this report focuses on various sessions that discussed integrating viral hepatitis into existing harm reduction programs and the success of a pilot program that seeks to provide comprehensive pre- and post-test counseling, testing, and care.

### Integrating Viral Hepatitis Prevention

The Centers for Disease Control (CDC) began integrating viral hepatitis programs into existing HIV and STD programs in recent years in order to provide a more comprehensive approach to disease control. Lack of available funding to concentrate on a single disease— hepatitis C—was a main factor in developing an integrated approach. The CDC believes this approach is an essential step toward prevention and control of these diseases. However, there is limited experience as to the feasibility, efficacy, and effectiveness of integrated services.

Three CDC-funded Viral Hepatitis Integration Projects (VHIP)—Multnomah County (Portland), OR; New Mexico; and Seattle/King County, WA—discussed their efforts to successfully implement the CDC model. The focus of this session was to explore the successes and barriers to integration of viral hepatitis into existing harm reduction services.

The highlights of the discussion were the successes and

barriers to implementation.

### Success of Integration:

- ◆ Ability to reach a difficult-to-reach population since they already frequent existing services
- ◆ Use of existing staff, which will cut down on salaries and overhead expenses
- ◆ Filling in an important gap in services for pre-existing client base

### Barriers to Integration:

- ◆ Lack of additional hepatitis services (for example, you can test but not offer additional medical care)
- ◆ Staff feeling overwhelmed with additional responsibilities
- ◆ Challenge of providing licensed medical care, such as blood draws and vaccination at street-based sites
- ◆ Services do not reach some specific populations that may be at risk
- ◆ Many affected by hepatitis will not use these integrated services.

Overall, the integration of services is seen as a success if properly planned and executed. The approach of combining these services is a practical solution made necessary by the lack of funding and of a good, solid overall disease-prevention policy, but this strategy is a hotly debated topic within the HCV community. Many people believe that HCV will be

*See Harm Reduction on page 7*

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## HEALTHWISE *Continued from page 4*

◆ Look at the big picture: Some days will probably be harder than others. However, assessing the broader picture may actually provide a different perspective.

◆ Do not blame everything on treatment: Look around at people who are not receiving treatment for HCV. It is likely you will notice that they get sick, complain of headaches, sore throats, fatigue, and occasional aches. Learn to recognize signs of illness that may require medical intervention.

◆ Maintain balance. Establish healthy and regular eating, sleeping, and exercise patterns that are *attainable*.

◆ Consider that bravery is an action performed while feeling afraid: If you find yourself feeling scared, remind yourself how courageous you are.

◆ Seize the opportunity for humor: Laughter feels great and may have a positive effect on the immune system.

◆ Do something enjoyable every day: This is a time for healing. Healing is more than just taking medicine. Do something that is rejuvenating on a daily basis.

◆ Do something for someone else. Reach outside of yourself to keep from becoming too wrapped up in self-concerns. However, do not neglect yourself. Find balance between helping others and staying healthy.

◆ Talk to the winners: Many people have completed treatment and have great insight as well as hindsight as to how to succeed through the process.

◆ Try not to fear discomfort and uncertainty. Fear can be more uncomfortable than the object of fear.

◆ Remember that all journeys are an opportunity for self-knowledge. Enjoy the adventure.

One patient commenting on treatment said, "It's like being at high altitude, without the scenery." Another expressed it as, "It felt like a preview of what it will be like when I get old. The only difference was that I felt great when it was over." A third patient said, "It felt like I was swimming in very deep water during a triathlon. I found out I was a good swimmer after all." Whether you feel like you are swimming, aging, or hiking, know that you can do this.

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## Side Effects *Continued from page 3*

sion, psychoses, aggression, and violent behavior. Suicidal ideations or attempts may occur. Depression is often manifested as irritability or difficulty with anger control. Counseling and support groups as well as relaxation techniques, exercise and hydration are effective tools in managing psychiatric events. Practitioners may consider the use of antidepressants early during the course of treatment. The SSRIs and SNRIs are particularly useful. It is often effective to begin patients on antidepressants before beginning therapy, particularly if the patient has experienced psychiatric problems in the past. Patients with a history of neuropsychiatric disorders have an increased risk of experiencing symptoms during treatment. It is advised and often necessary to involve the help of a psychiatrist or therapist in the management of patients with pre-existing psychiatric illnesses.

One third of patients experience alopecia (hair loss) with interferon treatment. Reassurance that hair will return upon cessation of treatment is often helpful, but thinning hair may be distressing to many throughout the course of the treatment. Patients should be advised to avoid frequent washing, using sticky hair products such as gel or mousse, hair dryers or curlers, chemicals such as dyes or permanents, and constricting headwear. Using mild shampoos such as baby shampoo or Nioxin, as well as satin pillowcases may be helpful. Patients may consider a shorter style, haircuts, or use of a wig until treatment is over.

One third of treated patients experience anorexia. Patients are encouraged to consume an adequate number of calories each day. Caloric intake can be enhanced by trying small frequent meals or by eating larger meals during times when the appetite is better. To gain more calories, patients may mix instant breakfast or protein powders with whole milk or ice cream. Dietary supplements such as Ensure or Boost can be used as between meal supplements to help maintain weight. Weight should be monitored at monthly visits. If weight loss persists, a consult with a dietician can be useful. Weight loss is often due to nausea and anorexia, so controlling these symptoms is essential. Many patients experience taste alteration, which may cause anorexia. Red meat may taste bitter. Chicken, fish, beans or peanut butter may be more palatable sources of protein. Marinating meats to change the flavor can help as can serving foods cold or at room temperature. Nausea occurs in more than one third of patients and may be controlled with antiemetics, such as promethazine (Phenergan), prochlorperazine (Compazine) or ondansetron (Zofran). Drinking cool clear beverages with a slice of citrus fruit or flat ginger ale, and eating dry foods such as toast or

## Harm Reduction *Continued from page 5*

ignored in this setting and that not all people with HCV will be comfortable accessing services lumped together with HIV and other sexually transmitted diseases. As a result many experts believe that multiple approaches are needed to access the entire population at risk.

The workshop ended with a comment that the CDC will soon be releasing a call for new funding proposals in Spring 2003. Unfortunately, it was also stated that the funding will not be increased because of the budgetary reallocation to the potential threat of the West Nile virus and of bioterrorism.

Developing effective harm reduction messages for counselors to use is one of the most difficult barriers to overcome in the integrated setting. Various agencies discussed the messages they developed in a session called “Counseling and Case Management for People with Hepatitis C.” The Multnomah County Health Viral Hepatitis Integration Program developed two messages—a core message for people with hepatitis C, and a general message for all clients at risk.

### **Core message for people living with hepatitis C:**

- ◆ Reduce or abstain from alcohol and other liver-toxic substances

- ◆ Get vaccinated against hepatitis A and hepatitis B
- ◆ Find and see a health care provider routinely

### **Specific message for people at risk:**

- ◆ Use new or clean syringes and all injection equipment—use needle exchange
  - ◆ If you can’t use new needles, clean equipment with water-bleach-water for three minutes. Even though this method has not been proven to kill HCV, it can reduce the risk of transmission of HCV and other diseases
  - ◆ Have an overdose prevention plan
  - ◆ Use barriers when blood may be involved in sexual activities
  - ◆ Meet the client at their level with clearly defined messages.

There was also a discussion on the importance of meeting clients “where they are at” by assessing their readiness, willingness, and ability to change behaviors. As well, some techniques were presented for working with people who are unsure, not ready, or who may be ready to change behaviors.

This session ended with a discussion on hepatitis C and harm reduction within the context of a needle exchange program. Clean Needles Now (CNN) provides health education, including HCV transmission information, that is specific to injection drug users and other drug users.

Information about the liver, testing options, and self-care for living with hepatitis C is given. CNN provides their clients with “positive packets” that contain practical information about living with hepatitis C by incorporating specific wellness strategies, such as drinking water, stress reduction techniques, diet, exercise, strategies for meeting specific needs, and information on the effect of their drug use on the liver.

### **Lessons learned from the Hepatitis Project (New York City)**

Putting into practice the goal of integrating viral hepatitis principles into existing services that include viral hepatitis counseling, testing, and follow-up medical care is the ultimate goal of screening, but follow-up medical care is the most difficult component to implement due to cost restraints.

Michael Kluger, MPH (New York University School of Medicine) presented study results from a program founded in 1999 in New York City called the Hepatitis Project at the Lower East Side Harm Reduction Center (NEX and HRC). This pilot project was started to address the issues of testing, post-test counseling, care, and support. To date, the program has tested approximately 465 individuals, with 25% of their clients testing positive for hepatitis A, 39% positive for hepatitis B (with 6% having chronic HBV), and 51% testing positive for hepatitis C. In addition, they have administered 240 hepatitis A vaccines, 270 hepatitis B vaccines, and provided education to countless others. Of interesting note is that this study found that 63% of the participants reported that they had never been screened for hepatitis—the omission of which is viewed as a lost opportunity to identify an at-risk population.

Kluger noted that screening without offering a link to follow-up care contradicts the definition of screening. Their goal was to offer an accessible and affordable panel of medical providers to perform PCR confirmatory testing for hepatitis, to determine if chronic infection is present, and to provide follow-up medical care if necessary. The goal of the program is to offer informal referrals to a local primary care physician for all those who test positive. Since the Project’s population is largely composed of injection drug users, every effort was made to refer clients to medical providers who are sensitive to this population.

Providing these services for clients in organizations that are generally poorly funded is the biggest obstacle to overcome. As would be expected, a major expense of staffing a medical clinic is the salary of trained medical professionals: a nurse practitioner (\$28.50/hr), a physician assistant (\$28.50/hr), and a physician (\$80.00/hr). In addition, a nurse practitioner or physician assistant cannot provide services unless a physician is present or accessible by telephone, which carries a large price tag. These

# Pruritus: Dealing with that Itch

By Liz Highleyman

Pruritus is itching that may be localized to a specific part of the body, such as the palms of the hands and soles of the feet, or may be a more generalized all-over itchy feeling. Some people even report that it feels like their internal organs itch. Itching is common in people with chronic hepatitis C, especially those with advanced liver disease and cirrhosis.

Experts believe pruritus in people with liver disease is due to the accumulation of toxins (such as bilirubin) that are not effectively processed or filtered by the damaged liver. One function of the liver is the production of bile, which helps digest fats. Cholestasis, or blockage of the flow of bile through the liver, can result in a build-up of bile acids and bilirubin in the blood. High bilirubin levels cause jaundice (yellowing of the skin and eyes), and pruritus is common in people with jaundice. Certain extrahepatic (outside the liver) conditions associated with HCV, such as autoimmune conditions, may also lead to itching. More commonly, itching due to dry skin can be a side effect of treatment with interferon/ribavirin; this is not the same as pruritus due to advanced liver damage.

Pruritus symptoms can range from annoying mild itching to severe itching that interferes with daily life. Often the itching is worse at night, and may prevent sleep. Simple scratching typically does not relieve pruritus. As a result, some people risk skin infection and injury by scratching themselves with sharp objects.

Use of moisturizing lotion, baby oil, or petroleum jelly can help relieve itching due to dry skin. Apply these after a bath or shower to hold in moisture. Some people also find oatmeal baths soothing. Drinking enough water can also help prevent skin dryness. Soft, loose clothing may help, as well as a comfortable climate that is neither too hot nor too cold. Signs of infection (redness, pain, swelling, and accumulation of pus) should be reported to a healthcare provider and, if necessary, be treated with antibiotics.

Certain drugs can help reduce itching. Some people find that antihistamines, such as diphenhy-

dramine (Benadryl) or hydroxyzine (Atarax), help relieve symptoms and allow better sleep. For pruritus due to cholestasis, cholestyramine (Questran) and colestipol (Colestid) may be effective. These drugs are bile acid binders that attach to bile acids in the blood and help eliminate them from the body. They can also interfere with the absorption of other medications, so other drugs should be taken two hours before or after bile acid binders. Some studies have shown that opiate antagonists such as naloxone (Narcan), naltrexone (Revia), and nalmefene (Revex)—which are used to block the effects of opiate drugs—can also reduce severe itching. Rifampin, phenobarbital (Luminal), ondansetron (Zofran), and ursodiol (Actigall) may also be used, and several other medications are under study.

Experimental treatments for pruritus include plasmapheresis (in which blood plasma is removed, filtered, and returned to the body) and ultraviolet (UV) light therapy. Liver transplant is the only cure for severe itching in people with advanced liver disease. For most people with less advanced hepatitis C, though, practical measures and medications are often sufficient to overcome the itch.

## Ribavirin *Continued from page 2*

innovating new drugs. They're innovating new patents.”

The Greater Access to Affordable Pharmaceuticals Act, sponsored by Schumer and Senator John McCain (R-AZ), passed last July by a bipartisan vote of 78-21. The bill removes the automatic 30-month extension provision; instead, requests for patent extensions will be considered on a case-by-case basis. Two related bills are being considered by the House: the Prescription Drug Fair Competition Act (HR 5373), sponsored by Reps. Sherrod Brown (DOH) and Henry Waxman (D-CA), and the Prescription Drug Affordability Act (HR 5311), sponsored by John Thune (R-SD). Last October, President George Bush (who opposed the McCain-Schumer bill) also got into the act, announcing his own initiative to make generic drugs more available.

Efforts to reform the drug patent system are supported by an unlikely coalition of consumer advocates, state officials, employers, and insurance companies—all of whom have been hit hard by the rising cost of prescription drugs.

## Harm Reduction *Continued from page 7*

obstacles were overcome by the use of volunteer medical professionals, comprising third year medical residents, attending physicians, and medical students. In addition, the volunteer's mother institution picked up the benefit costs associated with paid salaries and any medical malpractice insurance. Kluger commented that the success of the program was in large part due to the compassion and dedication of these medical residents.

Kluger ended the session with the following recommendations:

### Follow-up Care

1. Every attempt should be made to cultivate an accessible and affordable panel of medical professionals
2. Work with infectious disease specialists or internists comfortable treating hepatitis
3. Provide hepatitis C PCR confirmatory testing when possible because of the poor follow-up

### Data Storage and Confidentiality

Since the clinic serves a population that is underserved and contains records of people who are usually viewed as potential criminals by the local authorities, it is essential that the confidentiality of the clients be maintained.

1. Use unique identifiers
2. Don't collect personal contact information
3. Keep all files password protected
4. Don't use laptops because of their mobility
5. Use electronic medical records
6. Maintain offsite backup files

### Funding

The most difficult aspect of a project of this type is to find available funding.

1. Little funding is available in the absence of a research agenda
2. Federal grants can sometimes become available to combat hepatitis
3. Free vaccines are sometimes available to eligible organizations
4. Team up with public hospitals or clinics
5. Explore grants for student projects offered through medical schools and foundations

It was clear from these sessions that a crucial ingredient in integrating hepatitis C services is a staff with a compassionate vision and a dedicated commitment to serving their clients. In this respect, one can only admire and respect the people who are paving the way for improved support and care for their clients and the HCV community.

## Side Effects *Continued from page 6*

crackers frequently alleviates nausea. It is also important to rule out abnormalities in thyroid function since this is a potential side effect of interferon therapy.

A number of patients will experience cough. Patients may obtain relief by increasing fluid intake, using a humidifier, sucking on hard candy or chewing gum and avoiding irritants such as smoke. Over the counter cough medications may be used. If ineffective, a practitioner may consider prescription cough medications such as Tessalon, Perles, or codeine.

Many patients will experience a cutaneous reaction at the injection site. There will typically be an area of redness surrounding the injection site which may last for several weeks. Reassurance that this reaction is normal and common is helpful. Patients may rotate injection sites, apply ice to the site prior to injecting medication, be sure alcohol on the skin is dry before injecting, inject the drug at room temperature, inject at a 90-degree angle and hold the needle in for 3 seconds after injecting. The injection site should not be massaged. Hydrocortisone creams applied twice daily may be useful. Swelling or red streaks from the injection site should be reported to the practitioner, as these may be signs of infection requiring antibiotics.

Insomnia is not uncommon. About 40% of patients experience restless sleep, which can lead to irritability, difficulty concentrating and intensification of other side effects. Useful techniques include relaxation techniques such as warm baths, music and massages as well as having a consistent routine before going to bed. Avoiding stimulants such as caffeine or decongestant medications is helpful. Over the counter medications such as Benedryl or Tylenol PM at bedtime is often helpful. Prescription medications such as amitriptyline (Elavil), zaleplon (Sonata) or zolpidem (Ambien) may be necessary.

Pruritus (itching) occurs in 28-29% of patients. Avoidance of perfumed soaps or lotions, hot baths, and saunas is helpful. Lukewarm showers, oatmeal based bath accessories or lotions, patting skin dry rather than rubbing it, using soaps for sensitive skin, and wearing sunscreen are helpful. Hydrocortisone creams and oral antihistamines are often needed to alleviate these symptoms. A dermatology consult may be necessary in serious cases.

Preparing patients for all possible side effects to be experienced during treatment with interferon and ribavirin is important in achieving compliance. Support and encouragement from the practitioner as well as friends and family are equally as important. Patient's symptoms should be acknowledged and handled effectively to increase tolerability and compliance of treatment.

## **Clinical Trials**

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